APPLICATION TO FSANZ

Application to amend Standard 1.5.3 of the Food Standards Code, Irradiation of Food, to increase the maximum energy of X-Rays permitted to irradiate food from 5 MeV to 7.5 MeV.

Submitted 19/09/2022

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C. Executive Summary

Steritech Pty Ltd. has operated a food irradiation facility at Narangba, Queensland since 2003. Its radiation source is the radioactive isotope cobalt-60 (^{60}Co) which continuously emits gamma rays. There are increasing issues with the supply and cost of ^{60}Co, including security issues with the transport and use of radioactive sources. There is a trend towards replacing ^{60}Co with electrically-driven accelerator sources producing high-energy, high-power electron or X-Ray radiation only when required. Such sources will increase the long-term sustainability of irradiation facilities. The new 2020 Steritech irradiation facility at Merrifield, Melbourne is an accelerator producing X-Rays for irradiation of food.

Steritech is applying for a variation to Standard 1.5.3, section 1.5.3 – 7 of the Australia New Zealand Food Standards Code (the Code). The proposed variation seeks to increase the maximum energy for machines generating X-Rays from 5 to 7.5 megaelectronvolts (MeV) provided that the X-Ray target is made of tantalum or gold.

No change is sought to the currently approved foods in the Code that may be irradiated or the conditions imposed (sections 1.5.3 – 3, 4, 5), including the dose range. The variation requested is a technical adjustment to the delivery of the radiation dose only.

The primary purpose of the requested variation is to increase the efficiency with which the electron beam produced in an accelerator is converted into X-Rays which are then absorbed in the food. An increase in efficiency of 40 to 50% will be achieved when the maximum operating voltage of the accelerator is increased from 5 to 7.5 MeV. This will translate to increasing the radiation processing rate from approximately 12 pallets per hour to 17/18 pallets per hour.

A secondary purpose is to increase the sustainability of food irradiation through making the choice of an X-Ray source a more economic option for processors and to reduce the previous dependence on a radioactive source of radiation ^{60}Co.

If operated at 7.5 MeV rather than 5 MeV, the 40 to 50% increase in overall efficiency will result in -

- A comparable decrease in processing time and increased throughput;
- More rapid turnaround times that will reduce supply chain costs, reduce the time produce is out of temperature-controlled containers and keep food quality at the highest level possible;
- Greater ability to manage the variable throughput demands of an industry dealing with a range of perishable, seasonal products;
- Greater penetration into, and greater dose uniformity within, the food;
- Reduced costs to the food industry as a result of the above advantages.

The Codex General Standard for Irradiated Foods recommends 5 MeV as the maximum energy for X-Rays. This Standard was first issued in 1983 before X-ray sources became a practical option for commercial processing and when 5 MeV was thought to be the maximum energy likely to be used. Most countries still follow that recommendation.

If amended as requested, Standard 1.5.3 will no longer comply exactly with the Codex General Standard for Irradiated Foods. However, the USA, Canada, Indonesia, India and the Republic of Korea have already raised the maximum permitted energy for X-ray production to 7.5 MeV in their food regulations. As the need for irradiation treatments expands and the use of X-Rays becomes more common, other countries are expected to raise the energy maximum. The proviso that the X-Ray target is made of tantalum or gold is in place because some other metal targets could theoretically induce higher amounts of radioactivity in the food than desirable.

The increased capital cost of a higher energy accelerator will be offset by cheaper operating costs resulting from increased efficiency and throughput. A change to 7.5 MeV X-Rays will result in lower costs to clients. A theoretical, best-case calculation suggested that the costs per ton of food treated might be 33% lower for 7.5 MeV X-Rays than 5 MeV X-Rays.

FSANZ has approved a series of applications to irradiate fresh produce, culminating in approval to treat all fresh produce except dried pulses, legumes, nuts and seeds. The approvals acknowledge the importance of phytosanitary treatment options to obtain market access for exports and to protect domestic horticulture. Irradiation provides an alternative option with several advantages to treatments that include chemical treatments and fumigation with an ozone-depleting gas.

Australian exports of irradiated fresh produce have been growing steadily since 2004. The approval by FSANZ for the phytosanitary irradiation of all fresh fruit and vegetables and the opening of a new X-Ray facility have further accelerated growth. The domestic (inter-state) use of irradiation has grown from less than 100 tons to over 1000 tonnes per year in less than 2 years. In 2021-22, Steritech facilities irradiated 7777 tonnes of fresh produce for export. The increased efficiency and reduced costs obtained with X-Rays with a maximum energy of 7.5 MeV will further enhance the competitiveness and use of phytosanitary irradiation.

Consumers should benefit from the decreased costs to the food trade and may see a greater variety of fresh produce on retail shelves. Generally, consumer perceptions of food irradiation are unlikely to change but a few well-informed consumers may appreciate the use of a radiation source that can be switched off when not in use rather than a radioactive source emitting continuous radiation.

Labelling requirements will be unchanged. Consumers may be more familiar with the term X-Rays rather than ionizing radiation should industry choose to use the term X-Rays on labels.

The proposed change will be cost neutral to the government agencies that regulate food irradiation facilities. Generally, the government will benefit from the potential to increase exports and protect local industry from pests.

Encouraging the use of X-Ray treatments of fresh produce through greater efficiency will have environmental benefits. The use of methyl bromide will be further reduced. X-Rays are only produced when required and there is no need for the storage and transportation of radioactive sources. This is positive for the environment, security and public acceptance.

There are no new toxicological or microbiological safety or nutritional adequacy issues implicit in this application since no change is requested to change the approved dose levels. The type and amount of chemical change brought about in the food depends upon the dose (the energy absorbed in the food). They do not depend upon the energy of the incident radiation.

The radiations permitted under Standard 1.5.3 do not increase the natural levels of radioactivity in the food significantly. Experimental methods cannot detect any induced radioactivity in food irradiated with either 5 or 7.5 MeV X-Rays. Theoretical calculations also show that any induced radioactivity and consequent radiation dose to consumers above natural levels are negligible at both energies provided the X-Ray converter is restricted to tantalum or gold.

None of the information in this application is confidential and no exclusive capturable commercial benefit will accrue to the applicant.

D. Application to amend Standard 1.5.3 of the Food Standards Code, Irradiation of Food, to increase the maximum energy of X-Rays permitted to irradiate food from 5 MeV to 7.5 MeV.

D.1 Structure of the application

This application requests a change to the conditions under which one of the permitted sources of irradiation of food is delivered. The technical issues involved are very different to those in previous applications to vary Standard 1.5.3 which focussed on the foods to be irradiated, radiation dose and the reasons for the treatment.

The application has the following structure:

- Section E provides background information on aspects of the delivery of radiation technology relevant to this specific application.

- **Section F provides information to meet the General Requirements for Applications to vary the Food Standards Code (Application Handbook 3.1).**

- **Section G provides information to meet the requirements for applications related to irradiated foods (Application Handbook 3.5.3).**

- Section H is a Supporting Document (SD1) that provides detailed data and analysis of radioactivity in food induced by high-energy X-Rays.

- Section I: References

- Section J: Letters of support

E. Background Information

E.1 Ionising radiations used to treat food and their properties

The Australia New Zealand Food Standards Code (the Code) permits three of the four sources of radiation recommended by the Codex Alimentarius to be used for the irradiation of food (FSC 2021; CAC 2003). They are –

(a) gamma rays from the radionuclide cobalt-60 (^{60}Co); or

(b) X-rays generated by or from machine sources operated at an energy level not exceeding 5 megaelectronvolts; or

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

Each of the permitted sources and types of radiation have advantages and disadvantages which have influenced the commercial development of facilities using them (WHO 1988; IAEA 2021).

Gamma rays and X-Rays are photon radiations, that is, they are part of the electro-magnetic energy spectrum. They may be thought of as waves or packets of energy moving at the speed of light and able to transfer energy through space. Having neither mass nor electrical charge, they penetrate deeply into materials. They are suitable for processing food in large containers or pallets.

The only difference between gamma and X-Rays is one of definition. Gamma rays are produced during the decay process of radioactive isotopes, ^{60}Co in the case of food irradiation. X-Rays are produced when an electron beam produced in an accelerator strikes a heavy metal target converting electron beam energy into X-Rays. Once produced, gamma and X-Rays are indistinguishable.

Electron beam radiation is produced in accelerators and comprises sub-atomic charged particles moving close to the speed of light (Cleland 2013). Electrons have mass and a negative charge and are subjected to coulombic interactions. Electrons in the beam lose energy rapidly and steadily as they pass through material. They are suitable for processing food in thin packages or streams.

All three types of radiation lose energy through interactions with the orbital electrons of the atoms in the food. Orbital electrons are ejected from the atoms which become ionised (electrically charged). The ejected electrons also have high energy and proceed to ionise other atoms. Most of the effects result from these secondary electrons. As all three radiations lose energy in the same way, there is no need to regulate which of the permitted radiations can be used for an approved application (CAC 2003; EFSA 2011).

The amount and type of change in the food depends only on the energy absorbed in the food (the dose). There is no dependence on the initial energy of the radiation itself.

E.2 Radiation processing and its development

Commercial development of industrial radiation processing gathered pace during the 1950s and 1960s. ^{60}Co was used for food because it was relatively easy and cheap to obtain, facilities were very simple to operate and the penetration of the gamma rays was an advantage. The sterilization of medical and healthcare products expanded very rapidly for the same reasons.

There are almost 300 ^{60}Co facilities used for sterilization and food irradiation world-wide (Chmielewski and Berejka 2008; Woolston 2013; GIPA 2017; IAEA 2021). Many gamma facilities operate as multi-purpose facilities for both sterilisation and food. About 30 countries are thought to be irradiating food with 12 to 15 producing commercially significant volumes (Roberts 2016).

Electron beams from low-energy (< 1 MeV[1]) accelerators found use in modifying surfaces and thin materials (IAEA-iiA 2011). However, high-energy accelerators capable of producing electron beams that could penetrate more than a few millimetres into food were very expensive, complex and unreliable until the 1990s. They remain more expensive and complex than ^{60}Co facilities.

High energy electron beam machines are now used for medical product sterilisation and there are approximately 75 such machines operating world-wide (GIPA 2017; NAS 2021), a number that is steadily increasing. A few are used to irradiate foods in relatively thin packages on a conveyer (e.g., ground beef in the USA or spicy chicken legs and wings in China). For all applications of low and high energy machines, reviews published in 2011 and 2013 stated there were between 1400 and 1800 industrial electron facilities world-wide respectively (IAEA-iiA 2011; Cleland 2013) and there are now significantly more (IAEA 2021).

Commercial X-ray facilities were developed even more slowly than electron beam facilities because X-Rays production requires an extra step, the inefficient conversion of an electron beam into X-Rays.

E.3 Production of X-Rays and its efficiency

X-Rays have the same penetrating properties as gamma rays and have long been considered a more desirable source because, unlike gamma rays, they are only produced when needed.

As shown in Figure 1, a narrow beam of fast-moving electrons created in an accelerator exits through a thin window and is magnetically scanned to a suitable width. The electrons hit a heavy metal plate (the X-Ray converter) producing X-Rays which then pass through the food product.

Most of the kinetic energy of the electrons is converted to heat in the target, with only a small fraction converted into X-Rays (usually far less than 10%). This inefficiency leads to X-Rays being the most expensive (capital and operating) type of radiation to use. Conversion efficiency is known to increase as the energy of the electron beam is increased (IAEA 1995).

An X-Ray facility was established to treat medical products in Bridgeport, USA in 2002. More recently, three other large scale industrial facilities for non-food items have been commissioned, one in Daniken, Switzerland, one in Austria and one in the Netherlands (IAEA 2021). Plans are in place for non-food X-Ray facilities in Ireland, the Netherlands and Germany, three in the U.S.A. and one in Thailand (IAEA 2021).

[1] 1 electron volt (eV) = the amount of kinetic energy gained by a single electron accelerating from rest through an electric potential difference of one volt in vacuum. 1 MeV = 10^6 eV.

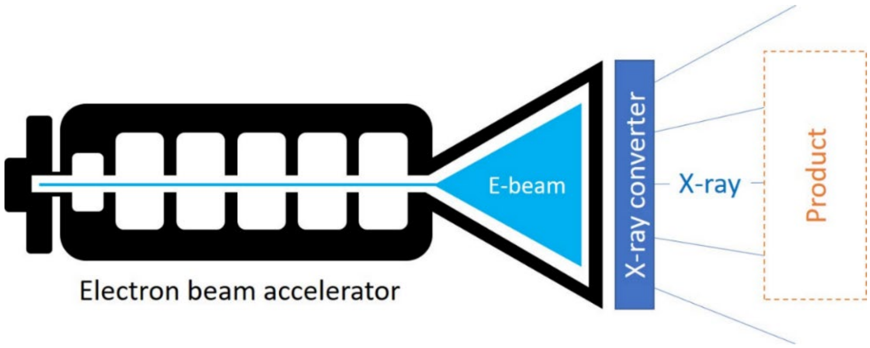

Figure 1: Schematic of X-ray production in a high energy accelerator system (reproduced from IAEA 2021 and with permission from MEVEX Corporation)

The first X-Ray facility to irradiate fresh fruits and vegetables was built in Hawaii, USA, in 2000 (Follett and Weinstein 2012). It was seen as a demonstration facility but it is still in operation. The year 2020 may have been the turning point in the industrial development of X-Ray technology. X-Ray facilities for food started commercial operations in Australia. A Thai facility began conducting research into phytosanitary treatments with commercial production expected in 2022. There are X-Ray-capable machines in Viet Nam and The Republic of Korea although these operate mainly in the electron beam mode.

The construction of four more facilities started in U.S.A. (2), Mexico and Italy, two of which intend to treat mostly food. In summary, there are now several X-Ray facilities treating food commercially and the number is expected to increase significantly in the next few years (IAEA 2021).

E.4 Choice of source and sustainability

The lack of dependence of accelerators on a radioactive source and the ability to 'switch off' the radiation emission when not required has always been recognized as an environmental and public perception advantage. Machine sources avoid the need to safeguard large quantities of radioactive material, which can be costly. Security concerns have also made the licensing of new gamma irradiators and international transportation of radioactive material more difficult, and a switch from ^{60}Co to machine sources is receiving international encouragement (IAEA 2004; IAEA 2015a; NRC 2008; NTI 2016; WINS 2016; NAS 2021), including in Australia (ARPANSA 2022a).

Recently, demand for ^{60}Co has tended to outstrip supply and its price has been increasing. The major market for ^{60}Co is in the sterilisation of medical and health care products which can make it difficult for the smaller food irradiation market to access supplies. There are relatively few suppliers of ^{60}Co and supply issues are happening more frequently, for example during the Covid-19 epidemic.

The last 10 years have seen a profound change with more accelerator facilities than ^{60}Co being established (IAEA 2021). As X-Ray facilities become more cost competitive, more options for radiation source type become available and the irradiation processing industry will become more sustainable. Cost competitiveness will be further assisted if the production of X-Rays becomes more efficient by using accelerators at the highest practical energy.

E.5 Induced radioactivity in food

All foods are slightly radioactive and contribute to the natural background dose of radiation that everyone receives unavoidably. Irradiation of food must not induce any significant extra radioactivity in the food. If the incident radiation energy is above a certain threshold, the radiation can interact not only with the orbital electrons but with the nuclei of the atoms in the food. The threshold in atoms of the elements found in food is approximately 2.2 MeV (IAEA 2002). Above this energy, nuclear interactions can cause changes producing new isotopes in the food which may be -

1. stable (non-radioactive),
2. unstable and therefore radioactive (a radioactive isotope or radionuclide) but which decays rapidly before the food is consumed,
3. a radioactive isotope with a lifetime greater than the time between processing and consumption of the food.

Gamma rays from ^{60}Co have an energy below 2 MeV and cannot induce radioactivity. X-Rays above 2.2 MeV can theoretically induce radioactivity in food with the probability increasing with increasing energy. Experimental measurements have failed to detect any induced activity with either 5 or 7.5 MeV X-Rays (IAEA 2002; Grégoire *et al* 2003a, b; Song *et al* 2018). However, caution has led to confirmatory, theoretical calculations of induced activity at both these energies by an expert group (IAEA 2002) and by the USDA when it approved raising the maximum permitted operating energy for X-Ray production to 7.5 MeV (USFDA 2004). The calculations showed that any induced radioactivity and dose to consumers was negligible compared with the natural radioactivity and background dose.

It is relevant that when the Codex General Standard was first issued in 1983, high energy X-Ray facilities were not practical and the Codex decided to set a limit to the operating energy of 5 MeV on the grounds that theoretical calculations showed that any induced radioactivity was negligible compared to natural background and because higher energy facilities were thought to be unlikely.

F. General Information

F.1 APPLICANT DETAILS

Applicant	[redacted]
Contact	[redacted]
Nature of applicant's business	The applicant is Steritech, a family-owned, Australian business providing contract sterilisation and decontamination services including irradiation of health care products, packaging, pet products, quarantine goods and food
Prepared by	[redacted]
Contributors/ Collaborators	[redacted]
Date submitted	19/09/2022

F.2 PURPOSE OF THE APPLICATION

This application seeks a variation to the Australia New Zealand Food Standards Code (the Code), Standard 1.5.3, section 1.5.3 – 7 (FSC 2021). The proposed variation would increase the maximum energy for machines generating X-Rays from 5 to 7.5 megaelectronvolts (MeV)[2] provided that the X-Ray target is made of tantalum or gold. Other potential target materials such as tungsten could theoretically induce extra radioactivity in the food (IAEA 2002 and see Section H, SD1).

Suggested new wording in the Code is: X-Rays generated by or from machine sources operated at an energy level not exceeding 7.5 MeV provided that the X-Ray target is made of tantalum or gold.

No other variation is sought and the variation seeks a change only to the technical delivery of an already permitted irradiation treatment, namely an increase in the operating voltage of the X-Ray

[2] 1 electron volt (eV) = the amount of kinetic energy gained by a single electron accelerating from rest through an electric potential difference of one volt in vacuum. 1 MeV = 10^6 eV.

source. Specifically, there would be no change to the foods that may be irradiated, or the conditions imposed (Standard 1.5.3 – 3, 4, 5), including the dose range. Gamma rays from ^{60}Co and electrons generated by or from machine sources operated at an energy level not exceeding 10 MeV would remain as permitted sources of radiation for food treatment.

F.3 JUSTIFICATION

Two of the four irradiation processing facilities operated by Steritech Pty in Australia are licensed to irradiate both food and non-food items. There are no facilities in New Zealand that irradiate food. A facility sited at Narangba, near Brisbane, has processed food using gamma-rays from the radioactive isotope ^{60}Co since 2003. The second Steritech food irradiation facility began operations in 2020 in Merrifield, Melbourne, and uses X-Rays generated by an electrically-driven accelerator.

From 1999 to 2020 FSANZ has assessed the technological need, safety and nutrient profile of various foods. These assessments concluded that there was an established need to irradiate the currently permitted foods and that there were no public health and safety issues associated with their consumption when irradiated up to maximum prescribed doses.

As phytosanitary irradiation has been the only application of food irradiation in Australia to date, the intended benefits for this application have been used to justify the requested variation to the Code. The benefits would, however, apply to any other applications of food irradiation.

F.3.1 Need for the variation

The primary purpose of the requested variation is to increase the efficiency with which the electron beam generated in the accelerator is converted into X-Rays. An increase in efficiency of 40 to 50% is expected when the maximum operating voltage of the accelerator is increased from 5 to 7.5 MeV (IAEA 1995; Miller 2006; Petwal, Bapna and 3 others 2007; Cleland and Stichelbaut 2013; private communication, F. Stichelbaut, March 7th, 2022).

A secondary purpose is to increase the sustainability of food irradiation facilities and, by extension, the sustainability of phytosanitary irradiation for Australian exports of fresh produce.

F.4 Advantages of the proposed variation

Immediate benefits that flow from the 40 to 50% increase in efficiency of X-Ray production are –

- More rapid turnaround times within the irradiation facility; this reduces supply chain costs (e.g., through less downtime for drivers of delivery trucks), reduces the time that temperature sensitive fruits and vegetables are out of their temperature-controlled containers, and keeps food quality at the highest level possible. Steritech estimate that processing capacity will increase from 12 pallets per hour to 17-18 pallets per hour approximately.
- Improved management of the variable demands, especially the peaks, of a horticulture industry dealing with a range of seasonal, perishable products.
- Reduced costs to the food industry from the above advantages and the reduced irradiation time since irradiation charges are based on the time taken to irradiate the product.
- Greater penetration into the food (Cleland 2013); this will have the benefit of creating greater uniformity in the dose distribution through the food and make it simpler to meet

maximum to minimum dose criteria, or to treat larger food packages or packages of mixed density.

Irradiation of food in large packages or pallets has traditionally been carried out at gamma irradiation facilities such as the one at Narangba. Both gamma and X-Ray facilities can be operated safely, but machine reliability and capital cost issues associated with high energy accelerators have only been overcome relatively recently and make accelerator-based sources a practical proposition.

Providing source options other than ^{60}Co through increased efficiency of X-Rays will result in -

- a more sustainable industry in the event that ^{60}Co becomes less available for use or more costly.
- less public concern about the siting of facilities if the source of radiation is an accelerator that does not produce radiation when switched off and does not require the use and transportation of radioactive material.

The costs of ^{60}Co have been rising sharply and the potential security risks of diversion of the material for terrorist uses has led to efforts to transition from ^{60}Co to machine sources of radiation (IAEA 2004; IAEA 2015a; NRC 2008; NTI 2016; WINS 2016; ARPANSA 2022b; NAS 2021). Decreasing the operational costs of X-ray facilities by an increase the permitted operating voltage will allow such facilities to be a more economic option for processors and influence their choice of source. Increasing the viability of X-Ray sources will future proof the irradiation industry against potential problems with ^{60}Co sources. The choice of source for the new Steritech facility at Merrifield was driven by such considerations.

F.5 Relative costs

A higher capital cost will be incurred by installing an accelerator capable of operating at 7.5 MeV rather than 5 MeV together with some extra shielding. Approximately A$1 million might be added to the capital cost, a relatively small fraction of the total cost of over A$15 million to establish a radiation facility (personal communication, Steritech Pty Ltd). Note that the Merrifield plant has already been purchased and licensed to operate, and is capable of generating 10 MeV electron beams.

The increased capital cost will be offset by cheaper operating costs resulting from increased efficiency and throughput. Overall, a change to 7.5 MeV X-Rays should result in lower costs to clients since costs are based on the processing time. The actual saving will depend upon local conditions. A theoretical calculation in which all factors except energy were held constant suggested that the costs per ton of food treated would be approximately 33% lower for 7.5 MeV X-Rays than 5 MeV X-Rays (IAEA 1995).

The methods and costs of dose measurement (dosimetry) and process control are unchanged in increasing the X-ray energy from 5 to 7.5MeV.

F.6 Industry (horticultural) interest, benefits and support

Phytosanitary irradiation of fresh produce has been the only commercial use of food irradiation in Australia to date. The major contribution of the horticulture industry to the Australian economy and employment is recognised. The production value of fruits, nuts, grapes and vegetables was $9.6b in

2019-20 despite drought conditions (ABS 2021). The value of exports of fresh fruits and vegetables was $1.4b (HIA 2021a, b). Phytosanitary treatment of regulated pests is often a requirement for market access across Australian state borders and for exports (NFFC 2020; PHA 2021).

F.6.1.1 Phytosanitary irradiation

The importance of phytosanitary treatments to trade in horticultural products has been central to several successful applications to amend Standard 1.5.3, culminating in the 2021 variation (A1193) that allows any fresh fruit or vegetable to be treated for a phytosanitary purpose (excepting dried pulses, legumes, nuts and seeds). The various applications have been supported by the horticulture industry, and by state and federal agencies responsible for trade and, especially, import and export market access. State government support is shown by the interstate quarantine agreement on phytosanitary irradiation (ICA 2011). Letters of industry support for this application are attached.

A range of treatment options including heat, cold, fumigation and irradiation are essential to meet different commodity, pest and importing country requirements. In recent years, irradiation has become increasingly a treatment of choice because it is chemical-free, does not involve an ozone-depleting gas (methyl bromide) and generally results in higher quality products (Roberts 2016). There are internationally agreed protocols for the application of phytosanitary irradiation (ICCP 2003; 2009). The global volume of horticultural commodities treated with phytosanitary irradiation has been increasing rapidly (see Figure 2), approaching 50,000 tonnes in 2019 (PSiP 2021).

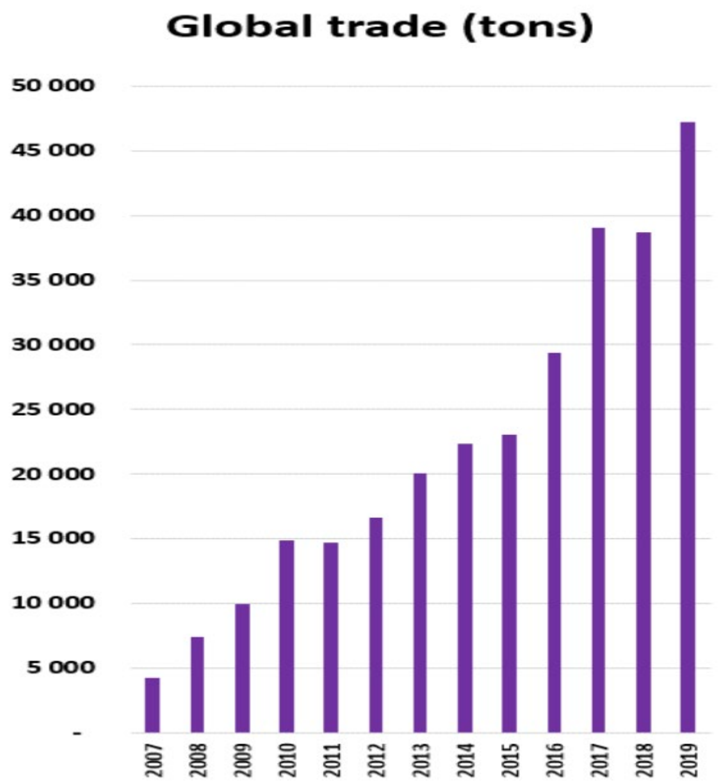

Figure 2 : Global trade in irradiated fruits and vegetables 2007-19 (PSIP 2021)

F.6.1.2 Existing and potential markets

Growth in export markets for irradiated fresh produce has grown steadily since 19 tonnes of irradiated mango was shipped to New Zealand in 2004. Growth has accelerated in recent years (see

Table 1) with extra impetus coming from the opening of the Merrifield facility in January 2020, and the approval by FSANZ for phytosanitary irradiation of all fresh fruit and vegetables. This growth has occurred despite problems with drought and with airfreight and flights due to Covid-19.

Table 1: Australian irradiated exports (tonnes) in recent growing seasons

	Growing Season				
	2017-2018	**2018-2019**	**2019-2020**	**2020-2021**	**2021-22**
New Zealand					
Mango	1297	1357	1491	1282	1805
Tomato	269	517	211	92	359
Capsicum	9	0	5	15	5
Papaya	22	57		3	6
Table Grapes			1387	1003[a]	528[a]
Melons					452
Zuccini					18
Lychee			406	554	572
USA	107				
Mango	12	114	121	215	358
Lychee		16	54	174	185
Viet Nam					
Table Grape	1747	2105	1234	904[b]	2695
Mandarin	55	103	190	25	40
Orange	54	14	22		
Cherry	402	609	512	552	645
Stone Fruit					56
Indonesia					
Plum	0	16			
Cherry			17	18	26
Table Grape					8
Persimmons					5
Malaysia					
Mango	14	15	78	3	2
Thailand					
Persimmon				9	12
Total	**4204**	**5306**	**5619**	**4737**	**7777**

[a]Volumes reduced due to effects of Covid-19 on air freight/flights.

Table 1 shows that the fresh products treated have included 14 different commodities exported to 6 different countries.

Domestically, less than 100 tonnes of irradiated fresh produce per annum was moved between states until 2019/20; this was mostly Queensland fresh produce treated for fruit fly and consigned to Tasmania, South Australia and Western Australia. There has been a remarkable surge in domestic use in the last 18 months as a result of the Merrifield facility and the generic approval of fresh fruit and vegetables, with produce now also entering Tasmania (Table 2). In Table 2, the weight of a pallet varies with the product treated, but an average would be approximately 0.8 tons.

Table 2: Inter-state trade in irradiated fresh produce

Season	Number of Pallets	Produce
2017-18[a]	22	Tomatoes
2018-19[a]	18	Tomatoes
2019-20[b]	120	Mango; stonefruit
2020-21[c]	150	Mango; stonefruit
2021-2022[c]	1378	Apples; Blueberries; Baby broccoli; Citrus; cherries; cauliflower; carrots; capsicum; Dates; Figs, Grapes; Kiwifruits; lemons; limes; Leafy Greens; mango; Pears; Persimmons; Raspberries; Strawberries; stonefruit; tomatoes

[a]Only Narangba facility operating
[b]Merrifield facility operational for only part of year + Narangba
[c]Merrifield and Narangba facilities fully operational

In total (export + domestic), Steritech facilities irradiated almost 9,000 tons of fresh produce in the 2021-22 season with approximately 30 types of produce treated.

The commodities irradiated at the Narangba facility in Queensland for many years have mainly come from growers in Queensland. Transport time and costs limited the use of that facility by growers from other states such as Victoria, South Australia and southern New South Wales. The newer, X-Ray facility in Melbourne provides a phytosanitary irradiation option for major production regions. It is already providing new export opportunities, for example grapes to Vietnam and New Zealand. An increase in X-ray energy to 7.5 MeV at the Melbourne facility will lower the costs to growers and encourage this new initiative.

Irradiated exports to countries that only permit X-ray treatments with 5 MeV X-Rays could still proceed, as the Merrifield accelerator is capable of operating at both 5 and 7.5 MeV. This would currently include important markets such as Viet Nam although a change to the Vietnamese regulation to permit treatment with 7.5 MeV X-Rays is widely expected shortly.

F.6.2 Public safety

Irradiation facilities have been operating safely since the 1960s both globally and in Australia and New Zealand. No new design or safety issues are involved in increasing the maximum energy level of an electron beam/X-ray facility from 5 MeV to 7.5 MeV. Globally there are up to 75 accelerators operating with electron beams at up to 10 MeV that are used for sterilisation with a few used for food irradiation (GIPA 2017, IAEA 2021).

Existing commercial irradiation facilities in Australia are 3 contract gamma facilities operated by Steritech at Melbourne, Sydney and Narangba (Queensland) and an electron beam/X-ray facility at

Merrifield, Melbourne. In New Zealand there is a gamma facility in Upper Hutt (New Zealand) operated by MSD Animal Health, mainly for its in-house requirements. These facilities sterilise a range of medical, health care, packaging and other products. The Steritech facilities in Narangba and Merrifield are the only ones also licensed to irradiate food.

Irradiation facilities are regulated and licensed by the relevant federal, state and local authorities in Australia and the Ministry of Health's Office of Radiation Safety in New Zealand. These competent authorities follow the guidance of the International Atomic Energy Agency (IAEA) in assessing irradiation facility design for human health and environmental safety and in licensing and auditing the operation of any facility.

The criteria for safe design and operation of electron beam, gamma and X-ray facilities are well-established and are based on the IAEA Safety Standards Series No SSG-8 (IAEA 2010). An overview including relevant ISO/ASTM standards for food irradiation facilities is provided in a Manual of Good Practice in Food Irradiation (IAEA 2015b). The requirements and methodologies for dosimetry and process control are unaffected by an increase in maximum X-ray energy from 5 MeV to 7.5 MeV. An overview of dosimetry and process control is provided by an IAEA document (IAEA 2015b).

The only design consideration in increasing the maximum energy of the electron beam is a small increase in the thickness of the concrete shielding (the Biological Shield). The procedures for evaluating shielding requirements for electron beam energies well in excess of 7.5 MeV are established and used for medical (cancer radiotherapy machines), medical product sterilisation and research applications. Provided the converter material is gold or tantalum, there are no issues of induced radioactivity in the food, shielding or other structural materials (IAEA 2002 and Section H).

F.6.3 Consumer safety

The safety of food irradiated with 5 or 7.5 MeV maximum energy X-Rays is discussed in Section G.

F.6.4 Consumer choice and perceptions

If Standard 1.5.3 is amended to permit the use of 7.5 MeV maximum energy X-Rays, the lower processing and supply chain costs at the higher energy should be passed on to the consumer. Other consequences for the consumer will be minimal.

At retail there will be little difference in the type or quality of irradiated commodities offered for sale. A greater range of commodities may be offered for sale via the Melbourne facility as reduced costs encourage new clients. It is most unlikely that the proposed amendment will have a negative effect on most consumer opinion. There is a possibility that there will be a positive effect on the opinion on a small number of well-informed consumers due to the potential to reduce the use of radioactive materials.

Consumer opinion on food irradiation has been fully discussed in previous successful applications to FSANZ to permit the irradiation of fruits and vegetables. In the relevant literature, consumers are generally asked about their views on "irradiation" without reference to the radiation source. If information on the radiation sources is provided it is basic, and the usual assumption has been that the radiation source will be ^{60}Co. In a few surveys, even participants supportive of food irradiation have recorded a level of discomfort with the idea of a radioactive source being involved in food irradiation.

It seems reasonable that consumers would be less concerned by a non-radioactive machine source of radiation than a radioactive source, but this assumption has not been the subject of a statistically robust scientific survey. There may be a small sub-set of consumers with sufficient knowledge of irradiation processing to appreciate the differences between electron beam or X-Ray sources and radioactive sources. This may or may not translate to greater acceptance of food irradiation.

F.6.5 Labelling

There is a mandatory requirement to label irradiated food, no matter how minor the ingredient. The labelling requirements for irradiated food do not require technical details of the process to be provided. Irradiated foods must be accompanied by a statement to the effect that the food has been treated with ionising radiation. Irradiated foods are usually described as "irradiated" or "treated with irradiation".

Currently, the wording of the statement is not prescribed. Food manufacturers can select the wording, so long as the statement indicates to the effect that the food has been treated with ionising radiation and is not false and misleading under the requirements of Australian Consumer Law and the New Zealand Fair Trading Act 1986.

There will not to be any false and misleading aspects if the term 'X Rays' is used on a food label. X-Rays are ionising radiation, and this is a well-established technical fact. A search of the internet verifies this and there is an abundance of information on X- Rays to describe its ionising potential and effects on chemical bonds. The use of the term X-Ray is a familiar to consumers because of the common use of X-Rays in medical imaging, and may be a less confusing term for consumers than the generic term 'ionising irradiation'.

F.6.6 Environment

An increase in the maximum X-Ray energy permitted for food irradiation will encourage increasing use of irradiation as opposed to alternative phytosanitary measures that use methyl bromide or chemical treatments. Methyl bromide is an ozone-depleting gas that is still allowed for quarantine pre-shipment treatments under the Montreal Protocol on Substances that Deplete the Ozone Layer (UNEP 2020). Methyl bromide has been almost phased out under the Protocol for other uses.

Quarantine/biosecurity agencies world-wide are reducing methyl bromide use with the aim of phasing out its use as a phytosanitary treatment. The US supports international efforts to reduce methyl bromide usage through the use of alternatives (UNEP 2020; Chin 2016; USDA 2018). The US is the largest market for irradiated fresh produce and fruit exporting countries targeting the US market have found that the USDA encourages replacement of methyl bromide with a pre-shipment irradiation treatment.

The effect on electrical power usage and any consequent CO_2 emissions of operating an accelerator at 7.5 MeV will be minimal. At the higher energy there is a potential for increased power usage, depending upon other operating conditions. However, the utilisation of the electron beam energy is increased 40 – 50% and any potential increase will be mitigated by the faster processing time. It is probable that the power usage and emissions per unit of food processed will be similar at 5 and 7.5 MeV.

In a ^{60}Co facility, gamma radiation is emitted continuously and needs constant shielding whether in operation or not. It also requires the transportation of radioactive ^{60}Co from where it is produced to the facility before start-up. Fresh ^{60}Co is required every 18 months to two years during operation and ^{60}Co sources that have reached the end of their useful life are transported back to the manufacturer for recycling.

Gamma facilities have an excellent operational safety record and the environmental risks of operation and transport of the ^{60}Co sources are negligible. However, an accelerator source only emits radiation when it is powered on and no radioactive material is involved. Although solid scientific evidence is lacking, a public preference for electron beam and X-ray sources based on perceived environmental safety grounds is generally acknowledged.

There is a security concern with radioactive sources that does not exist with accelerator sources. In recent years concern has increased about the potential for diversion of radioactive material for a 'dirty bomb' or other terrorist uses. The sources of most concern tend to be medical and small industrial radiography sources rather than those found in industrial processing facilities. However, there is now an internationally recognised effort to switch to non-radioactive sources for both industrial and medical uses (IAEA 2004; IAEA 2015a; NRC 2008; NTI 2016; WINS 2016) including in Australia (ARPANSA 2022b).

F.6.7 Similar applications overseas

Over 60 countries have approved one or more uses of food irradiation. All have regulations based on the Codex General Standard for Irradiated Foods (CAC 2003). The Codex Standard recommends four sources of radiation including X-Rays generated from machine sources operated at or below an energy level of 5 MeV. Most countries place that restriction on X-Ray sources.

Five countries have already changed their regulation to permit a maximum operating energy of 7.5 MeV provided the X-ray target material is tantalum or gold. They are the USA, India, Indonesia, Canada and South Korea (USFDA 2004; GI 2012; NADFC 2013; CG 2016; MFDS 2020).

Many of the countries likely to consider X-ray facilities in the future are those that already use ^{60}Co generated gamma irradiation as a phytosanitary treatment of some commodities exported to the USA. In 2020, at least 9 countries other than Australia were exporting irradiated fresh produce to the USA (USDA 2018). Before allowing these commodities to be imported, the US authorities enter into a reciprocal agreement with the exporting country that the exporting country will agree to the same rules that are applied to foods imported into the USA. To date, the USA has not insisted that regulations in the exporting country allow the use of 7.5 MeV X-Rays. It has not been an issue but it may become one in the future.

As experience with electron beam machines increases and more capacity is needed for applications that require penetrating radiation, more countries will consider X-ray facilities. They will then be faced with the issue that 5 MeV X-Rays are not as efficient as 7.5 MeV X-Rays. It is expected that more countries will change their food irradiation regulations to allow the use of the higher energy.

F.7 Regulatory impact information

F.7.1.1 Consumers

This has been addressed above (F.6.3, F.6.4 and F.6.5)

F.7.1.2 Government

The technical change in process delivery proposed in this application will have no consequences for the government agencies that interact with the irradiation industry. Regulatory control of a facility as both an irradiation and a food facility will not be affected and is cost neutral.

The control of insect and other pests is vital to the sustainability of the horticulture industry, to export market access and to the movement of produce between states (NFFC 2020). Government provides significant support for pest control through research and its quarantine and inspection services (PHA 2021).

The importance of phytosanitary treatments to the Australian and New Zealand horticulture industries and broadening the treatment options to include irradiation has been central to several successful applications to modify Standard 1.5.3.

F.7.1.3 Impact on international trade

The likely impact of an increase to the maximum permitted operating energy of X-Ray facilities on increasing Australian fresh produce exports has been discussed above.

The proposed variation will not, of itself, impact international trade generally as no changes to the applications approved under Standard 1.5.3 are proposed. However, the likely increase in export trade due to decreased costs will add to the world-wide trend of increasing trade in irradiated fresh produce (PSiP 2019). This will increase the likelihood of more countries expecting to have the reciprocal right to import irradiated fresh produce into Australia.

F.7.1.4 Costs and benefits

The relative capital and operating costs of 5 and 7.5 MeV X-Ray facilities were discussed earlier. The benefits of the proposed application arise simply from the 40 to 50% increase in efficiency and speed of processing expected for changing to the higher operating voltage. The increased efficiency will lead to reduced costs to horticultural clients as processing charges are based on processing time (IAEA 1995). These reduced costs should be passed on to consumers.

The proposed variation is cost neutral to government regulators of irradiation facilities as discussed earlier. Improved cost competitiveness for irradiated fresh produce will benefit government more generally through improving overseas market access and trade, and maintaining a high level of biosecurity in domestic trade. Phytosanitary irradiation has already helped to maintain and expand Australia's horticultural export trade. Small but significant and increasing markets (see Table 1) have been gained in New Zealand (mango, litchi, tomato, capsicum), the USA (mango, litchis), Vietnam (grape, cherry, orange, mandarin), Indonesia (cherry, plum), Malaysia (mango) and Thailand (persimmons). The X-ray facility in Melbourne will further enhance market access, especially if a maximum energy of 7.5 MeV can be applied to achieve extra efficiency and reduced costs.

F.8 INFORMATION TO SUPPORT THE APPLICATION

Information related specifically to the irradiation of food as required by section 3.5.3 of the FSANZ Application Handbook is provided mainly in Section G.

F.8.1 Literature searches and references

This application involved two issues not previously addressed in previous applications. These were the efficiency of conversion of 5 and 7.5 MeV electron beams into X-Rays, and the potential for induced radioactivity in the food.

Literature searches were conducted in March 2022 using the PUBMED, SCOPUS, Science Direct, SciFinder, Springer and ProQuest databases.

F.8.1.1 Conversion efficiency

The increased efficiency with which energetic electrons are converted into X-Rays as the electron energy increases has been known since the development of the early X-Ray tubes used in medicine from the early 20th century. Efficiency only became an issue when X-Rays were considered as an irradiation source for industrial purposes. In 1995, a report of an expert consultation convened by the IAEA considered the relationship between electron energy and conversion efficiency in detail and included earlier references (IAEA 1995). Since that time, some work has been conducted mainly by equipment manufacturers to refine the calculations of the IAEA report especially with regard to the design of the target using Monte Carlo modelling methods. Much of this work is unpublished though discussed openly at scientific meetings.

We have carried out a literature search for relevant publications from 1995 using the terms –

- Induced activity + food + X-Rays
- Induced activity + X-Ray energy + food

Several papers were found are quoted in Section G. In addition, we have corresponded with a leading modelling group based within the Ion Beam Applications accelerator manufacturing group based in Belgium. Permission has been given to quote their latest, unpublished data (F. Stichelbaut, personal comm. 2022). All the published and recent unpublished data fall within a similar range for the increase in efficiency as the operating voltage is increased from 5 to 7.5 MeV. The increase is 40 to 50% as used in this application.

F.8.1.2 Induced radioactivity

The International Atomic Energy Agency (IAEA) convened an expert panel that produced the seminal work on induced radioactivity in food (IAEA 2002). This detailed and referenced all the work done prior to 2002. The USFDA was the first national authority to authorise the use of X-Rays with a maximum energy of 7.5 MeV. In issuing its decision (USFDA 2004), the USFDA used the IAEA publication and cited a few other studies conducted in the period up to 2004.

Our literature search using the linked terms -

- *“Induced + radioactivity + food”*
- *"X-Rays + induced radioactivity + food”*
- *"X-Rays + processing + induced radioactivity"*

provided a few papers relevant to this application published after 2005. Most appeared to be reviews of earlier work and contained no new information.

A paper in 2018 (Song *et al* 2018) could not detect induced radioactivity in chicken meat irradiated with 7.5 MeV X-Rays at 30 kGy and is quoted in Section G. Miyahara (2006) and Furuta and Ito (2013) have published in Japanese. An English abstract of the Miyahara paper states that what are described as small amounts of radioactivity were found in electron beam irradiated foods at 24 MeV. The Furuta and Ito (2013) paper appears to be a simple review of earlier work but there is no English abstract available.

F.8.2 Data related to safety studies

This application does not seek any change to the foods that may be irradiated or to the doses that may be applied to them. FSANZ has already assessed the toxicological and microbiological safety and nutritional adequacy of existing uses.

The only safety issue raised by this application is the possibility of inducing significant radioactivity in the food. Sections G and H provide the data to show that induced radioactivity is not a public health and safety concern.

F.9 ASSESSMENT PROCEDURE

This application is limited to a technical adjustment to the delivery of the radiation dose only. No change is sought to the foods that may be irradiated or the conditions imposed within Standard 1.5.3 (sections 1.5.3 – 3, 4, 5). The applicant suggests that the General Procedure would be the most appropriate assessment procedure for this application.

F.10 CONFIDENTIAL INFORMATION (COMMERCIAL AND NON-COMMERCIAL)

None of the information supplied in this application is confidential.

F.11 EXCLUSIVE CAPTURABLE COMMERCIAL BENEFIT

No ECCB will be conferred on the applicant by the approval of this application.

- The principles of the production and properties of X-Rays have been well documented in the scientific literature since their discovery in 1895, including the increasing efficiency of conversion of the electron beam energy into X-Rays as the beam energy increases.
- Industrial and medical accelerators capable of producing electron beams of 10 MeV energy and greater are widely used in many countries and the equipment is available from several suppliers including suppliers in Belgium, Canada, China, Japan and South Korea.
- There are approximately 75 high energy electron accelerators operating world-wide for medical product sterilisation (GIPA 2017; NAS 2021), a number that is increasing rapidly (IAEA 2021). It would be a relatively simple technical change to convert these to X-Ray use.
- High-energy X-Ray facilities for non-food applications are operating in the USA, Switzerland, Austria and the Netherlands with more planned for Ireland, the Netherlands and Germany (IAEA 2021).

- X-Ray facilities for food are now operating commercially in Hawaii and Australia, and for research in Thailand. There are X-Ray capable machines operating in Viet Nam and South Korea although these are usually operated in the electron beam mode.

F.12 INTERNATIONAL AND OTHER NATIONAL STANDARDS

F.12.1 International

The Codex General Standard for Irradiated Foods (CODEX STAN 106-1983, Rev.1-2003) recommends the following types of ionizing radiation to treat food (CAC 2003):

a) Gamma rays from the radionuclides ^{60}Co and ^{137}Cs;

b) X-Rays generated from machine sources operated at or below an energy level of 5 MeV;

c) Electrons generated from machine sources operated at or below an energy level of 10 MeV.

The initial Codex standard was issued in 1983 and based on the earlier study of the Joint Expert Committee on Food Irradiation (JECFI 1981). At that time, high voltage accelerator technology was still developing. X-Ray sources were regarded as a research option for the future that would probably be limited to approximately 5 MeV. It is only recently that such sources and, especially, the use of X-Rays with a maximum energy above 5 MeV have been seriously considered by the food processing industry.

F.12.2 National

As countries developed their food irradiation legislation, all followed the Codex recommendation for the types of radiation that could be used. More than 60 countries now have legislation permitting the irradiation of food under defined conditions based upon the Codex recommendations and most still permit X-Rays to be used only if the source of the X-Rays operates at or below 5 MeV.

If Standard 1.5.3 is amended as requested, it will no longer comply exactly with the Codex General Standard for Irradiated Foods. However, several national regulations now permit X-Rays generated at a maximum energy of 7.5 MeV to be used (USFDA 2004; GI 2012; NADFC 2013; CG 2016; MFDS 2020) provided the X-ray target material is tantalum or gold. Standard 1.5.3 of the Code already varies from the Codex Standard in that it does not permit ^{137}Cs to be used.

F.13 STATUTORY DECLARATIONS

Statutory Declaration – Australia

Statutory Declaration – Australia

STATUTORY DECLARATION

Statutory Declaration Act 1959 1

I, Murray Lynch CEO, Steritech, 160 South Gippsland Highway, Dandenong South VIC 3175 make the following declaration under the Statutory Declaration Act 1959.

1. The information provided in this application fully sets out the matters required.
2. The information provided in the application is true to the best of my knowledge and belief.
3. No information has been withheld that might prejudice this application, to the best of my knowledge and belief.

I understand that a person who intentionally makes a false statement in a statutory declaration is guilty of an offence under section 11 of the Statutory Declarations Act 1959, and I believe that the statements in this declaration are true in every particular.

[signature of person making the declaration]

Murray Lynch

Declared at Melbourne on 22nd April, 2022

Before me,

Mario Romano

CPA # 9205852

160 South Gippsland Highway, Dandenong South VIC 3175

[Signature of person before whom the declaration is made] [Full name, qualification and address of person before whom the declaration is made (in printed letter)]

Statutory Declaration - New Zealand

Statutory Declaration

I *(Enter your full name)*

PETER BROOKES ROBERTS

of *(Enter the address where you live)*

12A WAITUI CRESCENT, WAIWHETU, LOWER HUTT, NEW ZEALAND 5010

(Enter your occupation – for example, bricklayer, teacher, unemployed)

SCIENCE CONSULTANT

solemnly and sincerely declare that

(List the facts in your own words. Number each point to make it clearer)

Note: What you write must be true. You can be prosecuted if you make a false declaration.

1. The information provided in this application fully sets out the matters required, and

2. The information is true to the best of my knowledge and belief, and

3. No information has been withheld that might prejudice this application to the best of my knowledge and belief.

I witnessed this declaration electronically and am satisfied to its validity as best as I am able.

I make this solemn declaration conscientiously believing the same to be true and by virtue of the Oaths and Declarations Act 1957.

Note: Do not complete the following section until you are with the person witnessing your declaration.

Your signature

P B Roberts

Declared at *(Place, for example town or city)*

Lower Hutt

(Day/month/year)

30 03 20

Before me *(Name of official witness)*

Glenda Barratt

G.D. Barratt, JP
#11083
LOWER HUTT
Justice of the Peace for New Zealand

Signature of official witness

(For example, a Justice of the Peace, solicitor or another person authorised to take a statutory declaration)

F.14 CHECKLIST

General requirements (3.1.1)		
Check	**Page No.**	**Mandatory requirements**
		A Form of application
		√*Application in English*
		√*Executive Summary (separated from main application electronically)*
√		√ *Relevant sections of Part 3 clearly identified*
		√ *Pages sequentially numbered*
		√ *Electronic copy (searchable)*
		√ *All references provided*
√		B Applicant details
√		C Purpose of the application
		D Justification for the application
√		√ *Regulatory impact information*
		√ *Impact on international trade*
√		E Information to support the application
		√ *Data requirements*
		F Assessment procedure
		√ *General*
√		☐ *Major*
		☐ *Minor*
		☐ *High level health claim variation*
		G Confidential commercial information
		☐ *CCI material separated from other application material*
√		☐ *Formal request including reasons*
		☐ *Non-confidential summary provided*
		H Other confidential information
√		☐ *Confidential material separated from other application material*
		☐ *Formal request including reasons*
		I Exclusive Capturable Commercial Benefit
√		☐ *Justification provided*

	J International and other national standards
√	√ *International standards*
	√ *Other national standards*
√	K Statutory Declaration
	L Checklist/s provided with application
√	√ *3.1.1 Checklist*
	√ *All page number references from application included*
	√ *Any other relevant checklists for Chapters 3.2–3.7*

G. REQUIREMENTS FOR IRRADIATED FOODS

G.1 Foods or food ingredients to be irradiated

This application seeks no change to the foods or food ingredients that can be treated by ionizing radiation under FSC Standard 1.5.3 – Sections 3, 4 and 5. In practice, fresh produce treated for a phytosanitary purpose have been the only foods treated in Australia.

G.2 Technical need

G.2.1 Efficiency gains from increasing the maximum energy of X-Rays from 5 to 7.5 MeV

Converting an electron beam to X-Rays has the advantage of producing a more penetrating radiation that is equivalent to that of ^{60}Co gamma rays. For 5 and 7.5 MeV maximum energy X-Rays the penetration is even greater than for ^{60}Co gamma rays (Cleland 2013). The disadvantage is that only a small fraction of the kinetic energy of the electron beam is converted to X-Rays with the remainder dissipating as heat.

The economics of commercial irradiation require as much of the initial power of the source to be absorbed within the intended target (the food) as possible. The overall utilization of gamma or electron beam power can only be discussed in general terms. Exact utilization figures are highly dependent on the design of the facility especially the way in which the food packages or pallets are presented to, and conveyed around, the radiation source.

^{60}Co emits gamma rays isotropically, that is uniformly over a full 360^{o}. Some of the rays will not be directed at the food and others will be absorbed in surrounding equipment. The gamma rays that are incident on the food are absorbed exponentially and some of their energy is not deposited in the food. Even with the best facility design it is generally thought (Woolston 2013) that a maximum of about 30% of the gamma ray energy is captured within the food (the photon energy utilization).

A 1995 consultants' report (IAEA 1995) discussed the overall utilisation of electron beam power in an X-Ray facility. For a given electron beam energy (MeV), the utilization of electron beam power (kW) in the food is mainly determined by the efficiency of conversion of the kinetic energy of the electrons to X-Rays that are emitted from the X-Ray converter in a forward direction (the direction of the beam).

Most of the energy in the electron beam is converted to heat in the metal converter. Minor energy losses occur due to electron self-absorption in the window through which the beam exits the accelerator and in the converter. A small fraction of the incident electron energy exits the converter as X-Rays. The X-Rays are mainly directed forward in the direction of the beam but are also scattered over a fairly wide angle. Only X-Rays which are directed through the food product are utilised (see Figure 3).

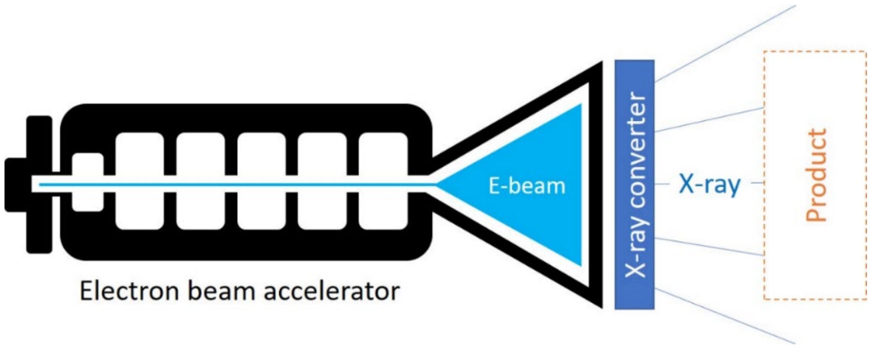

Figure 3: Schematic of X-ray production in a high energy accelerator system (reproduced from IAEA 2021 and with permission from MEVEX Corporation).

The 1995 report (IAEA 1995) clearly showed that increasing the incident electron beam energy from 5 to 7.5 MeV increased the efficiency with which X-Rays were emitted in the forward direction and passed through the food product. Conversion efficiency varies with target design such as target material and thickness. Several more recent publications have estimated conversion efficiency in the forward direction using computer modelling studies (Miller 2006; Petwal, Bapna and 3 others 2007; Cleland and Stichelbaut 2013). Although there are minor differences due to the assumptions used, all the studies agree that there is an increase in conversion efficiency of approximately 40 – 50% when the maximum operating energy is increased from 5 to 7.5 MeV.

Recent studies at a leading manufacturer of industrial X-Ray systems, IBA Belgium, used the Geant3 modelling tool with an optimized target comprising a layer of tantalum, a layer of water and a layer of steel (private communication, F. Stichelbaut, March 7th, 2022). The results, shown in Table 3, show a 42% increase in X-Rays emitted from the target in the forward direction.

Table 3: Calculated increase in conversion efficiency for 5 and 7.5 MeV electron beams

	Energy MeV	Conversion efficiency %	Increase
Electrons converted into X-Rays	5	15 to 16	+25 to +47%
	7.5	20-22	
X-Rays emitted forward emerging from the target	5	11	+42%
	7.5	15.6	

In practice, the overall utilization of electron beam power is now considered to be approximately 40 to 50% for medium density materials in well-designed X-Ray facilities. This figure was also used in an economic analysis of food irradiation facilities (Dethier and Mullier 2018). Depending upon the accelerator design and supplier and the local costs of power, the cost savings due to increased efficiency may be partly offset by slightly higher capital and other operating costs (e.g., cooling water).

This increase in efficiency is the basis for this application and the expected reduction in operating costs and increasing utilization of the technology.

G.3 Food products likely to contain irradiated food or food ingredient

This application seeks no change to the foods or food ingredients that can be treated by ionizing radiation under FSC Standard 1.5.3 – Sections 3, 4 and 5. In practice, fresh produce treated for a phytosanitary purpose have been the only foods treated in Australia.

G.4 Safety of irradiation

The USFDA cited the increased conversion efficiency and extra penetration of X-Rays produced at the higher energy level as the purpose of its new rule (USFDA 2004). In evaluating the safety of the increase in maximum energy from 5 to 7.5 MeV the FDA concluded that the change presented no new issues of chemical safety. The FDA also evaluated the extra radioactivity induced in the food as trivially low and resulting in an inconsequential increase in radiation exposure to consumers.

G.4.1 Toxicological and microbiological safety

All three types of radiation (gamma, electrons and X-Rays) cause orbital electrons to be ejected from atoms. These secondary, ejected electrons also have high initial energy and ionise further atoms nearby. It is the cascade of secondary electrons that produce most of the radiation effects and chemical reactions within the material for all three types of radiation. Therefore, the mechanism by which changes are brought about by gamma rays, X-Rays and an electron beam are essentially identical, as are the chemical reaction products (EFSA 2011). The amount of chemical change is set by the absorbed dose. It is not affected by the energy of the incident radiation.

There are, therefore, no new toxicological or microbiological safety issues implicit in this application.

G.4.2 Induced Radioactivity in food

Although the chemical changes in the food are not dependent on the energy of the incident radiation, there is an increasing probability of changes in the nuclei of atoms as the incident energy increases. Some changes in the nuclei induce radioactivity in the food. Any increase in radioactivity over the level found naturally in all food has the potential to lead to increased radiation exposure of the consumer. This potential safety issue is summarized briefly in this section with details given in Section H, Supporting Document 1 (SD1).

Radioactivity can theoretically be induced into food by irradiation with X-Rays above 2.2 MeV and the amount induced increases with the energy of the X-Rays. A report of the WHO/IAEA/FAO Joint Expert Committee on Food Irradiation considered the induction of radioactivity by 5 MeV X-Rays and 10 MeV electrons JECFI (1981). At that time, it was considered unlikely that practical X-ray sources would be developed at energies above about 5 MeV. The recommendations of the Codex General Standard and consequent national food irradiation legislation were based on the finding (JECFI 1981; WHO 1994; EFSA 2011) that the potential for these radiations to induce radioactivity and any consequent radiation exposure of consumers is negligible though not absolutely zero.

X-rays with a maximum energy of 7.5 MeV will have a higher probability of inducing radioactivity in the food than 5 MeV X-Rays, and this should be considered in this application.

Induced radioactivity has not been detected experimentally with irradiation with either 5 or 7.5 MeV X-Rays (IAEA 2002; Grégoire *et al* 2003a, b; Song *et al* 2018). An IAEA report (IAEA 2002) provided theoretical calculations of the activity that might be induced by high doses (30 and 60 kGy[3]) of high energy X-Rays. Induced radioactivity was found to be a small fraction of the activity found in non-irradiated foods.

The activity in non-irradiated foods contributes to the radiation exposure of people due to several sources of ionizing radiation found naturally in the environment, an inevitable background dose.

The radiation dose to consumers eating 40 kg per annum of food that had been treated 48 hours previously with 60 kGy of 5 MeV X-Rays or 30 kGy of 7.5 MeV X-Rays was calculated to be 1/30,000 of the annual exposure dose to natural sources of radiation, including exposure from non-irradiated food (IAEA 2002).

Section H, SD1, derives the potential dose from induced activity to a person consuming 40 kg per year of irradiated food that had been irradiated 24 hours previously to a dose of 10 or 1 kGy of 7.5 MeV X-Rays. The potential dose from irradiating food with 10 kGy was calculated to be 0.06% of the dose received from non-irradiated food and 0.01% of the dose from all natural sources of exposure.

For phytosanitary irradiation with a maximum dose of 1 kGy from 7.5 MeV X-Rays, induced radioactivity would contribute no more than 0.006% of the effective dose to consumers from non-irradiated food even if 25% of all fresh produce was to be irradiated and consumed within 24 hours.

In practice, the dose to consumers would be less than those discussed above because the average and mean energy of X-Rays produced would be less than the maximum energy (ARPANSA 2022b)

Further information to support the safety of the food at the requested increased maximum energy for machines generating X-Rays of 7.5 MeV is in Supporting Document 1 (SD1), see Section H.

G.5 Nutritional impact of irradiation

As discussed in Sections E and G.4.1, the amount of chemical change brought about by irradiation depends solely on the dose, the energy transferred to the food. It is not affected by the energy of the incident radiation. The potential nutritional impact of irradiation is a result of the chemical changes caused by the irradiation dose. As this application seeks no change to the dose applied to foods permitted to be irradiated, there is no nutritional impact that has not been previously considered by FSANZ in the assessment of earlier, approved applications to irradiated food.

G.6 Checklist

Irradiated foods (3.5.3)		
Check	**Page No.**	**Mandatory requirements**
√		A.1 Nature of the food or food ingredient to be irradiated
√		A.2 Technological need

[3] Gy = Gray, the unit of absorbed radiation energy (dose) = 1 Joule per kg. 1 kGy = 1000 Gy

√	A.3 Food products likely to contain irradiated food
√	B Safety information
√	C Nutritional impact

H. Supporting Document SD1

H.1 INDUCED RADIOACTIVITY PRODUCTION AND THE POTENTIAL RADIATION EXPOSURE OF CONSUMERS FROM IRRADIATION OF FOOD BY 5 AND 7.5 MeV X-RAYS.

This Supporting Document and its Annex (H2) summarise the calculations and findings relevant to the Application found in an IAEA Report, "Natural and Induced Radioactivity in Food" (IAEA 2002). It then proceeds to relate the findings to Standard 1.5.3 and the proposed variation.

To be meaningful, any induced activity must be put in the context of the radioactivity in non-irradiated food and the radiation we are exposed to in our natural environment. This supporting document discusses –

- Natural radioactivity in non-irradiated food.
- The radiation exposure (dose) to consumers from natural sources of radiation, including non-irradiated food.
- Experimental attempts to measure induced radioactivity by high energy X-Rays.
- Calculations of induced radioactivity from 5 and 7.5 MeV X-Rays derived from IAEA (2002).
- Potential radiation exposure from induced radioactivity derived from IAEA (2002).
- The implications of induced radioactivity for Standard 1.5.3 and, in particular, the exposures and potential health risks involved from phytosanitary treatment of fresh produce.
- Annnex – Derivation of key data used in this Supporting Document.

H.1.1 Natural radioactivity in food

People are inevitably and continuously exposed to radiation. Natural sources of radiation in our environment are cosmic rays, external terrestrial radioactivity (in soil and buildings), radioactive gases inhaled from the air and radioactivity ingested with food. These natural sources and their effects are assessed by the United Nations Committee on the Effects of Atomic Radiation (UNSCEAR) and are reviewed at regular intervals (UNSCEAR 2000, 2008).

Foods contain a wide range of concentrations of radioactive isotopes (radionuclides) of which an isotope of potassium (^{40}K) and U/Th series isotopes in the U/Th decay series[4] are the most significant (UNSCEAR 2000, 2008). Concentrations in food depend upon the composition of the specific food and how and where it is produced. ^{40}K activity has been measured to range from 45 to 650 Bq per kg

[4] U/Th = Uranium/Thorium

of food[5]. Potassium, including ^{40}K, is maintained in the body under homeostatic control. Therefore, levels of ^{40}K in the body are more or less uniformly distributed even if eaten in varying amounts. The activity of the many U/Th isotopes that may be found in food such as ^{210}Po, ^{228}Th and ^{226}Ra is highly variable. For example, typical values for ^{228}Th and ^{226}Ra are 0.01 to 1.26 Bq per kg. Unlike potassium, levels in the body are directly dependent on the amount consumed.

Although U/Th activities are much less than ^{40}K activity, the effects of radiation exposure due to the two types of isotopes are similar. As discussed later, this is because of the more damaging effects of the type of radiation (alpha-rays) emitted some by U/Th isotopes.

A value of 300 Bq per kg is often taken as a representative global value of the natural radioactivity in food (UNSCEAR 2000, 2008). Table 4 summarizes natural radioactivity found in foods.

Table 4: The range and accepted average for natural radioactivity in food (UNSCEAR 2000)

Radionuclide	Activity (Bq/kg)
^{40}K	45 to 650
U/Th	0.01 to 1.26
Total (accepted average)	300

H.1.2 Radiation exposure of consumers from natural sources

UNSCEAR issues regular estimates of global averages of exposure from each natural source of radiation exposure (UNSCEAR 2000, 2008) based on information provided by national authorities including the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA). Exposures can vary greatly due to latitude and altitude (cosmic), soil composition, building materials and lifestyle (terrestrial and inhalation) and diet and production conditions (food).

The Gray (Gy)[6] is the unit of absorbed dose, the radiation energy absorbed. A different unit is used when measuring the potential harm from the absorbed dose. The biological harm from radiation exposure is measured as an effective dose which is weighted to account for different effectiveness of different radiations and the different susceptibility of different tissues. Effective dose is defined with a unit of a Sievert (Sv)[7] with low effective doses expressed as mSv. For exposure to gamma photons and electrons (beta rays), 1 Gy = 1 Sv. For more damaging neutrons and alpha-rays, 1 Gy may equal to 5 Sv or more depending upon the actual particle energy.

The derivation of the effective dose from cosmic, terrestrial and food sources of radiation is complex but well understood. Radiation exposure from radionuclides in food is dependent upon the radioactive half-life, the biological half-life (how long the element remains in the body), the distribution of the radionuclide through the body and the different sensitivity to harm of different tissues. The International Commission for Radiological Protection (ICRP) is the international body

[5] Bq= Becquerel, the unit of radioactivity. 1 Bq = 1 disintegration per second. An older unit is the Curie (Ci) with 1 Ci = 3.7 x 10^{10} Bq

[6] Gy = Gray, the unit of absorbed radiation energy (dose) = 1 Joule per kg. 1 kGy = 1000 Gy

[7] Sv = Sievert, a unit of absorbed radiation energy in tissue that takes into account the effectiveness of the specific radiation to cause harm in tissues. I Sv = 1 Joule per kg. For photon and electron beam irradiation 1 Sv = 1 Gy. A Sv can be greater than1 Gy for radiations with heavy ions such as emitted by U/Th isotopes and for neutrons.

charged with recommending practices for radiation protection of the general public and those occupationally exposed. The ICRP recommends methodologies for estimating effective doses based on exposure to radiation or radioactivity from cosmic, terrestrial, inhalation and ingestion sources (ICRP 2007; ICRP 2012 and over 140 other publications (ICRP 2021)). The ICRP methodology is applied by UNSCEAR and national radiation protection authorities to derive radiation exposure to sources of radiation.

UNSCEAR (2000) considers the world-wide range of effective dose from the ingestion of food to be 0.2 to 0.8 mSv. Table 5 shows the annual effective dose from all sources of radiation exposure as a global average and for Australia.

Table 5: Average annual exposure to natural sources of ionising radiation

Source	Annual Effective Dose (mSv)	
	Global average[a]	Australian average[b]
Cosmic rays	0.39	0.3
External terrestrial	0.48	0.6
Inhalation	1.26	0.5
Ingestion – ^{40}K	*0.17*	*0.2*
Ingestion – U/Th series	*0.12*	*0.1*
Total ingestion	0.29	0.3
Total all sources	**2.4**	**1.7**

[a] Adapted from UNSCEAR (2000)

[b] Adapted from ARPANSA (2022c)

H.1.3 Experimental studies to measure induced radioactivity

Experimental studies of induced radioactivity in food have been published both prior to the IAEA (2002) report (as listed in that report) and after (Grégoire *et al* 2003a, b; Song *et al* (2018). Some experiments involved irradiation with electrons only or X-Rays with energies above 7.5 MeV. Most have concentrated on measuring specific induced radioisotopes, such as ^{24}Na.

Experimental measurement of induced radioactivity is difficult since the induced activity is much lower than the amount of natural radioactivity. Some early results were inconsistent, but the IAEA report (IAEA 2002) was able to reconcile the findings with its theoretical calculations.

The later papers of Grégoire *et al* (2003a, b) examined the effects of 7.5 MeV X-Rays on ground beef (15 kGy) and medical products (25-30 kGy). Theoretical calculations were made and verified by experiment. The results were consistent with the conclusions of the IAEA report and showed that the activity induced in the ground beef 24 hours after treatment was considerably less than the natural activity and that any additional dose received by consumers would be orders of magnitude lower than exposures to natural sources of radiation.

Song *et al* (2018) irradiated ground chicken meat at 30 kGy with 7.5 MeV X-Rays. Gamma ray spectrometry of non-irradiated and irradiated ground chicken meat showed that the activity induced was below the detection limit and, therefore, considerably less than the natural radioactivity.

Over the last ten years, considerable experience has been gained with the sterilization of medical devices at energies higher than 5 MeV at the X-Ray facility in Daniken, Switzerland. Products tested by the Swiss Government Accredited Laboratory (SUVA) include polymers (PP, PE, PS, PVDF), animal feed, implants (stainless steel, ceramic-aluminium oxides, products made of titanium, aluminium and niobium), and bone cement. All products tested at the maximum acceptable dose (typically between 30 and 50 kGy) have been declared non-activated (Steris 2020), a finding confirmed by the later more general studies of Michel *et al*. (2021).

The experiments discussed above demonstrate that any radioactivity induced by irradiation with 7.5 MeV X-Rays will be much less than the natural radioactivity in food (IAEA 2002) and probably negligible.

Nevertheless, authorities concerned with food safety (JECFI 1981, USFDSA 2004, EFSA 2011) have always given consideration to the theoretical calculation of induced radioactivity.

H.1.4 Calculations of induced radioactivity

The IAEA report (2002) is the major reference work for calculations of induced radioactivity in foods.

The Report (IAEA 2002) estimated the radioactivity induced in food by gamma rays from ^{60}Co and ^{137}Cs, 10 MeV electrons and 5 and 7.5 MeV X-Rays. The report is extremely detailed. We emphasise that SD1 considers mainly those sections of the report relevant to X-Rays and is an outline only of the concepts and methodology.

H.1.5 Photo-neutron reactions

X-Rays are a photon[8] radiation. Radioactivity can be induced in food by several mechanisms when the incident photon has sufficient energy. The photon is absorbed and, depending upon its energy, can expel different particles from the nucleus; neutrons, protons, deuterium, tritium or alpha-particles. The mechanism of most significance for photon (X-Ray) energies up to 7.5 MeV relevant to food irradiation is the photo-neutron reaction. This occurs when a photon approaches a nucleus with an energy greater than the binding energy holding the neutron within the nucleus. The neutron is ejected (a photo-neutron) and may be captured by (absorbed into) a nearby atom. Ejection and capture both result in the formation of a new isotope. The isotope formed may be -

4. stable (non-radioactive),
5. unstable and therefore radioactive (a radioactive isotope or radionuclide) that decays rapidly before the food is consumed,
6. a radioactive isotope with a lifetime greater than the time between processing and consumption of the food.

When food is irradiated with X-Rays with energies in the range 2 to 7.5 MeV, photoneutrons are produced mainly through interaction with the nuclei of the isotopes ^{2}H, ^{13}C and ^{17}O. The daughter isotopes remaining after ejection of the neutron are stable. Induced radioactivity results mainly from neutron capture by elements within the food.

[8] Photons are a discrete bundle or quantum of electromagnetic energy. Gamma rays are also photons.

If the photon energy is below the threshold for a photo-neutron reaction then no radioactivity will be induced at any dose level. If the photon energy is above the threshold, then the amount of activity induced will be proportional to the absorbed dose.

Photo-neutrons can be generated in any material with which photons of sufficient energy interact. The Report showed that photo-neutrons generated within the accelerator window, conveyor materials and packaging were insignificant in inducing radioactivity in the food compared to the photo-neutrons generated within the food itself.

H.1.6 Restriction to the target material

Heavy metals are required for efficient conversion of the electron energy to X-Rays. Tungsten, tantalum and gold have been the main materials considered for the converter. Tungsten has a threshold energy 6.7 MeV and significant photo-neutron production occurs with 7.5 MeV electrons. It is not considered a suitable converter material as significant radioactivity would be induced in the target and other facility equipment and the neutrons generated would introduce further radioactivity into the food.

The common isotope of Tantalum (^{181}Ta) has a threshold energy of 7.6 MeV. A low abundance isotope (^{180m}Ta) has a threshold energy of 6.6 MeV but photo-neutron production in the converter at 7.5 MeV is insignificant compared to the photo-neutron production within the food itself. The threshold energy for gold is 8.07 MeV.

The variation sought to Standard 1.5.3 adds the restriction that the target material be tantalum or gold. Other authorities that have approved a maximum energy of 7.5 MeV for X-Rays have also imposed this restriction (USFDA 2004; GI 2012; NADFC 2013; CG 2016; MFDS 2020).

H.1.7 Reference food

A reference food was established to be representative of all food in the IAEA report. The elemental composition of the reference food was similar to that of meat. 43 elements were listed and the calculations set out to estimate the activity that would result from the capture of photo-neutrons by all the natural isotopes (both stable and radioactive) of these elements. The natural abundance of each isotope was used to calculate its contribution to a unit mass of the reference food.

H.1.8 Calculation details and results

Calculation of the radioactivity induced in the food required the use of cross-sections for photo-neutron production or capture for each isotope in the reference food. These cross-sections were obtained from standard nuclear physics texts. Nuclear cross-sections provided a means of measuring the probability that a reaction will occur between two interacting particles.

The steps involved in the calculation were the same for both 5 and 7.5 MeV X-Rays:

- Calculating the number of neutrons produced per unit of radiation energy absorbed in the food (Gy); this requires the use of cross sections for photo-neutron production for each isotope in the reference food.

- Assessing which of the isotopes left after a neutron has been ejected are radioactive. Radioactivity is close to zero for 7.5 MeV X-Rays and insignificant compared with the activity induced by the capture of neutrons by other isotopes in the food.
- Calculating the number of neutrons that are produced by absorption of a neutron in the food per kGy of X-Rays. The possibility of neutrons entering the food from production of neutrons in the accelerator window or the X-Ray converter was considered but can be neglected at energies 7.5 MeV or below and provided the X-Ray converter is made of tantalum or gold not tungsten.
- The neutron flux is then estimated (neutrons/cm^2/s) and the fluence (the time integral of the flux).
- An allowance is made for some neutrons that may escape from the food without a collision.
- The concentration of each isotope in the reference food is obtained from the elemental composition and natural abundance of the isotopes.
- The thermal cross-section for neutron capture[9] for each isotope is then used to calculate the number of new isotopes formed.
- Some isotopes formed are stable; those that are radioactive with a half-life of more than a few minutes are summed to provide the induced radioactivity immediately after irradiation.

The key results in the Report are found in Table 16 on p. 104 and section 10 of the text (IAEA 2002).

It was found that, per kGy, approximately twice as many photo-neutrons were generated by 7.5 MeV X-Rays as by 5 MeV X-Rays. The Report used 30 kGy of 7.5 MeV X-Rays and 60 kGy of 5 MeV X-Rays as equivalent for the basis of their calculations (the Report was concerned with high doses).

It was calculated that a neutron fluence of 3x10^8 neutron/cm^2 was associated with 30 and 60 kGy of X-Rays from 7.5 and 5 MeV X-Rays respectively.

Thirty-three isotopes were induced in the food with half-lives greater than a few minutes. Of these, the four isotopes contributing most to the activity immediately after irradiation are ^{38}Cl, ^{42}K, ^{24}Na and ^{32}P. Table 6 shows these key isotopes, their half-life and the activity induced in a model food after treatment with 60 or 30 kGy of X-Rays from 5 and 5 MeV X-Rays respectively.

The activity of a radioactive isotope remaining when the food is consumed depends on the half-life (the time over which activity reduces by one-half) and the elapsed time between irradiation and consumption. The IAEA report considered the activity remaining immediately and 48 hours after irradiation. The activities at these times are shown in Table 6.

The values shown in Table 6 refer to the maximum energy of the X-Rays produced. The actual energy spectrum of the X-Rays produced by conversion of an electron beam is highly dependent on the target design but the mean and median energy of X-Rays produced will be significantly less that the maximum (ARPANSA 2022b) and the activity induced in practice will be considerably less than shown in the Table 6.

[9] The neutrons are initially produced with high energy (fast neutrons). They lose energy rapidly through collisions and become low energy (thermal neutrons). Thermal neutrons far more likely to be captured by an interaction with a nucleus.

Table 6: Induced activity (Bq/kg) of the major radioactive isotopes induced in a model food immediately and 48 hours after irradiation with a dose of 60 kGy of 5 MeV X-Rays or 30 kGy of 7.5 MeV X-Rays (values are rounded and calculated from Table 16 and section 10 of IAEA (2002) as shown in Section H2, the Annex to SD1).

			Bq/kg	
Isotope	**Half-life**	**Time after irradiation**	**30 kGy at 7.5 MeV**	**60 kGy at 5 MeV**
^{38}Cl	37 minutes	0	90	
^{42}K	12.4 hours		28	
^{24}Na	15 hours		40	
^{32}P	14.3 days		1	
Total			**159**	
^{38}Cl	37 minutes	48 hours	0	
^{42}K	12.4 hours		2	
^{24}Na	15 hours		3	
^{32}P	14.3 days		1	
Total			**6**	

The IAEA Report concluded that any induced activity would be only a fraction of the global average of activity found in non-irradiated food (300Bq/kg, see Table 4) 48 hours after irradiation.

H.1.9 Potential radiation exposure from induced radioactivity

The conversion of induced activity in the food to the effective dose to the consumer was obtained from the conversion tables provided by the International Commission on Radiological Protection (ICRP 2012). This is the same method as used to calculate the effective dose from natural radioactivity in non-irradiated food by UNSCEAR (see above).

As noted earlier, the effective dose from any radioactive isotope depends on its physical half-life, the biological half-life and its distribution around the body and the radiation sensitivity of the organs in which it is found. When more than one radioactive isotope is involved, the effective dose is not simply proportional to the total activity.

It was assumed that 40 kg of irradiated food would be consumed per year. For an irradiation dose of 30 or 60 kGy of X-Rays from 7.5 and 5 MeV X-Rays respectively, the effective dose was calculated to be 1.8×10^{-3} mSv per year[10] if the food was consumed immediately.

The effective dose was obtained by adding up the effective doses for all the radioactive isotopes induced in the model food (column 7 of Table 16 in the IAEA (2002) Report).

[10] IAEA (2002) actually reports this number as 1.3×10^{-3} mSv per year. We believe this to be a typographical error as the four isotopes that dominate effective dose immediately after irradiation total 1.7×10^{-3} mSv per year. We note that the senior author of the report used the same data in an earlier paper and quoted a value of 1.8×10^{-3} mSv per year (Brynjolfsson 1999).

If consumption was delayed for 48 hours the effective dose was estimated to be less than 1.0×10^{-4} mSv per year.

As shown earlier (Table 5), the effective dose from non-irradiated food and from all natural sources of radiation are 0.29 and 2.4 mSv per year respectively (global averages). On this basis, the report concluded that the induced activity produced by 30 kGy of 7.5 MeV X-Rays was insignificant.

The values calculated refer to the maximum energy of the X-Rays produced. The actual energy spectrum of the X-Rays produced by conversion of an electron beam is highly dependent on the target design but the mean and median energy of X-Rays produced will be significantly less than the maximum (ARPANSA 2022b) and the radiation exposures in practice will be considerably less than calculated here.

H.1.10 Implications for Standard 1.5.3

The calculations in the previous section can be used to show that if Standard 1.5.3 is amended to allow X-Rays with a maximum energy of 7.5 MeV, there will be a negligible increase in risk to consumers.

Standard 1.5.3 permits the irradiation of herbs and spices to a maximum absorbed dose of 30 kGy. Herbal infusions may be irradiated to a maximum absorbed dose of 10 kGy. Herbs, spices and herbal infusions are minor dietary items, contribute little to nutrition and consumption is much less than 40 kg per year. They are also usually stored for long periods before use. The induced radioactivity will therefore have decreased to much less than that calculated at 48 hours after irradiation.

Based on the calculations and considerations above, if herbs, spices and herbal infusions were to be irradiated in Australia, any induced radioactivity would be of no public health and safety concern.

The food irradiation application that is of present interest in Australia is phytosanitary irradiation which may be conducted up to a maximum absorbed dose of 1 kGy. Any different, future applications are unlikely to be permitted above a maximum absorbed dose of 10 kGy.

Induced activity is proportional to the absorbed dose in the food and the effective dose to a consumer will be proportional to the absorbed dose and amount of irradiated food consumed per year. Therefore, it is possible to make a *pro rata* calculation of the effective dose from consuming 40 kg of food treated with either 1 or 10 kGy of 7.5 MeV X-Rays.

As fresh produce is moved to the consumer as quickly as possible after irradiation, this application has used the conservative assumption that the food is consumed 24 hours rather 48 hours after irradiation.

The values obtained are shown in Table 7 and compared with the radioactivity in non-irradiated food and from all background sources of radiation exposure (see Table 5, Australian values).

The derivation from the IAEA (2002) Report of the data for Table 7 is provided in Section H2, the Annex to SD1.

Table 7: A comparison of radioactivity (Bq/kg) in non-irradiated food and the induced activity in food 24 hours after treatment with 10 or 1 kGy of 7.5 MeV X-Rays: the annual exposure (effective dose, mSv/year) to Australian consumers from all natural sources of exposure, from non-irradiated food and from 40 kg of food treated with 10 or 1 kGy of 7.5 MeV X-Rays.

	Radioactivity (Bq/kg)
Non-irradiated food[a]	300
	Induced Radioactivity (Bq/kg)
Irradiated food 10 kGy	7
Irradiated food 1 kGy	0.7
	Effective Dose (mSv/year)
All natural sources (Australian value)[b]	1.7
Non-irradiated food (Australian value)[c]	0.30
Irradiated food 10 kGy	0.0002
Irradiated food 1 kGy	0.00002

[a]Taken from UNSCEAR (2000,2008) from a global average of ^{40}K and U/Th series activity

[b]Derived from ARPANSA (2022c), summing effective dose from cosmic rays, terrestrial radiation, inhaled and ingested radioactivity

[C]Derived from ARPANSA (2022c)

The model calculation for the effective dose due to induced radioactivity was based on consumption of 40 kg of the irradiated food per year. In 2017-18, the average Australian adult consumed 1.7 serves of fruit and 2.4 serves of vegetables (255g fruit and 180g vegetables) per day (ABS 2018). On this basis the average annual consumption of fruits and vegetables is approximately 160 kg per year. The consumption of 40 kg per year, used in Table 7, is equivalent to the assumption that about 25% of all fresh produce consumed in Australia would be irradiated. This is extremely unlikely.

The model calculation was based on the elemental composition of a reference food similar to meat (IAEA 2002). Elemental compositions can vary widely between different foods, or even varieties of the same food. The three elements that contribute most to radioactivity from 24 hours to a few days after irradiation are sodium, potassium and phosphorus (IAEA 2002 and Table 6). Table 8 compares the concentrations in these three elements in the reference food with the concentrations in beef and fruits as obtained from the New Zealand Food Composition Tables (MoH 2009).

Table 8: Sodium, Potassium and phosphorus concentrations in various foods

	Concentration (mg/100g)		
Food	Sodium	Potassium	Phosphorus
Reference food[a]	75	400	200
Topside beef[b]	47	450	205
Fresh fruit[c]	1 to 32	72 to 520	7 to 54

[a] Derived from Table 3 (IAEA 2002)

[b] MoH (2009)

[c] MoH (2009); the range for all fresh fruits listed

The data of Table 8 suggest that the concentrations of these key elements and, therefore, the induced activity to be expected will be no greater than those used in the model calculation and probably less for fresh fruits. The differences are within the uncertainties of the calculations.

In summary, a consumer eating 40 kg per year of food treated to 10 kGy with 7.5 MeV X-Rays 24 hours previously might receive a dose of 2×10^{-4} mSv from induced radioactivity. This is approximately 0.06% of the dose received from non-irradiated food and 0.01% of the dose from all natural sources of exposure (Table 7). This an overestimate as the mean and average energy of the X-Rays would be less than 7.5 MeV (ARPANSA 2022b).

Induced radioactivity from the irradiation of fresh produce for a phytosanitary purpose with the maximum dose of 1 kGy of 7.5 MeV X-Rays would contribute no more than 0.006% of the effective dose to consumers from non-irradiated food even if 25% of all fresh produce was to be irradiated.

H.1.11 Potential health detriment to consumers

Health risks from radiation exposure are assessed by an international body, the ICRP (ICRP 2007, 2012). Although genetic damage caused by exposures is considered, the major risk to health from chronic, low dose exposures is an increase in the incidence of cancer above the natural (non-radiation) incidence. Preventative responses to radiation exposure at a national level, such as dose limits to the public and radiation workers, are based on the ICRP conclusions for increased cancer risk.

The ICRP takes data from survivors of the atomic bombs dropped on Hiroshima and Nagasaki, from people exposed medically and occupationally and from animal studies to calculate the increased cancer risk. The exposures involved were far higher doses than are experienced from exposure to background radiation and no statistically useful data exist to calculate risks from low dose exposures close to background levels accurately (ICRP 2005). Attempts to estimate risk from an extra exposure that is a minute fraction of natural background levels have no scientific foundation.

In order to estimate the risks at low doses, for example when setting dose limits for exposures in the workplace or the environment, the ICRP extrapolates the data from the high dose exposures to lower doses using a conservative, precautionary approach. This approach assumes that the risk is directly proportional to the effective dose received even at the lowest doses.

Estimating the increased cancer risk from induced radioactivity in food should be regarded as notional only. However, using the ICRP approach to risk that the increased risk is proportional to effective dose, then the percentage increase in cancer risk is the same as the percentage increase in effective dose. For Australia, the extra cancer incidence due to the ingestion of 40 kg per year of food treated to 10 kGy with 7.5 Mev X-Rays is estimated to be 0.06% of that from non-irradiated food and 0.01% of that from all background sources.

H.2 ANNEX TO SD 1: DERIVATION OF KEY DATA USED IN THIS APPLICATION (Tables 6 and 7)

H.2.1 Data in the IAEA Report (IAEA 2002).

In the IAEA Report, the key information on induced radioactivity for X-Rays is contained in section 10.2 and Table 16.

Section 10.2 states that it was calculated that 3 x 10^8 neutrons/cm^2 is the neutron fluence produced in food with either 60 kGy of 5 MeV X-Rays or 30 kGy of 7.5 MeV X-Rays. That is, 7.5 MeV X-Rays are twice as effective as 5 MeV X-Rays in producing induced radioactivity.

Table 16 of the Report lists:

1. The 33 radioactive isotopes formed immediately after treatment with 5 and 7.5 MeV X-Rays (column 1).
2. The activity in Bq/g produced from one photo neutron/cm^2. This value has been obtained from standard nuclear physics tables as outlined in the general text of the IAEA report (column 2).
3. The half-life of each of the 33 radioactive isotopes (column 3) which allows calculation of how much activity will remain at times after treatment.
4. The effective dose (mSv/year) from consumption of 40 kg/year of the reference food exposed to a fluence of 3 x 10^8 neutrons/cm^2 immediately after irradiation (column 7). Column 7 is also the effective dose from either 60 kGy of 5 MeV X-Rays or 30 kGy of 7.5 MeV X-Rays given to 40 kg of food which is consumed annually immediately after irradiation (see above).

H.2.2 Derivation of data for Table 6 of this Application

The activity (Bq/g) for each radioactive isotope produced from irradiation by 60 kGy of 5 MeV X-Rays or 30 kGy of 7.5 MeV X-Rays is obtained by multiplying the Bq/g (column 2 of the Report) by 3 x 10^8 neutrons/cm^2, the fluence associated with the X-Ray doses. This gives the activity at zero time after irradiation.

Example, for ^{38}Cl, 3.0 x 10^{-10} (Bq/g) x 3 x 10^8 neutrons/cm^2 = 9 x 10^{-2} Bq/g.

Table 6 indicates the activity/kg, 9 x 10^{-2} x 1000 = 90 Bq/kg immediately after irradiation (time 0).

The half-life of each radioactive isotope (the time to decay to 50% of the original activity) can then be used to derive the activities remaining 48 hours after irradiation.

Examples, ^{38}Cl has a half-life of 37 minutes. In 48 hours, it would have decayed over nearly 80 half-lives, and the remaining activity would be effectively zero. ^{42}K decays by 50% every 12.4 hours, so in 48 hours it would have decayed over almost 4 half-lives. Thus, the activity of 28 Bq/kg at zero time would reduce to approximately 2 Bq/kg at 48 hours (28 x 50% x 50% x 50% x 50% = 2), as shown in Table 6.

H.2.3 Derivation of data for Table 7 of this Application

The effective dose from non-irradiated food and all sources of background radiation are obtained from UNSCEAR (2000, 2008) and ARPANSA (2022c) and were shown in Table 5.

Induced activity for each radioactive isotope is proportional to the absorbed dose in the food. The effective dose to a consumer will be proportional to the absorbed dose in the food and the amount of irradiated food consumed per year. Therefore, it is possible to make a *pro rata* calculations of the induced activity and effective dose from consuming 40 kg of food treated with either 1 or 10 kGy of 7.5 MeV X-Rays.

Table 6 shows the induced radioactivity immediately after irradiation with a dose of 30 kGy of 7.5 MeV X-Rays. Induced radioactivity is 3 and 30 times less for doses of 10 kGy and 1 kGy respectively. After 24 hours, decay will have further reduced the total activity to the values shown in Table 7.

Adding all the data in column 7 of the IAEA Report gives an effective dose from consuming 40 kg of the model food immediately after irradiation by a neutron fluence of 3×10^8 neutrons/cm^2 or 30 kGy of 7.5 MeV X-Rays. The total is 1.8×10^{-3} mSv/year[11], 1.7×10^{-3} mSv coming from the 4 isotopes discussed in this Application.

The effective dose will be 3 and 30 times less for irradiation with 10 and 1 kGy respectively, that is 6×10^{-4} mSv and 0.6×10^{-4} mSv respectively. Allowing for radioactive decay over 24 hours gives approximately 2×10^{-4} mSv and 2×10^{-5} mSv respectively, as shown in Table 7.

[11] IAEA (2002) actually reports this number as 1.3×10^{-3} mSv per year. We believe this to be a typographical error as the four isotopes that dominate effective dose immediately after irradiation total 1.7×10^{-3} mSv per year. We note that the senior author of the report used in an earlier paper derived a value of 1.8×10^{-3} mSv per year the same data (Brynjolfsson 1999).

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J. Letters of Support

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23 March 2022

To whom it may concern,

The Australian Table Grape Association (ATGA) is writing in support of Steritech's submission to FSANZ to enable more efficient X-Ray machines to be used, increasing capacity of existing infrastructure to handle forecasted increases in demand.

Irradiation is increasingly used as an end point treatment to prevent the spread of fruit fly and enable commercial shipments to be transported to markets without compromising fruit quality.

Table grapes are a highly seasonal crop, meaning there is a very high demand for X-Ray treatments for one month of the year, low demand for another five months of the year and no demand for the remaining six months of the year.

Historically, Australian table grapes producers have exported 2000-4000 pallets of fruit per year using irradiation. This is shipped to two existing markets with established irradiation protocols. From March 14 to 22nd of this year, the industry treated more than 1000 pallets for export. This was over 25% of the annual demand for treatment in just 8 days.

This extreme peak in demand is common and expected to grow as new irradiation export protocols are pursued. It poses a significant issue in the future if treatment capacity does not grow with demand.

The cost of establishing additional treatment facilities is expensive. The initial investment requires tens of millions in capital investment with significant ongoing operational costs.

By allowing higher MeV X-Ray sources to be used, service providers can safely and effectively increase industry treatment capacity at a fraction of the cost of building a new facility.

The cost of horticultural production in Australia is already significantly higher than in many other countries. It is important that Australia uses advancements in technology to offset these costs, to maintain a competitive position in the global market.

The Australian Table Grape industry supports the submission and hopes for a timely approval, noting numerous new irradiation export protocols are forecast in the coming 24 months.

Sincerely,

Jeff Scott
Chief Executive Officer

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24 March 2022

<u>Letter supporting amendment to standard 1.5.3 to allow 7.5 MeV X-Ray</u>

To FSANZ,

The Australian mango crop is largely produced in Queensland and Northern Territory. It yields between 55,000 to 80,000 pallets of fruit each season. Queensland and Northern Territory are recognised as having fruit fly that must be controlled and prevented from spreading to South Australia, Tasmania, and Western Australia. These markets have a combined population of approximately 5 million consumers, or 20% of Australia's population.

The domestic market for Australian mangoes utilises Dimethoate dips and sprays (CTMO1, ICA-02) and Methyl Bromide fumigation (ICA-04) to meet biosecurity requirements. While these chemical-based treatments have been considered effective and safe for historic trade, pursuit of safer, more sustainable, and more reliable alternatives is expected to increase the demand for irradiation.

Furthermore, there is a recognised risk that Dimethoate and Methyl Bromide treatments could be suspended or phased out in the future with limited warning. To avoid a costly disruption of trade impacting more than 10,000 pallets of existing mango trade, phytosanitary irradiation capacity must be increased urgently as a preparedness measure.

The most effective way of scaling existing phytosanitary irradiation infrastructure capacity is by approving 7.5 MeV X-Ray sources. It has been proven safe and effective through reviewed science and is already approved by several other countries.

The Australian mango industry association supports the proposed amendment for food standard 1.5.3. The industry is hopefully changes are promptly recognised for the benefit of Australian consumers and mango producers.

Yours sincerely,

Brett Kelly
AMIA Chief Executive Officer