

Supporting Document 2

Risk and technical assessment report – Application A1092

Irradiation of Specific Fruits & Vegetables

Summary

FSANZ has previously assessed the potential toxicological hazard and nutritional adequacy of various irradiated tropical fruits, persimmons, tomatoes and capsicums, and concluded that there are no public health and safety issues associated with their consumption when irradiated up to a maximum dose of 1 Kilogray (kGy).

There is an established technological (phytosanitary) need to irradiate a range of fruits as a quarantine measure for the control of fruit fly and other insect pests within the dose range of 150 Gy to 1 kGy.

The purpose of this risk assessment was to determine if specific fruits irradiated up to 1 kGy are as safe as non-irradiated fruits.

There are negligible risks to public health and safety associated with the consumption of the specified fruits which have been irradiated up to a maximum dose of 1 kGy. This conclusion is based on the following considerations:

- Compounds potentially formed during food irradiation, such as 2-alkylcyclobutanones (2-ACBs), are found naturally in non-irradiated food. There is a low potential to generate 2-ACBs because of the low lipid content of the specified fruits.
- Furan, a volatile genotoxic carcinogen in experimental animals, was detected at low levels in grapes irradiated at 5 kGy (5 times higher than the maximum dose requested in this application), but not in other fruits (Limit of Quantitation=1 ppb). No data was available for fruit irradiated at 1 kGy but the amount of furan present would be expected to be lower. Dietary surveys in Europe show that many non-irradiated foods contain furans at levels comparable to grapes irradiated at 5 kGy.
- Available data indicate that the carbohydrate, fat, protein and mineral content of foods are unaffected by irradiation at doses up to 1 kGy.
- For irradiated and non-irradiated fruit the differences in vitamin concentrations, including vitamin C, are generally within the range of natural variation that normally occurs with different cultivars, seasons, growing conditions and post-harvest storage and processing.
- The safety of irradiated food has been extensively assessed by national regulators and international scientific bodies. The weight of scientific opinion is that irradiated food is safe for consumption when irradiated at doses necessary to achieve the intended technological function and in accordance with good irradiation practice

- There is a history of safe consumption of irradiated food in many countries.
- Adverse effects reported in cats and dogs following exclusive consumption of specific brands of pet foods irradiated at 50 kGy are unlikely to be relevant for humans.

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1 Introduction

Food Standards Australia New Zealand (FSANZ) received an Application from the Queensland Department of Agriculture, Fisheries and Forestry (DAFF) to permit the irradiation of the following fruits and fruiting vegetables¹, as a phytosanitary measure:

- Apple (*Malus domestica*)
- Apricot (*Prunus armeniaca*)
- Cherry (*Prunus avium*)
- Honeydew (*Cucumis melo*)
- Nectarine (*Prunus persica* var. *nectarina*)
- Peach (*Prunus persica*)
- Plum (*Prunus domestica*)
- Rockmelon (*Cucumis melo*)
- Strawberry (*Fragaria x ananassa*)
- Table grape (*Vitis vinifera*)
- Zucchini (courgette²) and scallopini / summer squash (*Cucurbita pepo*).

Zucchini (courgette³) and scallopini are all members of the summer squash family. The Applicant has indicated that the edible portions of zucchini (courgette) /scallopini are botanically fruits, but are usually classed as vegetables in nutritional tables. In the *Australia New Zealand Food Standards Code* (the Code), they are classified as fruiting vegetables, cucurbits in Schedule 4 of Standard 1.4.2 – Maximum Residue Limits. However, due to the common usage of the word ‘vegetable’, in this document, zucchini (courgette) and scallopini are referred to as vegetables. .

Approval for an irradiation dose of up to 1000 Gray (1 kGy) is sought.

Standard 1.5.3 – Irradiation of Food prohibits the sale of irradiated foods unless the food is listed in the Standard. A pre-market assessment is required before irradiated fruits and vegetables can be sold in Australia or New Zealand.

FSANZ has previously undertaken risk assessments of irradiation of herbs, spices and herbal infusions, a range of tropical fruits, persimmons, tomatoes and capsicums (Applications A413, A443, A1038 and A1069). These assessments concluded that there are no health and safety issues associated with the consumption of herbs and spices, and various tropical fruits and vegetables (breadfruit, carambola, custard apple, lychee (or litchi), longan, mango, mangosteen, papaya, persimmons, rambutan, tomatoes and capsicums), irradiated at 2-30 kGy and 150 Gy to 1 kGy, respectively, according to Good Manufacturing/Irradiation Practices (GMP and GRP, respectively) (FSANZ 2001, 2002, 2011 and 2013). The assessments also concluded that irradiation for these fruits and vegetables, herbs and spices is unlikely to have a significant impact on the nutrient intake of the Australian and New Zealand populations as the fruits and vegetables are minor contributors to the dietary intakes of nutrients when considered in the context of the total diet.

1.1 Objective of the Risk Assessment

The objective of this risk assessment was to assess the technological ((phytosanitary) need, safety, and nutrient adequacy of irradiation of specific fruits and vegetables for Australian and New Zealand consumers.

¹ Zucchini (courgette) and scallopini are classified as fruiting vegetables, cucurbits in Schedule 4 of Standard 1.4.2 Maximum Residue Limits.

² The names zucchini and courgette are used interchangeably

To meet the objectives of this risk assessment, the following key questions were posed:

1. Has the technological purpose for using irradiation as a quarantine measure for these fruits and vegetables been established?
2. Is the dose range requested by the Applicant consistent with quarantine requirements?
3. What is the risk to public health and safety for Australian and New Zealand consumers from any compounds formed following irradiation of the requested fruits and vegetables?
4. Does irradiation affect the nutrient composition of the requested fruits and vegetables?
5. If so, how does this compare to effects from other post-harvest and processing procedures?
6. Taking into account potential market share and trade of the irradiated fruits and vegetables in question, in both Australia and New Zealand, would any changes in the nutrient composition of these fruits and vegetables, following irradiation, have the potential to affect the nutritional adequacy of diets for Australian and New Zealand populations?
7. What are the combined cumulative nutritional effects on the nutritional adequacy of diets for Australian and New Zealand populations from irradiation of both the currently permitted irradiated foods and requested fruits and vegetables?

The Risk Assessment report is structured to address each of these questions:

- technological need assessment – which assessed whether irradiation at up to 1 kGy is effective as a phytosanitary measure and consistent with quarantine requirements (risk assessment questions 1 and 2)
- hazard assessment, which evaluated whether the irradiation of the specific fruits and vegetables at the proposed level could generate hazardous compounds (risk assessment question 3)
- nutrition assessment, which evaluated whether irradiation at the proposed level would significantly alter the nutritional composition of the specified fruits and vegetables, and examined the effect of other post-harvest and processing procedures on nutrient levels in the specific fruits and vegetables (risk assessment questions 4 and 5)
- dietary intake assessment, which examined whether there would be any nutritional disadvantages from consumption of irradiated specific fruits and vegetables (risk assessment questions 6 and 7).

Based on the hazard, nutrition and dietary intake assessment components, the risk to public health and safety has been characterised.

1.2 Risk Assessments by other agencies & scientific bodies

The safety of irradiated foods has been evaluated by regulatory agencies in other countries and international scientific bodies including the Joint FAO/IAEA/WHO Expert Committee on Food Irradiation (JECFI) (WHO 1977 & 1981), International Consultative Group on Food Irradiation (WHO 1994) and Study Group on High-Dose Irradiation (WHO 1999), Health Canada (2008) and the European Food Safety Authority (EFSA 2011a).

These reviews have examined the efficacy, safety and nutritional effects of irradiation on a wide range of foods. The weight of scientific opinion is that irradiated food is safe for consumption when irradiated at doses necessary to achieve the intended technological function and in accordance with good irradiation practice (GRP).

2 Technological (phytosanitary) need and quarantine requirements

2.1 Current status of food irradiation for phytosanitary purposes in Australia and New Zealand

To date, FSANZ has approved the irradiation of herbs, spices and herbal infusions, a range of tropical fruits (mango, breadfruit, carambola, custard apple, litchi, longan, mangosteen, papaya and rambutan), persimmons, tomatoes and capsicums. Specific advice on technological need and appropriate dose ranges for phytosanitary purposes was sought at that time from the then Biosecurity Australia (BA) (now the Australian Government Department of Agriculture) and MAF Biosecurity (now New Zealand Ministry for Primary Industries).

Examples of previous approvals by the Australian and New Zealand authorities of irradiation for quarantine purposes are as follows:

Commodity	Date	Purpose	Dose
Fresh mangoes imported from India (BA) ⁴	August 2008	Phytosanitary need for control of fruit flies, mealy bugs, red-banded mango caterpillar and mango weevils	400 Gy
Litchis exported from Australia (Biosecurity NZ) ⁵	September 2008	Control of Fruit fly and Hemiptera (bugs)	Minimum of 250 Gy
Mangoes and Papaya exported from Australia (Biosecurity NZ) ⁶	2004 and 2006, respectively	Control of Fruit fly and other insect pests	250 Gy
Tomatoes and capsicums exported from Australia to New Zealand (NZ Ministry for Primary Industries) ⁷	August 2011	Control of fruit fly	150 Gy to 1 kGy

⁴ http://www.daff.gov.au/_data/assets/pdf_file/0003/771906/Mangoes_from_India_Final_Report.pdf

⁵ <http://www.biosecurity.govt.nz/files/regs/imports/risk/aus-litchi-ra.pdf>

⁶ 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>

⁷ <http://www.biosecurity.govt.nz/files/ihs/capsicum-au.pdf> and <http://www.biosecurity.govt.nz/files/ihs/tomato-au.pdf>

In 2011, the use of irradiation for phytosanitary purposes for domestic trade was approved by all states and territories in Australia. This treatment is available to businesses under the national Interstate Certification Assurance (ICA) Scheme as Operational Procedure Number 55 (i.e. ICA 55⁸) and conforms to the principles of 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) that provides technical guidance on the specific procedures for the application of ionising radiation as a phytosanitary treatment for pests or articles.

ICA 55 also sets the minimum doses required as follows:

- 150 Gy for fruit flies of the family Tephritidae.
- 300 Gy for the mango seed weevil.
- 400 Gy for all pests of the class Insecta except pupae and adults of the order Lepidoptera.

2.2 International evidence to support irradiation against fruit flies and other regulated pests

Irradiation is 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 Gy to 1 kGy for prevention of the emergence of adult fruit flies for all fruits and vegetables. Further support for the efficacy of irradiation as a phytosanitary treatment for fruit fly exists in the US. In 2006, the US Animal and Plant Health Inspection Service (APHIS) approved generic irradiation doses of 150 Gy to reduce fruit fly infestation on specific fruits.

In this application, the minimum dose requested is 150 Gy, which is a generic treatment for fruit fly species. The proposed treatment range of 150 Gy minimum dose and 1 kGy maximum dose will comply with ISPM 18 and 28 requirements and is identical to the current levels approved for tropical fruits, persimmons, tomatoes and capsicums in Standard 1.5.3.

Currently, irradiation is an approved treatment to control quarantine pests in 17 fruits and seven vegetables for export from Hawaii to the USA mainland. There is also ongoing research to look at lower doses for phytosanitary needs, which will assist reducing costs, improving quality and increasing capacity due to shorter treatment times. As an example, the Mediterranean fruit fly is controlled in mandarins with a combination treatment of a radiation dose of 30 Gy and cold treatment (1 degree Celsius for 2 days (Follett and Weinart, 2012)).

2.3 Australian and New Zealand quarantine agencies' support for irradiation against fruit flies and other regulated pests

The Commonwealth Department of Agriculture (previously DAFF Biosecurity) has provided a letter of support indicating that irradiating fresh horticultural commodities at doses of 150 Gy to 1 kGy is an effective phytosanitary measure against fruit fly and other quarantine pests.

Similarly, the NZ Ministry for Primary Industries has recommended irradiation as an effective quarantine treatment for fruit fly and other pests of quarantine concern to New Zealand.

⁸ [www.daff.qld.gov.au/ data/assets/pdf file/0008/69578/ICA-55.pdf](http://www.daff.qld.gov.au/data/assets/pdf_file/0008/69578/ICA-55.pdf)

2.4 Conclusion

In summary, advice received by FSANZ from the relevant quarantine authorities is that irradiation of the fruits and vegetables in question for the purpose of pest disinfection would provide an effective alternative to currently used disinfection methods. The proposed minimum dose of 150 Gy and maximum dose of 1 kGy will provide a dose range in order for quarantine agencies to consider irradiation as a treatment for pest disinfection of the specified fruits and vegetables. FSANZ understands that irradiation is viewed as an important pest reduction protocol for acceptance of Australian produce for interstate trade and in other countries.

However, the Commonwealth Department of Agriculture and the NZ Ministry for Primary Industries will still need to independently perform an import risk assessment (for quarantine purposes) on irradiation of the fruits and vegetables in question, specifically for food imported into Australia or New Zealand. These assessments are separate from the approval processes in the food regulatory regime.

Response to Question 1: *Has the technological purpose for using irradiation as a quarantine measure for these fruits and vegetables been established?*

Yes. Irradiation is an internationally accepted quarantine measure for control of fruit fly and other insect pests.

Response to Question 2: *Is the dose range requested by the Applicant consistent with quarantine requirements?*

The dose range sought by the applicant (up to 1 kGy) is sufficient to meet domestic and international quarantine requirements.

3. Hazard assessment

3.1 Introduction

The scope of this hazard assessment was to evaluate supplementary data published since FSANZ's most recent evaluation of irradiated tomatoes and capsicums (in 2013)⁹ covering the safety of food irradiation in general, and specifically, the potential hazard of radiolytic compounds generated by the irradiation of the specified fruits and vegetables. The conclusion of this previous hazard assessment was that tomatoes and capsicums irradiated up to a maximum dose of 1 kGy are as safe to consume as non-irradiated tomatoes and capsicums on the basis of the following considerations:

- An evaluation of supplementary data published since 2002 raised no public health and safety issues associated with the consumption of irradiated foods.
- Compounds formed during food irradiation are found naturally in non-irradiated food.
- The safety of irradiated food has been extensively assessed by national regulators and international scientific bodies.
- The irradiation of a number of tropical fruits 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.
- There is a history of safe consumption of irradiated foods in many countries.

⁹ <http://www.foodstandards.gov.au/code/applications/Pages/applicationa1069irra5511.aspx>

3.2 Evaluation

3.2.1 Compounds generated in irradiated foods

There are a number of compounds that may be generated during the irradiation of food (so-called radiolytic compounds) including free radicals, various hydrocarbons, formaldehyde, amines, furan and 2-alkylcyclobutanones (2-ACBs) (Sommers et al 2007; Vranova & Ciesarova 2009). However, the majority of these compounds are not unique to irradiated food and are naturally present at low levels in food, or are generated via other processing treatments (e.g. thermal processing).

2-ACBs are considered to be uniquely formed during food irradiation. There has been an isolated report of 2-ACBs being detected in some non-irradiated foods such as cashews and nutmeg (Variyar et al 2008). However, this report has not been replicated in more recent studies, including one which used a newly developed and more sensitive analytical method for 2-ACBs (Chen et al 2012, Leung et al 2013).

FSANZ evaluated the genotoxic potential of 2-ACBs as part of the risk assessment prepared in relation to Applications A1038 (persimmons) and A1069 (tomatoes and capsicums). The weight-of-evidence indicated that 2-ACBs are not genotoxic, with numerous laboratory animal studies demonstrating that long-term consumption of irradiated foodstuffs (that would contain low concentrations of 2-ACBs and other radiolytic compounds) is safe. Further, independent evaluations conducted by the European Commission's (EC) Scientific Committee on Food (2002), the WHO (2003), Health Canada (2008) and the European Food Safety Authority (EFSA 2011b) have concluded that, based on the current scientific evidence, 2-ACBs in irradiated foods do not pose a health risk to consumers.

It is worth noting that the amount of 2-ACBs formed during irradiation is dependent on the lipid content of the food. The maximum total lipid content of the specified fruits and vegetables in this application is 0.4% fat (FSANZ 2010), which is very low and hence there is limited potential to generate 2-ACBs. Additionally, the total lipid content of the specified fruits and vegetables is lower than that of custard apple (0.6%) and comparable to that of rambutan (0.4%), capsicum (0.1-0.2%), tomato (0.1%), lychee (0.1%), mango (0.2%) and papaya (0.1%) (FSANZ 2010). These fruits have previously been assessed by FSANZ as safe for consumers when irradiated up to 1 kGy.

Furan, a volatile genotoxic carcinogen in experimental animals, can be formed at low concentrations in some thermally-processed and irradiated foods, and is derived predominantly from sugars (e.g. glucose, fructose and sucrose) and ascorbic acid (Fan 2005; Vranova & Ciesarova 2009). Fan and Sokorai (2008a) measured furan in freshly-cut fruits and vegetables that had been irradiated at 5 kGy (i.e. 5 times higher than the maximum dose requested in this application). No quantifiable furan was detected in irradiated or non-irradiated rockmelon or honeydew melon. Low levels of furans were identified in irradiated grapes (up to 3.6 ng/g), and furans were detected in irradiated apples and strawberries, but at a level below the limit of quantitation [(LOQ) = 1 ng/g].

The levels of furans detected in irradiated grapes were similar to levels that occur in heat-treated foods, such as jarred baby foods. In 2011, EFSA reported mean furan levels of 3-49 ng/g in baby foods. High furan levels are also found in coffee, with up to 106 ng/100mL in coffee made from roasted beans. The mean dietary furan exposure across several surveys in Europe was estimated to range between 30 and 590 ng/kg bw/day for adults, between 20 to 130 ng/kg bw/day for adolescents, between 40 and 220 ng/kg bw per day for other children, between 50 to 310 ng/kg bw/day for toddlers and between 90 and 220 ng/kg bw/day for infants (EFSA 2011c).

3.2.3 Supplementary data

A search of the scientific literature published since FSANZ's most recent evaluation of irradiated persimmons (i.e. from 2012 to May 2014) did not identify any relevant supplementary data on the safety of irradiated food or on the toxicity of 2-ACBs or other radiolytic compounds.

3.2.4 Other relevant safety matters

FSANZ is aware of publications and reports suggesting that irradiated pet foods are responsible for the development of adverse health effects in cats and dogs. Therefore, FSANZ has considered whether these reports raise any safety concerns of relevance to humans who consume irradiated foods.

FSANZ has previously considered reports of adverse neurological effects (leukoencephalomyelopathy) in specific pathogen-free cats associated with the exclusive consumption of dry feed that had been irradiated in the range of 26-54 kGy (Cassidy et al 2007; Caulfield et al 2009). While the exact aetiology of the leukoencephalomyelopathy remains to be determined, Caulfield et al (2009) suggested that the long-term, exclusive consumption of highly irradiated feed with a reduced Vitamin A content and a high peroxide content may have been responsible for the pathology.

Consumption of a specific brand of imported dry cat or dog food that had been irradiated at 50 kGy to comply with Australian Quarantine requirements also resulted in neurological effects in cats involving movement (ataxia) (Child et al 2009). The cause of the neurological effects for this one brand of dry pet food was not established, but dogs consuming the same dried food were unaffected. This product is no longer imported into Australia.

The levels of irradiation used for these dry pet food incidents are 25 to 50 times greater than that being proposed for irradiation of the current specified fruits and vegetables for phytosanitary purposes. At high doses of irradiation (25-50 kGy), Vitamin A was shown to be reduced (Caulfield et al 2009). Since this highly irradiated food was the sole source of nutrition for cats, a nutritional deficiency occurred. This situation is unlikely to be relevant for humans because a low level of irradiation (1 kGy) does not appreciably reduce vitamin levels and it is unlikely that the specified fruits and vegetables would ever be the sole dietary sources of the affected nutrients.

These two studies (Cassidy et al 2007; Caulfield et al 2009) were also reviewed by EFSA in 2011 as part of its updated hazard assessment on the safety of irradiated foods. While EFSA expressed some uncertainty about the relevance of the observations in cats to humans, and noted the need for additional data, it also noted the lack of a similar effect in dogs fed the same irradiated diet or from observations in rodents or humans. EFSA's overall conclusion was that the weight-of-evidence indicates that consumption of irradiated food is safe for humans.

FSANZ is also aware that the United States Food and Drug Administration (USFDA) is actively investigating the cause of illnesses reported in dogs which may be associated with the consumption of irradiated jerky pet treat products
<http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm360951.htm>.

These pet treat products are also irradiated up to 50 kGy to control microbes. To date, extensive testing by the USFDA has not identified a contaminant which could account for the pathology observed, but further testing is still underway.

More recently (24 January 2014) it was reported that two of the top-selling brands of jerky treats for pets returned to US store shelves, a year after the nationwide recall¹⁰.

FSANZ does not consider that these studies have implications for the safety of food irradiated at up to 1 kGy, and will continue to monitor any developments in this area and consider any related issues for irradiation of food for human consumption.

3.3 Conclusions

The specific fruits identified in A1092 irradiated up to a maximum dose of 1 kGy are as safe to consume as their non-irradiated counterparts on the basis of the following considerations:

- There is a low potential to generate 2-ACBs because of the low lipid content of this produce. The weight-of-evidence indicates that 2-ACBs are not genotoxic.
- Furan, a genotoxic carcinogen, was not detected in rockmelon or honeydew melons irradiated at 5 kGy, and only levels below the limit of quantitation were detected in strawberries and apples (<1 ppb) irradiated with 5 kGy. Low levels of furan (2–3.6 ng/g) were detected in grapes irradiated with 5 kGy, which is five-times higher than the maximum dose sought in this application. This level of furans is at the low end of the range commonly found in baby foods, while higher natural levels are found in coffee
- Adverse effects reported in cats and dogs following exclusive consumption of specific brands of irradiated pet foods are unlikely to be relevant for humans. Humans do not exclusively eat any fruit which has been irradiated at doses up to 50 times the levels required for quarantine purposes (up to 1 kGy) so potential vitamin deficiencies are unlikely to occur.

Response to Question 3: *What is the risk to public health and safety for Australian and New Zealand consumers from any compounds formed following irradiation of the requested fruits?*

Since no hazard has been identified following irradiation of food at 1 kGy, the risk posed by consuming irradiated fruits is considered to be negligible.

4. Nutrition Assessment

4.1 Previous FSANZ considerations of the effect of irradiation on nutrients in food

FSANZ has previously evaluated the effect of low-dose irradiation on the nutrient profile of various fruits in relation to Applications A443 (Irradiation of tropical fruits – breadfruit, carambola, custard apple, lychee, longan, mango, mangosteen, papaya and rambutan), A1038 (Irradiation of persimmons) and A1069 (Irradiation of tomatoes and capsicums). These evaluations concluded that the macronutrient and mineral content of these foods was unaffected by irradiation up to a dose of 1 kGy, although the concentrations of certain water soluble irradiation-sensitive vitamins (e.g. thiamin, vitamins C and E, and β -carotene) may potentially be reduced. However, any impact on vitamin content would be no greater than from other forms of food processing.

¹⁰ <http://www.dailyhealthheadlines.com/article/health-headlines/no-answers-jerky-treats-back-in-stores-as-pet-mystery-lingers>
http://www.pennlive.com/midstate/index.ssf/2014/01/pet_jerky_treats_returning_to.html

As the tropical fruits and persimmons are not widely consumed in Australia and New Zealand, they contribute minimally to total dietary vitamin intake and hence there are unlikely to be any nutritional disadvantages from consuming these irradiated fruits. Furthermore, despite the high consumption of tomatoes and capsicums it was concluded that even in a “worst case scenario” of vitamin C losses, the dietary intakes of vitamin C would remain adequate in the Australian and New Zealand populations.

In 2014, FSANZ published a literature review of the effects of phytosanitary irradiation (up to 1 kGy) on fruits and vegetables. The review considered the effects of irradiation on pome, stone, berry, citrus, tropical and other fruits, as well as cucurbit and fruiting vegetables. In addition, evidence for the extent of natural variation and the effects of processing on nutrient content of fruits and vegetables were reviewed. The review concluded that there was no effect of irradiation on macronutrient or mineral composition of fruits and vegetables. Carotenes and vitamin C were identified as the nutrients at risk of depletion in irradiated fruits and vegetables. No evidence of carotene depletion in fruits or vegetables irradiated with up to 1 kGy was identified. The effects of irradiation on vitamin C were variable; however the change in vitamin C levels following irradiation rarely exceeds the range of natural variation, or the changes associated with other processing techniques. Nevertheless, the review concluded that the effects of irradiation on vitamin C levels should be considered in assessing the nutritional impact of food irradiation (FSANZ 2014).

4.2 Evaluation

In this evaluation, the literature review of the effects of irradiation with up to 1 kGy on the vitamin C profile of these fruits and vegetables was updated, and data provided by the applicant considered.

4.2.1 Summary and update of the FSANZ literature review for specific fruits

The FSANZ literature review identified isolated published reports of irradiation-associated losses of vitamin C in apples, apricots and strawberries.

However, the levels of vitamin C in the irradiated fruits remained within the range of natural variation for non-irradiated fruit. In addition:

- the vitamin C levels in irradiated strawberries remained higher than the levels reported for frozen and canned strawberries
- The vitamin C levels in irradiated apples were higher than non-irradiated fruits after 6 months storage.

As part of the nutrition risk assessment, the published literature was searched for any recent, relevant publications. One publication was identified on the effects of irradiation on peaches. This study tested the effects of irradiation with 0.5 and 1.0 kGy either alone or in combination with 40°C or 60°C hot water treatment. Ascorbic acid was measured by titration before treatment and after one and two weeks. Ascorbic acid content decreased with time in both control, hot water treated and irradiated peaches. Ascorbic acid levels were similar or higher in irradiated peaches, irrespective of hot-water treatment, compared to non-irradiated peaches (Zaman 2013).

4.2.2 Unpublished studies

Unpublished data were provided by the Applicant on the effects of irradiation and storage on nutrient composition of the specified fruits included in this application. These data were made available to FSANZ during the writing of the literature review, and were incorporated into the analysis and interpretation.

A summary of the relevant literature reviewed by FSANZ for this application is presented in Table 2, alongside the applicant's data for vitamin C levels in the specified fruits and vegetables. The data provided by the applicant showed no significant effect of irradiation on vitamin C levels. Vitamin C levels in six of the 12 fruits and vegetables were detected at levels that were at or below the limit of quantitation (1mg/100g). These low values were not the result of analytical error which was checked with the use of spiked samples. The possible explanations for the low vitamin C levels include the effects of post-harvest handling of produce, cultivar differences, and environmental influences during production.

Table 2: Range of vitamin C (mg/100 g) content in specific fruits and vegetables associated with natural variation and irradiation

Fruit	Natural variation	Processing	Published data on fruits and vegetables irradiated with ≤ 1 kGy		Applicant data on irradiated fruits and vegetables			
			Control	Irradiated	Control	0.15 kGy	0.6 kGy	1.0 kGy
Apple	0.4-35	0-12	0.4-1.5	0.4-2.4	T1 ¹¹ : 0.9* T2: 0.7*	T1: 1.0* T2: 0.6*	T1: 0.8* T2: 0.5*	T1: 0.9* T2: 0.3*
Apricot	3-16	3-5	.4-5.5	.3-5.5	T1: 0.5* T2: 0.3*	T1: 0.5* T2: 0.2*	T1: 0.4* T2: 0.3*	T1: 0.5* T2: 0.3*
Cherry	7-25	Not available	7-20	10-19	T1: 0.8* T2: 0.5*	T1: 0.7* T2: 0.5*	T1: 0.5* T2: 0.3*	T1: 0.7* T2: 0.5*
Nectarine	4-14	Not available	Not available		T1: 1.4 T2: 4.4	T1: 1.7 T2: 5.6	T1: 2.0 T2: 6.0	T1: 2.0 T2: 6.3
Peach	4-13	1-10	8**-9	7-9	T1: 0.8* T2: 0.8*	T1: 0.8* T2: 0.6*	T1: 0.8* T2: 0.6*	T1: 0.9* T2: 0.5*
Plum	3-10	0-2	Not available		T1: 1.1* T2: 0.4*	T1: 1.2 T2: 0.3*	T1: 1.3 T2: 0.4*	T1: 0.8* T2: 0.3*
Honeydew melon	12-50	Not available	11-21	No adverse effect	T1: 12 T2: 13	T1: 17 T2: 7	T1: 15 T2: 9	T1: 14 T2: 13
Rockmelon	27-41	Not available			T1: 27 T2: 23	T1: 27 T2: 18	T1: 22 T2: 20	T1: 18 T2: 20
Strawberry	32-185	12-41	59-100	60-95	T1: 50 T2: 48	T1: 49 T2: 56	0.4 kGy T1: 49 T2: 46	T1: 48 T2: 51
Table grape	0-7	Not available	Not available [#]		T1: 1.4 T2: 1.0*	T1: 1.0* T2: 0.9*	T1: 1.3 T2: 0.8*	T1: 1.2 T2: 0.9*
Zucchini (courgette)	0-30	13-29	Not available		T1: 6.2 T2: 7.0	T1: 12.6 T2: 8.5	T1: 8.9 T2: 9.6	T1: 8.4 T2: 11.1

Note: the data sources for natural variation, processing and published data on irradiation can be found the FSANZ literature review "Nutritional impact of phytosanitary irradiation of fruits and vegetables" (FSANZ 2014). *values are at limit of reporting, **control peaches were spoiled at a later time-point. There was no difference in vitamin C levels at the same time-point.

[#]One study assessed the effects of 1 kGy irradiation in combination with heat treatment on table grapes.

4.3 Discussion and conclusion

The published literature indicates that irradiation up to 1 kGy does not reduce the nutritional quality of fruits and vegetables. Vitamin C levels can be diminished by irradiation, but the extent of diminution is generally similar to that produced by other post-harvest handling and processing. The data provided by the applicant found no significant change in vitamin C levels following irradiation, except those associated with storage which occurred in both irradiated and non-irradiated fruits and vegetables. In the assessment of the current application, there is no evidence to indicate that vitamin C levels in the specified irradiated fruits and vegetables would be lower than that found in comparable non-irradiated fruits and vegetables.

¹¹ Time 1 was one day after treatment and time 2 was between 7 and 50 days after treatment depending on the commodity.

Response to Question 4: *Does irradiation affect the nutrient composition of the requested fruits and vegetables?*

The applicant's data showed no significant change in vitamin C levels following irradiation with up to 1 kGy. In addition, published data show vitamin C levels remain within the range of natural variation following irradiation up to a maximum of 1 kGy.

Response to Question 5: *If so, how does this effect compare to effects from other post-harvest and processing procedures?*

Vitamin C levels were not significantly different between irradiated and non-irradiated fruits and vegetables.

5. Dietary intake assessment

Based on the literature review conclusions and recommendations, and considering the provided data, a full dietary assessment was not required. Specifically, as the levels of vitamin C in irradiated produce were within the range of natural variation, no risk to vitamin C intakes was identified.

Response to Question 6: *Taking into account potential market share and trade of the irradiated requested fruits and vegetables, in both Australia and New Zealand, would any changes in the nutrient composition of these fruits and vegetables, following irradiation, have the potential to affect the nutritional adequacy of diets for Australian and New Zealand populations?*

As the vitamin C content was within the range of natural variation there is minimal potential for consumption of irradiated fruits and vegetables to affect the nutritional adequacy of the Australian and New Zealand populations.

Response to Question 7: *What are the combined cumulative nutritional effects on the nutritional adequacy of diets for Australian and New Zealand populations from irradiation of both the currently permitted irradiated foods and requested fruits and vegetables?*

Vitamin C levels are similar between irradiated and non-irradiated fruits and vegetables and would therefore not contribute to any cumulative loss of vitamin C across the diet.

6. Risk characterisation

Irradiation of fruits and vegetables is an internationally-accepted means of disinfesting produce. For Australian produce, the critical pest for which irradiation is effective is the fruit fly. Irradiation doses below 1 kGy are sufficient to control fruit fly for quarantine purposes.

There are negligible food safety risks associated with the formation of radiolytic compounds in the specified fruits and vegetables. The low lipid content of the fruits and vegetables (0.4 g/100 g or less) means there is a low potential to generate 2-ACBs. Furan formation in the majority of the fruits and vegetables was not detected, with negligible levels in apples and strawberries. The low levels generated in table grapes are also unlikely to present a toxicological hazard.

Irradiated fruits and vegetables have been consumed in a number of countries, including the USA, for many years without any human health and safety issues being identified.

Data submitted by the Applicant on levels of a range of nutrients in the specified fruits and vegetables irradiated at doses up to and including 1 kGy, and at two storage times, showed no significant effects of irradiation on nutrient levels. The Applicant's data are the most relevant available to the consideration of this Application as they are generated from fruit and conditions comparable to those proposed in the current application.

Most vitamins are labile and levels in fresh produce are highly variable, due to a range of factors including cultivar, growing conditions, ripeness, storage time and post-harvest storage and handling. The documented effects of irradiation on vitamin levels are generally smaller than effects associated with other handling or processing steps, such as duration of storage, ripeness, heating, canning or freezing.

Of those vitamins potentially more affected by irradiation, vitamin C and vitamin A (from pro-vitamin A carotenoids such as β -carotene) are the only nutrients present in the specified fruits and vegetables at nutritionally relevant levels. The literature review conducted by FSANZ found β -carotene levels were not significantly reduced by irradiation. The unpublished data provided by the Applicant demonstrated no significant losses of vitamin C in irradiated fruits and vegetables, which was consistent with the published literature.

The nutrition assessment found no significant risk of adverse effects on nutrient composition of irradiated fruit. In combination with consideration of the dietary modelling undertaken in a previous assessment of tomatoes and capsicums (A1069), and the conclusions of the FSANZ literature review on the nutritional impacts of phytosanitary irradiation, it was determined that no further dietary modelling assessment was required.

Irradiation of apples, apricots, cherries, honeydew melons, nectarines, peaches, plums, rockmelons, scallopini, strawberries, table grapes and zucchini (courgette) at up to 1 kGy does not present a toxicological or nutritional safety concern.

7. References

Arvanitoyannis IS (2010) Irradiation of Food Commodities: Techniques, Applications, Detection, Legislation, Safety and Consumer Opinion. Elsevier.

Caulfield CD, Kelly JP, Jones BR, Worrall S, Conlon L, Palmer AC & Cassidy JP (2009) The experimental induction of leukoencephalomyelopathy in cats. *Vet. Pathol.* **46**: 1258-1269.

Cassidy JP, Caulfield C, Jones BR, Worall S, Conlon L, Palmer AC & Kelly J (2007) Leukoencephalomyelopathy in specific pathogen free cats. *Vet. Pathol.* **44**: 912-916.

Chen S, Tsutsumi T, Takatsuki S, Matsuda R, Kameya H, Nakajima M, Furuta M, Todoriki S (2012) Identification of 2-alkylcyclobutanones in nutmeg (*Myristica fragrans*) *Food Chemistry* **134**: 359–365

Child G, Foster DJ, Fougere BJ, Milanc JM & Rozmanec M (2009) Ataxia and paralysis in cats in Australia associated with exposure to an imported gamma-irradiated commercial dry pet food. *Australian Veterinary Journal* **87**: 349–351

EC (2002) Statement of the Scientific Committee on Food on a Report on 2-alkylcyclobutanones. SCF/CS/NF/IRR/26 ADD 3 Final. http://ec.europa.eu/food/fs/sc/scf/out135_en.pdf

EFSA (2011a) Statement summarising the Conclusions and Recommendations from the Opinions on the Safety of Irradiation of Food adopted by the BIOHAZ and CEF Panels. *EFSA Journal* **9**(4):2107

EFSA (2011b) Scientific opinion on the chemical safety of irradiation of food. *EFSA Journal* **9**(4):1930

EFSA (2011c) Update on furan levels in food from monitoring years 2004-2010 and exposure assessment. *EFSA Journal* **9**(9):2347

Fan X (2005) Formation of furan from carbohydrates and ascorbic acid following exposure to ionizing radiation and thermal processing. *J. Agric. Food Chem.* **53**: 7826-7831.

Fan X & Sokorai KJ (2008a) Effect of ionizing radiation on furan formation in fresh-cut fruits and vegetables. *J. Food Sci.* **73**(2): C79-C83.

Fan X, Sokorai KJ (2008b) Retention of quality and nutritional value of 13 fresh-cut vegetables treated with low-dose radiation. *Journal of Food Science* **73**(7):S367–S372.

Follett PA and Weinart ED (2012) Phytosanitary irradiation of fresh tropical commodities in Hawaii: Generic treatments, commercial adoption and current issues. *Radiation Physics and Chemistry*, **81**: 1064-1067.

FSANZ (2001) Application A413 - Irradiation of Herbs and Spices.
<http://www.foodstandards.gov.au/foodstandards/applications/applicationa413irradiationofherbsandspices/index.cfm>

FSANZ (2002) A443 – Irradiation of tropical fruit.
<http://www.foodstandards.gov.au/foodstandards/applications/applicationa443irradiationoftropicalfruit/index.cfm>

FSANZ (2010) NUTTAB. Australian Food Composition Tables. Available online at <http://www.foodstandards.gov.au/consumerinformation/nuttab2010/>

FSANZ (2011) Application A 1038 – Irradiation of persimmons.
<http://www.foodstandards.gov.au/foodstandards/applications/applicationa1038irra4655.cfm>

[FSANZ \(2013\) Application A1069 – Irradiation of tomatoes and capsicums.
http://www.foodstandards.gov.au/code/applications/Pages/applicationa1069irra5511.aspx](http://www.foodstandards.gov.au/code/applications/Pages/applicationa1069irra5511.aspx)

FSANZ (2014) Nutritional impact of phytosanitary irradiation of fruits and vegetables
<http://www.foodstandards.gov.au/publications/Pages/Nutritional-impact-of-phytosanitary-irradiation-of-fruits-and-vegetables.aspx>

Health Canada (2008) Evaluation of the significance of 2-dodecylcyclobutanone and other alkylcyclobutanones. Available online at <http://www.hc-sc.gc.ca/fn-an/secure/irradiation/cyclobutanone-eng.php>

IPPC (2003). International Plant Protection Convention. International Standards for Phytosanitary Measures, ISPM No. 18 Guidelines for the Use of Irradiation as a Phytosanitary Measure. Secretariat of the International Plant Protection Convention. Food and Agriculture Organisation of the UN, Rome, Italy, 2006. Accessed February 2012 at [https://www.ippc.int/index.php?id=1110798&tx_publication_pi1\[showUid\]=23881&frompage=13399&type=publication&subtype=&L=0#item](https://www.ippc.int/index.php?id=1110798&tx_publication_pi1[showUid]=23881&frompage=13399&type=publication&subtype=&L=0#item)

International Standards for Phytosanitary Measures, ISPM No. 28 Phytosanitary Treatments for Regulated Pests (2007), Secretariat of the International Plant Protection Convention. Food and Agriculture Organisation of the United Application to amend the Food Standards Code, Standard 1.5.3 - Irradiation of Food 87 Nations, Rome, Italy.

Leung EMK, Tang PNY, Ye Y, Chan W (2013) Analysis of 2-Alkylcyclobutanones in Cashew Nut, Nutmeg, Apricot Kernel, and Pine Nut Samples: Re-evaluating the Uniqueness of 2-Alkylcyclobutanones for Irradiated Food Identification. *J. Agric. Food Chem.* **61**: 9950–9954

Sommers CH, Delincée H, Smith JS & Marchioni E (2007) Toxicological Safety of Irradiated Foods. Chapter 4 in: Food Irradiation Research and Technology (eds CH Sommers & X Fan), Blackwell Publishing, Ames, Iowa, USA. doi: 10.1002/9780470277638.

Variyar PS, Chatterjee S, Sajilata MG, Singhal RS & Sharma A (2008) Natural existence of 2-alkylcyclobutanones. *Journal of Agriculture & Food Chemistry* **56**: 11817-11823.

Vranova J & Ciesarova (2009) Furan in food – a review. *Czech Journal of Food Science* **27**(1): 1-10.

WHO (1977) Wholesomeness of irradiated food. Joint FAO/IAEA/WHO Expert Committee on Food Irradiation. WHO Technical Report Series 604. FAO Food & Nutrition Series 6. WHO, Geneva.

WHO (1981) Wholesomeness of irradiated food. Joint FAO/IAEA/WHO Expert Committee on Food Irradiation. WHO Technical Report Series 659. WHO, Geneva.

WHO (1994) Safety and nutritional adequacy of irradiated food. Geneva.

WHO (1999) High-dose irradiation: Wholesomeness of food irradiated with doses above 10 kGy. Joint FAO/IAEA/WHO Study Group on High-Dose Irradiation. WHO Technical Report Series 890. Geneva.

WHO (2003) WHO statement on 2-dodecylcyclobutanone and related compounds. Available online at <http://www.cidrap.umn.edu/cidrap/files/32/who2003.pdf>

Zaman A, Ihsanullah I, Shah AA, Khattak TN, Gul S, Muhammadzai IU (2013) Combined effect of gamma irradiation and hot water dipping on the selected nutrients and shelf life of peach. *J Radioanal Nucl Chem* **298**: 1665–1672