



APPLICATION A1038 IRRADIATION OF PERSIMMONS EXPLANATORY STATEMENT

Executive Summary

Purpose

Application A1038 received from Queensland Primary Industries and Fisheries, requests amendment of Standard 1.5.3 – Irradiation of Food to permit the irradiation of persimmons as a phytosanitary measure¹. The Applicant stated that approval would allow increased domestic and international trade in persimmons as there are rigorous requirements in place for an appropriate and efficacious treatment for fruit fly for quarantine purposes. Irradiation would provide persimmon growers with another treatment method for phytosanitary purposes for fruit fly.

Food Standard Australia New Zealand's (FSANZ's) specific objectives in considering A1038 have been to:

- protect public health and safety in relation to the proposed irradiation of persimmons by ensuring that irradiated persimmons are safe and nutritionally adequate to consume
- ensure that there is a technological justification to irradiate persimmons for a quarantine purpose and that the doses used achieve that technological need
- ensure adequate information relating to irradiated persimmons is provided to consumers to enable informed choice.

FSANZ concludes that approval of irradiation of persimmons at a minimum dose of 150 Gray (Gy) and a maximum of 1 Kilogray (kGy) does not pose a significant human health risk for Australian or New Zealand consumers. Irradiation is technologically justified as it will provide an efficacious treatment to reduce fruit fly infestation which is of quarantine concern.

After an evaluation of data published since 2002, FSANZ has concluded that there are no safety concerns arising from chemical products produced from irradiated foods or changes to the composition of persimmons following irradiation that are likely to cause public health and safety concerns. As persimmons are not widely consumed in Australia and New Zealand, they are minor contributors to the total dietary intake of vitamins.

¹ A phytosanitary measure is any legislation, regulation or official procedure having the purpose to prevent the introduction and/or spread of quarantine pests, or to limit the economic impact of regulated non-quarantine pests.

Therefore, there are unlikely to be any nutritional disadvantages for Australian and New Zealand consumers from eating irradiated persimmons. The key risk assessment findings are detailed in **Supporting Document 1 (SD1)**.

FSANZ takes a case-by-case approach with a pre-market assessment being completed for each application concerning irradiation of foods. As the Risk Assessment has concluded that there are no health, safety or nutritional concerns, FSANZ is recommending that this Application be approved subject to fulfilling the following conditions under Standard 1.5.3:

- irradiation of persimmons only for the purposes of pest disinfection for a phytosanitary objective
- adherence to a minimum dose of 150 Gy and a maximum of 1 kGy.

The current mandatory labelling of irradiated foods and record requirements will apply to irradiated persimmons. Based on the risk assessment findings, no additional mandatory labelling requirements are proposed.

Australian and New Zealand consumers are generally aware of food irradiation, but some consumers also hold concerns about the use of the technology. The consumer response to food irradiation is not dissimilar to their response to other new food technologies, where perceived risks and benefits of the technology will inform subsequent decisions made by consumers. While aware of food irradiation, consumers' understanding of the issue may contribute to a perception of increased risk. Information and education may assist in addressing the information gap. A Fact Sheet² on the FSANZ website will serve to assist in providing information on irradiated food to the general public.

Additional Amendments

Additional amendments are recommended to Standard 1.1.1 – Application, Interpretation and General Prohibitions and to Standard 1.5.3 in order to provide improved clarity, interpretation, and operation of Standard 1.5.3. These do not change the intent of Standard 1.5.3 to permit the irradiation of food on a case-by-case basis. These recommendations include changes made since consultation on the Assessment Report, taking account of submitter's comments.

- The following amendments have been approved:
- insertion of the terms 'kGy' and 'kiloGray' in the Glossary of symbols and units in clause 8 of Standard 1.1.1 as there is presently no listing for these
- the unit 'Gray' is inserted into clause 8 of Standard 1.1.1 to replace 'Grays'
- re-structuring and re-ordering of Standard 1.5.3 and inserting new clauses for foods permitted to be irradiated and conditions under which a food can be re-irradiated
- removal of extraneous material and provision of more clarity around the specific purpose of irradiating a food
- inserting a reference to New Zealand in the Purpose in relation to laws that govern radiation control, and the operation of irradiation facilities

² <http://www.foodstandards.gov.au/consumerinformation/foodirradiation.cfm>

- deletion of the definition of a technological need and re-irradiation as both are covered under other requirements in Standard 1.5.3
- deletion of the requirement for a minimum dose as a condition in column 3 of the purpose in the Table to clause 4 to achieve the technological purpose of irradiating a food, as the intent is now covered by revised provisions in clause 4
- deletion of all references to good manufacturing practice (GMP) in Standard 1.5.3 as a condition for handling food before and after irradiation. This is covered by other provisions, relating to food safety requirements, currently in the Code and covered in existing New Zealand legislation, including the Food Hygiene Regulations 1974 or under an approved food safety program via the New Zealand Food Act 1981
- deletion of subclause 4(2) from Standard 1.5.3. The conditions in column 3 of the Table of Foods permitted to be irradiated prescribe a technological purpose to irradiate foods which includes any purpose associated with food hygiene (e.g. bacterial decontamination). Therefore, there is no need to retain subclause 4(2) in Standard 1.5.3.
- deletion of the second example 'treated with ionising electrons' in subclause 6 (1) as this is potentially misleading to consumers
- deletion of the current subclause 6(4) relating to labelling of irradiated foods other than for retail as it is repetitive and unnecessary and covered by other provisions in the Code.

The approved variations are provided at Attachment 1A. They include amendments made subsequent to the consultation on the draft variations proposed at Assessment (Attachment 1B), taking into account public comments received on the terminology of irradiation units, the need for record keeping, the usefulness of the labelling examples in the current standard and enforceability issues relating to references to unsuitable and unsafe food.

Assessing the Application

In assessing A1038 and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters as prescribed in section 29 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act):

- whether costs that would arise from a food regulatory measure developed or varied as a result of the Application outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure
- there are no other measures that would be more cost-effective than a variation to Standard 1.5.3 that could achieve the same end
- any relevant New Zealand standard
- any other relevant matters.

A1038 was assessed under the General Procedure with one round of public consultation.

Decision

To approve the draft variations, subject to amendment, to Standards 1.1.1– Application, Interpretation and General Prohibitions and 1.5.3 – Irradiation of Foods to permit the use of irradiation of persimmons, including additional amendments to Standard 1.5.3.

Reasons for Decision

FSANZ has approved the sale of irradiated persimmons in Australia and New Zealand on the basis of the available scientific evidence, for the following reasons:

- The safety assessment did not identify any public health and safety concerns.
- The use of irradiation is technologically justified.
- The proposed additional amendments are justified to provide improved clarity, interpretation, and operation of Standard 1.5.3.
- A regulation impact assessment process has been undertaken that fulfils the requirement in Australia and New Zealand for an assessment of compliance costs. The assessment concluded that the use of irradiation (Option 3) provides a net benefit.
- There are no other measures that would be more cost-effective than a variation to Standard 1.5.3 that could achieve the same end.

Consultation

Consultation on the Assessment Report was conducted over a period of six weeks; 75 submissions were received. Summaries of these are in **Attachment 3** of this report.

Consultation is an essential part of FSANZ's standard-development process. We acknowledge the interest in food regulation shown by individuals and organisations through submissions. We are grateful for this community support. Every submission is reviewed by the project team concerned, which identifies the issues involved and prepares responses to each issue which are included in this Approval Report. This consultative process is a cornerstone of standard development.

Amendments following Public Consultation

FSANZ sought public comment on the draft variations shown at Attachment 1B. Taking into account comments received, FSANZ amended the draft variations. The approved draft variations are provided at Attachment 1A.

The draft variations were amended to:

- insert the unit 'Gray' into clause 8 of Standard 1.1.1 to replace 'Grays'
- insert a reference to New Zealand in the revised purpose in relation to laws that govern radiation control, and the operation of irradiation facilities
- re-insert the two examples 'treated with ionising radiation and 'irradiated (name of food) into subclause 6 (1) with the exception of the example 'treated with ionising electrons'

- delete the reference to unsafe or unsuitable food in the revised Purpose and revised delete sub-clause 4(2) and in addition, deletion of the current wording in subclause 4(2) from Standard 1.5.3
- reinsert clause 5 record keeping requirements in Standard 1.5.3.

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SUPPORTING DOCUMENTS

The following material, which was used in the preparation of this Approval Report, is available on the FSANZ website at

<http://www.foodstandards.gov.au/foodstandards/applications/applicationa1038irra4655.cfm>

SD1: Risk Assessment Report (Approval)

SD2: Overview of the food irradiation process and a glossary of technical terms (Approval)

SD3: Summary of literature on consumers and food irradiation

SD4: Amendments to Standard 1.5.3 (mark-up) (Approval)

Introduction

Application A1038, received on 19 November 2009 from Queensland Primary Industries and Fisheries, requests amendment of Standard 1.5.3 – Irradiation of food to permit the irradiation of persimmons as a phytosanitary measure³.

Irradiation is a physical treatment in which food is exposed to a defined dose of ionising radiation. It is used on food in more than 40 countries worldwide. Irradiation of food can control insect infestation, reduce the numbers of pathogenic or spoilage microorganisms, and delay or eliminate natural biological processes such as ripening, germination or sprouting in fresh food. Like all preservation methods, irradiation should supplement rather than replace good food hygiene, handling, and preparation practices (Arvanitoyannis, 2010).

The intent of A1038 is to have an effective measure available for disinfestation of pests of quarantine significance on persimmons.

Persimmons are a host fruit for fruit flies. Because of this, there are quarantine barriers against their trade in the southern States of Australia and in some other countries. Successful trade between areas where fruit flies are endemic and areas with a fruit fly quarantine barrier requires application of an appropriate treatment that is accepted by the interstate market or the importing country.

The minimum dose requested by the Applicant for the purpose of a phytosanitary treatment is 150 Gray (Gy)⁴ and the maximum dose requested is 1000 Gy (1kilogray (kGy)). Letters of support were provided from Horticulture Australia Limited (HAL), the Persimmons Industry Association Inc., the Australian Persimmon Export Company and the Domestic Quarantine and Market Access Working Group (DQMAWG)⁵.

Irradiation will provide persimmon growers with another treatment method for phytosanitary purposes for the fruit fly host. Other possible treatments (e.g. cold, heat, methyl bromide fumigation) can cause significant product losses, they are expensive and they may not meet quarantine requirements of other countries. In addition, there is a potential loss of current chemical disinfestation treatments (fenthion, dimethoate and methyl bromide) for fruits flies due to the phasing out of these chemicals. Therefore, approval of irradiation could allow another alternative treatment to be available to treat the fruit fly host. In summary, the Applicant has stated that approval could facilitate domestic and international trade in persimmons as irradiation meets the requirements for an appropriate and efficacious treatment for fruit fly for quarantine purposes.

The relevant quarantine agencies, Biosecurity Australia (BA) and the New Zealand Ministry of Agriculture and Forestry (NZMAF) will still need to independently perform an import risk assessment (for quarantine purposes) on irradiation of persimmons, specifically for food imported into Australia and/or New Zealand. These assessments are separate from the FSANZ and the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) approval process.

For a glossary of technical terms in relation to food irradiation see **Supporting Document 2**.

³ A phytosanitary measure is any legislation, regulation or official procedure having the purpose to prevent the introduction and/or spread of quarantine pests, or to limit the economic impact of regulated non-quarantine pests.

⁴ The **gray** (abbreviation: Gy) is the international unit of absorbed radiation dose of ionising radiation (for example, X-rays and gamma rays)

⁵ <http://www.domesticquarantine.org.au/>

1. The Issue / Problem

Standard 1.5.3 prohibits the sale of irradiated foods unless the food is listed in the Table to clause 4 in Standard 1.5.3, and as such, a pre-market assessment is required before irradiated persimmons can be sold in Australia or New Zealand.

The purpose of this Application was for FSANZ to consider whether there was justification in providing approval to irradiate persimmons under the requirements of Standard 1.5.3.

2. Current Standard

Permission to irradiate foods is considered on a case-by-case basis and approved when the food has been assessed as safe, nutritionally adequate and where there is a strong technological justification.

To date, FSANZ has considered, and subsequently approved, two Applications which sought permission to irradiate foods, namely (i) Irradiation of herbs, spices and herbal infusions (Application A413) and (ii) Irradiation of a range of tropical fruits (mango, breadfruit, carambola, custard apple, litchi, longan, mangosteen, papaya and rambutan) (Application A443).

Standard 1.5.3 allows the use of gamma rays from the radionuclide cobalt 60, x-rays generated by or from machine sources operated at an energy level not exceeding 5 mega-electronvolts⁶; or electrons generated by or from machine sources operated at an energy level not exceeding 10 mega-electron volts. The former Australia New Zealand Food Standards Council (composed of Health Ministers from the Commonwealth, States and Territories and New Zealand) approved these sources of radiation for use on food and Standard 1.5.3 was subsequently gazetted on 2 September 1999.

Where foods have been irradiated or contain irradiated ingredients or components and are available for retail sale in Australia and/or New Zealand, the label must carry a statement to the effect that the food or the particular ingredient(s) or component(s) it contains has been treated with ionising radiation. Subclause 6(2) of Standard 1.5.3 requires this statement to appear in the ingredient list or elsewhere on the label. These provisions apply only to foods permitted to be irradiated and listed in the Table to clause 4 of Standard 1.5.3, for example herbs and spices and selected tropical fruits.

Standard 1.5.3 also requires that irradiated food or food containing irradiated ingredients or components that are exempt from bearing a label, and which are displayed for sale, must have a written statement that the food, ingredient or component of the food has been treated with ionising radiation. This requires irradiated food sold unpackaged and displayed for sale, including ready to eat foods, to be accompanied by a written statement advising consumers of the treatment of the food with ionising radiation.

While Standard 1.5.3 mandates the use of a label statement, it does not prescribe the wording. Three examples are provided: '*Treated with ionising radiation*', '*Treated with ionising electrons*' and '*Irradiated (name of food)*'.

While the use of a labelling statement is mandatory for irradiated food, FSANZ notes that the use of the international Radura symbol⁷ (below) could also be used in addition to the mandatory labelling requirements.

⁶ A mega-electron volt is a unit of energy

⁷ The **Radura** is the international symbol indicating a food product has been irradiated.



2.1 Approval to irradiate foods in other countries

Permissions to irradiate a food vary considerably in different parts of the world and either are based on a case-by-case or a generic approach (without any foods specifically listed) as adopted by Codex (**see Table 1**).

The 1983 Codex standard for irradiated foods (revised 2003) requires that the maximum absorbed dose to a food should not exceed 10 kGy, except when necessary to achieve a legitimate technological purpose⁸. No specific foods are mentioned, although Standard 1.5.3 states:

- The irradiation of food is justified only where it fulfils a technological need or where it serves a food hygiene purpose and should not be used as a substitute for good manufacturing practices.

Table 1: Summary of permissions for irradiated foods

Country	Food	Dose range (kGy)
European Union	Dried aromatic herbs, spices and vegetable seasonings	10
Canada ⁹	Onions Potatoes Wheat, flour, whole wheat flour Whole or ground spices and dehydrated seasonings Fresh Beef to control microbial decontamination Frozen ground beef to control microbial decontamination Poultry to control microbial decontamination Shrimp and Prawns to control microbial decontamination Mangoes (Disinfestation)	0.15 0.15 0.75 10 1.5 to 4.5 2.0 to 7 1.5 to 3 1.5 to 5 0.15 to 1
USA ¹⁰	Fruit and vegetables (to control insects and other arthropods and to inhibit maturation (e.g., ripening or sprouting) Poultry to control foodborne pathogens Beef (Refrigerated) to control microbial decontamination Beef (Frozen) to control microbial decontamination Dry or dehydrated aromatic substances (e.g., spices and seasonings) to control microorganisms Fresh foods to control microorganisms Eggs for control of salmonella	1 3 4.5 7 30 1 3.0
Australia/New Zealand	Herbs, spices and herbal infusions (Disinfestation or decontamination) Tropical fruits (mango, breadfruit, carambola, custard apple, litchi, longan, mangosteen, papaya and rambutan) to control pests of quarantine concern	6 to 30 0.15 to 1
Thailand	Selected tropical fruits (mango, mangosteen, lychee, longan, rambutan and pineapple for disinfestation)	0.4

⁸ http://www.codexalimentarius.net/download/standards/16/CXS_106e.pdf

⁹ In Canada, permission to irradiate beef, poultry, shrimp, prawns and mangoes are still in the process of Final Approval.

¹⁰ In the USA, food irradiation is considered as a food additive under their legislation.

Country	Food	Dose range (kGy)
Philippines	Mangoes for disinfestation	1
	Onions for sprout inhibition	0.3 to 1
	Garlic for disinfestation	.3 to 1
Vietnam	Seafood for decontamination	2 to 7.5
	Frozen Fruits for decontamination	2 to 3
	Dragon fruits to control pests	1
Indonesia	Mango to control insects	0.75
	Papaya, mushroom, tomatoes, bananas and broccoli for shelf-life extension	1-2
	Fresh meat and chicken for decontamination of pathogens	5-7
India	Mangoes to control insects	0.25 to 0.75
	Fresh meat and chicken for decontamination of pathogens	2.5 to 4
	Spices for decontamination	6.0 to 14
	Raisins, figs and dried dates to control insects	0.25 to 0.75
	Fresh seafoods for shelf-life extension	1 to 3

International Standards for Phytosanitary Measures 18 (*ISPM No. 18*) – *Guidelines for the Use of Irradiation as a Phytosanitary Measure*, International Plant Protection Convention, 2003 (ISPM, 2003) provides technical guidance on the specific procedures for the application of ionising radiation as a phytosanitary treatment for pests or articles.

The American Society for Testing and Materials, *ASTM F1355-06 Standard Guide for Irradiation of Fresh Agricultural Produce as a Phytosanitary Treatment* (ASTM, 2006) also provides for procedures for the radiation disinfestation of fresh fruits as a quarantine treatment.

3. Objectives

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 of the FSANZ Act. These are:

- the protection of public health and safety; and
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

4. Questions to be answered

The key questions which FSANZ has considered as part of this assessment are:

- Has the technological purpose for using irradiation as a quarantine measure for persimmons been established?
- Will the dose used achieve the technological function of use of irradiation as a quarantine measure?
- When persimmons are irradiated, are there any new compounds formed that may impact on public health and safety?
- As a form of food processing, what is the impact from irradiation on the nutrient composition of persimmons?
- Would a change in the nutrient composition of persimmons from irradiation affect the nutritional adequacy of Australian and New Zealand diets containing persimmons?

RISK ASSESSMENT

5. Risk Assessment Summary

Full details of the risk assessment prepared in relation to this application are provided in **SD1**. A summary of this risk assessment follows.

5.1 Safety and nutritional adequacy of irradiated foods

FSANZ has previously assessed the safety and nutritional adequacy of various irradiated tropical fruits. This assessment was conducted in 2002¹¹. At that time, FSANZ concluded that there were no public health or safety issues associated with their consumption when irradiated up to a maximum dose of 1 kGy.

The current Application seeks to extend the existing permission for the irradiation of tropical fruits to include persimmons. The purpose of the risk assessment was to determine whether persimmons irradiated up to a maximum dose of 1 kGy are as safe as non-irradiated persimmons. The risk assessment takes account of the previous consideration and includes an assessment of further data on the safety of irradiated foods that has become available since the assessment conducted in 2002. The compositional data on irradiated persimmons and the level of consumption of persimmons in Australian and New Zealand were also taken into consideration.

FSANZ concludes that there are no public health or safety issues associated with the consumption of persimmons, which have been irradiated up to a maximum dose of 1 kGy.

This conclusion is based on the following considerations:

- The safety of irradiated food has been extensively assessed by national regulators and international scientific bodies and there have been no identified public health or safety concerns.
- There is a history of safe consumption of irradiated food in many countries.
- Available data indicate that the carbohydrate, fat, protein and mineral content of foods are unaffected by irradiation at doses up to 1 kGy. Therefore, irradiation is unlikely to affect the presence of macronutrients and minerals in persimmons.

¹¹ <http://www.foodstandards.gov.au/srcfiles/A443%20FAR%20-%20Irradiation%20Tropical%20Fruit.pdf>

- The concentrations of certain vitamins may be decreased as a result of the irradiation process. However persimmons are not widely consumed in Australia and New Zealand and they contribute minimally to the total dietary intake of these vitamins. Therefore, there are unlikely to be any nutritional disadvantages for Australian and New Zealand consumers from eating irradiated persimmons.
- The irradiation of several tropical fruits is already permitted in Australia and New Zealand. FSANZ has not previously identified any public health or safety issues associated with the consumption of these or other permitted irradiated foods.
- There is no safety concerns arising from chemical products (e.g. alkylcyclobutanones¹² (2-ACBs)) produced from irradiated foods. Supplementary data published since 2002 have confirmed that 2-ACBs are not genotoxic. New data indicate that 2-ACBs previously considered to be uniquely formed during food irradiation are actually present in some non-irradiated foods.

5.2 Issues raised during public consultation on the risk assessment

The issues raised by submitters are summarised in Attachment 3 and addressed below.

5.2.1 General comments on FSANZ's risk assessment

Some submitters believed that FSANZ had not performed a rigorous risk assessment, had been selective in its citing of the literature on the safety of irradiated persimmons and that numerous scientific studies have revealed the potential harmful effects of food irradiation.

5.2.1.1 FSANZ Response

FSANZ undertakes risk assessments in accordance with the most up-to-date international risk assessment procedures¹³. The available studies indicate that irradiation of persimmons does not pose a significant human health risk for Australian or New Zealand consumers. FSANZ's conclusions on the safety of irradiated foods are consistent with a recent review by the European Food Safety Authority (EFSA)¹⁴.

FSANZ's comprehensive search of the scientific literature undertaken as part of the current assessment process did not identify any studies which revealed potential harmful effects from irradiated foods. The weight-of-evidence indicates that food is safe when irradiated at doses necessary to achieve the intended technological function and in accordance with good radiation practice.

FSANZ undertook a comprehensive literature search and included studies on the metabolism, genotoxicity and carcinogenicity of radiolytic compounds in addition to the analysis of radiolytic compounds in various irradiated foods. The weight-of-evidence of the existing database, plus data on the safety of irradiated foods that has become available since the assessment conducted in 2002, indicated that there were no new public health or safety considerations that need to be addressed as part of the current Application.

¹² Particular chemical compounds (molecules) that are found following irradiation of food

¹³ <http://www.foodstandards.gov.au/scienceandeducation/scienceinfsanz/> and http://www.foodstandards.gov.au/srcfiles/Food%20Related%20Health%20Risks%20WEB_FA.pdf

¹⁴ <http://www.efsa.europa.eu/en/efsajournal/pub/1930.htm>.

FSANZ has not assumed that irradiated persimmons are safe to eat on the basis of the existing permission for irradiated tropical fruits. FSANZ considers that the generic data previously considered in relation to the safety of irradiated tropical fruits are a relevant and necessary inclusion in the current assessment. On this basis, the existing permission for the irradiated tropical fruits provides a useful platform on which to evaluate the safety of irradiated persimmons. This platform has been supplemented with new published data on the toxicity of irradiated foods or 2-ACBs, in addition to persimmon-specific compositional, nutritional and consumption data.

5.2.2 *Irradiated cat food*

A number of submitters questioned FSANZ's apparent lack of consideration of the recent studies in cats. These comments refer to the association of certain imported cat food that had been irradiated with neurological symptoms and the death of several cats. Several published studies seemingly replicated the neurological effect in germ-free cats fed a diet of highly irradiated pet food.

5.2.2.1 FSANZ Response

There is a body of evidence associating high-dose irradiation of dried pet food and the development of a chronic neurological syndrome in cats. While the precise mechanism of this neurological syndrome remains to be defined, it has been hypothesised to be due to the loss of certain vitamins and/or the generation of peroxides (Caulfield et al 2009). FSANZ, along with veterinary experts in government and the private sector, considers that these neurological effects were cat-specific. FSANZ has concluded that the observations in cats are not relevant to humans. FSANZ had assessed the recent studies in cats prior to the Assessment Report being publicly available, but did not include it in the Risk Assessment Report at the Assessment stage, because it was considered to be a cat-specific effect.

FSANZ notes the assessment of the cat studies by EFSA in 2009 as part of its updated hazard assessment on the safety of irradiated foods. While EFSA expressed some uncertainty about the relevance of the observations in cats to humans and the need for additional data, it noted the lack of a similar effect in dogs fed the same irradiated diet or from observations in rodents or humans. EFSA's overall conclusion was that at this point in time it was safe for humans to consume irradiated food.

FSANZ will continue to monitor any developments in this area and consider any related issues for irradiation of food for human consumption.

5.2.3 *Production of harmful chemical products in irradiated foods*

A number of submitters raised concerns over the potential for irradiation to produce chemical products in foods that may have adverse effects for humans and create toxic radiolytic substances which do not exist naturally. Concerns were expressed over the genotoxic potential of 2-ACBs in light of a small proportion of *in vitro* genotoxicity studies which reported that certain 2-ACBs damaged genetic material. The submitters indicated that there was extensive evidence that these compounds were harmful to human health and that EFSA had concluded that these compounds were genotoxic. One submitter suggested that FSANZ had made a very narrow assessment of potential adverse effects by making an assessment only at a macronutrient level. As irradiation may have different effects on the individual fatty acids present in foods, as a minimum, the fatty acid profile of persimmons should have been included in the Report.

5.2.3.1 FSANZ Response

FSANZ has considered the toxicity of radiolytic compounds formed following food irradiation as part of the current Application (see Section 2.1.3 of SD1). The majority of radiolytic compounds are not unique to irradiated foods. They occur in some unprocessed foods and are sometimes formed by conventional food processing techniques (e.g. thermal processing). While one class of radiolytic compounds, the 2-ACBs, has been considered unique to irradiated food, new data suggests that these compounds are present in some non-irradiated foods, such as cashew nuts and nutmeg. The inclusion of this data in the risk assessment was intended to illustrate that, qualitatively; humans may not be uniquely exposed to these substances from irradiated food as has been the prevailing view.

FSANZ evaluated these studies (refer to SD1). The genotoxicity studies which reported positive effects were non-standard studies and the overall weight of evidence indicates that there is no genotoxicity potential. EFSA has recently published an updated hazard assessment on the safety of irradiated foods¹⁵, concluding that some 2-ACBs may induce DNA damage *in vitro*. However, EFSA noted that the majority of genotoxicity assays on 2-ACBs or irradiated foods, including over sixty *in vitro* and *in vivo* mutagenicity studies, have shown no effect. EFSA concluded that a genotoxic risk for 2-ACBs in humans is unlikely.

Several 2-ACBs are used as markers to detect irradiated foods (Stevenson *et al*, 1990) and a European Standard (EN 1758) to detect 2-ACBs in fat-containing irradiated food is available (see section 6.4). 2-ACBs have been found to be markers for detection of irradiated mango and papaya with the relative percentage of fatty acids and type determining the presence of the specific 2-ACBs (Stewart *et al*, 2000). FSANZ notes that 2-ACBs can be formed from fatty acids in fat-containing irradiated foods. Table 2.1 in section 2.1.3 of SD1 summarises the different types of 2-ACBs that may be formed and the fatty acids from which they are derived. The types and concentrations of 2-ACBs in irradiated food depend on the lipid content and composition of the non-irradiated food in addition to the irradiation dose.

Table 2 (below) outlines the fatty acid composition of persimmons based on analysis from three countries and indicates that the concentration of total and individual fatty acids is very low ($\leq 0.2\%$). Therefore, although there is a potential for production of 2-ACBs in high fat-containing foods, given the low concentration of total and individual fatty acids in persimmons, FSANZ concludes that there are no safety issues for consumers.

Table 2: Fatty acid composition of raw persimmon (*Diospyros kaki*) per 100g edible portion as assessed in Australia, New Zealand and the USA

Fatty acid	Australia ^a	New Zealand ^b	USA ^c
Total fat (g)	0.2	0.2	0.2
Saturated fat (g)	0.0	Trace	<0.1
Monounsaturated fat (g)	0.0	0.1	<0.1
Polyunsaturated fat (g)	0.0	0.1	<0.1
Omega 3 (g)	0.0	0.0	0.0

¹⁵ <http://www.efsa.europa.eu/en/efsajournal/doc/1930.pdf>

Fatty acid	Australia ^a	New Zealand ^b	USA ^c
Omega 6 (g)	0.0	0.0	NA

^a Data from NUTTAB 2006 online version

(<http://www.foodstandards.gov.au/consumerinformation/nuttab2006/onlineversionintroduction/onlineversion.cfm?action=getFood&foodID=06D10208>)

^b Data from The Concise New Zealand Food Composition Tables (2009) (http://www.crop.cri.nz/home/products-services/nutrition/foodcompdata/fcd-products/Concise_8_Edition.pdf), species of persimmon not specified

^c Data from USDA National Nutrient Database (http://www.nal.usda.gov/fnic/foodcomp/cgi-bin/list_nut_edit.pl)
NA, not assessed

5.2.4 *Effects on nutrition of irradiated foods*

Many submitters raised issues relating to the possible adverse cumulative effects on nutrition of eating a number of irradiated foods.

5.2.4.1 FSANZ Response

FSANZ acknowledges the importance of assessing the aggregate effect of all existing irradiation permissions on the total diet of Australian and New Zealand consumers.

FSANZ has treated the previous two irradiation Applications separately in assessing the impact of irradiation on the nutrient intake of the Australian and New Zealand populations. The assessment of Application A413 concluded that herbs, spices and herbal infusions were insignificant sources of radiation sensitive nutrients including vitamin A, vitamin C, vitamin E, thiamin and folate.

The aggregate effect of irradiation of all tropical fruits was considered in Application A443 using a conservative 'worst case' scenario. The contribution of the entire 'other tropical fruit' group and 'other fruits' group (which includes persimmons) to specific nutrient intakes was estimated for the Australian and New Zealand populations. FSANZ concluded that these broad fruit categories were minor sources of irradiation-sensitive nutrients β -carotene, folate, vitamin C and thiamin and vitamin E for the Australian and New Zealand populations.

The nutrition assessment for A1038 has considered consumption data from the most recent national nutrition surveys in Australia and New Zealand from 1995–2007. This indicated that persimmons were consumed by less than 1% of the population.

FSANZ has conducted conservative modelling in the past which has found that the irradiation of persimmons and all existing foods permitted for irradiation under Standard 1.5.3 are unlikely to affect the nutritional adequacy of the diet in Australia and New Zealand. Assessment of future applications to irradiate food will include consideration of the aggregate effect of all existing irradiation permissions on the total diet of Australian and New Zealand consumers. FSANZ concludes that irradiation at doses less than 1 kGy would have little effect on the nutrient profile of either tropical fruits or persimmons compared to traditional forms of food processing.

Some submitters stated that FSANZ had not considered the health impacts on overseas consumers of irradiated foods exported from Australia. FSANZ, in consultation with its food regulatory partners, is responsible for protecting the public health and safety of Australian and New Zealand consumers through maintaining and amending food regulations set out in the Code. FSANZ does not have any powers in relation to food for export and is not obligated to consider any potential dietary impact on overseas consumers of persimmons or other irradiated foods exported from Australia.

Measures in the Code apply to food produced or imported into Australia and FSANZ would not expect that consumers in countries to which persimmons may be exported, would experience adverse nutritional effects from eating irradiated persimmons.

Another issue raised by submitters related to greater vitamin losses for irradiated foods when compared with non-irradiated foods. FSANZ acknowledges that in some studies it has been shown that the vitamin C content of certain irradiated fruit (for example, mango, late season grapefruit, carambola, and Imperial mandarin) is significantly lower than for non-irradiated fruit during storage (Lacroix *et al.*, 1990; Mitchell *et al.*, 1992; Moy and Wong, 2002; Patil *et al.*, 2004; Youssef *et al.*, 2002). As the number of consumers of persimmons in Australia and New Zealand is relatively low and fruit consumption is seasonal, it is likely that persimmons are very minor contributors to the total dietary intake of vitamin C (and vitamins E, β -carotene, and certain B vitamins) when considered within the context of the overall diet. Furthermore, dietary intakes of vitamin C in Australia and New Zealand are adequate. Therefore the irradiation of persimmons is unlikely to decrease the adequacy of the dietary intake of vitamin C by the Australian and New Zealand populations.

A submitter requested clarification of the term 'compositionally similar' in the Risk Assessment Report. The use of the term 'fruit of similar composition' refers to the fruit included in the risk assessment. FSANZ agreed that this term was not clear and it has amended the Risk Assessment Report.

One submitter suggested that a lack of primary, specific and recent data on the effect of irradiation on persimmons was a concern. FSANZ acknowledges that there is only one study included in the risk assessment investigating the specific effects of irradiation on the nutrient composition of persimmons (Mitchell *et al.*, 1992). However, the available data indicate that the carbohydrate, fat, protein and mineral content of other foods (including fruit) are not affected by irradiation at doses up to 1 kGy. Therefore, irradiation is unlikely to affect the presence of macronutrients and minerals in persimmons.

As well as specific data on persimmons, published studies of the effect of irradiation on fruit as a commodity group was considered in totality and FSANZ did not require the Applicant to supply additional specific data on persimmons.

5.3 Conclusions

Taking into account the issues raised in public submissions, FSANZ has concluded that the available studies indicate that irradiation of persimmons does not pose a significant human health risk for Australian or New Zealand consumers. There are no changes to the composition of persimmons following irradiation that are likely to cause public health and safety concerns. Irradiation of persimmons up to a maximum dose of 1 kGy employing proper irradiation practices is considered safe for Australian and New Zealand consumers.

As with other forms of food processing, irradiation will have some impacts on the nutrient composition of persimmons; however, there are few indications that these impacts are any greater than other forms of food processing, especially for irradiation doses up to a maximum of 1 kGy.

Risk Management

FSANZ's regulatory approach varies depending on the nature of the risks identified and there are a number of approaches used to manage identified risks. These can include establishing specifications, compositional and/or labelling requirements and where necessary, restriction or prohibition.

Drawing on the conclusions from the risk assessment, the following sections discuss other broader issues including technological need, packaging, irradiation facilities and dosimetry, methods of verification and labelling of irradiated foods that require consideration in the development of regulations for irradiation of persimmons.

6.1 Technological need and efficacy of the irradiation process

To date, FSANZ has approved the irradiation of herbs, spices and herbal infusions and irradiation of a range of tropical fruits (mango, breadfruit, carambola, custard apple, litchi, longan, mangosteen, papaya and rambutan)

Specific advice on technological need and appropriate dose ranges for phytosanitary purposes for both applications was sought at that time from Biosecurity Australia (BA) and Biosecurity New Zealand (now part of the New Zealand Ministry of Agriculture and Fisheries (NZMAF)). FSANZ has viewed the current Application as an extension of use of irradiation into other fruit, commensurate with previous approvals of tropical fruits.

Examples of recent approvals by BA and NZMAF for quarantine purposes are as follows:

Commodity	Date	Purpose	Dose
Fresh mangoes imported from India (BA) ¹⁶	August 2008	Phytosanitary need for control of fruit flies, mealy bugs, red-banded mango caterpillar and mango weevils	400 Gy
Litchis exported from Australia (Biosecurity NZ) ¹⁷	September 2008	Control of Fruit fly and Hemiptera (bugs)	Minimum of 250 Gy
Mangoes and Papaya exported from Australia (Biosecurity NZ) ¹⁸	2004 and 2006, respectively	Control of Fruit fly and other insect pests	250 Gy

Irradiation is an approved phytosanitary treatment for fruits and vegetables in other countries (see Table 1 in section 2.1). Irradiation is also a known effective treatment for fruit fly infestation. For fruits and vegetables that are hosts to the fruit fly the required treatment is applied in accordance with international requirements (under ISPM 18; 2003). The required treatment would specifically comply with *ISPM 28, Irradiation Treatment for Fruit Flies of the Family Tephritidae* (2007) within the dose range of 150Gy to 1kGy for prevention of the emergence of adult fruit flies for all fruits and vegetables. Further support for the efficacy of irradiation as a phytosanitary treatment for fruit fly exists in the US. In 2006, the US Animal and Plant Health Inspection Service (APHIS) approved generic irradiation doses of 150 Gy to reduce fruit fly infestation on specific fruits.

The Applicant has also confirmed with BA and NZMAF that the minimum dose of 150 Gy and the maximum of 1 kGy approved for use on tropical fruits for treatment of fruit fly under Application A443¹⁹ is also an appropriate and efficacious dose for irradiation of persimmons. Both BA and NZMAF have provided letters to FSANZ recommending that irradiation is an effective quarantine treatment for fruit fly and other pests which are of quarantine concern to Australia and New Zealand.

¹⁶ http://www.daff.gov.au/_data/assets/pdf_file/0003/771906/Mangoes_from_India_Final_Report.pdf

¹⁷ <http://www.biosecurity.govt.nz/files/regs/imports/risk/aus-litchi-ra.pdf>

¹⁸ http://www.hortaccess.com.au/page/plant_quarantine_food_safety.html

<http://www.biosecurity.govt.nz/files/ihs/mango-au.pdf>

<http://www.biosecurity.govt.nz/files/biosec/policy-laws/intl/sps/transparency/notifications/nz1341-ft.pdf>

¹⁹ <http://www.foodstandards.gov.au/srcfiles/A443%20FAR%20-%20Irradiation%20Tropical%20Fruit.pdf>

6.1.1 Issues raised during public consultation

A number of submitters suggested that no technological purpose to irradiate persimmons had been established and that there were a number of other equally effective alternative treatments available.

6.1.1.1 FSANZ Response

FSANZ does not compare the effectiveness of irradiation against other treatments such as chemicals; heat/cold etc. Advice received by FSANZ from the relevant quarantine authorities are that irradiation of persimmons for the purpose of pest disinfection would provide an effective alternative to currently used disinfection methods. The proposed minimum dose of 150 Gy and maximum dose of 1 kGy will provide a dose range in order for quarantine agencies to consider irradiation as a treatment for pest disinfection of persimmons. FSANZ understands that irradiation is viewed as an important pest reduction protocol for acceptance of Australian produce for interstate trade and in other countries. Recently, the Plant Biosecurity and Product Integrity Group of the Queensland Government produced an interstate Certification Assurance arrangement for irradiated foods²⁰. This is additional recognition of the established technological need to irradiate foods for interstate trade.

In conclusion, disinfection of persimmons by irradiation is a valid treatment for quarantine purposes and meets the requirements of a technological need (pest disinfection) under Standard 1.5.3. Insect pests of quarantine significance represent a major barrier in gaining access to some markets. Irradiation is considered an efficacious treatment on persimmons.

The international Plant Protection Convention (IPPC), Codex Alimentarius, quarantine agencies in Australia, New Zealand and the USA endorse irradiation as a legitimate phytosanitary treatment.

6.2 Packaging

There are potential risks from chemicals, inherent in packaging, migrating into persimmons following irradiation. At a low maximum dose of 1 kGy, packaging material in contact with persimmons would not undergo significant alteration of its functional properties or yield materials which could transfer to the food as a result of irradiation at phytosanitary doses, which would be a public health or safety issue. The following paragraphs discuss how any potential risk is managed in relation to the packaging of irradiated persimmons.

Irradiation of persimmons will be undertaken after packaging of the fruits. The standard fruit packages used for packing fresh persimmon fruits are the same as those currently used for packing mango, papaya and litchi currently destined for irradiation, albeit with specific dimensions to suit the particular fruit type. Therefore, food to be processed by irradiation, and the packages and packing materials used or intended for use in connection with food so processed, must be of suitable quality and in an acceptable hygienic condition, appropriate for the purpose of such processing. It is the responsibility of Australian and New Zealand food manufacturers and retailers to ensure that their products are safe and that they comply with all relevant legislation.

²⁰ <http://www.phau.com.au/ica-docs/190-ica-55.pdf> and <http://www.domesticquarantine.org.au/index.cfm?objectID=44F9C72D-A63D-3F2E-C127EE6E7389B7D8&action=detail&state=QLD&id=ICA-55>.

Standard 1.4.3 – Articles and Materials in Contact with Food regulates food packaging materials in general terms, but does not specify individual packaging materials for food contact or how they should be produced or used. Standards Australia has developed an Australian Standard for Plastics Materials for Food Contact Use (AS2070-1999) which details standards for plastic materials for food contact use. AS2070 refers to the USA Code of Federal Regulations and the EU Directives on plastics suitable for use on irradiated foods.

The *ASTM Standard Guide F1640-09 Standard Guide for Packaging Materials for Foods to Be Irradiated* (2009), formulated by the American Society for Testing and Materials (ASTM) Subcommittee on Food Irradiation Processing and Packaging addresses issues in the selection and use of packaging materials for food and agricultural products to be irradiated. The Applicant advised that corrugated or fibre board fruit boxes used for packaging persimmons were made from components consisting of kraft (manufactured from a blend of pine and eucalypt fibre) and recycled papers (manufactured from various sources of paper stock), inks, adhesives and various coatings. Amcor, Carter Holt Harvey and Visy are the main manufacturers and suppliers of the fibre board fruit and produce packages in Australia. The materials used in manufacturing the fibre board packages and the plastic inserts are appropriate and are currently approved for use in irradiating fruits and vegetables at the disinfestation dose applied (150 Gy–1 kGy), under the USA Code of Federal Regulations.

The Purpose of Standard 1.5.3 currently has a reference to packages and packing materials used or intended for use in connection with irradiated food being of a suitable quality, in an acceptable hygienic condition, and appropriate for the purpose of such processing. However, FSANZ has removed the reference to packages and packaging materials as this reference is not appropriately considered to be a ‘purpose’ for Standard 1.5.3. In addition, the provisions in Standard 1.4.3 also apply to packaging used for irradiation.

6.3 Irradiation facilities and dosimetry

It is mandatory that any food permitted to be irradiated is treated in a licensed radiation facility. There are currently three commercial irradiation facilities operating in Australia. All three irradiation facilities use gamma radiation from radioactive Cobalt-60. There is an Australian Quarantine and Inspection Service (AQIS) approved treatment facility in New Zealand – Schering Plough Animal Health Upper Hutt, New Zealand.

The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA²¹) regulates Australian Government entities, whereas the activities of non-Australian Government entities are regulated by relevant State and Territory authorities.

The radiation facilities are licensed in accordance with any relevant State, Territory and New Zealand law governing radiation control and operation. In Australia, this responsibility is under the jurisdiction of the following State/Territory Departments:

- ACT Health, Radiation Safety Section
- NSW Department of Environment and Climate Change
- Northern Territory Department of Health and Community Services
- Queensland Department of Health
- South Australia Environment Protection Authority
- Tasmanian Department of Health and Human Services
- Victorian Department of Human Services
- Western Australia Radiological Council, Department of Health.

²¹ <http://www.arpansa.gov.au/index.htm>

All matters including occupational health, safety and welfare regulations are regulated by the relevant regulatory authorities, i.e. all national, state, territory and local government Authorities.

In New Zealand, the National Radiation Laboratory (NRL) under delegated authority from the Ministry of Health regulates all radiation facilities and radioactive substances and apparatus. The NRL administers the Radiation Protection Act 1965 and the Radiation Protection Regulations 1982.

The New Zealand legislation controls the use of ionising radiation and requires:

- users of radioactive materials or irradiating apparatus to hold a licence (users will also normally be required to comply with a Code of Safe Practice)
- importers, exporters and dealers of radioactive material to obtain a consent
- vendors and purchasers of irradiating apparatus to notify all transactions
- transporters of radioactive material to comply with transport regulations

The Applicant has provided FSANZ with extensive details of the procedure undertaken to ensure proper dosimetry. This will ensure compliance in accordance with the desired dose for each treatment that is required for approval by regulatory agencies and for developing quality control procedures.

6.3.1 Issues raised during public consultation

Some submitters had concerns with the safety of irradiation facilities and of the transport of radioisotopes (Attachment 3). However, these matters are not addressed by the Code, but are regulated by relevant State/Territory authorities under their radiation protection legislation as detailed above.

6.4 Methods of verification for irradiated foods

Current detection methods for irradiated food are able to detect whether a food has been irradiated or not, but cannot accurately measure absorbed doses. The control of the dose is managed by proper validation of the process prior to routine processing and is established and controlled by accurate dosimetry and maintenance of records by irradiation facilities under the existing State/Territory or New Zealand irradiation licensing requirements.

The currently available techniques are limited to foods containing bone, fat-containing foods or light emission²²:

- EN 1784:2003 Detection of irradiated food containing fat - Gas chromatographic analysis of Hydrocarbons
- EN 1785:2003 Detection of irradiated food containing fat - Gas chromatographic/mass spectrometric analysis of 2-alkylcyclobutanones
- EN 1786:1996 Detection of irradiated food containing bone - Method by (electron spin resonance) ESR spectroscopy
- EN 1787:2000 Detection of irradiated food containing cellulose by ESR spectroscopy
- EN 1788:2001 Thermoluminescence detection of irradiated food from which silicate minerals can be isolated
- EN 13708:2001 Detection of irradiated food containing crystalline sugar by ESR spectroscopy
- EN 13751:2002 Detection of irradiated food using photostimulated luminescence

²² Source: http://ec.europa.eu/food/food/biosafety/irradiation/anal_methods_en.htm

- EN 13783:2001 Detection of irradiated food using Direct Epifluorescent Filter Technique/Aerobic Plate Count (DEFT/APC) - Screening method
- EN 13784:2001 DNA comet assay for the detection of irradiated foodstuffs - Screening method
- EN 14569:2004 Microbiological screening for irradiated food using LAL/GNB procedures

Detection of irradiated food containing cellulose by ESR spectroscopy (*EN 1787:2000*) may have practical application in fruit and vegetables. However, the technique is limited to detection of irradiated fruits for up to three weeks after treatment. However, detection tests can assist to enforce labelling requirements by identifying irradiated fruit.

6.4.1 Issues raised during public consultation

One submitter was concerned there was a lack of methods of detection for irradiated foods. It is correct that there is no internationally recognised single method of detection for irradiated foods; rather there are various methods. No method of detection is absolutely specific in measurement of the actual dose applied as the changes that irradiation induces in foods is minimal. However, control of dose is also managed by accurate dosimetry and maintenance of records under the requirements of Standard 1.5.3.

6.5 Labelling of irradiated foods

There is a mandatory requirement to label irradiated foods and FSANZ is not proposing any changes to those labelling requirements (refer to section 2). However, FSANZ is recommending some minor changes to specific labelling requirements. The first of these is deletion of the statement 'treated with ionising electrons' in subclause 6(1) of Standard 1.5.3 as this may be misleading for consumers. In addition, FSANZ also recommends deletion of subclause 6(4) relating to labelling of irradiated foods other than for retail, as it is repetitive and unnecessary and covered by other provisions in the Code. For a fuller discussion of these issues see 7.5 below. The following issues were raised during public consultation.

6.5.1 Adequacy and legibility of current labelling requirements

Some submitters raised concerns around the adequacy and legibility of current labelling requirements for irradiated foods. Other submitters were concerned that labelling would be removed as a requirement in Standard 1.5.3 (either in the current Application or under the Review of Food Labelling Law and Policy). Submitters were concerned that individual fruits would not be labelled and were of the view that labelling should be mandated. It was thought that accompanying signage was not sufficient as a sign would not offer the same degree of information at the point of consumption.

6.5.1.1 FSANZ Response

In the absence of a food product label, the mandatory labelling statement must be displayed in close proximity to the food. These requirements reflect the status quo and FSANZ is not recommending a relaxation of labelling requirements for irradiation of approved foods.

Any information required on a food label must comply with the legibility requirements in Standard 1.2.9 – Legibility Requirements. Standard 1.2.9 requires that all food labels present information so that it is legible, prominent (such as to afford a distinct contrast to the background), and in English. Non-compliance with the Code would be a matter for enforcement agencies.

The recommendations made for drafting changes at Assessment were for clarification purposes, rather than a change to existing requirements. Subclause 6(3) of the current Standard permits the information to be displayed on or in connection with the display of the food, which is consistent with similar provisions in the Code (for example, labelling of genetically modified food).

The term 'label' is defined in clause 2 of Standard 1.1.1 to mean *any tag, brand, mark or statement in writing or any representation or design or descriptive matter on or attached to or used in connection with or accompanying any food or package.*

FSANZ has recently viewed some examples of labelled stickers collected from supermarkets and provided by industry on individual fruits. This demonstrates that industry is voluntarily labelling individual tropical fruits (e.g. mangoes) when exported to New Zealand. In some circumstances, labelling on the stickers also includes the optional Radura symbol.

In response to submitter concerns about recommendations made in the final Report of the Review of Food Labelling Law and Policy²³, the Report includes the recommendation that the requirement for mandatory labelling of irradiated food be reviewed (Recommendation 34). A whole-of-government response is being prepared to the recommendations, and is expected to be considered by Ministers in December 2011. FSANZ will respond to any requests from Ministers to review the issue of mandatory labelling of irradiated food, should this occur.

6.5.2 Wording of labelling statements

Some submitters believed that FSANZ should prescribe a labelling statement, for example 'Irradiated', 'Treated with radiation', 'Treated with (or by) irradiation', 'Irradiated with electrons' or 'Irradiated with X-rays'.

Two submitters proposed that certain labelling statements be prohibited as they considered them to be potentially misleading, for example 'Cold pasteurisation', 'Picowaved', and 'Electronically treated'.

- Two submitters supported the removal of the current example 'Treated with ionising electrons'. One submitter suggested that positive statements be prohibited, for example 'Treated with irradiation – to protect New Zealand's environment'. In their view, the use of a positive statement about without a requirement to state negative impacts was biased and inappropriate for fair consumer education.

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6.5.2.1 FSANZ Response

FSANZ acknowledges the new labelling statements proposed by submitters and suggestions from others to prohibit the use of certain statements. However, subclause 6(1) of Standard 1.5.3 does not prescribe wording to be used to identify irradiated foods. As noted earlier, FSANZ will respond to any requests from Ministers to review the issue of mandatory labelling of irradiated food, should this occur. An indication of the purpose of food irradiation (e.g. a positive statement such as 'Treated with irradiation – to protect the New Zealand environment') would not be prohibited from being placed on the label provided that it was not false, misleading or deceptive or likely to mislead or deceive.

²³ <http://www.foodlabellingreview.gov.au/internet/foodlabelling/publishing.nsf/content/labelling-logic>.

6.5.3 *Enforcement issues*

Some submitters were of the view that there is a lack of enforcement activity in relation to labelling of irradiated foods.

6.5.3.1 FSANZ Response

While FSANZ is responsible for considering the enforceability of a provision during standards development, the adequacy of enforcement activity is outside our objectives in developing a food standard and is the responsibility of the states and territories in Australia, and NZMAF in New Zealand.

6.5.4 *Radura symbol*

- Two submitters suggested that the Radura symbol be prohibited. One of these submitters was of the view that the symbol was designed to lead consumers to believe that irradiation is clean and green. The other submitter was concerned that it appeared more like an endorsement for a health foundation than a warning sign.

One submitter supported the use of the Radura symbol. They also suggested that industry have the option to add a phrase in conjunction with the symbol that adequately depicted the reason for the treatment.

6.5.4.1 FSANZ Response

The Radura is the international symbol indicating a food product has been irradiated. The Radura is usually green and resembles a plant in a circle. The top half of the circle is dashed. Graphical details and colours vary between countries²⁴. While Standard 1.5.3 does not mandate its use, it does not prohibit the voluntary addition of the symbol, as long as the mandatory labelling statement is also present.

The European Union regulations do not provide for the use of the Radura logo and rely exclusively on labelling in the respective languages of the Member States. The US Food and Drug Administration (USFDA) requires that irradiated foods be labelled and that the Radura symbol is included on the label.

FSANZ stated in the Final Assessment Report to Application A443 that the optional use of the Radura symbol on irradiated foods would be permitted in conjunction with mandatory labelling requirements. This is consistent with the current International Codex Standard for Labelling of Pre-Packaged Foods (CODEX STAN 1-1985).

In response to the submitter suggestion to add a phrase that adequately depicts the reason for treatment, FSANZ notes that, subject to the mandatory labelling requirements being met, there is nothing to prevent industry from voluntarily adding this type of phrase or statement to the label.

6.5.5 *Conclusions - Labelling of irradiated foods*

FSANZ has considered submitters' comments as discussed above and has decided not to change the current labelling requirements as there are no new considerations that indicate that the current mandatory labelling requirements need changing. Submitters' comments on the changes to Standard 1.5.3, including the amendments to specific labelling clauses, are discussed further in Section 7.5.

²⁴ Ehlermann DAE (2009) The Radura-terminology and food irradiation. Food Control, 20, 526-528.

These changes do not alter the provisions – they are intended to provide clarity and reduce repetition.

6.6 Risk Management Strategy

FSANZ concludes that approval of irradiation of persimmons at a minimum dose of 150 Gy and a maximum of 1 kGy poses no significant risk to public health and safety for Australian or New Zealand consumers. Irradiation is technologically justified as it will provide an efficacious treatment to reduce fruit fly infestation which is of quarantine concern.

In determining the most appropriate risk management strategy, FSANZ's mandate is confined to the section 18 objectives of the FSANZ Act (**see sections 3 and 12**). On the basis of the risk assessment, FSANZ approves irradiation of persimmons subject to fulfilling the following requirements under Standard 1.5.3:

- irradiation of persimmons only for the purposes of pest disinfection for a phytosanitary objective
- adherence to a minimum dose of 150 Gy and a maximum of 1 kGy
- Additionally the current mandatory labelling of irradiated foods and record keeping requirements will apply to irradiated persimmons.

Other matters, such as general exposure to radiation, damage to the environment and occupational health issues for workers are outside FSANZ's mandate and are covered by other risk management measures, such as controls imposed by the assessment of radiation licence applications.

7. Recommended amendments to Standard 1.5.3

FSANZ recently engaged the Office of Legislative Drafting and Publishing (OLDP) to conduct a legislative audit of the Code, to identify areas in the Code which are unclear and to ensure that the Code reflects best practice drafting technique. Although the OLDP did not make any specific recommendations about Standard 1.5.3, FSANZ identified changes which could be made concurrently with the assessment of A1038. These changes would provide clarity around interpretation and operation of Standard 1.5.3 without changing the intent of the Standard to maintain an overall prohibition of the irradiation of food, unless permitted on a case-by-case basis.

FSANZ liaised with the Applicant who was in full agreement with the proposed additional amendments to Standard 1.5.3.

To assist in understanding the proposed amendments refer to **Attachment 2** and a revised (tracked changes) version of the Standard in **Supporting Document 4**.

The proposed amendments at Assessment, issues raised by submitters with regard to the amendments during the public consultation period and FSANZ's response are detailed in sections 7.1 to 7.5.

A number of submitters questioned why FSANZ chose to propose additional amendments to the Standard which were not being specifically requested by the Applicant. Although agreeing with FSANZ's approach, NZMAF suggested that for transparency, the amendments should be communicated in the title of the consultation to indicate to stakeholders the additional reforms proposed to the Standard in Application A1038.

FSANZ felt that it was timely and convenient to address these issues in this Application, where FSANZ had identified areas in Standard 1.5.3 which might be improved concurrently within the assessment of A1038. This approach is in line with previous changes within other standards arising from applications e.g. the GM Standard. Inclusion of these changes was done with the support of the Applicant.

FSANZ has amended the description of the Application in the Work Plan and for any future references to the description/purpose of this Application.

7.1 Insertion of new units for dosage in the Glossary of Symbols

At Assessment, FSANZ proposed to include 'kGy' and 'kiloGrays' in the Glossary of symbols in clause 8 of Standard 1.1.1 as there are presently no listing for these in the Glossary of symbols and units.

NZMAF suggested that the unit 'Gray' should be singular, rather than the plural 'grays' as currently defined in clause 8 of Standard 1.1.1.

FSANZ agreed with this suggestion and has amended the draft variation accordingly.

7.2 Amendments to provide clarity to the Purpose and Definitions in Standard 1.5.3

The Purpose was revised to remove extraneous material and provide more clarity around the purpose of irradiating a food. The Purpose now reflects that foods should not be irradiated, unless a specific permission is given, dosage requirements are adhered to, and the irradiation is undertaken for a specific purpose.

The Purpose currently has a reference to packages and packing materials used or intended for use in connection with irradiated food being of a suitable quality, in an acceptable hygienic condition, and appropriate for the purpose of such processing. However, FSANZ has removed the reference to packages and packaging materials as this reference is not appropriately considered to be a 'purpose' for the Standard. In addition, the provisions in Standard 1.4.3 also apply to packaging used for irradiation (**see section 6.2 above**).

The current text in the Purpose, pertaining to irradiation facilities and Codes of Practice for irradiated foods, has been amended as follows:

- Irradiation of foods must be carried out in facilities that are appropriately licensed and registered for the purpose of irradiation.
- An additional reference to international laws governing radiation control has been included, to cover foods that may be imported.

The definition of technological need has been deleted because the specific purpose of irradiating a food is a mandatory requirement specified in Column 3 of the Table of foods permitted to be irradiated. Therefore, there is now no need for a specific definition of technological need.

The definition of re-irradiation has been deleted as it is proposed to create a new clause (see clause 5 of Attachment 1A) which specifies conditions under which a food can be re-irradiated.

7.2.1 *Issues raised during public consultation*

NZMAF suggested an amendment to the Purpose section in relation to irradiation facilities and Codes of Practice for irradiated foods as proposed at Assessment to include a reference to New Zealand.

FSANZ has corrected the accidental deletion of this reference.

7.3 **Structural changes to Standard 1.5.3 and proposed new clauses**

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At Assessment the following changes were proposed:

- Amendment and re-ordering of the Table of Provisions to reflect the variations.
- Amendment and relocation of clause 2(2) referring to re-irradiation of a food to a new clause 5 (see below) in order to clarify the intent of these provisions.
- Amendment of clause 4 as follows:
 - insertion of a permission to irradiate persimmons with accompanying minimum and maximum doses and a condition that persimmons may only be irradiated for the purposes of pest disinfestation for a phytosanitary objective
 - deletion of all references to good manufacturing practice (GMP) in Standard 1.5.3 as a condition for handling food before and after irradiation, as this is covered by other provisions, relating to food safety requirements, currently in the Code and covered in existing New Zealand legislation, including the Food Hygiene Regulations 1974 or under an approved food safety program via the New Zealand Food Act 1981
 - deletion of the condition that the minimum dose of irradiation necessary to achieve the technological purpose be used because a minimum dose is already specified in Column 2 of the Table to clause 4
 - insertion of a new prohibition on irradiating food that is either unsafe or unsuitable to more accurately and clearly reflect the intention that irradiation is only to be used for the specified purpose, and not to clean up food which is unsafe or unsuitable.
- Insertion of a new clause 5 specifying conditions under which a food can be re-irradiated. This clarifies and incorporates the previous existing exemptions for the re-irradiation of food.

7.3.1 *Issues raised during public consultation*

7.3.1.1 Prohibition on irradiating food that is unsafe or unsuitable

At Assessment, FSANZ noted that the Model Food Provisions in the State/Territory Food Acts contain a definition of unsafe and unsuitable food. However, there are no such definitions in the Code or in the New Zealand Food Act.

Therefore, FSANZ specifically invited comments on the impacts on New Zealand of this reference to unsafe or unsuitable food in the drafting at Assessment.

NZMAF suggested a preference for a definition of unsafe or unsuitable food to be included in Standard 1.5.3. South Australia (SA) Health commented that while the intent proposed by FSANZ was understood, it would be difficult for enforcement agencies to determine if a food was unsafe or unsuitable, before it was irradiated. They suggested that either the drafting be revised, or the original words be reinstated, in order to make it clear that irradiating a food would require a demonstration of technological need and that it must be associated with a food hygiene purpose.

The New Zealand Food and Grocery Council (NZFGC) commented that irradiation may, in the future, have particular application to the provision of foods that are 'super safe' for immuno-compromised, young, elderly or pregnant people. In those specific populations some foods may be unsafe because of the presence of particular pathogens at certain levels, but entirely acceptable for the general population. The reference to unsafe or unsuitable food does not differentiate between these specific populations and the general population.

FSANZ has considered the following four Options in relation to these issues:

- Option 1. Retain the words currently in Standard 1.5.3.
- Option 2. Proceed with the revised Purpose and revised subclause 4(2) and consider definitions for unsafe or unsuitable food for inclusion in a separate process.
- Option 3. Insert definitions of safe and suitable into Standard 1.5.3 similar to those proposed in the new draft Food Bill being progressed in New Zealand.
- Option 4. Delete the statement relating to unsafe and unsuitable food in the revised Purpose and revised subclause 4(2) and the current wording in subclause 4(2) from Standard 1.5.3. This removes the existing redundancy of the provision without introducing new terminology or definitions.

The conditions in Column 3 of the Table of Foods permitted to be irradiated prescribe a technological purpose to irradiate foods which includes any purpose associated with food hygiene (e.g. bacterial decontamination). Therefore, there is no need to retain the current subclause in Standard 1.5.3 and Option 1 is not supported. However, FSANZ notes the concerns raised in relation to inserting the wording of 'unsafe and unsuitable' food and therefore proposes that the approach taken at Assessment is not supported (Option 2). Any proposed definitions should be the subject of public consultation and there will be no further opportunity to seek public comment and impacts for other jurisdictions and industry on Option 3.

Therefore FSANZ has decided that Option 4 is the best approach.

7.3.1.2 Deletion of all references to good manufacturing practice (GMP)

At Assessment, FSANZ proposed to delete all references to GMP as a condition for irradiating foods. Radiation Advisory Services suggested that references to GMP should be retained and that the amendment to exclude irradiation of unsafe or unsuitable food should not proceed as they are linked to each other.

Standard 1.5.3 does not operate in isolation to other standards in the Code. FSANZ maintains that use of the term GMP in Standard 1.5.3 as a condition for handling food before and after irradiating foods is covered by other provisions, relating to food safety requirements, currently in the Code, e.g. Standards 3.2.2 and 3.2.3 in relation to food safety practices and food premises and equipment.

However, Chapter 3 of the Code does not apply in New Zealand. Food handling and hygiene requirements in New Zealand are already covered in existing New Zealand legislation, including the Food Hygiene Regulations 1974 [http://www.legislation.govt.nz/regulation/public/1974/0169/latest/DLM42658.html?search=ts regulation food resel&p=1&sr=1](http://www.legislation.govt.nz/regulation/public/1974/0169/latest/DLM42658.html?search=ts%20regulation%20food%20resel&p=1&sr=1) or under an approved food safety program via the *Food Act 1981* <http://www.legislation.govt.nz/act/public/1981/0045/latest/DLM48687.html>.

FSANZ also notes that the conditions in column 3 of the Table of Foods permitted to be irradiated determine the technological purpose. The retention of GMP within Standard 1.5.3 is therefore unnecessary.

FSANZ has decided that the draft variation be retained.

7.3.1.3 Deletion of the definition of technological need and a minimum dose to achieve the technological purpose

At Assessment, FSANZ proposed that the definition of technological need be deleted because the specific purpose of irradiating a food is a mandatory requirement specified in Column 3 of the Table of foods permitted to be irradiated. Therefore, there was no need for a specific definition of technological need.

The reference to a minimum dose could also be deleted in Column 3 because a minimum dose is already specified in Column 2 of the Table to clause 4.

SA Health proposed that the definition of technological need and reference to use of a minimum dose (in Column 3 of the Table to clause 4) to achieve the purpose of irradiating a food should be retained as a condition in Standard 1.5.3. They suggested that both terms are related and have the intent of providing a clear requirement that only the lowest dose necessary should be used when irradiating a food.

FSANZ notes that the intent of the Standard was that both a minimum and maximum dose was listed for the foods permitted to be irradiated in the Table to clause 4. FSANZ has now discovered an inconsistency with regard to the lack of reference to use of a minimum dose (in Column 3) if irradiating a food for the purpose of bacterial decontamination.

FSANZ proposes to revisit whether or not a minimum dose is necessary to be listed in Standard 1.5.3. Recently BA advised FSANZ that a lower dose of 70 Gy may now be efficacious for specific fruit fly species. Therefore, FSANZ considers that to achieve the intent of always using a minimum effective dose, FSANZ would consider not listing a minimum dose, but rely on advice from the relevant quarantine agencies to set the minimum dose. In addition, FSANZ notes that the Code does not currently specify a minimum effective level for anti-microbial food additives; therefore, there may be no reason to specify a minimum dose for the purpose of irradiating a food for bacterial decontamination in Standard 1.5.3.

In conclusion, FSANZ has considered this issue and acknowledges that further amendments should be the subject of public consultation. As there is no further opportunity to seek public comment and impacts for other jurisdictions, industry and consumers, FSANZ will address these issues in a future Application or Proposal.

FSANZ has decided that there be no change to the draft variation at Approval.

7.3.1.4 Amendment to the minimum dose for irradiation of herbs and spices

SA Health was concerned that the draft amendments to the Table to clause 4 meant that there would be no minimum dose specified in Column 2 for irradiation of herbs and spices and no condition in column 3 for a minimum dose to achieve the technological purpose. They were concerned that there was no explanation provided as to why this change was proposed by FSANZ.

The final report for Application A413 (refer to p 27)²⁵ recommended that the minimum dose for the control of sprouting and pest disinfestation, including control of weeds, based on advice from quarantine agencies, should not be specified, but be based on the appropriate level of protection to be determined by relevant quarantine agencies. Therefore, no minimum dose was listed. However, a maximum dose of 6 kGy was set in Column 2.

FSANZ has decided not to change the draft variation, as minimum doses have never been listed in relation to the technological needs (control of sprouting and pest disinfestation, including control of weeds) for herbs and spices in the Table to clause 4.

7.3.1.5 Table to clause 4

FSANZ received an enquiry (which was not part of a submission) as to why FSANZ proposed to replace the purpose for irradiating herbs and spices and herbal infusions from 'decontamination' as a condition in Column 3 of the Table to clause 4 to the term 'bacterial decontamination'. The enquirer pointed out that the Final Assessment Report for A413 stated that most of the microbes present on herbs and spices were aerobic spore-forming bacteria, predominantly *Bacillus* species although a wide variety of non-sporing bacteria and fungi might also be present. The enquirer advised FSANZ that both Canada and the USA use the term 'microbial decontamination'.

Since Standard 1.5.3 was established, there have been several instances where FSANZ has been requested to interpret what the term 'decontamination' refers to for herbs and spices in the Table to clause 4. That is, does it cover quarantine treatment, rather than a treatment against microbes? Therefore, considering that FSANZ assessed the efficacy of irradiation for herbs and spices on bacteria, supported by data provided by the Applicant and did not assess its efficacy for quarantine purposes, it was proposed at Assessment for this Application that the term 'bacterial' decontamination be referred to in Column 3, rather than the original term 'decontamination'.

FSANZ acknowledges that the Final Assessment Report for Application A413 refers (on page 56) to a wide variety of non-sporing bacteria and fungi that might also be present on herbs and spices. This assessment of the efficacy of irradiation on herbs and spices and herbal infusions focused on the pathogens identified as commonly present in herbs and spices, and therefore likely to pose a public health and safety issue for consumers. These consisted of *Salmonella*, *Escherichia coli*, *Bacillus cereus*, and *Clostridium perfringens* with *Salmonella* found infrequently, but in a wide variety of spices. Hence, FSANZ considered it necessary to amend Standard 1.5.3 to refer to 'bacterial decontamination' in order to reflect that the approval for irradiation of herbs and spices was based on evidence of its efficacy against a range of pathogenic bacterial species and is not intended to encompass decontamination of other organisms.

FSANZ has determined that there is no need to change the draft variation. FSANZ proposes to retain the term 'bacterial decontamination' as a condition in Column 3 of the Table to clause 4 for foods that are irradiated for the purpose of bacterial decontamination.

²⁵ http://www.foodstandards.gov.au/srcfiles/A413_FAR.pdf.

7.4 Removal of other unnecessary provisions

7.4.1 Deletion of the clause relating to records for food irradiation

Clause 5 of Standard 1.5.3 currently has the following provisions that require the keeping of certain records in relation to the irradiation of food:

- (1) *Records must be kept at a facility where food is irradiated in relation to –*
 - (a) *the nature and quantity of the food treated;*
 - (b) *lot identification;*
 - (c) *the minimum durable life of the food treated;*
 - (d) *the process used;*
 - (e) *compliance with the process used;*
 - (f) *the minimum and maximum dose absorbed by the food;*
 - (g) *an indication whether or not the product has been irradiated previously and if so, details of such treatment;*
 - (h) *date of irradiation.*
- (2) *The records required to be kept by subclause (1) must be kept for a period of time that exceeds the minimum durable life of the irradiated food by 1 year.*

FSANZ believed that detailed records which cover the above requirements were also a requirement of licensing authorities and were fully documented by licensed irradiation facilities (**see section 6.3**).

For example, AQIS has specific documents that refer to the maintenance of records for irradiated goods:

- a copy of a Gamma Irradiation certificate from the AQIS website
http://www.daff.gov.au/_data/assets/pdf_file/0009/1177515/gamma-cert.pdf
- Class 4.2 Quarantine Approved Premises Criteria for premises utilised for gamma irradiation treatment of goods and packaging, as required by AQIS.
http://www.daff.gov.au/aqis/import/general-info/qap/class4/quarantine_approved_premises_criteria_4.2.

FSANZ received advice from industry that the records kept in relation to irradiated articles are basically the same, whether or not they are food for quarantine purposes or medical goods. In relation to food, there is always a record of the commodities irradiated, the dose they receive, date of treatment and a process for ensuring compliance with the process. FSANZ also noted that clauses 4 and 6 of Standard 1.2.1 – Application of Labelling and Other Information Requirements could require the provision of information about the irradiation of a food, where a purchaser or relevant authority has requested this information. Therefore, FSANZ questioned whether clause 5 provided any additional value in Standard 1.5.3 and recommended deletion of this provision at Assessment.

7.4.2 Issues raised during public consultation

NZMAF and Radiation Advisory Services were of the view that clause 5 should be retained, as currently in New Zealand the legislative and record-keeping and traceability requirements for licensed irradiation facilities do not cover the current requirements in clause 5.

In addition, they suggested that without the record keeping requirements in clause 5, NZMAF would not be able to ensure that an irradiation facility is keeping the necessary records and could not take enforcement action, if necessary.

Therefore in order to maintain the enforceability of the Code in New Zealand, FSANZ will retain the current record-keeping requirements in Standard 1.5.3.

7.5 Proposed changes to the labelling of irradiated foods

With respect to the current provisions for the labelling of irradiated foods, and for clarity of interpretation of these provisions, FSANZ has clarified and reformed specific labelling requirements in Standard 1.5.3.

7.5.1 Removal of all examples of labelling of irradiated foods from Standard 1.5.3

Subclause 6(1) contains the following boxed examples of statements for irradiated foods:

‘TREATED WITH IONISING RADIATION’
‘TREATED WITH IONISING ELECTRONS’
‘IRRADIATED (name of food)’

FSANZ considers the example statement ‘*Treated with ionising electrons*’ is potentially misleading to consumers in that they may not understand that it indicates the food has been irradiated. FSANZ proposed in the Assessment Report that the Example box be deleted and the remaining examples be relocated to a future ‘guidance’ document. FSANZ also proposed that the ‘guidance’ document could also provide information on the voluntary use of the International Radura symbol on the label, in addition to the mandatory statement required by the Code.

7.5.1.1 Issues raised during public consultation

Food Irradiation Watch supported the retention of the labelling examples in Standard 1.5.3. Radiation Advisory Services supported the preparation of a guidance document on labelling if the current labelling examples are removed, and NZMAF requested clarification in regard to the scope and timing of the future guidance document on the labelling of irradiated foods.

FSANZ has revisited this issue and agrees that these examples do serve a purpose to assist industry and consumers with examples of statements that may be used on irradiated foods.

Given the recommendation is to retain two of the three examples in subclause 6(1); FSANZ is of the view that a guidance document on labelling examples is no longer warranted. FSANZ also considers that the current Fact Sheet contains adequate information around the labelling of irradiated foods, examples and the Radura symbol to provide guidance to consumers and industry.

FSANZ has decided to retain the two examples ‘*Treated with ionising radiation*’ and ‘*Irradiated (name of food)*’ in clause 6(1). The example ‘*Treated with ionising electrons*’ will be removed.

7.5.2 Clarification of the cross reference in subclause 6(3)

Subclause 6(3) states the following:

Where an irradiated food, or a food containing an irradiated food as an ingredient or component, is not required to bear a label pursuant to clause 2 of Standard 1.2.1, there must be displayed on or in connection with the display of food a statement that the food has been treated with ionising radiation, or that it contains an ingredient or component that has been treated with ionising radiation, as the case may be.

To improve the clarity of subclause 6(3), at Assessment FSANZ proposed to amend the cross-reference to clause 2 in Standard 1.2.1 to subclause 2(1).

There were no submitter comments on this issue, so the drafting at Assessment remains unchanged.

7.5.3 Deletion of subclause 6(4)

Subclause 6(4) states the following:

Notwithstanding clause 3 of Standard 1.2.1, the label on a package of irradiated food which is sold other than for retail sale must include –

- (a) a statement that the food has been irradiated; and*
- (b) the minimum and maximum dose of the irradiation; and*
- (c) the identity of the facility where the food was irradiated; and*
- (d) the date or dates of irradiation.*

Subclause 6(4) is unusual in that there are no similar provisions in other Standards in the Code (e.g. Standard 1.5.2 – Food produced using Gene Technology) that include specific labelling requirements for food not for retail sale. Therefore, it was proposed at Assessment to delete subclause 6(4) as it was repetitive and was adequately covered under other provisions in the Code.

For example, clause 4 of Standard 1.2.1 provides that where a purchaser or relevant authority has so requested, a package of food (not for retail sale) must be accompanied with sufficient information to enable the purchaser to comply with the labelling or other declaration requirements of the Code. This would include mandatory labelling requirements that reside in other standards (e.g. ‘irradiated food’; ‘genetically modified’ statement; food identification requirements in Standard 1.2.2 – Food Identification Requirements).

7.5.3.1 Issues raised during public consultation

NZMAF requested that FSANZ specify the other provisions in the Code that require this information to be held.

FSANZ notes that the requirement for food not for retail sale to include a statement that the food has been irradiated (paragraph 6(4) (a)) is already captured by clause 4 of Standard 1.2.1. It is the responsibility of the purchaser of the food to request the information that enables them to comply with the labelling or other declaration requirements of the Code. The supplier must have the information in order to respond to the request. Therefore, when food not for retail sale is irradiated and then purchased and later sold for retail sale, mandatory labelling requirements in clause 6 of Standard 1.5.3 can be met by the retailer. FSANZ also notes that it is not intended for the information required in paragraph 6(4)(b)–(d) to appear on the label of irradiated food for retail sale, or in displayed in close proximity to the unpackaged food.

FSANZ notes that the information currently required in paragraph 6(4)(b)–(d) would be kept by the licenced facility where the food was irradiated, as mandated under clause 7. This information is of benefit to enforcement agencies that wish to monitor compliance with Code requirements. Enforcement agencies are able to refer to the name and address of the supplier of the food, which is required to be on the label or in documentation accompanying that food. The supplier of the food that is either packaged or unpackaged must keep adequate records about the food they provide.

FSANZ has concluded that the information currently required under subclause 6(4) is redundant and can be deleted as proposed at Assessment.

7.6 Other issues raised during public consultation

Some submitters were of the view that approval to irradiate persimmons may damage Australia's reputation as a producer of clean, healthy and pure foods. FSANZ's position is that food irradiation is another option for pest control compared to other currently available practices including chemical treatments. Irradiation may be used to destroy the unwanted pests that can accompany food when it is traded regionally or imported from other countries.

Some submitters suggested that FSANZ should reconsider its case-by-case approvals and approve fresh fruit and vegetables as a group for pest disinfection. FSANZ's view is that the overall basis and intent of Standard 1.5.3 is to allow applications to be made to FSANZ on a case-by-case basis. Health Ministers agreed to this as an appropriate approach in 1999 and any departure from this would require a change to this agreed approach.

8. Options

FSANZ is required to consider the impact of various regulatory (and non-regulatory) options on all sectors of the community, which includes consumers, food industries and governments in Australia and New Zealand.

Irradiated foods are required to be listed in the Table to clause 4 of Standard 1.5.3. As they require a pre-market approval under the Standard, it is not appropriate to consider non-regulatory options to address this Application.

Three regulatory options were identified for this Application:

Option 1: Reject the draft variations, thus not approving the use of irradiation on persimmons.

This Option maintains the *status quo* by not permitting the irradiation of persimmons in Standard 1.5.3.

Option 2: Approve the draft variations as proposed at Assessment (Attachment 1B) to permit the use of irradiation on persimmons under Standard 1.5.3 and additional amendments to the Standard as proposed at Assessment.

This Option will result in an amendment to the Table to clause 4 of Standard 1.5.3 to permit the use of irradiation as a phytosanitary measure on persimmons at a minimum dose of 150 Gy and a maximum of 1 kGy. Amendments are proposed to the Standard in order to provide improved clarity, interpretation, and operation of the Standard. These do not change the intent of the Standard to permit the irradiation of food on a case-by-case basis or the labelling provisions.

Option 3: Approve the draft variations as proposed at Assessment, to permit the use of irradiation on persimmons under Standard 1.5.3 and additional amendments to Standard 1.5.3, subject to amendment (Attachment 1A).

9. Impact Analysis (RIS ID: 12010)

9.1 Affected Parties

Approval to irradiate persimmons has the potential to impact on consumers, industry and governments.

The parties affected by this application are:

- those sectors of the food industry wishing to use irradiation as a phytosanitary treatment for persimmons and operators of irradiation facilities and exporters
- retailers who sell irradiated persimmons to consumers
- consumers who may wish to purchase irradiated fruits in order to avoid chemical residues in fruit or conversely, consumers who wish to avoid the purchase of irradiated foods
- government agencies enforcing the food regulations.

The Applicant presented a case that the use of irradiation was technologically justified and an efficacious treatment and would provide access to new markets for Australian persimmon growers.

The Applicant also stated that this alternative treatment would provide the persimmon industry with an option to use irradiation as a phytosanitary measure if current chemical treatments were withdrawn from use. The Applicant describes this technology as simple, safe and versatile.

The costs and benefits to the affected parties are further expanded below under the three proposed Options.

9.2 Benefit Cost Analysis

FSANZ is required to consider the impact of various regulatory and non-regulatory options on all sectors of the community, especially relevant stakeholders who may be affected by this Application. The benefits and costs associated with the proposed amendment to the Code have been analysed using regulatory impact principles.

Some submitters stated that the commercial and economic benefits of irradiated persimmons were unsubstantiated.

In accordance with the Best Practice Regulation Guidelines, completion of a preliminary assessment for this application indicated a low or negligible impact. The Office of Best Practice Regulation advised that the Application appeared to be of a minor or machinery nature; notified approval of the preliminary assessment and further advised that a Regulatory Impact Statement (RIS) was not required.

FSANZ received letters of support from Horticulture Australia Limited (HAL), Persimmons Industry Association Inc., the Australian Persimmon Export Company and the Domestic Quarantine and Market Access Working Group (DQMAWG) who all believe that there are commercial and economic benefits in approval of irradiation on persimmons

9.2.1 *Option 1: Reject the draft variations*

9.2.1.1 Consumers

There could be a benefit to consumers who prefer not to consume irradiated foods, due to a belief that such foods are potentially unsafe and/or nutritionally inadequate or that there is no technological justification to irradiate foods.

A potential cost to consumers was identified as the possible limitation of the supply of persimmons due to the possible phase out of chemicals that normally reduce fruit fly disinfestation if there was not an efficacious alternative treatment. This was expected to be a minor cost to consumers.

9.2.1.2 Industry

No benefits to industry were identified.

The following were identified as costs for industry:

- Loss of trade opportunities and access to markets where current disinfestation methods are not accepted.
- Costs in research and development incurred in an attempt to identify alternative treatments as existing chemical or other treatments are phased out.

9.2.1.3 Government

There are no benefits to Governments in maintaining a prohibition.

No costs were identified, although lack of approval may be regarded as unnecessarily trade restrictive.

9.2.2 *Option 2: Approve the draft variations as proposed at Assessment.*

9.2.2.1 Consumers

The following were identified as benefits for consumers:

- There may be greater availability of persimmons in some markets/regions in Australia and New Zealand.
- Irradiation may result in better quality fruit for the consumer depending on the dose of irradiation, as heat and cold treatments can affect fruit quality.
- Fruit may be able to be transported for longer periods while maintaining desirable sensory qualities for consumers.
- Provides choice to consumers who wish to avoid exposure to other treatments such as chemicals.
- Approval of irradiated persimmons may increase competition in the marketplace, improve selection and seasonal availability and increase price competition.
- Mandatory labelling will ensure that consumers who wish to avoid irradiated fruits can do so.

The following were identified as costs for consumers:

- There may be a restriction of choice for consumers who believe that irradiated foods may be nutritionally inferior or less safe than non-irradiated foods and who therefore seek to avoid consuming such foods.
- A transient increase in price of irradiated persimmons as a result of the cost of establishment of any new equipment that may be needed to effectively irradiate persimmons.

9.2.2.2 Industry

The following were identified as benefits for industry:

- An alternative phytosanitary measure if the current treatments are restricted.
- An increased shelf life and quality of fruit.
- Increased trade opportunities and increased markets available to persimmon growers due to an alternative treatment being available to meet quarantine requirements. Permission to irradiate could facilitate market access to New Zealand and Southeast Asia (namely, Singapore, Thailand, Hong Kong and Malaysia).
- Possible boost to the State of Queensland's economy, ensuring the livelihood of local growers. Australian persimmon production represents a gross value of \$8-10 million dollars with Queensland accounting for approximately 40% of the Australian industry.
- Possible benefit to industry by being a cost-effective technology in relation to other alternative treatments (hot water, vapour heat treatment, cold or heat treatment) without some of the inherent quality issues that alternative treatments may cause in fruits.

The following were identified as costs for industry:

- The initial set-up costs in establishing an irradiation facility including building and capital may be significant.
- There are likely to be voluntary costs to industry of treatment of the fruit, transport, labelling irradiated foods.
- There could be a cost in ascertaining consumer acceptance of irradiated persimmons.

However, business entities wishing to make use of the permission will decide to do so, on the basis of the commercial gains they hope to create e.g. by reducing their cost or extending market access.

9.2.2.3 Government

The following were identified as benefits for Government:

- An additional pest disinfestation treatment at a time when some methods are not accepted or are being phased out (e.g. some chemical treatments). This may facilitate trade.
- Possible enhanced economic development in rural and regional Australia.
- Amendments to Standard 1.5.3 should benefit State/Territory/New Zealand enforcement agencies with regard to the interpretation of the Standard.

The following were identified as costs for Government:

- Australian and New Zealand quarantine agencies may incur costs in order to assess irradiation treatments for specific pests to meet relevant quarantine import requirements for persimmons.

- The cost involved in enforcing the record keeping requirements in Standard 1.5.3 which were also required and enforced by radiation licensing authorities.

9.2.3 *Option 3: Approve the draft variations proposed at Assessment, subject to amendment.*

This Option provides similar costs and benefits as Option 2. However, FSANZ considered the comments received during the public consultation period and amended the draft variations in order to provide further clarity and enforceability of Standard 1.5.3. The benefits of this option were improved enforceability in regard to interpretation of the Standard.

9.3 Comparison of Options

Option 1 would not allow the use of irradiation on persimmons. It may impose costs on consumers by reducing availability of persimmons if permissions for current chemical treatments are removed. It may deny Australian persimmon growers access to new markets and may hinder regional development.

Option 2 allows the use of irradiation, which has been determined to be safe for pest disinfection, it is supported by the scientific risk assessment, it most clearly achieves the objectives of providing assurance of the safety of consuming irradiated fruits, providing labelling information to consumers that serve to give them informed choice, and may allow persimmon growers to access new markets. This is likely to be a net benefit for industry but changes to Standard 1.5.3 as indicated by submitters may have some adverse impacts on jurisdictions and consumers.

Option 3 is preferred because, it deliver similar outcomes to Option 2, and avoids the potential negative impacts identified by submitters in relation to amendments to other elements of Standard 1.5.3. . It also meets Australia and New Zealand's requirements under the World Trade Organization (WTO) by virtue of consistency with other international regulations on irradiated fruits.

This Option inserts additional words to provide more clarity in Standard 1.5.3 and re-inserts specific clauses where they are still needed for enforcement purposes or for information for consumers.

Risk Communication

The types of concerns identified by Australians and New Zealanders include: exposure to radiation, reduction in nutrition and wholesomeness of foods, damage to the environment, and occupational health issues for workers and the use of irradiation as a substitute for safe food production (Gamble et al 2002).

A summary of the relevant research related to consumer awareness, understanding and acceptance of food irradiation is given in **Supporting Document 3**. As demonstrated by markets in various nations, consumers are willing to purchase food that has been irradiated (Bruhn 1995; International Consultative Group on Food Irradiation 1999). Australian and New Zealand consumers are generally aware of food irradiation but also hold concerns about the use of the technology. The response to food irradiation is not dissimilar to their response to other new food technologies, where perceived risks and benefits of the technology will inform subsequent decisions made by consumers. While aware of food irradiation, consumers' understanding is limited and this may contribute to perception of increased risk. Information and education may assist in addressing the information gap.

It is evident that a significant information gap exists in relation to consumers' knowledge about food irradiation. FSANZ can play a role in terms of providing factual information in relation to the Application, and education material such as a fact sheet on irradiation to facilitate increasing consumer awareness of irradiation. However, other agencies and bodies can also play a role in providing relevant information to consumers in relation to this technology.

For example, industry can specify the purpose of the irradiation process, such as 'disinfestation to control critical quarantine pests'. Other relevant authorities, such as departments of agriculture also have a role to play in providing information on the Biosecurity aspects of the technology and the benefits to both the economy as a whole and industry in general.

10. Consultation

Consultation on the Assessment Report was conducted over a period of six weeks. Seventy-five submissions were received of which 66 were opposed to food irradiation and nine were in support of the Application (**Attachment 3**). FSANZ has taken all submitters' comments into consideration in completing the Approval Report and those related to the risk assessment and risk management of the approval of persimmons and the proposed amendments to Standard 1.5.3 are addressed in Sections 5 to 8.

10.1 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

The inclusion of permissions to irradiate persimmons would have a trade enabling effect as it would permit irradiated persimmons to be sold in Australia and New Zealand and also allow imports into Australia and New Zealand and sold, where currently they would be prohibited.

For this reason, there was no need to notify this Application under the Sanitary or Phytosanitary Measures (SPS) Agreement.

Addressing FSANZ's objectives

The legislative objectives that FSANZ is required to meet when developing or varying a food standard are noted in section 3. FSANZ has considered that the primary objectives of most relevance to this Application is the protection of public health and safety and the provision of adequate information relating to food to enable consumers to make informed choices (labelling). With regard to the third objective, the prevention of misleading and deceptive conduct, FSANZ considers it is of less direct relevance although it was also taken into consideration.

11.1 Protection of public health and safety

FSANZ concludes that approval of irradiation of persimmons at a minimum dose of 150 Gray (Gy) and a maximum of 1 Kilogray (kGy) does not pose a significant human health risk for Australian or New Zealand consumers (see Section 6).

11.2 Provision of adequate information relating to food to enable consumers to make informed choices (labelling)

The mandatory requirements under Standard 1.5.3 to label irradiated foods will provide adequate information for consumers to make informed purchase decisions. Based on the risk assessment findings, no additional mandatory labelling requirements are proposed (see Section 7.5).

11.3 Prevention of misleading or deceptive conduct

FSANZ has considered this objective and concludes there is one potentially misleading aspect to this Application in regard to the second example 'treated with ionising electrons' in subclause 6 (1). This statement is potentially misleading to consumers. Therefore, FSANZ concluded that this example be deleted from Standard 1.5.3. However, no deceptive conduct aspects to this assessment were identified.

12. Conclusion and Decision

FSANZ has concluded that approval for the use of irradiation for persimmons does not pose a significant human health risk for any age group and satisfies the requirements in the FSANZ Act.

FSANZ has considered the primary objective of protection of public health and safety and has concluded that safety assessment did not identify any public health concerns.

FSANZ considers that current labelling requirements meet the objective of providing adequate information to enable informed choice, and that prevention of misleading and deceptive conduct is not directly relevant to this application.

Decision

To approve the draft variations, subject to amendment, to Standards 1.1.1– Application, Interpretation and General Prohibitions and 1.5.3 – Irradiation of Foods to permit the use of irradiation of persimmons, including additional amendments to Standard 1.5.3.

12.1 Reasons for Decision

FSANZ has approved the sale of irradiated persimmons in Australia and New Zealand on the basis of the available scientific evidence, for the following reasons:

- The safety assessment did not identify any public health and safety concerns.
- The use of irradiation is technologically justified.
- The proposed additional amendments are justified to provide improved clarity, interpretation, and operation of Standard 1.5.3.
- A regulation impact assessment process has been undertaken that fulfils the requirement in Australia and New Zealand for an assessment of compliance costs. The assessment concluded that the use of irradiation (Option 3) provides a net benefit.
- There are no other measures that would be more cost-effective than a variation to Standard 1.5.3 that could achieve the same end.

13. Implementation and Review

The draft variations will come into effect on the date of gazettal.

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ATTACHMENTS

- 1A. Draft variations at Approval to the *Australia New Zealand Food Standards Code*
- 1B. Draft variations at Assessment to the *Australia New Zealand Food Standards Code*
2. Explanatory Statement of variations to Standards 1.1.1 and 1.5.3 (at Approval)
3. Summary of submissions

**Draft variations to the *Australia New Zealand Food Standards Code*
(Approval)**



Food Standards (Application A1038 – Irradiation of Persimmons) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 3 of this variation.

Dated DATE OF GAZETTAL

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

1 Name

This instrument is the *Food Standards (Application A1038 – Irradiation of Persimmons) Variation*.

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

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

3 Commencement

These variations commence on **DATE OF GAZETTAL**.

SCHEDULE

[1] **Standard 1.1.1** of the *Australia New Zealand Food Standards Code* is varied by –

[1.1] *omitting from the table to clause 8 –*

Gy	Grays
----	-------

substituting –

Gy	Gray
----	------

[1.2] *inserting in the table to clause 8 –*

kGy	kiloGray
-----	----------

[2] **Standard 1.5.3** of the *Australia New Zealand Food Standards Code* is varied by –

[2.1] *omitting the Purpose, substituting –*

Purpose

This Standard prohibits irradiation of food unless an express permission is given. All permissions in the Standard are subject to dosage requirements, and only apply where irradiation is undertaken for a permitted purpose.

Irradiation of foods must be carried out in facilities that are appropriately licensed and registered for the purpose of irradiation. There are various State, Territory, Commonwealth, New Zealand and International laws governing radiation control, and the operation of irradiation facilities. Other relevant Codes of Practice such as the Codex Alimentarius General Standard for Irradiated Foods 1983, and its associated Code of Practice for the Operation of Irradiation Facilities Used for the Treatment of Foods, also apply to irradiation processes.

[2.2] *omitting the definitions of **re-irradiate** and **technological need** from clause 1*

[2.3] *omitting clause 2, substituting –*

2 General prohibition on irradiation of food

Food must not be irradiated unless there is a specific permission in this Standard to irradiate the food.

[2.4] *omitting clause 4, the Table to clause 4 and clause 5, substituting –*

4 Foods permitted to be irradiated

A food listed in column 1 of the Table to this clause may be irradiated, provided that –

- (a) irradiation is only carried out for a purpose or purposes listed in column 3 of the Table to this clause; and
- (b) the absorbed dose of radiation is not below the minimum dose value or above the maximum dose value specified in column 2 of the Table to this clause.

Table to clause 4

Column 1	Column 2	Column 3
Food	Minimum and Maximum Dose (kGy)	Purpose
Bread fruit Carambola Custard apple Longan Litchi Mango Mangosteen Papaya (Paw paw) Persimmon Rambutan	Minimum: 150 Gy Maximum: 1 kGy	Pest disinfestation for a phytosanitary objective.
Herbs and spices as described in Schedule 4 to Standard 1.4.2 Herbal infusions – fresh, dried or fermented leaves, flowers and other parts of plants used to make beverages, excluding tea	Minimum: none Maximum: 6 kGy	Control of sprouting and pest disinfestation, including control of weeds.
Herbs and spices as described in Schedule 4 to Standard 1.4.2	Minimum: 2 kGy Maximum: 30 kGy	Bacterial decontamination.
Herbal infusions – fresh, dried or fermented leaves, flowers and other parts of plants used to make beverages, excluding tea	Minimum: 2 kGy Maximum: 10 kGy	Bacterial decontamination.

5 Permission to irradiate

- (1) A permission to irradiate a food is not a permission to irradiate the food more than once.
- (2) However, subclause (1) does not prohibit the irradiation of a food –
 - (a) which is prepared from materials that have been irradiated at levels not exceeding in any case 1 kGy; or
 - (b) which contains less than 50 g/kg of irradiated ingredients; or
 - (c) where the required full dose of ionising radiation is applied to the food in divided doses for a specific technological reason.

[2.5] *omitting the second example from the Examples under subclause 6(1)*

[2.6] *omitting the words clause 2 from subclause 6(3), substituting subclause 2(1)*

[2.7] *omitting subclause 6(4)*

[2.8] *inserting –*

7 Record keeping

- (1) Records must be kept at a facility where food is irradiated in relation to –
 - (a) the nature and quality of the food treated; and

- (b) lot identification; and
- (c) the minimum durable life of the food treated; and
- (d) the process used; and
- (e) compliance with the process used; and
- (f) the minimum and maximum dose absorbed by the food; and
- (g) an indication whether or not the product has been irradiated previously and if so, details of such treatment; and
- (h) date of irradiation.

(2) The records required to be kept by subclause (1) must be kept for a period of time that exceeds the minimum durable life of the irradiated food by 1 year.

[2.9] *updating the Table of Provisions to reflect these variations*

Draft variations to the *Australia New Zealand Food Standards Code* (Assessment)

Section 94 of the FSANZ Act provides that standards or variations to standards are legislative instruments, but are not subject to disallowance or sunseting

Commencement: On gazettal.

[1] **Standard 1.1.1** of the *Australia New Zealand Food Standards Code* is varied by inserting in the table to clause 8 –

kGy

kiloGray

[2] **Standard 1.5.3** of the *Australia New Zealand Food Standards Code* is varied by –

[2.1] *omitting the Purpose, substituting –*

Purpose

This Standard prohibits irradiation of food unless an express permission is given. All permissions in the Standard are subject to dosage requirements, and only apply where irradiation is undertaken for a permitted purpose.

A permission to irradiate a food does not apply if, prior to irradiating the food, the food is either unsafe or unsuitable.

Irradiation of foods must be carried out in facilities that are appropriately licensed and registered for the purpose of irradiation. There are various State, Territory, Commonwealth and International laws governing radiation control, and the operation of irradiation facilities. Other relevant Codes of Practice such as the Codex Alimentarius General Standard for Irradiated Foods 1983, and its associated Code of Practice for the Operation of Irradiation Facilities Used for the Treatment of Foods, also apply to irradiation processes.

[2.2] *omitting the definitions of **re-irradiate** and **technological need** from clause 1*

[2.3] *omitting clause 2, substituting –*

2 General prohibition on irradiation of food

Food must not be irradiated unless there is a specific permission in this Standard to irradiate the food.

[2.4] *omitting clause 4, the Table to clause 4 and clause 5, substituting –*

4 Foods permitted to be irradiated

(1) A food listed in column 1 of the Table to this clause may be irradiated, provided that –

- (a) the absorbed dose of radiation is not below the minimum dose value or above the maximum dose value specified in column 2 of the Table to this clause; and
- (b) irradiation is only carried out for a purpose or purposes listed in column 3 of the Table to this clause

(2) A permission to irradiate a food does not apply if, prior to irradiating the food, the food is either unsafe or unsuitable in accordance with the Act.

Table to clause 4

Column 1	Column 2	Column 3
Food	Minimum and Maximum Dose (kGy)	Purpose
Bread fruit Carambola Custard apple Longan Litchi Mango Mangosteen Papaya (Paw paw) Persimmon Rambutan	Minimum: 150 Gy Maximum: 1 kGy	Pest disinfestation for a phytosanitary objective.
Herbs and spices as described in Schedule 4 to Standard 1.4.2 Herbal infusions – fresh, dried or fermented leaves, flowers and other parts of plants used to make beverages, excluding tea	Minimum: none Maximum: 6 kGy	Control of sprouting and pest disinfestation, including control of weeds.
Herbs and spices as described in Schedule 4 to Standard 1.4.2	Minimum: 2 kGy Maximum: 30 kGy	Bacterial decontamination.
Herbal infusions – fresh, dried or fermented leaves, flowers and other parts of plants used to make beverages, excluding tea	Minimum: 2 kGy Maximum: 10 kGy	Bacterial decontamination.

5 Permission to irradiate

- (1) A permission to irradiate a food is not a permission to irradiate the food more than once.
- (2) However, subclause (1) does not prohibit the irradiation of a food –
 - (a) which is prepared from materials that have been irradiated at levels not exceeding in any case 1 kGy; or
 - (b) which contains less than 50 g/kg of irradiated ingredients; or
 - (c) where the required full dose of ionising radiation is applied to the food in divided doses for a specific technological reason.

[2.5] *omitting the Examples under subclause 6(1)*

[2.6] *omitting the words clause 2 from subclause 6(3), substituting subclause 2(1)*

[2.7] *omitting subclause 6(4)*

[2.8] *updating the Table of Provisions to reflect these variations*

Explanatory Statement

Apart from permitting the use of irradiation on persimmons in the Table to clause 4 of Standard 1.5.3, FSANZ also proposes amendments to improve the clarity, interpretation, and operation of the Standard without changing the intent of the Standard to maintain an overall prohibition of the irradiation of food, unless permitted on a case-by-case basis.

[Item 1]

This Item includes 'kGy' and 'kiloGray' in the Glossary of symbols in clause 8 of Standard 1.1.1 – Application, Interpretation and General Prohibitions as there is presently no listing for these in the Glossary of symbols and units.

The unit 'Gray' is inserted into clause 8 of Standard 1.1.1 rather than plural 'grays'.

[Item 2.1]

This item proposes a revision of the Purpose of Standard 1.5.3 to remove extraneous material and provide more clarity around the purpose of irradiating a food.

A reference to New Zealand has been inserted in the Purpose in relation to laws that govern radiation control, and the operation of irradiation facilities.

The reference to packages and packaging materials used for irradiated foods has been removed from the purpose. There is no requirement or reason that FSANZ is currently aware of, above the general provisions in Standard 1.4.3 Articles and Materials in Contact with food that needs a reference in regard to packaging in Standard 1.5.3.

[Item 2.2]

This item deletes the definition of both re-irradiation and technological need. The definition of technological need is deleted because the purpose of irradiating an irradiated food is identified in Column 3 of the table of foods permitted to be irradiated.

The definition of re-irradiation is deleted as it is proposed to create a new clause (see **clause 5 of Attachment 1**) under permission to irradiate a food specifying conditions under which a food can be re-irradiated.

[Item 2.3]

Clause 2(2) referring to re-irradiation of a food has been deleted, amended and relocated to a new clause 5 (see below) in order to clarify the intent of these provisions.

[Item 2.4]

This item:

- inserts permissions to irradiate persimmons with accompanying minimum and maximum doses and a condition that persimmons may only be irradiated for the purposes of pest disinfestation for a phytosanitary objective

- deletion of all references to good manufacturing practice (GMP) in Standard 1.5.3 as a condition for handling food before and after irradiation. This is covered by other provisions, relating to food safety requirements, currently in the Code and covered in existing New Zealand legislation, including the Food Hygiene Regulations 1974 or under an approved food safety program via the New Zealand Food Act 1981
- deletes the requirement for a minimum dose as a condition in column 3 of the purpose in the Table to clause 4 to achieve the technological purpose as the intent is now covered by revised provisions in clause 4
- deletes subclause 4(2). The conditions in column 3 of the Table of Foods permitted to be irradiated prescribe a technological purpose to irradiate foods which includes any purpose associated with food hygiene (e.g. bacterial decontamination). Therefore, there is no need to retain the subclause 4 (2) in Standard 1.5.3.
- creates a new clause (clause 5) specifying conditions under which a food can be re-irradiated.

[Item 2.5]

This item deletes the second example 'treated with ionising electrons' in subclause 6 (1) as this is potentially misleading to consumers

[Item 2.6]

This Item improves the clarity of subclause 6(3) by extending the cross reference to clause 2 in Standard 1.2.1 to subclause 2(1).

[Item 2.7]

This item deletes specific labelling requirements that are repetitive and adequately covered under other provisions in the Code that require this information to be held.

[Item 2.8]

This Item retains requirements relating to record keeping requirements in Standard 1.5.3 but changes the clause number.

[Item 2.9]

This item includes amendments to the Table of Provisions and re-ordering to reflect the variations.

Summary of submissions

Do not support the Application

Issues	Submitters
<p>The safety, nutritional and cumulative adverse dietary effects from irradiated foods (see section 5)</p> <p>Issues relating to the adequacy of FSANZ's risk assessment on irradiated foods; the general safety of irradiated foods (including recent studies showing adverse effects in cats); scientific studies that had revealed the potential harmful effects of food irradiation; the potential of irradiating foods to produce chemical products in foods that may have adverse effects for humans; the possible adverse cumulative effect on nutrition of eating a number of irradiated foods; the greater vitamin losses from irradiated foods compared to non-irradiated foods; the lack of specific data on the composition of persimmons; and health impacts on overseas consumers of irradiated foods exported from Australia. Clarification of the term 'compositionally similar' was sought in the Risk Assessment Report.</p> <p>FSANZ had selectively cited literature to support the safety and approval of the Application.</p> <p>Prior approval of irradiated tropical fruits was not a sound basis to assume that irradiated persimmons were safe for consumers particularly without post-market surveillance of currently irradiated foods. Food irradiation created toxic radiolytic substances, which do not exist in natural food. There was extensive evidence that these compounds were harmful to human health and the European Food Safety Authority (EFSA) had concluded that these compounds were genotoxic.</p>	<p>Private individuals (Dawn Joyce, Renaee Churches, Edward Handcock, Kerrie Fraser, Jack Ingram, R Ward, J Phillips, Shirley Harris, Jaime Mejia, Lorraine Gurney, Wendy Flannery, Robert Brasher, Brent Wayling, Nathan Hebbard, Greg Vail, Ivan Perger, Heather Phelong, Bronwyn Hancox, David Hancox, B Phelong, Lucinda Scarwn, Andrew Hocking, Martin Oliver, Deborah Stacey, Mitsuo Languisa, Raye Mitchell, Rosemarie Severin, Russell Seres, Marcia George, Rachel Evans, Paul Brecht, Sonia Messinger, Marika Kahle, Gloria Paterson, Karen Beaumont, Anna Clements, Sally Martin, Asa Mark, Hilary Baine, Sonya Fletcher, Shelly Flynn, Jonathon Pipke, Ruth Rendely, Aleksandra Turjak, Michael Slater, Fran Murrel, Cathy Watson, Marie O'Connell, Gloria Paterson, Maria Roeckmann, Toni McPherson, Kim Stewart, Jon Lamb, AR Wheadon, Norma Forrest, Annette Brownlie, Elizabeth Borland, Hans-Peter Schnellboegl, Erica Hedberg, Tania Cummings, Mr Arnold Ward); Sustainable Agriculture and Communities Alliance Inc.; Gene Ethics Network; Food Irradiation Watch; Food and Water Watch.</p> <p>GeneEthics Network</p> <p>Food Irradiation Watch</p>

Issues	Submitters
<p>Labelling of irradiated foods (see section 6.5)</p> <p>Issues relating to adequacy and legibility of current labelling requirements for irradiated foods; concerns that individual fruits were not labelled and that labelling would be removed as a requirement in Standard 1.5.3 (either in the current Standard or under the Review of Food Labelling Law and Policy) and the lack of enforcement of labelling.</p> <p>FSANZ should prohibit use of the term ‘treated with ionising electrons; mandate the labelling of individual fruits; remove positive labelling and prohibit the radura symbol as it has been designed to lead consumers to believe that irradiation is clean and green. The labelling statements ‘Irradiated’, ‘Treated with radiation’, ‘Treated with (or by) irradiation’, ‘Irradiated with electrons’ or ‘Irradiated with X-rays’ should be prescribed. Concerned with the changes to the labelling of irradiated foods which were not related to the Application.</p>	<p>Private individuals, Food Irradiation Watch, the Sustainable Agriculture and Communities Alliance Inc, Food and Water Watch and the Gene Ethics</p> <p>Food Irradiation Watch, Food and Water Watch and GeneEthics Network</p>
<p>Other general issues (see sections 6.1, 6.3, 6.4, 7.6 and 9.2)</p> <p>Issues relating to the lack of an established technological need to irradiate persimmons; general concerns with the safety of irradiation facilities, the transport of radioisotopes and the lack of a method of detection for irradiated foods; approval of persimmons may damage Australia’s reputation as a producer of clean, healthy and pure foods; and the commercial and economic benefits of irradiated persimmons are unsubstantiated.</p>	<p>Private individuals, Food Irradiation Watch, the Sustainable Agriculture and Communities Alliance Inc, Food and Water Watch and the GeneEthics Network</p>
<p>Amendments in Application A1038 versus via a separate process (see section 7)</p> <p>Why FSANZ chose to propose additional amendments to Standard 1.5.3 which were not being specifically requested by the Applicant as the proposed amendments to improve clarity, interpretation and operation of Standard 1.5.3 are not minor in nature?</p>	<p>Food Irradiation Watch and GeneEthics Network</p>

Support the Application

NSW Food Authority, The Food and Beverages Importers Association (FBIA), New Zealand Food and Grocery Council (NZFGC), Food Technology Association of Australia, Queensland Health, Radiation Advisory Services, Department of Health South Australia (SA Health), New Zealand Ministry of Agriculture and Forestry (NZMAF) and Horticultural Access Solutions all supported the Application; however, specific comments were provided on the proposed amendments to Standard 1.5.3.

Issues	Submitters
<p>Safety of irradiated foods (see section 5)</p> <p>The Risk Assessment Report would benefit from more discussion on how the interpretation of a new long-term study in rats fits alongside other studies conducted to date.</p>	<p>NZMAF</p>
<p>Labelling of irradiated foods (see section 6.5)</p> <p>Supported the preparation of a guidance document on labelling if the current labelling examples are removed. Suggested industry should have the option to add a phrase that adequately depicts the reason for treatment.</p> <p>Requested clarification of the scope and timing of the future guidance document on the labelling of irradiated foods.</p>	<p>Radiation Advisory Services</p> <p>NZMAF</p>
<p>Generic approval of foods (see section 7.6)</p> <p>FSANZ should reconsider its case-by-case approvals and approve fresh fruit and vegetables as a group for pest disinfection.</p>	<p>Horticulture Access Solutions Pty Ltd and Radiation Advisory Services</p>
<p>Amendments to Standard 1.5.3 (see section 7)</p> <p>Why FSANZ chose to propose additional amendments to Standard 1.5.3 which were not being specifically requested by the Applicant.</p> <p>Agreed with FSANZ's approach to undertake amendments in Application A1038, but suggested that this should be communicated in the title of the Application to indicate to stakeholders the additional reforms proposed to Standard 1.5.3.</p>	<p>SA Health</p> <p>NZMAF</p>
<p>Insertion of new units for dosage in the Glossary of Symbols (see 7.1)</p> <p>Suggested that in clause 8 of Standard 1.1.1 – Application, Interpretation and general Prohibitions, the unit 'Gray' should be singular rather than plural 'grays'.</p>	<p>NZMAF</p>

Issues	Submitters
<p>References to irradiation facilities (see 7.2.1)</p> <p>Suggested an amendment in the purpose to include New Zealand in the reference to laws governing radiation control, and the operation of irradiation facilities.</p>	<p>NZMAF</p>
<p>Reference to prohibiting irradiation on unsafe or unsuitable food (see 7.3.1.1)</p> <p>The intent proposed by FSANZ is understood but difficult for enforcement agencies to establish if a food was unsafe or unsuitable before it was irradiated. The drafting should be revised or the original words be reinstated in order to make it clear that irradiating a food will require a demonstration of technological need and that it must be associated with food hygiene.</p> <p>A definition of 'unsafe or unsuitable' food should be included in Standard 1.5.3.</p> <p>Irradiation may in the future have particular application to the provision of foods that are 'super safe' for immune-compromised, young, elderly or pregnant people. In those specific populations, some foods might be unsafe because of the presence of particular pathogens at certain levels, but entirely acceptable for the general population. A reference to unsafe or unsuitable food does not differentiate between these specific populations and the general population.</p>	<p>SA Health</p> <p>NZMAF</p> <p>NZFGC</p>
<p>Good manufacturing practices (GMP) in Standard 1.5.3 (see 7.3.1.2)</p> <p>References to GMP should be retained and the amendment to exclude irradiation of unsafe or unsuitable food should not proceed as they are both linked to each other.</p>	<p>Radiation Advisory Services</p>
<p>Definition of a minimum dose to achieve the technological purpose (see 7.3.1.3)</p> <p>The concept of a minimum dose to achieve the purpose of irradiating a food should be retained.</p>	<p>SA Health</p>

Issues	Submitters
<p>Amendment to the minimum dose for irradiation of herbs and spices (see 7.3.1.4)</p> <p>Concerned that the Table to clause 4 is being amended so that there was no minimum dose specified in Column 2 for irradiation of herbs and spices and no condition in column 3 for a minimum dose to achieve the technological purpose. Concerned that there was no explanation provided as to why this change was proposed.</p>	<p>SA health</p>
<p>Deletion of the clause relating to records for food irradiation (see 7.4.1)</p> <p>Clause 5 should be retained as currently in New Zealand the legislative and record-keeping and traceability requirements for licensed irradiation facilities in New Zealand do not cover the current requirements in clause 5 and there needed to be a mechanism in place to monitor the compliance of irradiation facilities with record-keeping requirements and take enforcement action, if necessary.</p>	<p>NZMAF and Radiation Advisory Services</p>
<p>Deletion of subclause 6(4) of Standard 1.5.3 (see 7.5.3)</p> <p>Requested that FSANZ specify the other provisions in the Code that required this information to be held. It is currently unclear and the rationale behind the need for this information to be provided on the label needs to be provided.</p>	<p>NZMAF</p>