2 February 2024
280-24

Call for submissions – Application A1261

Irradiation – Increase in maximum energy level

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. FSANZ has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at current calls for public comment and how to make a submission.

All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published as soon as possible after the end of the submission period.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at information for submitters.

For information on how FSANZ manages personal information when you make a submission, see FSANZ's Privacy Policy.

Submissions should be made in writing; be marked clearly with the word 'Submission'. You also need to include the correct application or proposal number and name. Electronic submissions can be made by emailing your submission to submissions@foodstandards.gov.au. FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices.

There is no need to send a hard copy of your submission if you have submitted it by email. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 15 March 2024

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.
Questions about making a submission or application and proposal processes can be sent to standards.management@foodstandards.gov.au.

Submissions in hard copy may be sent to the following addresses:

Food Standards Australia New Zealand
PO Box 5423
KINGSTON ACT 2604
AUSTRALIA

Food Standards Australia New Zealand
PO Box 10559
WELLINGTON 6140
NEW ZEALAND

Tel +61 2 6271 2222 Tel +64 4 978 5630

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Supporting document

The following document which informed the assessment of this application is available on the FSANZ website[1]:

SD1 Risk and technical assessment report

[1] Application A1261 Irradiation - increase in the maximum energy level (foodstandards.gov.au)

Executive summary

Steritech Pty Ltd has 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[2] (MeV) to 7.5 MeV, provided the X-ray target of the machine source is made of tantalum or gold.

The Applicant has stated that 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%. It is estimated that this would result in an increase in the Applicants processing capacity from 12 pallets/hour to 17-18 pallets/hour.

While the application seeks to increase the maximum energy from 5 to 7.5 MeV there will be no change to the absorbed dose of irradiation in foods. Since it is the absorbed dose of the irradiation that is important in determining any compositional changes to food (and not the incident maximum energy) there are no anticipated changes to food composition associated with the change.

No new evidence was identified that would alter FSANZ's previous conclusion that there are no safety concerns associated with the irradiation of the permitted commodities at the approved absorbed doses as per the Code. Available toxicity and genotoxicity studies with foods irradiated with 7.5 MeV X-rays using doses higher than those approved in the Code showed 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.

The USA, Canada and South Korea have regulated to increase the maximum energy level of the machines generating X-rays of up to 7.5 MeV and the use of tantalum or gold as the X-ray target to irradiate food. India and Indonesia also permit the use of X-rays generated from machines operating up to 7.5 MeV. This is consistent with the International Plant Protection Convention (IPPC) 2023 Food and Agriculture Organization (FAO) International Standard for Phytosanitary Measures (ISPM 18) which observes the use of irradiation to treat food using X-rays generated from machine sources at an energy level up to 7.5 MeV

For reasons set out in this report, FSANZ has therefore prepared a draft variation to the Code which, if approved, would 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.

FSANZ now seeks submissions to assist consideration of the draft variation to the Code.

[2] 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 is to amend the Australia New Zealand Food Standards Code (the Code) to increase the maximum energy level for machines generating X-rays permitted to irradiate food from 5 to 7.5 megaelectronvolts[3] (MeV) provided the machine's X-ray target is made of tantalum or gold.

No other changes to the Code are requested as part of the application. The application has not requested any changes to the foods that are permitted to be irradiated or the dose range or other conditions for irradiation of the foods. It also excludes any changes to how irradiation of foods can be achieved using 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.

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;
(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 relating to irradiated food.

[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

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 UN 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 2023 FAO IPPC International Standard for Phytosanitary Measures (ISPM 18, IPPC 2023) states that ionizing radiation may be provided by radioactive isotopes (gamma rays from cobalt-60 or caesium-137), electrons (up to 10 MeV) or X-rays (up to 7.5 MeV) generated from machine sources. The unit of measurement for absorbed dose is the gray (Gy).

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.

The Codex irradiation 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. 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 *Australia New Zealand Food Standards Act* (FSANZ Act)
- it related to a matter that warranted the variation of a food regulatory measure.

1.6 Procedure for assessment

The application is being assessed under the General Procedure.

2 Summary of the assessment

2.1 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 from 5 to 7.5 MeV increases the efficiency of generating X-rays to irradiate food by approximately 40-50%. This is for both phytosanitary treatment to control pests and sanitary treatment for food quality and safety purposes.

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 from non-food sources.

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 changes in maximum energy 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 that would alter these conclusions. As the proposed increase in maximum energy level will not result in an increased absorbed dose in food, there are no new chemical safety concerns. 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.

2.2 Risk management

The risk management options available to FSANZ, after assessment, were to either reject the application or to prepare a draft variation to amend the Code.

For reasons set out in this report, FSANZ has decided to prepare a draft variation amending paragraph 1.5.3—7(b) in the Code requested to increase the maximum energy level for machine sources generating X-rays, which are permitted to irradiate food, from 5 MeV to 7.5

MeV provided the X-ray target used by the machine source is made of tantalum or gold.

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) that food can be irradiated using X-rays up to 7.5 MeV. The use of higher energy sources up to 7.5 MeV to produce X-rays provided the X-ray target is made of tantalum or gold is also consistent with permissions in the USA, Canada and South Korea.

2.2.1 Labelling of irradiated food

The existing requirement for mandatory labelling of irradiated foods at section 1.5.3—9 will 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. The words used in the statement must not contradict or detract from the effect of the statement (see subsection 1.1.1—8(2)).

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.

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 are also no restrictions in the Code regarding its voluntary use. However, even if the symbol is included on the food label, it must still display the mandatory labelling requirements for irradiated foods.

Figure 1 *The Radura symbol*

2.2.2 Risk management conclusion

For reasons set out in this report, FSANZ considers it is appropriate to prepare a draft variation to amend paragraph 1.5.3–7(b) in the Code as proposed.

If approved, the effect of the amendment would be 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.

2.3 Risk communication

2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a standard communication strategy to this application. All calls for submissions are notified via the Food Standards Notification Circular, media release, FSANZ's social media channels and Food Standards News.

The process by which FSANZ approaches standards development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on the draft variation.

The draft variation will be considered for approval by the FSANZ Board considering all public comments received from this call for submissions.

2.3.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are not substantially the same as existing international standards and the proposed measure may have a significant effect on trade.

There is a relevant international standard, being the Codex Standard CXS 106-1983 which differs to the application since it recommends that the maximum energy for machines generating X-rays used to irradiate food be operated at or below 5 MeV, in comparison to the application's request to increase it to 7.5 MeV. However, there is also a recent 2023 FAO International Plant Protection Convention (IPPC) International Standard for Phytosanitary Measures (ISPM 18) which observes the use of irradiation to treat food using X-rays (up to 7.5 MeV) generated from machine sources. As well there are several countries that do permit the higher energy level.

It is noted that increasing the energy level is not a mandatory requirement rather it is voluntary. FSANZ considers it is unlikely to have a significant effect on international trade. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 FSANZ Act assessment requirements

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

2.4.1 Section 29

2.4.1.1 Consideration of costs and benefits

Changes have been made to the impact analysis requirements by the Office of Impact Analysis (OIA)[4]. Impact analysis (including Regulatory Impact Statements, or RISs) is no longer required to be finalised with the OIA.

Prior to these changes, the OIA advised FSANZ that a RIS was not required for applications relating to the irradiation of fruits and vegetables. This was due to an earlier Office of Best

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

Practice Regulation (OBPR, being the former name of the OIA) 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.[5]

Under the new impact analysis requirements, FSANZ must decide whether a RIS should be prepared. FSANZ's assessment is that a RIS is not required in relation to the draft variation because the impacts of the proposed amendment to the Code (if approved) 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 is 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 resulting from the proposed draft measure (if approved).

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 irradiation energy level of machine sources generating X-rays (in the circumstances 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.[6] 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. It is also 40-50% more efficient form of using X-ray irradiation compared to using 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 within quarantine regions within Australia. Therefore, if the cost of irradiation lowers then the cost of inter-Australian trade may also reduce.

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.

There would be no cost impact on industry. Use of the permitted forms of ionising radiation at higher energy levels would be voluntary and therefore individual businesses within the

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

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 call for submissions, consumers would continue to be informed 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

In FSANZ's view, the likely benefits to community, government and industry, which would arise from the proposed draft measure, would outweigh the likely associated costs.

2.4.1.2 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.

2.4.1.3 Any relevant New Zealand standards

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

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2 Subsection 18(1)

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

2.4.2.1 Protection of public health and safety

FSANZ undertook a safety assessment (see SD1) and 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.

2.4.2.2 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 2.2.1 of this report would provide information to enable consumers to make informed choices.

2.4.2.3 The prevention of misleading or deceptive conduct

There were no issues identified with this application relevant to this objective.

2.4.3 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) which observes the use of irradiation to treat food using X-rays (up to 7.5 MeV) generated from machine sources. Section 1.4.1 notes there are irradiation of food permissions in three countries that are fully consistent with the requested amendments to the Code of this application and two others that permit using X-rays up to 7.5 MeV but without a qualification on the X-ray target material. Amending the Code as proposed would promote further consistency between the irradiation of food in Australia and New Zealand with other 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 from 5 to 7.5 MeV to generate X-rays as requested by the application 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 treatment efficiency and rate of throughput of irradiating food. This would improve the efficiency of the irradiation treatment for various foods and make these food industries more internationally competitive. It would also allow the local irradiation of food industries 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[7]**

There is no policy guideline for irradiated foods.

3 Draft variation

The draft variation to the Code is at Attachment A and is intended to take effect on gazettal.

A draft 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.

[7] Formerly known as the Forum on Food Regulation.

4 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. https://assets.ippc.int/static/media/files/publication/en/2023/04/ISPM_18_2023_En_Irradiation_PostCPM-17_2023-04-14.pdf accessed on 24 January 2024

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. Draft variation to the Australia New Zealand Food Standards Code
B. Draft Explanatory Statement

Attachment A – 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 – Draft Explanatory Statement

DRAFT 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 Authority accepted Application A1261 which sought 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 prepared a draft variation - the *Food Standards (Application A1261 – Irradiation – Increase in maximum energy level) Variation*.

2. Variation will be a legislative instrument

If approved, the draft variation would be a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and be publicly available on the Federal Register of Legislation (www.legislation.gov.au).

If approved, this instrument would not be 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 Food Ministers' Meeting (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 prepared 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 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 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. A call for submissions (including the draft variation) will be open for a six-week 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. This was due to an earlier Office of Best Practice Regulation (OBPR, being the former name of the OIA) reference number 13845 dated 15 May 2012. Prior to these changes, the OIA advised FSANZ that a RIS was not required for applications relating to the irradiation of fruits and vegetables. 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, FSANZ must decide whether a RIS should be prepared. Under the new approach, FSANZ's assessment is that a RIS is 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

If approved, this instrument would be exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

7. Variation

Clause 1 of the draft 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 draft variation provides that the Code is amended by the Schedule to the draft variation.

Clause 3 of the draft variation provides that the variation [if approved] will commence on the date of gazettal of the variation.

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

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[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.

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) refers to X-rays generated by or from machine sources operated at an energy level not exceeding 5 megaelectronvolts.

The new paragraph would refer 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 - at an energy level not exceeding 7.5 megaelectronvolts.

The effect of this amendment (if approved) would be 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.