FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

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Supporting document 1

Risk and technical assessment – Application A1261

Irradiation – Increase in maximum energy level

Executive summary

Steritech Pty Ltd has applied to amend the Australia New Zealand Food Standards Code (the Code) to increase the maximum energy levels for machines generating X-rays used to irradiate food from 5 to 7.5 megaelectronvolts (MeV[1]), provided the X-ray target of the machine source is made from tantalum or gold. The primary purpose of requesting this variation is to increase the efficiency of generating X-rays, which in turn increases the processing rate of irradiation treatment of food.

FSANZ has concluded the proposed amendment is technologically justified. Increasing the maximum energy from 5 to 7.5 MeV increases the efficiency of generating X-rays to irradiate food by approximately 40-50%. Increases in the efficiency of X-ray generation increase the treatment efficiency and rate of throughput of irradiating food for both phytosanitary treatment to control pests and sanitary treatment for food quality and safety purposes.

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

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

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

FSANZ concludes there are no public health and safety concerns associated with the

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

consumption of food irradiated with 7.5 MeV X-rays at the approved absorbed dose levels when using tantalum or gold as the X-ray target material.

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1 Introduction

Steritech Pty Ltd has applied to amend the Australia New Zealand Food Standards Code (the Code) to increase the maximum energy for machines generating X-rays used to irradiate food from 5 to 7.5 megaelectronvolts (MeV[2]), provided the X-ray target is made from tantalum or gold.

The applicant states that the primary purpose of requesting the variation to the Code is to increase the efficiency of converting the electron beam into X-rays which increases the processing rate of irradiation treatment of food. In addition it is expected to reduce the dependency on a radioactive source of radiation, being cobalt 60 (^{60}Co), which the applicant states increases the sustainability of food irradiation (not dependent on radioactive sources, storage and disposal) and is also more economic.

1.1 Objectives of the assessment

The objective of this risk and technical assessment was to assess the following risk assessment questions.

- What is the technological justification for increasing the maximum energy of X-rays permitted to irradiate food from 5 MeV to 7.5 MeV?
- How does irradiation using X-rays of 7.5 MeV compare to other permitted forms of irradiating food – what are the advantages and disadvantages of the different forms of irradiation?
- Why is it requested that the metal converter (also called X-ray target) used for irradiation at the maximum energy of 7.5 MeV need to be prescribed as only using the metals tantalum or gold?
- Does increasing the maximum energy of X-rays permitted to irradiate food from 5 MeV to 7.5 MeV produce any changes in the treated food, such as any increase in radioactivity?
- Does increasing the maximum energy of X-rays permitted to irradiate food from 5 MeV to 7.5 MeV produce any unsafe components in the irradiated food compared to other permitted forms of irradiation to treat food? If so, do these changes raise any safety concerns for the consumption of the treated food?

2 Food technology assessment

2.1 Background on food irradiation

Food irradiation is the process of applying ionising radiation to food to improve its safety or maintain its quality.

Food can be exposed to ionising radiation provided by radioactive isotopes (gamma rays from cobalt 60 (^{60}Co) or caesium137 (^{137}Cs))[3], and machine sources of electron beams or X-

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

[3] ^{137}Cs is not approved as a source of ionising radiation for food in Australia and New Zealand.

rays. Each of these sources have different operational characteristics, including their level of penetration, direction of emission, and dose rate (IAEA 2015). In Australia, food irradiation is undertaken using the radionuclide ^{60}Co and, more recently, X-rays.

During irradiation, energy is transferred from the source of ionising radiation into the product being treated. The amount of energy absorbed per unit mass of the treated product is expressed as the ‘absorbed dose’ or simply ‘dose’. Applying the specified minimum dose is critical in phytosanitary treatments, to ensure that the desired treatment outcome (e.g. pest mortality or sterility) is achieved, and the absorbed dose is measured using dosimeters (IAEA 2015). During irradiation, the food does not come into contact with the radioactive source. Rays pass through the food without heating it up to any great extent. No radioactive energy remains in the food after treatment.

Whilst irradiation facilities can differ in their construction and layout depending on the source of ionising radiation, the type of product being treated, and the purpose for irradiation, they are essentially a warehouse with the irradiator situated in a segregated irradiation chamber. In continuous irradiation, products may move continuously through the chamber via conveyer. In batch irradiators, products are taken in and out of the irradiation chamber upon completion of treatment. It is important for irradiation facilities to maintain well-separated areas for storing non-irradiated and irradiated products, particularly where phytosanitary irradiation is the objective. This is to avoid accidental intermingling of products whereby pest re-infestation might occur (IAEA 2015).

The treatment of foods with ionising radiation is an effective method for achieving phytosanitary and sanitary objectives.

Phytosanitary measures include those that protect the health of plants and, in particular, prevent the introduction or spread of pests that may be present in or on fresh produce, such as fruit flies and other insect pests (e.g. mealy bugs, mango weevils). Treatment may result in pest mortality, sterility, or failed development (i.e. no emergence of adults).

Sanitary measures include those that destroy microorganisms such as *Salmonella* and *Escherichia coli*, which might otherwise cause foodborne illnesses or reduce the shelf-life of foods by causing spoilage or decomposition (e.g. moulds, parasites, bacteria).

Irradiation also has several beneficial physiological effects on the treated plant such as slowing ripening and inhibition of sprouting in bulbs and tubers (e.g. potatoes and onions).

2.2 Comparison of different forms of food irradiation

Standard 1.5.3 – Irradiation of food lists three permitted sources of radiation that can be used to irradiate food, within section 1.5.3—7. They are:

(a) gamma rays from the radionuclide cobalt 60;
(b) X-rays generated by or from machine sources operated at an energy level not exceeding 5 megaelectronvolts;
(c) electrons generated by or from machine sources operated at an energy level not exceeding 10 megaelectronvolts.

Each of these permitted sources and types of radiation have their different advantages and disadvantages over the other forms. A detailed discussion of the relative merits of each is provided in a 2021 study by the Joint Food and Agriculture Organization (FAO)/International Atomic Energy Agency (IAEA) Centre (IAEA 2021).

Gamma rays and X-rays are the same types of radiation, using photons to irradiate food. The difference is only in definition, with gamma rays being emitted from a radioactive source, i.e. ^{60}Co, while X-rays are produced when an electron beam strikes a heavy metal target (such as tantalum or gold) converting the high energy electrons into X-rays. Electron beam irradiation is produced by an accelerator to produce high energy electrons.

Gamma rays and X-rays penetrate deeply into foods when used to irradiate so they are suitable to treat large containers or pallets of food. Electrons in an electron beam used to irradiate food lose energy quickly so they are only suitable to treat food in thin packages or streams.

It is also important to note that the impact of the irradiation of the food is not dependent on the source of the irradiation. That is, a given absorbed dose of gamma rays, electron beams or X-rays gives rise to an equivalent effect (EFSA 2011).

Additional advantages and disadvantages of the different forms of food irradiation treatment are provided in the sections below.

2.2.1 Gamma rays from radioactive source (^{60}Co)

A main advantage of using gamma rays for food irradiation is that it is widely used and understood form of food irradiation. As well the equipment and facilities are simpler and easier to use and maintain compared to the newer forms of food irradiation.

Gamma rays have good penetration to irradiate food, including full pallet loads. However the dose rates are slower than with electron beams, and less than X-rays.

One of the main disadvantages is that it uses a radioactive source to produce the gamma rays. This has its own risks as well as disposal issues of spent sources. There are also tight supply issues, with one dominant supplier and the costs of sources increasing.

Gamma rays cannot be turned off as they are always being produced due to the radioactive decay of the isotope source.

2.2.2 Electron beams

The main advantage of using electron beams to irradiate food is the fast rate of treatment, being faster than other methods of irradiation. Electron beams are produced by accelerators so they can be turned off when the machines are switched off. They also have good energy efficiency, better than the other forms of irradiation.

A major disadvantage with electron beams use is they have low penetration into the food to be irradiated. Therefore they can only be used for smaller, thinner food packages and those with lower density and have poor dose uniformity of the treated food.

2.2.3 X-rays

X-ray beams are produced by accelerators so they can be turned off when the machines are switched off. They use an electron accelerator as the initial part of their production. Like gamma rays they have good food penetration so can be used to irradiate high-density material, larger packages and even pallets of food. The dose rates are higher than with gamma radiation.

A disadvantage is that the system to produce and use X-rays is more complex and so more expensive to install than for the other two methods. There are also less of these units used commercially so less experience with their use.

2.3 Assessment of the technological justification of increasing energy of the X-ray source

X-rays used for irradiation of food are produced using an electron beam generated by an accelerator. These fast-moving electrons are focused to hit a heavy metal plate (called the X-ray converter, or X-ray target) which produces the X-rays that are used to irradiate the food.

Most of the kinetic energy of the fast-moving electrons is converted into heat on the X-ray converter with only a small proportion (usually far less than 10%) converted into X-rays. This would be expected to make X-ray use for food irradiation more expensive than the other technologies.

However, there is an increase in efficacy of 40-50% when the maximum operating voltage of the electron beam accelerator is increased from 5 to 7.5 MeV (IAEA 1995, Miller 2006, Petwal et al 2007, Cleland and Stichelbaut 2013). The increase in efficiency for the production of X-rays results in a concomitant increase in efficiency of processing the irradiation of food. As a result the applicant estimates that it would result in an increase in its processing capacity from 12 pallets/hour to 17-18 pallets/hour.

An overall increase in efficiency of the X-ray irradiation unit also results in shorter processing times and increased throughput of the irradiation unit. That means that the food is out of its normal temperature-controlled storage facilities for less time and there is greater penetration and greater dose uniformity within the irradiated food. Benefits for the irradiation facility also include greater efficiency and flexibility for treating food at its plant.

There are no additional changes to how the plant is operated, i.e. the methods for dose measurement (dosimetry) and process control are unchanged.

It is important to note that irradiation of the food is dependent only on the energy absorbed in the food, (being the irradiation dose) and not dependent on the initial energy of the X-ray beam itself (US FDA 2004).

2.4 Assessment of the metal converter (X-ray target) for source of X-rays

As noted in section 2.3 high energy X-rays are produced by a high energy electron beam, generated when an electron beam accelerator strikes a heavy metal target that subsequently produces X-rays. X-rays can be produced when high energy electrons hit any material. However, the most intense and efficient material for X-ray production is with high atomic number[4] metals, such as tantalum (atomic number 73), tungsten (atomic number 74) or gold (atomic number 79).

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[4] Atomic number equals the number of protons in the nucleus of the atom of the chemical element.

The application and further information received from the applicant noted that there is no need to specify the X-ray target when the maximum permitted energy of the X-rays is 5 MeV (as currently permitted in Standard 1.5.3). This is because the threshold energy to eject neutrons (photoneutrons) from all of the isotopes of the target metals (tantalum, tungsten and gold) is above 5 MeV. Photoneutrons can be ejected from the nucleus of an atom when a photon (in this case X-ray) has sufficient energy greater than the binding energy (or threshold energy) holding the neutron in the nucleus.

Tungsten has a threshold energy of 6.7 MeV and significant photo-neutron production and hence radioactivity can be induced using 7.5 MeV electrons. Therefore it is not considered a suitable X-ray target material. A common isotope of tantalum has a threshold energy of 7.6 MeV (above 7.5 MeV) so it is not an issue. A lower abundance isotope of tantalum has a threshold energy of 6.6 MeV but the photo-neutron production in the X-ray target is insignificant compared to photo-neutron production in the food itself so it is not a cause for radioactivity (see section 2.5). The threshold energy for gold is 8.0 MeV.

Tungsten is also not viewed as favourable since it is a brittle metal which is difficult to machine. Gold is suitable but due to its cost it is not usually considered a cost-effective option. Tantalum is therefore often used as the X-ray converter providing the best compromise with the X-ray yield, and physical and mechanical properties to be able to machine it for use (Cleland and Stichelbaut 2013, IAEA 2021).

The USA (US FDA 2004), Canada (CG 2016) and South Korea (MFDS 2020) have regulated to permit the use of tantalum or gold as the X-ray converter to irradiate food including with the increased energy of the electron beam of up to 7.5 MeV. Copies of these permissions were provided with the application. India (GI 2012) and Indonesia (NADFC 2013, in Indonesian) also permit the use of X-rays generated from machines operating up to 7.5 MeV, but they do not appear to specify the X-ray converter material.

2.5 Impact of increasing energy level of X-ray source on treated food

Experimental methods have not been able to detect any induced radioactivity in food irradiated with either 5 or 7.5 MeV X-rays (IAEA 2002, Grégoire et al 2003a, 2003b, Song et al 2018).

The US FDA concluded that ‘any radioactivity that may be induced in any food treated with 7.5 MeV X-rays will be trivially low and that any potential human exposure due to consumption of irradiated food will be inconsequential compared to that from radionuclides that are present naturally in food’ (US FDA 2004).

The Applicant estimated that the induced radioactivity for a person consuming 40 kg per year of irradiated food that had been irradiated 24 hours prior to consumption using a dose of 1 kGy of 7.5 MeV. The estimated inducted radioactivity was 0.006% of the dose from non-irradiated food, and 0.001% from all natural sources of radiation exposure.

As noted earlier in section 2.3, it is the dose of the irradiation that is important for any changes to the treated food (phytosanitary and sanitary treatment as well food quality purposes), not the energy source of the incident radiation. Since there is no change to the irradiation dose that is applied to the treated food as part of this application (with the dose limits provided and unchanged within Standard 1.5.3) there are no changes to the food composition or nutritional impacts (US FDA 2004). FSANZ considered these impacts as part of its consideration of earlier assessments of irradiation applications.

2.6 Food technology conclusion

FSANZ concludes that increasing the maximum energy for machines generating X-rays used to irradiate food from 5 to 7.5 MeV, provided the X-ray converter (or X-ray target) is made from the metals tantalum or gold, is technologically justified.

Increasing the maximum energy from 5 to 7.5 MeV increases the efficiency of generating X-rays to irradiate food by approximately 40-50 %. Increases in the efficiency of X-ray generation increase the treatment efficiency and rate of throughput of irradiating food for both phytosanitary treatment to control pests and sanitary treatment for food safety and quality purposes. This is advantageous to both the supplier of the food to be irradiated and the irradiating plant.

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

It is the dose of the irradiation that is important for any compositional or nutritional changes to the treated food, not the energy source of the incident radiation. Since there is no change to the irradiation dose due to this application there are no changes to the food composition or nutritional impacts. There are no identified negative food technology implications in increasing the maximum energy for machines generating X-rays used to irradiate food from 5 to 7.5 MeV.

3 Hazard assessment

3.1 Introduction

FSANZ has previously conducted risk assessments of the irradiation of fruit and vegetables, as well as herbs and spices (applications A413, A443, A1038, A1069, A1092, A1115 and A1193). These assessments concluded there are no food safety concerns associated with the consumption of these commodities when irradiated within the proposed (and ultimately approved) irradiation dose ranges.

There are a number of compounds, termed radiolytic compounds, which may be generated during the irradiation of food. FSANZ has previously concluded that radiolytic compounds are not produced at levels that are likely to result in harm following irradiation within the approved dose ranges. The levels of these compounds are generally comparable to those naturally present in cooked food.

As noted in section 2.3, it is the dose of radiation absorbed by the food, not the energy source of the incident radiation, that is important for any changes to the treated food including formation of radiolytic compounds. As the maximum doses permitted in the Code will remain unchanged, no new food chemical changes will be associated with the present application (US FDA 2004).

The purpose of the present hazard assessment was to evaluate new information published since FSANZ's previous assessments, as well as any additional information relating to the safety of foods irradiated with 7.5 MeV X-rays. Literature searches of PubMed were conducted[5] which identified a limited number of additional studies. These are reviewed

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[5] Search terms were “phytosanitary irradiation safety”, “phytosanitary irradiation toxic”, alkylcyclobutanone safety”, alkylcyclobutanone toxic”, “furan safety”, “furan toxic”, food irradiation

below.

3.2 Toxicity studies with food irradiated with 7.5 MeV X-rays

The literature search and information provided by the applicant identified two reports assessing the potential toxicity of foods irradiated with 7.5 MeV X-rays. These studies were reviewed as supporting information.

Genotoxicity studies with foods irradiated with 7.5 MeV X-rays (Jung et al 2014)

A series of genotoxicity studies with four freeze-dried foods irradiated at 30 kGy with 7.5 MeV X-rays (chicken, egg, green onion and black pepper) were reported in a journal article published in Korean[6].

A bacterial reverse mutation assay was conducted using *Salmonella enterica* ser. Typhimurium strains TA98, TA100, TA1535, and TA1537 in the presence or absence of metabolic activation (S9). A strain able to detect oxidising mutagens, cross-linking agents and hydrazines, such as TA102 or *Escherichia coli* WP2, was not included. No significant increases in the number of revertant colonies were observed at concentrations up to 5000 µg/plate. Positive controls produced the expected significant increases in revertant colonies, confirming the validity of the test system.

In an *in vitro* chromosome aberration assay with Chinese hamster ovary cells conducted in the presence and absence of S9, the X-ray irradiated foods showed no increase in the frequency of chromosome aberrations at concentrations up to 5000 µg/mL. Significant increases in chromosome aberrations were observed following treatment with the positive controls. A limitation of this study was the low number of metaphases evaluated (100 per treatment rather than the 300 recommended in OECD Test Guideline 473).

In addition, the X-ray irradiated foods did not show any increase in the frequency of micronucleated polychromatic erythrocytes in an *in vivo* micronucleus assay following administration of two oral doses (administered at 24-hour intervals), ranging from 250 – 2000 mg/kg bw/day, to male ICR mice. The positive control, cyclophosphamide, produced a significant increase in micronucleated polychromatic erythrocytes.

13-week toxicity study with food irradiated by 7.5 MeV X-rays (Song et al 2018) Regulatory status: Non-GLP

CD-1 (ICR) mice (12/sex/group, age 5 weeks) were fed a standard diet, diet containing freeze dried, powdered non-irradiated (0 kGy) chicken meat or chicken meat irradiated with 7.5 MeV X-rays at 30 kGy for 13 weeks. The concentration of chicken powder in the diet was 25,000 mg/kg (2.5%), calculated by the study authors to be approximately 2500 mg/kg bw/day. Clinical signs and mortality were observed daily. Body weight and food consumption were measured weekly. At the end of the study blood was collected for haematology and clinical chemistry analyses. A gross necropsy was performed, and selected organs including the liver, spleen, kidneys, testis/ovary, lung and heart were weighed. Microscopic examinations were performed on the liver and kidney.

No deaths or clinical signs of toxicity were observed during the study. There were no treatment-related adverse effects on body weight, body weight gain, food consumption,

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safety”, “food irradiation toxic”, “food irradiation X-ray”, “food irradiation X-ray toxic”, “food irradiation mycotoxin” and “food irradiation allergy”.

[6] Abstract and results tables in English, translated using https://www.deepl.com/en/translator/files

relative organ weights, haematology, clinical chemistry, gross pathology or histopathology observations.

3.3 Food irradiation and allergenicity

As part of application A1193, FSANZ noted that no evidence was identified to suggest phytosanitary irradiation could lead to increased allergenicity. A small number of studies published subsequent to that evaluation were located in the literature search and are discussed below.

Penumarti et al (2020) examined the concentration of selected allergenic proteins in untreated commercially available walnut, cashew, hazelnut and almond flours and flours treated with gamma irradiation at a dose ranging from 5.0 – 30.0 kGy. No substantial changes in total protein and allergenic protein content were observed following irradiation compared with untreated flour, and allergen content remained stable over a 24-month period.

The cashew nut allergen Ana o 3, purified from fresh cashews, was irradiated at 1, 3, 5 and 10 kGy in a cobalt-60 gamma irradiator. In a competitive inhibition Enzyme Linked Immunosorbent Assay (ELISA), IC_{50} values (the concentration that causes a 50% inhibition of antibody binding) increased dose-dependently at concentrations ≥ 3 kGy, indicating a reduced ability of irradiated Ana o 3 to bind anti-Ana o 3 IgE antibody. Release of histamine, interleukin-6 and tumour necrosis factor-α from human basophil cells incubated with Ana o 3 was also decreased with higher doses of irradiation (10, ≥ 3 and 10 kGy, respectively). No effects on potential allergenicity were observed at 1 kGy (Shen et al 2023).

Mei et al (2020) treated sand crab (*Ovalipes punctatus*) meat with electron beam irradiation at doses of 1, 3, 5, 7 and 9 kGy. A dose-dependent reduction in immunoreactivity of the major crustacean allergen, tropomyosin, measured by ELISA, was observed from 1 kGy. Western blot analysis showed that IgG antibody binding to tropomyosin was also reduced in a dose-dependent manner at ≥ 1 kGy. The reduction in immunoreactivity was accompanied by conformational changes in the protein structure of tropomyosin.

3.4 Assessments by other agencies

Five countries permit a maximum operating energy of 7.5 MeV. These are the USA, India, Indonesia, Canada and South Korea (US FDA 2004; GI 2012; NADFC 2013; CG 2016; MFDS 2020). The US FDA and Health Canada have also published their safety assessments of the use of 7.5 MeV X-rays (US FDA 2004; Health Canada 2016).

The US FDA's evaluation noted that because only the maximum energy limit for X-rays used to treat food would be increased with no change in the maximum dose that would be applied, there are no new chemical safety concerns. Any added radioactivity in food from the use of 7.5 MeV X-rays would be trivial compared to that from radionuclides naturally present in food. The US FDA concluded that the proposed use of 7.5 MeV X-rays for treating food is safe (US FDA 2004).

Health Canada considered the use of 7.5 MeV X-rays for the irradiation of fresh and frozen raw ground beef at maximum absorbed doses of 4.5 kGy and 7.0 kGy, respectively, and concluded there were no safety concerns with the proposed change to the maximum energy level. It was noted the Canadian Nuclear Safety Commission had concluded that increasing the operating energy level from 5.0 MeV to 7.5 MeV for X-ray machine sources, when the target material is tantalum or gold, would not significantly increase the background radioactivity of food (Health Canada 2016).

3.5 Hazard assessment conclusions

FSANZ has completed multiple evaluations of food irradiation. These assessments have all concluded that there are no safety concerns associated with the irradiation of the permitted commodities at the approved doses.

As the proposed increase in maximum energy level will not result in an increased absorbed dose in food, no new food chemical changes will be associated with the present application. Toxicity and genotoxicity studies with foods irradiated with 7.5 MeV X-rays using doses higher than those approved in the Code also found no evidence of adverse effects.

FSANZ has previously concluded that radiolytic compounds are not produced at levels that are likely to result in harm. The levels of these compounds in irradiated foods are generally comparable to those naturally present in cooked food. In addition, there is no evidence to indicate that phytosanitary irradiation at the proposed doses would increase the allergenicity of food, increase the toxicity associated with any mycotoxin contamination or result in additional dietary exposure to furan. No new evidence was identified that would alter these conclusions.

As noted in the food technology assessment, the induced radioactivity due to irradiation with 7.5MeV X-rays is much less than the natural radioactivity in non-irradiated food and even less than the natural levels of background levels of radiation consumers are exposed to from non-food sources.

Based on the available evidence, there are no public health and safety concerns associated with the proposed increase in maximum energy of X-Rays used to irradiate food.

4 Conclusions from the risk and technical assessment

Increasing the maximum energy for machines generating X-rays used to irradiate food from 5 to 7.5 MeV, provided the X-ray converter (or X-ray target) is made from the metals tantalum or gold, is technologically justified. Increasing the maximum energy from 5 to 7.5 MeV increases the efficiency of generating X-rays to irradiate food by approximately 40-50%.

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

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

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

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

5 References

ARPANSA (2022) Australian Radiation Protection and Nuclear Safety Agency. Ionising radiation and health. Understanding radiation. https://www.arpansa.gov.au/understanding-radiation/radiation-sources/more-radiation-sources/ionising-radiation-and-health

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

Cleland MR, Stichelbaut F (2013) Radiation processing with high energy X-Rays. Radiation. Physics and Chemistry. 84:91-99. at https://doi.org/10.1016/j.radphyschem.2012.06.038

EFSA (2011). European Food Safety Agency. Scientific opinion on the chemical safety of irradiation of food. EFSA Journal 9(4) 1930, j.efsa.2011.1930.

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

Grégoire O, Cleland MR, Mittendorfer J, Dababneh S, Ehlermann DAE, Fan X, Käppeler F, Logar J, Meissner J, Mullier B, Stichelbaut F, Thayer DW (2003a). Radiological safety of food irradiation with high-energy X-Rays: theoretical expectation and experimental evidence. Radiation Physics and Chemistry 67:169-183.

Grégoire O, Cleland MR, Mittendorfer J, Vander Donckt M, Meissner J (2003b) Radiological safety of medical devices sterilized with X-Rays at 7.5 MeV. Radiation Physics and Chemistry 67:149-167.

Health Canada (2016) Technical Summary – Health Canada's Safety Evaluation of Irradiation of Fresh and Frozen Raw Ground Beef. Bureau of Chemical Safety, Food Directorate, Health Products and Food Branch. Ottawa, Canada.

IAEA (1995) International Atomic Energy Agency. The development of x-ray machines for food irradiation. Proceedings of a Consultants' Meeting 16-18 October.

IAEA (2002) International Atomic Energy Agency. Natural and induced radioactivity in food. IAEA-TECDOC 1287. IAEA, Vienna.

IAEA (2015) International Atomic Energy Agency. Manual of Good Practice in Food Irradiation, Sanitary, Phytosanitary and Other Applications, Technical Report Series No 481. IAEA, Vienna

IAEA (2021) International Atomic Energy Agency. A Comparison of gamma, electron beam and X-ray sources of radiation for food irradiation. TECDOC-995, IAEA, Vienna

Jung D-W, Huang Y-H, Song B-S, Byun M-W, Kang I-J (2014) Genotoxicological Safety Evaluation of X-ray Irradiated Four Foods. Journal of the Korean Society of Food Science and Nutrition 43(10):1588-1593.

Mei K, Li G, Zhang J, Lou Q, Xu D, Yang W (2020) Studying on the IgG binding capacity and conformation of tropomyosin in Ovalipes punctatus meat irradiated with electron beam. Radiation Physics and Chemistry 168: 108525.

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

Miller RB (2006) Food irradiation using X-Rays. In: Electronic Irradiation of Foods. An introduction to the Technology. Chapter 4. Springer Science and Business Media, Berlin. ISBN 0387283862, 296pp.

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

Penumarti A, Szczepanski N, Kesselring J, Gabel E, Sheth R, Berglund J, Kim EH, Burks AW, Kulis MD (2021) Irradiated Tree Nut Flours for Use in Oral Immunotherapy. The Journal of Allergy and Clinical Immunology. In Practice. 9(1):321-327.

Petwal VC, Bapna SC, Sandha RS, Kottaiah S, Subbaiah KV (2007) Bremsstrahlung converter for high power EB radiation processing facility. Presentation to the Asian Particle Accelerator Conference. 29 January – 2 February, Indore, India.

Shen Y, Yu T, Wang Z, Li X, Wu Y, Chen H (2023) Non-thermal processing of cashews: irradiation reduces allergenicity by altering the structure of Ana o 3. Food and Function 14(4):1962-1970.

Song B-S, Lee Y, Park J-H, Kim J-K, Park H-Y, Kim D-H, Kim C-J, Kang I-J (2018) Toxicological and radiological safety of chicken meat irradiated with 7.5 MeV X-rays. Radiation Physics and Chemistry 144:211-217.

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