

**Supporting document 5**

Labelling Review Recommendation 34: Review of mandatory labelling of irradiated food

Irradiation as a treatment for food

FSANZ has estimated the size of the current Australian and New Zealand domestic markets for irradiated produce.

For Australia, the domestic market was estimated using domestically grown and irradiated produce volumes and imported irradiated produce volumes. In the year ending June 2016, most of the irradiated food (34 tonnes) available for retail sale was Australian grown irradiated produce. A smaller amount of produce (15 tonnes) had been imported for domestic consumption.

For New Zealand, the domestic market was estimated through imported produce volumes only, as New Zealand does not have an irradiation facility. All of the irradiated produce (1550 tonnes) was imported from Australia between July 2015 and June 2016. The New Zealand domestic market for irradiated food also had a wider range of irradiated produce available than in Australia.

In response to comments from some submitters, and as further background, FSANZ has provided information about:

* the reasons for using irradiation as a treatment for food
* the foods permitted to be treated with irradiation in Australia and New Zealand, and which of these reasons apply to them
* the alternatives to irradiation for fresh produce
* how food is irradiated
* the safety and nutritional adequacy of irradiated food.

**Table of Contents**

[1 Current Australian and New Zealand domestic markets for irradiated produce 2](#_Toc467141077)

[1.1 Australian domestic market 2](#_Toc467141078)

[1.2 New Zealand domestic market 3](#_Toc467141079)

[2 Reasons for using irradiation as a treatment for food 6](#_Toc467141080)

[3 Permissions for and purpose of irradiating food in Australia and New Zealand 6](#_Toc467141081)

[4 Alternatives to irradiation for fresh produce 8](#_Toc467141082)

[5 How food is irradiated 8](#_Toc467141083)

[6 Safety of irradiated food 9](#_Toc467141084)

[6.1 Key studies on the safety of irradiated foods 10](#_Toc467141085)

[6.2 Compounds generated following the irradiation of food 10](#_Toc467141086)

[6.3 Nutritional impacts of irradiated foods 11](#_Toc467141087)

[6.4 Irradiated cat food 11](#_Toc467141088)

[6.5 International guidance on the safe use of irradiation 12](#_Toc467141089)

[7 References 13](#_Toc467141090)

## 1 Current Australian and New Zealand domestic markets for irradiated produce

### 1.1 Australian domestic market

The size of the Australian domestic market has been estimated using volume data for irradiated produce only[[1]](#footnote-2). Information about irradiated herbs, spices and plant material for herbal infusions is not reported due to difficulties in collecting volume data for these particular commodities.

Market access within the Australian states and territories is approved by a 2011 national Interstate Certification Assurance Scheme as Operational Procedure Number 55 (ICA-55) (Department of Employment, Economic Development and Innovation, 2011). The ICA-55 provides blanket approval for irradiation as a phytosanitary treatment for all fresh fruits and vegetables, and covers fruit flies, mango seed weevil and all pests of the class Insecta except pupae and adults of the order Lepidoptera. The ICA-55 applies to any irradiated food that has been assessed as safe by FSANZ and permitted to be irradiated. All states and territories are signatories to the ICA-55.

Figure 1 illustrates the volume of Australian produce by season that was irradiated by the Queensland irradiation facility for domestic use. As an average across all produce types, one pallet is equivalent to one tonne of produce. The volume of produce has therefore been referred to in tonnes in this report.

**Figure 1. History of Australian irradiated produce for domestic use**

In the 2015-16 year, 23 tonnes of plums, 10 tonnes of capsicums and 1 tonne of tomatoes were irradiated. Prior to the year ending June 2014, mangoes were the only irradiated produce sold domestically in Australia. After the 2013-14 season, mango producers could verify that they were ‘seed weevil free’ (the main reason for irradiation treatment) and mangoes were no longer required to be irradiated to access the Western Australia market.

New domestic markets for capsicums and tomatoes were established in the 2013-14 season after permissions to irradiate these produce types were granted. A similar situation occurred in the 2015-16 season for plums.

The Australian Department of Agriculture and Water Resources is responsible for the biosecurity of imported food, including irradiated food imported from other countries. This Department undertakes a risk analysis of the food if it is a new (unapproved) commodity or if it is an approved commodity but from a different country. Vietnam, India and Pakistan are the only countries that have food irradiation facilities approved by Australia to treat food destined for the Australian domestic market; the latter two countries have only recently gained approval to treat mango. In the 2015-16 season, the only imported irradiated food for retail sale in Australia was litchi (also known as lychees), sourced from Vietnam. Trade volumes for this period have been estimated to be 15 tonnes. The proportion of irradiated lychees in the total traded volume for this fruit is not available.

### 1.2 New Zealand domestic market

For consistency with the approach taken in Australia, the size of the New Zealand domestic market has also been estimated using volume data for irradiated produce only.[[2]](#footnote-3)

All food imported into New Zealand is subject to import health standards that prescribe the biosecurity treatments that can be used to control unwanted pests. Import health standards are developed by the New Zealand Ministry for Primary Industries, include a separate biosecurity risk assessment, and are regulated under the Biosecurity Act 1993. Biosecurity measures that are currently permitted are set out Standard 152.02 Importation and clearance of fresh fruit and vegetables to New Zealand (New Zealand Ministry for Primary Industries 2016). At present, import health standards that permit irradiation to be used as a phytosanitary treatment are in place for Australian mangoes, litchis, papaya, tomatoes and capsicums. Import health standards have also been established for irradiated longan and litchi from Thailand, irradiated papaya from Hawaii and irradiated mangoes from Vietnam. Currently there are no New Zealand import health standards for apple, apricot, cherry, nectarine, peach, plum, honeydew, rockmelon, scallopini, strawberry, table grape and zucchini (courgette).

In the year ending June 2016, a total volume of 24,365 tonnes of non-irradiated fresh produce was exported from Australia to New Zealand. The total volume of irradiated produce from Australia was 1550 tonnes. This amount represents less than seven per cent of the combined irradiated and non-irradiated produce volumes. Australian export volumes to New Zealand by produce type are shown in Figure 2.

The New Zealand market for irradiated mangoes for the year ending June 2016 was significant, with 1024 tonnes imported from Australia between July 2015 and June 2016. This is due in part to it being an established market (irradiated mangoes have been available in New Zealand for eleven years) and the absence of local production. For the same season, the volume of imported irradiated litchis and papaya from Australia was 64 tonnes and 104 tonnes, respectively. Australian-irradiated litchis were introduced to the New Zealand market in 2005-6. Australian irradiated papaya followed in 2011-12.

Three hundred and forty-nine tonnes of irradiated tomatoes were imported from Australia in the period between July 2015 and June 2016. This time period was the third season for imports of this irradiated produce type and reflected a drop in volume from the first season (413 tonnes between July 2013 and June 2014). Nine tonnes of Australian irradiated capsicums were imported for the current period of July 2015 to June 2016. This volume decreased significantly from the first season (58 tonnes in July 2013 – June 2014).

For the same season of July 2015 – June 2016, no irradiated produce was imported from Thailand, Hawaii or Vietnam. Longan and litchi imported from Thailand were cold treated, and mangoes from Vietnam were treated by hot water dip. Papaya was not imported from Hawaii during this period.

**Figure 2. Australian irradiated produce imported into New Zealand**

## 2 Reasons for using irradiation as a treatment for food

A variety of processing methods are used to preserve foods and improve safety, such as drying, smoking, salting, pasteurisation, canning, refrigeration, freezing and chemical preservatives. Food irradiation is another effective food processing method that can be used to preserve foods and improve safety. Specifically, irradiation (if permitted) could be used to:

* kill or sterilise pests, such as fruit flies and other insect pests (e.g. mealy bugs, mango weevils), that are present in or on fresh produce. This allows fresh produce to be exported to Australian states and other countries that are fruit-fly free (and/or free of other regulated insect pests). Irradiation also decreases the need for other pest control practices that may damage the produce (such as heat/cold treatments).
* extend the shelf life of foods by destroying organisms that cause spoilage or decomposition (e.g. moulds, bacteria, insects)
* inhibit sprouting (e.g. potatoes) and delay ripening of fruit to extend its shelf life
* prevent foodborne illness by destroying bacterial organisms such as Salmonella and *Escherichia coli* (E. coli)
* sterilise foods used for medical purposes (e.g. food for immune-compromised patients), noting that the US approves irradiation of foods sterilised for use by astronauts in space[[3]](#footnote-4).

Like all preservation methods, irradiation should supplement rather than replace good food hygiene, handling, and preparation practices (Groth 2007; Arvanitoyannis 2010; Follett and Weinart 2012).

Irradiation is used as a treatment for food in more than 50 countries worldwide. In Australia, irradiation is typically used for fruit and vegetables as a final quarantine measure to ensure produce from fruit-fly infected areas does not pose a risk of introducing new species of fruit-fly into fruit-fly free areas of Australia and New Zealand and other countries the produce is exported to. Herbs and spices and herbal infusions may be irradiated to control sprouting and pest infestation, including control of weeds, and also for bacterial decontamination purposes.

## 3 Permissions for and purpose of irradiating food in Australia and New Zealand

Foods permitted to be irradiated in Australia and New Zealand under the *Australia New Zealand Food Standards Code* (the Code), and the purpose for which irradiation may be used as a treatment for these foods, are shown below in Table 1.

***Table 1:*** *Foods permitted to be irradiated in Australia and New Zealand and the purpose of irradiation*

|  |  |  |
| --- | --- | --- |
| Food | Minimum and Maximum Dose  (kGy)1 | Purpose |
| Apple  Apricot  Bread fruit  Capsicum  Carambola  Cherry  Custard apple  Honeydew  Litchi  Longan  Mango  Mangosteen  Nectarine  Papaya (paw paw)  Peach  Persimmon  Plum  Rambutan  Rockmelon  Scallopini  Strawberry  Table grape  Tomato  Zucchini (courgette) | Minimum: 150 Gy  Maximum: 1 kGy | Pest disinfestation for a phytosanitary objective. |
| Herbs and spices as described in Schedule 22 – Foods and classes of food  Herbal infusions – fresh, dried or fermented leaves, flowers and other parts of plants used to make beverages, but not does include tea | Minimum: none  Maximum: 6 kGy | Control of sprouting and pest disinfestation, including control of weeds. |
| Herbs and spices as described in Schedule 22 | 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. |

1 KiloGrays

## 4 Alternatives to irradiation for fresh produce

There are some alternatives to irradiation as a phytosanitary measure. These include:

* post-harvest chemicals (e.g. methyl bromide, dimethoate)
* refrigeration
* hot water dips
* vapour heat
* controlled atmosphere
* physical disinfestation, i.e. cleaning or washing.

There are advantages and disadvantages associated with each of these treatments. Depending on the treatment, the disadvantages can be the high cost of the treatment, an adverse effect on the quality of produce and shelf life, environmental concerns, the risk of chemical residues remaining on food and limited effectiveness against a broad range of insects. Some treatments require more handling of produce. Others take longer for produce to be processed, which can lead to missed market opportunities. When these treatments are used, there is no requirement to declare the use of the treatment on the food label.

These alternatives are not under consideration as part of this work. If certain produce presents a biosecurity risk for a particular market, producers need to consider which phytosanitary measures are permitted before the produce can enter that market. If more than one measure is available, the decision on which treatment to use will be based on cost, impact on quality and the effectiveness of the treatment.

Irradiation is one of the ‘tools in the toolbox’ of phytosanitary measures. There are currently two irradiation facilities in Australia, but the only facility licensed to irradiate food for a phytosanitary purpose is based in Queensland. This irradiated produce is sold domestically and is exported to New Zealand and to other countries. New Zealand does not have an irradiation facility to treat food, and any irradiated food available for sale is imported.

## 5 How food is irradiated

Food is irradiated via exposure to ionising radiation from one of three radioactive sources:

* gamma rays, which are emitted from radioactive forms of the element cobalt (Cobalt 60) or of the element caesium (Caesium 137)[[4]](#footnote-5)
* x-rays, which are generated by or from machine sources using electricity
* electron beam (also referred to as e-beam), which are generated by or from machine sources using electricity.

Cobalt 60 is used in Australia.

Gamma rays, e-beam and x-rays are a form of radiation that shares some characteristics with microwaves, but with much higher energy and penetration. These sources are also used to sterilise medical, dental and household products, and X-rays are used for medical imaging.  
  
The rays pass through the food just like microwaves in a microwave oven, but the food does not heat up to any significant extent.

Irradiation does not make foods radioactive, because the maximum levels set for the amount of radiation that can be used to treat food are too low. During irradiation the food never comes into contact with the radioactive source. No radioactive energy remains in the food after treatment.

Radiation is measured in kiloGrays (kGy). Technology allows for a precise dose to be measured. The doses permitted range from a maximum of 1 kGy for fruit and vegetables permitted to be irradiated, to 30 kGy for herbs and spices.

## 6 Safety of irradiated food

There is an extensive body of evidence demonstrating that the consumption of irradiated foodstuffs is safe for consumers. This evidence is detailed in the risk assessments prepared by FSANZ in relation to applications to permit irradiation of foods.

FSANZ assessed the safety of irradiated herbs, spices and herbal infusions in 2001 for the following purposes:

* sprout inhibition
* disinfestation
* decontamination
* control of weeds[[5]](#footnote-6).

The maximum doses for herbal infusions and herbs/spices were 10 kGy and 30 kGy, respectively, for bacterial decontamination. The scientific risk assessment concluded that the irradiated foods were safe to consume.

FSANZ has assessed the technological need, safety and nutrient profile of various fruits and vegetables irradiated for phytosanitary purposes. These assessments were conducted in:

* 2002 for breadfruit, carambola, custard apple, litchi, longan, mango, mangosteen, papaya and rambutan[[6]](#footnote-7)
* 2011 for persimmons[[7]](#footnote-8)
* 2013 for tomatoes and capsicums[[8]](#footnote-9), and
* 2014 for apple, apricot, cherry, nectarine, peach, plum, honeydew, rockmelon, scallopini[[9]](#footnote-10), strawberry, table grape and zucchini (courgette)[[10]](#footnote-11).

For each of these assessments, FSANZ concluded that there was an established need to irradiate these foods and that there were no public health and safety issues associated with their consumption when irradiated up to a maximum dose of 1 kGy. Refer to Table 2 in Section 4 for the current permissions in the Code.

Most recently FSANZ has approved permission to irradiate blueberries and raspberries for phytosanitary purposes against fruit flies and other regulated insect pests.[[11]](#footnote-12)

### 6.1 Key studies on the safety of irradiated foods

The safety of irradiated foods has been extensively examined in both long-term animal-feeding studies, including studies of up to 90 days’ duration with 35 different varieties of irradiated foods, and in studies in humans.

Research has shown that food irradiation is safe and effective. The process has been examined thoroughly by the European Community Scientific Committee for Food (SCF 1986) and the United States Food and Drug Administration (US FDA 1986).

The World Health Organization (WHO) has also examined, in detail, the safety and nutritional adequacy of irradiated foods and produced two extensive reports (WHO 1994, WHO 1999).

An FAO/IAEA/WHO expert committee examined the wholesomeness, safety and nutritional adequacy of irradiated food (WHO 1999). It concluded that:

*Food irradiated to any dose appropriate to achieve the intended technological objective is both safe to consume and nutritionally adequate. This conclusion is based on extensive scientific evidence that this preservation process can be used effectively to eliminate spores of proteolytic strains of Clostridium botulinum and all spoilage micro-organisms, that it does not compromise the nutritional value of foods, and that it does not result in any toxicological hazard.*

A 1999 WHO monograph on food irradiation prepared by the Joint FAO/IAEA/WHO Study Group evaluated an extensive database of long-term feeding studies conducted in laboratory animals (rats, mice, dogs, quails, hamsters, chickens, pigs and monkeys). These studies tested a range of foods that would have contained radiolytic compounds both naturally occurring and potentially unique to irradiated food (refer to the next section for a more detailed discussion on radiolytic compounds). For example, 22 studies of at least two years’ duration were conducted in rats, with many more studies conducted over shorter durations. In mice, 12 studies ranging up to two years were conducted, while long-term dog studies were conducted for 2−4 years. These studies found no evidence to indicate that the consumption of irradiated food is carcinogenic or caused any other adverse effects.

Consistent with these long-term bioassays, the weight-of-evidence from an extensive battery of *in vitro* and *in vivo* genotoxicity assays indicated that irradiated foods are not mutagenic.

### 6.2 Compounds generated following the irradiation of food

There are some compounds generated during the irradiation of foods. These are known as radiolytic compounds and include free radicals, various hydrocarbons, formaldehyde, amines, furan and 2-alkylcyclobutanones (2-ACBs). It is important to note that the majority of these compounds are not unique to irradiated food and are present naturally at low levels in food or are generated via other processing treatments (like heat).

FSANZ has previously evaluated a number of irradiated foods (specifically fruits and vegetables) with respect to the safety of food irradiation in general and specifically the potential hazard of radiolytic compounds generated by irradiation.

The conclusions of these risk assessments are that the formation of these compounds does not pose any public health and safety issues for consumers, including any genotoxic potential or increased risk of carcinogenicity.

For example, in relation to FSANZ’s recent assessment of an application seeking permission to irradiate blueberries and raspberries (Application A1115), furan has either not been detected, or detected at only low levels in a range of other fruits irradiated at 5 kGy (five times higher than the maximum dose sought in this application) and it is likely that furan levels are undetectable in blueberries and raspberries irradiated at doses up to 1 kGy. Furan is found in many non-irradiated foods (such as coffee and jarred baby foods) as a processing contaminant.

Based on the available evidence FSANZ concluded that there are no toxicological concerns resulting from the formation of new radiolytic products following irradiation. Irradiated food is considered equivalent to non-irradiated food that has been treated with more conventional treatment protocols (e.g. heating for quarantine purposes) with respect to safety, nutritional properties and wholesomeness.

### 6.3 Nutritional impacts of irradiated foods

A relatively small number of nutrients are sensitive to irradiation, with higher doses associated with greater nutritional loss. Nutrient loss can be minimised by the use of appropriate processing techniques, such as low temperatures and oxygen free conditions – but these conditions are not always practicable.

There has been no demonstrated effect of irradiation up to 1 kGy on the amount and nutritional quality of carbohydrates, proteins or fats and no evidence to suggest, or reason to think, that irradiation reduces the mineral content of food. There is a general hierarchy of vitamin sensitivity to irradiation, with vitamins A, C, E and thiamine being the most sensitive.

As fruits and vegetables are the predominant dietary sources of vitamin A (as carotene) as well as vitamin C, the major studies examining the effects of irradiation on fruit and vegetable quality have focussed on these nutrients.

In 2014[[12]](#footnote-13) FSANZ published a review of the impact of phytosanitary doses of irradiation on a wide range of fruits and vegetables. This review showed that phytosanitary doses of irradiation had no effect on carotene levels; did not decrease vitamin C in the majority of fruits and vegetables and had little effect on other non-vitamin bioactive compounds.

In some cultivars of some fruits, vitamin C levels decreased following irradiation. However, in the majority of these cases the vitamin C content of irradiated fruit remained within the range of natural variation. In addition, when the effects of these changes were assessed using dietary consumption patterns it was evident that these changes were unlikely to impact on dietary vitamin C intakes in Australia and New Zealand.

### 6.4 Irradiated cat food

Whilst all studies have shown the safety of foods for humans when irradiated according to recommended levels, there has been an issue relating to irradiated food and a neurological disorder in cats.

In 2008-09, there were reports that certain imported pet food products may have been responsible for the death of several cats. A research study has confirmed that irradiated cat food can result in neurological signs (hind limb ataxia) and accompanying histopathological lesions.

In November 2008 Champion Pet foods announced a voluntary recall of ‘Orijen’ brand dry cat food sold in Australia. The recall was only for Australia and was issued in response to reports from the Australian veterinary community of a number of cats showing neurological symptoms after consuming the cat food.

The cats showing disease were from different localities and had a wide age range. There were also substantial variations in the dietary history of the animals. Twenty one cats were euthanased because of the severity of the disease. After removal of the irradiated diet, 22 cats showed clinical improvement and seven recovered completely.

It is important to note that cats are quite sensitive with respect to a number of nutrients, including vitamin A. Cats are not able to synthesise their own vitamin A from carotene precursors – they require preformed vitamin A in their diet. They also have a high dietary fat requirement and specialised amino acid requirements.

FSANZ has assessed the study in cats and agrees that there is a body of evidence associating high-dose irradiation of dried pet food and the development of a chronic neurological syndrome in cats. However, the Australian Veterinary Association, Biosecurity Australia and FSANZ believe that this is a cat-specific effect. Pet food is not regulated in the Code.

### 6.5 International guidance on the safe use of irradiation

The 1983 Codex standard for irradiated foods (revised 2003)[[13]](#footnote-14) requires that the maximum absorbed dose for a food should not exceed 10 kGy, except when necessary to achieve a legitimate technological purpose. 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.*

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.

Further, fruit fly is not established in New Zealand and growers rely on other post-harvest disinfestation options to control other regulated insect pests. FSANZ understands that New Zealand currently has no interest in using irradiation as a treatment, but may consider it if conditions changed (e.g. if fruit fly became established and there were no other appropriate treatment options).

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1. Volume data for Australia sourced from Steritech and Department of Agriculture and Water Resources. [↑](#footnote-ref-2)
2. Volume data for Australian imported produce sourced from Steritech, and other imported produce sourced from New Zealand Ministry for Primary Industries. [↑](#footnote-ref-3)
3. Foods that are sterilized by irradiation are exposed to substantially higher levels of treatment than those approved for general use. [↑](#footnote-ref-4)
4. Note that Caesium137 is not approved as a source of ionising radiation for food in Australia and New Zealand [↑](#footnote-ref-5)
5. <http://www.foodstandards.gov.au/code/applications/Pages/applicationa413irradiationofherbsandspices/Default.aspx> [↑](#footnote-ref-6)
6. <http://www.foodstandards.gov.au/code/applications/pages/applicationa443irradiationoftropicalfruit/a443farexecsummary.aspx> [↑](#footnote-ref-7)
7. <http://www.foodstandards.gov.au/code/applications/Pages/applicationa1038irra4655.aspx> [↑](#footnote-ref-8)
8. <http://www.foodstandards.gov.au/code/applications/Pages/applicationa1069irra5511.aspx> [↑](#footnote-ref-9)
9. Scallopini and zucchini (courgette) are members of the summer squash family [↑](#footnote-ref-10)
10. <http://www.foodstandards.gov.au/code/applications/Pages/A1092-Irradiation.aspx> [↑](#footnote-ref-11)
11. <http://www.foodstandards.gov.au/code/applications/Pages/A1115IrradiationBlueberriesandRaspberries.aspx> [↑](#footnote-ref-12)
12. <http://www.foodstandards.gov.au/publications/Pages/Nutritional-impact-of-phytosanitary-irradiation-of-fruits-and-vegetables.aspx> [↑](#footnote-ref-13)
13. <http://www.codexalimentarius.net/download/standards/16/CXS_106e.pdf> [↑](#footnote-ref-14)