

15 March 2011

[5-11]

APPLICATION A1038 IRRADIATION OF PERSIMMONS ASSESSMENT REPORT

Executive Summary

Purpose

Application A1038 was received from Queensland Primary Industries and Fisheries to amend Standard 1.5.3 – Irradiation of Food, to permit the irradiation of persimmons as a phytosanitary measure¹. The Applicant has 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 will also provide persimmon growers with another treatment method for phytosanitary purposes for the fruit fly host.

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

The specific objectives in considering A1038 are 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 need 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. The key risk assessment findings are detailed in **Supporting Document 1 (SD1)**. 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.

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.

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. An updated Fact Sheet on the FSANZ website will serve to assist in providing information on irradiated food to the general public.

The proposed risk management approach is to approve the irradiation of persimmons subject to 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
- retain the current mandatory labelling of irradiated persimmons.

Additional Amendments

Additional amendments are proposed to Standards 1.1.1 and 1.5.3 in order to provide improved clarity, interpretation, and operation of Standard 1.5.3. These do not change the intent of the Standard to permit the irradiation of food on a case-by-case basis.

The following amendments are proposed:

- insertion of new units relating to dosage 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
- removal of extraneous material and provision of more clarity around the specific purpose of irradiating a food
- deletion of the definition of a technological need and re-irradiation as both are covered under other requirements in the Standard
- deletion of the clause relating to record keeping requirements and a specific clause relating to labelling of irradiated foods other than for retail. These clauses are either repetitive and unnecessary, potentially misleading to consumers, covered by other regulatory authorities, or by other provisions in the Code
- deletion of all references to good manufacturing practice (GMP) as a condition for irradiating foods, as this is a duplication of an overall requirement currently in the Code to use GMP in the manufacture of any food
- the condition that the minimum dose of irradiation necessary to achieve the technological purpose be used is deleted because a minimum dose is already specified in Column 2 of the Table to clause 4
- structural changes and re-ordering and insertion of new clauses for foods permitted to be irradiated and conditions under which a food can be re-irradiated

- a new prohibition on irradiating food that is either unsafe or unsuitable has been inserted 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

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.

Preferred Approach

To prepare draft variations 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

Reasons for Preferred Approach

The development of an amendment to the Code to give approval to the sale of irradiated persimmons in Australia and New Zealand is proposed 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 2) of Standard 1.5.3 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

FSANZ acknowledges that this Application will be of interest to a broad range of stakeholders and has applied a general communication strategy to this Application.

This will involve advertising the availability of the Assessment Report for public comment in the national press and making the reports available on the FSANZ website.

In addition, individuals and organisations that make submissions on this Application will be notified at each stage of the Application. If the FSANZ Board approves the draft variation to the Code, FSANZ will notify the Ministerial Council of its decision. Stakeholders, including the public, will be notified of the gazettal of changes to the Code in the national press and on the FSANZ website.

FSANZ has also produced a Fact Sheet to facilitate the general public's understanding of food irradiation. This is available on FSANZ's Website.

Invitation for Submissions

FSANZ invites public comment on this Report and the draft variations to the Code based on regulation impact principles for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in further considering this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information, separate it from your submission and provide justification for treating it as confidential commercial material. Section 114 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Alternatively, you may email your submission directly to the Standards Management Officer at submissions@foodstandards.gov.au. There is no need to send a hard copy of your submission if you have submitted it by email or the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 27 April 2011

SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED

Submissions received after this date will only be considered if agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions relating to making submissions or the application process can be directed to the Standards Management Officer at standards.management@foodstandards.gov.au.

If you are unable to submit your submission electronically, hard copy submissions may be sent to one of the following addresses:

**Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222**

**Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6143
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SUPPORTING DOCUMENTS

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

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

SD1: Risk Assessment report

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

SD3: Summary of literature on consumers and food irradiation

SD4: Proposed amendments to Standard 1.5.3 (marked up)

Introduction

An Application (A1038) was received on 19 November 2009 from Queensland Primary Industries and Fisheries to amend Standard 1.5.3 – Irradiation of food, to permit the irradiation of persimmons as a phytosanitary measure².

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).

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).

The intent of A1038 is to have available an effective measure in order that disinfestation of pests of quarantine significance can be achieved on persimmons.

The Applicant has stated in the application that a range of treatments are currently available for use on fresh fruit and vegetables, with each treatment having various advantages and disadvantages:

- *post harvest chemicals* such as dimethoate, fenthion and methyl bromide. However, due to environmental, occupational health and safety concerns or damage to fruit (methyl bromide) it is expected that their future availability could be restricted.
- *heat and cold treatments* are not an economical measure because of product damage and high costs under Australian conditions.

Persimmons are a host fruit for fruit flies. Because of this, there are quarantine barriers against their trade in 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 require a treatment which 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)³ and the maximum dose requested is 1000 Gy (1kilogray (kGy)). Letters of support were provided from Horticulture Australia Limited (HAL), Persimmons Industry Association Inc., the Australian Persimmon Export Company and the Domestic Quarantine and Market Access Working Group (DQMAWG)⁴.

The relevant quarantine agencies, Biosecurity Australia (BA) and Biosecurity New Zealand, 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, separate from the FSANZ and Ministerial Council approval process.

² 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.

³ The **gray** (abbreviation: Gy) is the international unit of absorbed radiation dose of ionising radiation (for example, X-rays and gamma rays)

⁴ <http://www.domesticquarantine.org.au/>

The Applicant has advised FSANZ that those quarantine agencies view irradiation as an efficacious treatment for quarantine purposes.

In summary, the Applicant has stated that approval would allow increased domestic and international trade in persimmons as there are rigorous requirements for an appropriate and efficacious treatment for fruit fly for quarantine purposes. Irradiation will also 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.

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

1. The Issue / Problem

The irradiation of persimmons is not currently permitted in Standard 1.5.3. As Standard 1.5.3 prohibits the sale of irradiated foods unless the food is listed in the Table to clause 4 in the Standard, a pre-market assessment is required before irradiated persimmons can be sold in Australia or New Zealand. The key requirement of the Standard is that irradiated foods should be safe, nutritionally adequate and that there should be a technological need for the irradiation process.

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

2. Current Standard

2.1 Background

Standard 1.5.3 – Irradiation of Food of the *Australian New Zealand Food Standards Code* (the Code) prohibits the irradiation of food, or food ingredients, unless there is a specific permission for a food in this 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.

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-electronvolts⁵; or electrons generated by or from machine sources operated at an energy level not exceeding 10 mega-electron volts. The Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) approved these sources of radiation for use on food and the Standard was subsequently gazetted on 2 September 1999.

2.2 Approval to irradiate foods in other countries

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

⁵ A mega-electron volt is a unit of energy

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 purpose⁶.

No specific foods are mentioned, although the standard 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 worldwide permissions for irradiated foods

Country	Food	Dose range (kGy)
European Union	Dried aromatic herbs, spices and vegetable seasonings	10
Canada ⁷	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 ⁸	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 0.25 to 1
Thailand	Selected tropical fruits (mango, mangosteen, lychee, longan, rambutan and pineapple for disinfestation)	0.4
Philippines	Mangoes for disinfestation Onions for sprout inhibition Garlic for disinfestation	1 0.3 to 1 .3 to 1
Vietnam	Seafood for decontamination Frozen Fruits for decontamination Dragon fruits to control pests	2 to 7.5 2 to 3 1
Indonesia Indonesia	Mango to control insects Papaya, mushroom, tomatoes, bananas and broccoli for shelf-life extension Fresh meat and chicken for decontamination of pathogens	0.75 1-2 5-7
India	Mangoes to control insects Fresh meat and chicken for decontamination of pathogens Spices for decontamination Raisins, figs and dried dates to control insects Fresh seafoods for shelf-life extension	0.25 to 0.75 2.5 to 4 6.0 to 14 0.25 to 0.75 1 to 3

⁶ http://www.codexalimentarius.net/download/standards/16/CXS_106e.pdf

⁷ In Canada, permission to irradiate beef, poultry, shrimp, prawns and mangoes are still in the process of Final Approval.

⁸ In the USA, food irradiation is considered as a food additive under their legislation.

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 brief 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 2002.⁹ At that time, FSANZ concluded that there are no public health and 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 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 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. FSANZ approached this assessment by independently evaluating new data relevant to the safety of irradiated food published since the last risk assessment in 2002. Also the compositional data on irradiated persimmons and the level of consumption of persimmons in Australian and New Zealand were taken into consideration.

It is concluded that there are no public health and 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:

- Supplementary data published since 2002 has confirmed that 2-alkylcyclobutanones¹⁰ (2-ACBs) are not genotoxic.
- 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.
- 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 vitamins. Therefore, there are unlikely to be any nutritional disadvantages for Australian and New Zealand consumers from eating irradiated persimmons. New data indicate that compounds previously considered to be uniquely formed during food irradiation (i.e. 2-ACBs) are actually present in some non-irradiated foods.

⁹ <http://www.foodstandards.gov.au/srcfiles/A443%20FAR%20-%20Irradiation%20Tropical%20Fruit.pdf>

¹⁰ Particular chemical compounds (molecules) that are found following irradiation of food

- The irradiation of several tropical fruits, which are compositionally similar to persimmons, is already permitted in Australia and New Zealand. FSANZ has not previously identified any public health and safety issues associated with the consumption of these or other permitted irradiated foods.
- The safety of irradiated food has been extensively assessed by national regulators and international scientific bodies.
- There is a history of safe consumption of irradiated food in many countries.

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 specifications, compositional and/or labelling requirements, and where necessary, restriction or prohibition. Drawing on the conclusions from the risk assessment, the following sections discuss approaches to managing any identified public health and safety risks and other broader issues requiring consideration in the development of regulations for irradiation of persimmons.

6. Issues

6.1 Safety, nutritional adequacy and quality of irradiated foods

The safety of irradiating persimmons has been examined by FSANZ. 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 status 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.

Although not a nutritional issue, at certain doses of irradiation, particularly at doses close to the proposed maximum of 1 kGy, the quality of the fruit can be affected. FSANZ notes that a recent report by Jordan et al (2007) investigated the quality of persimmons following irradiation at various doses. It was concluded that fruit can be irradiated for fruit fly disinfestation up to 250 Gy without loss of retail quality. Above that dose, there was an increased softening of the fruit which increased with increasing dose. However, the final quality of irradiated fruit is a commercial and marketing issue for growers of the fruit and operators of irradiation facilities. This will ultimately determine consumer acceptance of irradiation-treated produce.

6.2 Technological need and efficacy of the Irradiation Process

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).

Specific advice on technological need and appropriate dose ranges for phytosanitary purposes for both applications was sought at that time from Biosecurity Australia and the New Zealand Ministry of Agriculture and Fisheries¹¹. FSANZ is viewing 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 Biosecurity New Zealand for quarantine purposes are as follows:

Commodity	Date	Purpose	Dose
Fresh mangoes imported from India (BA) ¹²	August 2008	Phytosanitary need for control of fruit flies, mealy bugs, red-banded mango caterpillar and mango weevils	400 Gy
Litchi's exported from Australia (Biosecurity NZ) ¹³	September 2008	Control of Fruit fly and Hemiptera (bugs)	Up to 250 Gy
Mangoes and Papaya exported from Australia (Biosecurity NZ) ¹⁴	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 2.2). 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 150 to 1000 Gy for prevention of the emergence of adult fruit flies for all fruits and vegetables.

In 2006, the US Animal and Plant Health Inspection Service (APHIS) approved generic irradiation doses of 150 Gy for fruit flies and 400 Gy for all insects except pupa and adult Lepidoptera. If there was an identified need to irradiate other insects (other than fruit fly) or pupa and Lepidoptera, then a specific assessment of the doses needed would need to be undertaken by Australian and/or New Zealand quarantine agencies.

The Applicant has also confirmed with BA and Biosecurity New Zealand 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 A443¹⁵ is also an appropriate and efficacious dose for irradiation of persimmons.

Both BA and Biosecurity New Zealand 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.

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

¹¹ This function has now become the responsibility of Biosecurity New Zealand

¹² http://www.daff.gov.au/_data/assets/pdf_file/0003/771906/Mangoes_from_India_Final_Report.pdf

¹³ <http://www.biosecurity.govt.nz/files/regs/imports/risk/aus-litchi-ra.pdf>

¹⁴ 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>

¹⁵ http://www.foodstandards.gov.au_srcfiles/A443%20FAR%20-%20Irradiation%20Tropical%20Fruit.pdf

In addition, the dose range of 150–1 kGy has been endorsed as appropriate for use as a quarantine measure to prevent disinfestation by fruit fly on persimmons. FSANZ recognises that BA and Biosecurity New Zealand 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, separate from the FSANZ and Ministerial Council approval process.

6.3 Packaging

Irradiation of persimmons will be undertaken after packaging of the fruits. 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. Persimmons should also be handled before and after irradiation, according to good manufacturing practice, taking into account, in each case, the particular requirements of the technology. 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.

Standard 1.4.3 – Articles and Materials in Contact with Food in the Code 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.

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. Advice from the Applicant is that corrugated or fibre board fruit boxes used for packaging persimmons are 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 at the disinfestation dose applied (150 Gy–1 kGy) and are currently approved for use in irradiating fruits and vegetables, under the USA Code of Federal Regulations.

In summary, at a low maximum dose of 1 kGy, it would not be expected that packaging material in contact with persimmons would 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 and safety issue. 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.

6.4 Irradiation facilities and dosimetry

It is mandatory that any food, permitted to be irradiated, is treated in a licensed radiation facility. The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA¹⁶) regulates Australian Government entities; whereas, the activities of non-Australian Government entities are regulated by the respective State and Territory authorities.

¹⁶ <http://www.arpansa.gov.au/index.htm>

The radiation facilities are licensed in accordance with any relevant State, Territory and New Zealand law governing radiation control and operation. Currently 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.

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 in New Zealand. The NRL administers the Radiation Protection Act 1965 and the Radiation Protection Regulations 1982 on behalf of the New Zealand Government.

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

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. There are currently three commercial irradiation facilities operating in Australia. All three are nuclear irradiation facilities, using 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 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.

6.5 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 are not meant to be used to accurately measure absorbed doses. Therefore, 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. Therefore, there is not yet one simple and cost effective method developed for detecting whether food has been irradiated which reflects the very small, often undetectable chemical changes that occur post-irradiation.

The currently available techniques are limited to foods containing bone, fat-containing foods or light emission¹⁷:

¹⁷ Source: http://ec.europa.eu/food/food/biosafety/irradiation/anal_methods_en.htm

- 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
- 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. Detection tests however, can assist to enforce labelling requirements for identifying the irradiated fruit.

6.6 Labelling of irradiated foods

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, in accordance with Standard 1.2.1 – Application of Labelling and Other Information Requirements 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 food with ionising radiation.

The Standard provides three examples of such statements. These are 'Treated with ionising radiation', 'Treated with ionising electrons' and 'Irradiated (name of food)'. The use of the international Radura symbol¹⁸ (below) is optional and, if used, should be in close proximity to the name of the food and must be accompanied by the mandatory statement that the food has been treated with ionising radiation.

¹⁸ The **Radura** is the international symbol indicating a food product has been irradiated.



6.7 Consumers and food irradiation

A summary of the relevant research related to consumer awareness, understanding and acceptance of food irradiation is at **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.

6.8 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.

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). However, FSANZ's mandate is confined to safety and nutritional adequacy of foods and more broadly that irradiation is not used as a substitute for safe food production under the Section 18 objectives of the FSANZ Act (**see section 3**).

The other matters such as general exposure to radiation, damage to the environment and occupational health issues for workers are for other agencies that may examine such matters in their assessment of radiation licence applications.

The mandatory requirements under Standard 1.5.3 to label irradiated foods will provide adequate information to consumers to either purchase or avoid irradiated persimmons. Based on the risk assessment findings, no additional mandatory labelling is proposed.

FSANZ proposes to retain its current case-by-case approach to approval of irradiated foods. Furthermore, in regard to persimmons approval is 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
- retain the current mandatory labelling of irradiated persimmons

7. Proposed 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.

The audit has identified areas for improvement and, while implementing all of the recommendations from the audit will take some time, FSANZ has already made some changes to the way we write and present our standards. These include:

- providing explanatory statements with standards to explain the purpose or intent of the provisions
- examining existing provisions in the Code as part of applications to make improvements to those provisions
- placing greater emphasis on the intent of standards before drafting them.

In light of the legislative audit, and although the OLDP did not make any specific recommendations about Standard 1.5.3, FSANZ has identified areas in Standard 1.5.3 which may be concurrently addressed with the assessment of A1038. This would provide clarity around 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.

To assist in understanding the proposed amendments in sections 7.1 to 7.4 refer to a revised version of Standard 1.5.3 in **Supporting Document 4**.

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

It is proposed to include 'kGy' and 'kiloGrays' 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.

7.2 Amendments to provide clarity to the purpose and definitions of Standard 1.5.3

The Purpose of Standard 1.5.3 has been 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.

Currently the Purpose has a reference to packages and packing materials used or intended for use in connection with irradiated food being of a suitable quality and in an acceptable hygienic condition, appropriate for the purpose of such processing. However, it is proposed to remove the reference to packages and packaging materials as this reference is not appropriately considered to be a 'purpose' for the standard and the provisions in Standard 1.4.3 – Articles and Materials in Contact with Food apply to packaging used for irradiation (**see section 6.3 above**).

The current text in the purpose, pertaining to irradiation facilities and Codes of Practice for irradiated foods, has been strengthened to reflect the following:

- that irradiation of foods must be carried out in facilities that are appropriately licensed and registered for the purpose of irradiation

- to incorporate inclusion of an additional reference to international laws governing radiation control, to cover foods that may be imported.

The definition of technological need is deleted because the specific purpose of irradiating an irradiated food is a mandatory requirement to be identified 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 is deleted as it is proposed to create a new clause (see **clause 5 of Attachment 1**) under permission to irradiate a food, which specifies conditions under which a food can be re-irradiated.

7.3 Structural changes to Standard 1.5.3 and proposed new clauses

The Table of Provisions has been amended and re-ordered to reflect the variations.

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.

Clause 4 Foods permitted to be irradiated has been amended 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) as a condition for irradiating foods, as this is a duplication of an overall requirement currently in the Code to use GMP in the manufacture of any food
- the condition that the minimum dose of irradiation necessary to achieve the technological purpose be used is deleted because a minimum dose is already specified in Column 2 of the Table to clause 4
- a new prohibition on irradiating food that is either unsafe or unsuitable has been inserted 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.

A new clause 5 is created specifying conditions under which a food can be re-irradiated. This clarifies and incorporates the previous existing exemptions for the re-irradiation of food.

FSANZ calls for public comment on these proposed changes. In reference to food, irradiation is not be undertaken on food that is either unsafe or unsuitable under the Act, FSANZ notes that the Model Food Provisions in the State/Territory Food Acts contains a definition of unsafe and unsuitable food. However, there are no such definitions in the Code or New Zealand Food Act. Therefore, FSANZ specifically invites comments on the impacts on New Zealand of this reference to unsafe or unsuitable food in the current drafting.

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.

However, FSANZ is of the understanding that detailed records are also a requirement of licensing authorities (**see section 6.4 above**) which cover the above requirements in clause 5 of Standard 1.5.3 and are fully documented by licensed irradiation facilities.

For example, the Australian Quarantine and Inspection Service (AQIS) have 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.

In summary, the treatment facility must keep all dosimetry and treatment records and records are maintained to track the irradiated food product from receiving through shipping. All records must identify the irradiated product and be retained in accordance with requirements by appropriate Australian State/Territory or New Zealand licensing authorities.

Advice FSANZ received from industry is that the records kept in relation to irradiated articles are basically the same whether or not it is food or medical or quarantine. 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 questions whether clause 5 provides any additional value to Standard 1.5.3, because licensed irradiation facilities have existing records and traceability requirements which essentially cover all the current requirements. There is also various State/Territory and New Zealand regulation governing the use of ionising radiation which also requires record-keeping.

FSANZ also notes that clauses 4 and 6 of Standard 1.2.1 could require the provision of information about the irradiation of a food, where a purchaser or relevant authority has requested this information.

Therefore, FSANZ proposes to delete clause 5 of Standard 1.5.3 with the view that State/Territory and NZ legislation and current irradiation facilities already require record keeping for irradiated foods. In addition, other generic provisions in the Code (clause 4 and or 6 of Standard 1.2.1) cover the provision of information in relation to food. FSANZ calls for public comment on this approach and in addition, requests specific comment by State/Territory/New Zealand licensing authorities that there is in existence appropriate legislation that would cover the current requirements in clause 5 of Standard 1.5.3.

7.4.2 Proposed changes to the labelling of irradiated foods

In respect of the current provisions for the labelling of irradiated foods and for clarity of interpretation of these provisions, FSANZ proposes to implement some clarifications and reforms around the intent of the labelling requirements in Standard 1.5.3 (see 7.4.2.1 to 7.4.2.3).

However, FSANZ notes that the final Report of the Review of Food Labelling Law and Policy entitled *Labelling Logic* was released by the Australian Parliamentary Secretary for Health and Ageing, the Hon Catherine King MP, on 28 January 2011. The Report can be accessed online at

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

The Report provides an analysis of issues associated with food labelling and contains 61 recommendations. The Australia and New Zealand Food Regulation Ministerial Council has been tasked with developing a comprehensive, whole-of-government response to the recommendations in the Report by December 2011. FSANZ will be in a position to consider any recommendations relating to irradiated foods, once the whole-of-government response is finalised.

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

Current drafting of subclause 6(1) of Standard 1.5.3 contains the following boxed examples of statements for irradiated foods:

'TREATED WITH IONISING RADIATION'
'TREATED WITH IONISING ELECTRONS'
'IRRADIATED (name of food)'

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 proposes that the statement 'Treated with ionising electrons' be deleted and furthermore that the Example box itself be deleted and the remaining examples relocated in a future 'guidance' document.

The future '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.

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

Current subclause 6(3) of Standard 1.5.3 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), it is proposed to amend the cross reference to clause 2 in Standard 1.2.1 to subclause 2(1).

7.4.2.3 Deletion of sub clause 6(4) of Standard 1.5.3

Current subclause 6(4) of Standard 1.5.3 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 vertical 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 is proposed to delete sub clause 6(4) of Standard 1.5.3 as it is repetitive information and is adequately covered under other provisions in the Code that require this information to be held. For example, clause 4 of Standard 1.2.1 – Application of Labelling and Other Information Requirements 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).

FSANZ calls for public comment on these proposed labelling changes

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 Standard 1.5.3, it is not appropriate to consider non-regulatory options to address this Application.

Two regulatory options have been identified for this Application:

Option 1: Reject the Application, 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: Prepare draft variations to permit the use of irradiation on persimmons under Standard 1.5.3

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. Minor amendments are proposed 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 the Standard to permit the irradiation of food on a case-by-case basis.

9. Impact Analysis (RIS ID: 12010)

9.1 Affected Parties

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

Parties affected if permission is granted are:

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

The Applicant has presented a case that the use of irradiation is a technologically justified and efficacious treatment and will provide access to new markets for Australian persimmon growers. The Applicant also states that this alternative treatment will provide the persimmon industry with an option to use irradiation as a phytosanitary measure, pending that the current chemical treatments may be withdrawn from use. The Applicant describes this technology as simple, safe, versatile and efficacious.

Government regulatory agencies involved in approval for food irradiation, namely FSANZ and the relevant Australian and New Zealand quarantine agencies need to ensure that irradiation at the levels proposed, in relation to persimmons, results in food that is safe and nutritionally adequate, that there is a specific technological need and that the permitted dose is efficacious in meeting quarantine requirements. Enforcement agencies will be required to enforce labelling requirements for foods that have been treated with irradiation.

The costs and benefits to the affected parties are further expanded below under the two 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.

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 has advised that the application appears to be of a minor or machinery nature; notified approval of the preliminary assessment (RIS ID: 12010) and further advised that a Regulatory Impact Statement (RIS) is not required.

9.2.1 *Option 1: Reject the Application, thus not approving the use of irradiation for persimmons*

9.2.1.1 Consumers

There would 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. However, mandatory labelling would allow such foods to be avoided by those wishing to do so.

No costs to consumers were identified, except the possibility that the phase out of chemicals that normally reduce fruit fly disinfestation could limit the supply of persimmons. This is expected to be a minor cost to consumers.

9.2.1.2 Industry

No benefits to industry were identified. There may be costs associated with loss of trade opportunities and access to markets where current disinfestation methods are not accepted.

The Australian persimmon industry may not develop global competitiveness and market opportunities may be lost. The development of the Australian persimmon production industry may be reduced and further 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 due to the following reasons:

- there are no additional perceived costs on jurisdictions that enforce the labelling provisions of Standard 1.5.3
- lack of approval may be regarded as unnecessarily trade restrictive
- the scientific assessment determined that the irradiation persimmons was safe and that consumers would not be nutritionally compromised following consumption of irradiated persimmons.

No costs were identified.

9.2.2 Option 2: Prepare draft variations to permit the use of irradiation on persimmons under Standard 1.5.3

9.2.2.1 Consumers

The following may be identified as benefits for consumers:

- there may be an expansion of 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 have affected fruit quality previously and fruit may be able to be transported for longer periods while maintaining desirable sensory qualities for consumers
- 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
- some consumers may see the reduction in use of horticultural chemicals as a benefit.

The proposed deletion of the example statement 'Treated with ionising electrons' in Standard 1.5.3, should also benefit consumers, as currently the statement is potentially misleading to consumers in that they may not understand that it indicates the food has been irradiated.

There may be a cost to consumers who believe that irradiated foods may not be nutritionally equivalent to non-irradiated foods. Another cost might be a possible 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 may be identified as benefits for industry:

- an alternative phytosanitary measure if the current treatments are restricted
- increased trade opportunities and increased markets available to persimmon growers due to the high standards required for quality produce and to meet the rigorous quarantine requirements. Could facilitate exports by facilitating 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 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. It is noted that initial set up costs in establishing an irradiation facility including building and capital may be significant..

The permission to irradiate would provide industry with an alternative to current chemical treatments. This is a commercial decision and the cost or benefit of this choice does not require quantifying.

There are likely to be voluntary costs to industry of treatment of the fruit, transport, labelling irradiated foods and there is likely to be a cost in ascertaining consumer acceptance of irradiated persimmons.

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 may be 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
- potential increase in the efficiency of biosecurity negotiations between relevant quarantine agencies
- possible enhanced economic development in rural and regional Australia

The proposed additional amendments to Standard 1.5.3 should benefit State/Territory/New Zealand enforcement agencies in regard to the following:

- interpretation of the standard

- avoidance of duplication with other legislation in place by State/Territory/New Zealand radiation licensing authorities in regard to the record keeping requirements for irradiated foods
- deletion of labelling requirements which are either unnecessary or adequately covered by other standards in the Code.

An identified cost is that the relevant Australian and New Zealand quarantine agencies must undertake bilateral negotiations to determine, on a case-by-case basis, appropriate irradiation treatments for specific pests of quarantine concern to meet relevant quarantine import requirements for persimmons. This applies to imports into Australia and New Zealand and to domestically produced fruit that is subject to interstate trade within Australia. This may require extensive risk analysis, on the part of quarantine agencies with associated resource allocation.

9.3 Comparison of Options

Option 1 would not allow the use of irradiation on persimmons. It imposes costs on consumers by loss of choice where the safety and nutritional adequacy had been established. 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 disinfestation. The dose range proposed (150 Gy to 1 kGy) has been verified by the appropriate quarantine regulatory agencies as being adequate to fulfil the technological need of pest disinfestation. Option 2 does not subject consumers, the community or Governments to other costs other than those already highlighted.

Overall, **Option 2** is preferred because, as 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 provides a fair trading aspect to allow persimmon growers new markets and meets Australia's requirements under the World Trade Organization (WTO) by virtue of consistency with other international regulations on irradiated fruits.

Communication and Consultation Strategy

It is still evident that a significant information gap exists in relation to consumers' knowledge about food irradiation. However, there is an imperative for other agencies and bodies to also play a role in providing relevant information to consumers in relation to this technology. 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 bodies have roles to play and should be strongly encouraged to do so. For example, industry can have a role to play, facilitated by the labelling requirement in the Standard, to specify the purpose of the irradiation process, for example, '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. Communication

Public submissions are now invited on this First Assessment Report.

FSANZ would specifically like to invite stakeholders and affected parties to provide quantitative estimates (if available) as well as any other information or comments in regard to the following questions:

Scientific aspects of the application, in particular, any information relevant to the safety assessment.

Information on Australian and New Zealand consumers' knowledge of irradiation.

What are the potential costs and/or benefits of the proposed risk management options to you as a stakeholder?

Are there other affected parties that have not been identified in this regulatory impact statement that you feel should be included?

Are there other costs or benefits that you feel should be considered in the regulatory impact statement?

Do you consider that the benefits of progressing with approving this Application outweigh the costs? If you have any data or information to support your view, FSANZ would welcome the opportunity to consider it.

11. Consultation

11.1 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.

Conclusion

12. Conclusion and Preferred Option

It is 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.

Preferred Approach

To prepare draft variations 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

12.1 Reasons for Preferred Approach

The development of an amendment to the Code to give approval to the sale of irradiated persimmons in Australia and New Zealand is proposed 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 2) of Standard 1.5.3 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

It is proposed that the draft variations come into effect on the date of gazettal.

REFERENCES

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Jordan, R.A. (2007). Effect of irradiation treatment on the quality of sweet persimmons, PR 06008. Final Report, Horticulture Australia Ltd. Queensland Department of Primary Industries and Fisheries.

The American Society for Testing and Materials (ASTM) F1355 – 06 (2006). Standard Guide for Irradiation of Fresh Agricultural Produce as a Phytosanitary Treatment,' ASTM International, West Conshohocken, PA, DOI: 10.1520/F1355-06.

The American Society for Testing and Materials (ASTM) F1640 – 09 (2009). Standard Guide for Packaging Materials for Foods to Be Irradiated, ASTM International, West Conshohocken, PA, DOI: 10.1520/F1640-09. <http://www.astm.org/Standards/F1640.htm>

US FDA 21 CFR § 179.45 *Packaging materials for use during the irradiation of pre-packaged foods*, Subpart C.

ATTACHMENTS

1. Draft variations to the *Australia New Zealand Food Standards Code*
2. Explanatory Statement

Draft variations to the *Australia New Zealand Food Standards Code*

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 'kiloGrays' 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.

[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.

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
- deletes the reference to good manufacturing practice (GMP) as a condition for irradiating foods in column 3 of the Purpose in the Table to clause 4, as this is a duplication of an overall requirement currently in the Code to use GMP in the manufacture of any food

- 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(a) and (b)
- deletes requirements relating to record keeping requirements that are repetitive and unnecessary information and adequately covered by requirements by agencies that licence irradiation facilities and/or other provisions in the Code
- creates a new clause (clause 5) specifying conditions under which a food can be re-irradiated.

[Item 2.5]

This item deletes all examples of labelling statements as these are considered unnecessarily prescriptive. Additionally, the statement relating to ‘treated with ionising electrons’ is considered 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 includes amendments to the Table of Provisions and re-ordering to reflect the variations.