

19 March 2013
[04-13]

Approval Report – Application A1069

Irradiation of Tomatoes & Capsicums

Food Standards Australia New Zealand (FSANZ) has assessed an application made by the Department of Agriculture, Fisheries and Forestry (DAFF) Queensland¹ to provide permission to irradiate tomato (*Lycopersicon esculentum*) and capsicum (*Capsicum annuum*) as a quarantine measure.

On 26 September 2012, FSANZ sought submissions on a draft variation to a standard and published an associated report. FSANZ received 62 submissions.

FSANZ approved the draft variation on 7 March 2013. The COAG Legislative and Governance Forum on Food Regulation² (Forum) was notified of FSANZ's decision on 18 March 2013

This report is provided pursuant to paragraph 33(1)(b) of the Food Standards Australia New Zealand Act 1991 (the FSANZ Act).

¹ Previously known as the Queensland Department of Employment, Economic Development and Innovation (DEEDI)

² Previously known as the Australia and New Zealand Food Regulation Ministerial Council

Table of Contents

1. EXECUTIVE SUMMARY	3
2. INTRODUCTION	4
2.1 THE APPLICANT	4
2.2 THE APPLICATION	4
2.3 THE CURRENT STANDARD	4
2.4 REASONS FOR ACCEPTING APPLICATION	4
2.5 PROCEDURE FOR ASSESSMENT	4
3. RISK ASSESSMENT.....	5
3.1. TECHNOLOGICAL NEED AND EFFICACY OF THE IRRADIATION PROCESS.....	5
3.2. SAFETY AND NUTRITIONAL CONTENT OF IRRADIATED FOODS.....	5
3.3 OTHER RELEVANT SAFETY MATTERS	6
4. SUMMARY OF SUBMISSIONS	6
5. RISK MANAGEMENT	25
6. RISK COMMUNICATION	26
7. DECISION	26
7.1 REASONS FOR DECISION.....	26
8. COST/BENEFIT ANALYSIS.....	27
8.1 OPTION 1 – APPROVE THE DRAFT VARIATION TO STANDARD 1.5.3	27
8.1.1 Consumers	27
8.1.2 Industry	28
8.1.3 Government.....	29
8.2 OPTION 2 – APPROVE THE DRAFT VARIATION TO STANDARD 1.5.3 SUBJECT TO SUCH AMENDMENTS AS CONSIDERED NECESSARY	29
8.3 OPTION 3 – REJECT THE DRAFT VARIATION TO STANDARD 1.5.3	29
8.3.1 Consumers	29
8.3.2 Industry	30
8.3.3 Government.....	30
9. ADDRESSING FSANZ’S OBJECTIVES FOR STANDARDS-SETTING	30
9.1 PROTECTION OF PUBLIC HEALTH AND SAFETY	30
9.2 THE PROVISION OF ADEQUATE INFORMATION RELATING TO FOOD TO ENABLE CONSUMERS TO MAKE INFORMED CHOICES 30	
9.3 THE PREVENTION OF MISLEADING OR DECEPTIVE CONDUCT.....	30
9.4 SUBSECTION 18(2) CONSIDERATIONS	30
10. IMPLEMENTATION.....	31
11. REFERENCES	31
ATTACHMENTS.....	32
ATTACHMENT A – APPROVED VARIATION TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE	33
ATTACHMENT B – EXPLANATORY STATEMENT.....	35

Supporting documents

The following documents which informed the assessment of this Application are available on the FSANZ website at <http://www.foodstandards.gov.au/foodstandards/applications/applicationa1069irra5511.cfm>.

- SD1 (Approval) Food irradiation in Australia, New Zealand and other countries
- SD2 (Approval) Risk and Technical Assessment Report

1. Executive summary

Food Standards Australia New Zealand (FSANZ) received an Application from the Department of Agriculture, Fisheries and Forestry (DAFF) Queensland³ in association with the New Zealand Fresh Produce Importers Association (NZFPIA) to permit the irradiation of tomatoes and capsicums as a phytosanitary measure. In the past, phytosanitary measures for tomatoes and capsicums have primarily involved the use of the chemicals dimethoate and/or fenthion. However, since the use of dimethoate and fenthion for this purpose has now been restricted, other options such as irradiation need to be considered.

FSANZ has reviewed the rationale for the Application and current scientific evidence on both the safety of irradiated tomatoes and capsicums and the effect of irradiation on their nutritional composition. Relevant quarantine agencies in Australia and New Zealand also provided advice on whether irradiation is a valid treatment for quarantine purposes for the disinfestation of tomatoes and capsicums. Permitting the irradiation of tomatoes and capsicums will allow increased domestic and international trade in tomatoes and capsicums as there are rigorous requirements in place for an appropriate and efficacious treatment for fruit fly for quarantine purposes.

The safety assessment concluded that irradiation of tomatoes and capsicums, as proposed, is unlikely to generate significant levels of radiolytic compounds. Furan was not detected following irradiation of tomatoes and capsicums at 5 kGy while 2-alkylcyclobutanones (2-ACBs) are not expected to be of concern because of the low lipid content of tomatoes and capsicums. Available data shows that irradiation at doses of up to 1 kGy does not affect carbohydrate, fat, protein and mineral content of tomatoes and capsicums. Data submitted for tomatoes and capsicum by the Applicant showed no discernible effect on levels of the measured vitamins (vitamins A & C and β -carotene) at doses up to 1 kGy.

Estimated mean dietary intakes of the irradiation-sensitive vitamins A and C remain above Estimated Average Requirements following irradiation of tomatoes and capsicum at doses up to 1 kGy, even for the worst case scenario (loss of 15% following irradiation of all fresh tomatoes, capsicums and tropical fruits (existing irradiation permissions)). Assessment of the combined cumulative nutritional effects of both the currently permitted irradiated foods and irradiated fresh tomatoes and capsicums on population intakes of vitamin A and C led to an estimated decrease of less than 2% for this scenario.

Sixty three submissions were received following the call for submissions and the issues raised have been addressed in the Approval Report. The issues raised did not cause FSANZ to change its conclusions or the draft variation. Based on data provided in the Application and information from other sources, consumption of irradiated tomatoes and capsicums is considered safe and nutritionally adequate for Australian and New Zealand consumers. Other irradiated foods have been assessed as safe via permissions and consumption in other countries and an FAO/IAEA/WHO expert committee (1999) concluded that that irradiated food is safe to consume and nutritionally adequate.

A decision has been made to approve the draft variation to Standard 1.5.3 to permit the irradiation of tomatoes and capsicums by adding tomatoes and capsicums to the Table to clause 4 in Standard 1.5.3 with a minimum dose of 150 Gray (Gy) and a maximum dose of 1 kGy.

³ Previously known as the Queensland Department of Employment, Economic Development and Innovation (DEEDI)

2. Introduction

2.1 The Applicant

The Application was made by DAFF Queensland in association with the NZFPIA. DAFF Queensland brings together specialist knowledge, networks and services to work with businesses and industry sectors to support economic development for the benefit of all Queenslanders. NZFPIA represents wholesalers, traders and retailers who import fresh produce, including fruit and vegetables, into New Zealand. NZFPIA's members rely heavily on Australian produce, in particular imports from Queensland, to meet the needs of New Zealand consumers.

2.2 The Application

The Application was made by DAFF Queensland on 15 March 2012 to amend Standard 1.5.3 – Irradiation of Food to permit the irradiation of tomatoes and capsicums as a phytosanitary measure⁴.

2.3 The current Standard

Standard 1.5.3 prohibits the sale of irradiated foods unless specifically permitted in the Standard. FSANZ is required to undertake a pre-market assessment before irradiated tomatoes and capsicums can be sold in Australia or New Zealand.

The former Australia and New Zealand Food Standards Council (composed of Health Ministers from the Commonwealth, states and territories and New Zealand)⁵ approved two applications to irradiate plant based foods: herbs, spices and herbal infusions (A413), a range of tropical fruits (mango, breadfruit, carambola, custard apple, litchi, longan, mangosteen, papaya and rambutan) (A443). More recently persimmons (A1038) were approved by the Australia and New Zealand Food Regulation Ministerial Council (ANZFRMC).

For further background information on current permissions and consumption of irradiated foods in a range of countries, current risk management of food irradiation in Australia and New Zealand and general information on consumer awareness, understanding and acceptance of food irradiation refer to **Supporting Document 1 (SD1)**.

2.4 Reasons for accepting Application

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2)
- it related to a matter that warranted the variation of a food regulatory measure.

2.5 Procedure for assessment

The Application was assessed under the General Procedure.

⁴ 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.

⁵ Now known as the COAG Legislative and Governance Forum on Food Regulation (The Forum)

3. Risk Assessment

Full details of the risk assessment prepared in relation to this Application are provided in **Supporting Document 2 (SD2)**.

FSANZ has previously assessed the technological need, safety and nutrient profile of various irradiated tropical fruits and persimmons. These assessments were conducted in 2002⁶ and 2011⁷, respectively. FSANZ concluded that there was an established need to irradiate tropical fruits and persimmons and that there were no public health and safety issues associated with their consumption when irradiated up to a maximum dose of 1 kGy.

The purpose of this risk assessment was to determine the technological need to irradiate tomatoes and capsicums and whether tomatoes and capsicums irradiated up to a maximum dose of 1 kGy are as safe and nutritious as non-irradiated tomatoes and capsicums. The risk assessment takes account of the previous considerations and includes an assessment of data on the safety of irradiated foods that has become available since the assessments conducted in 2002 and 2011.

The nutritional impact of irradiating tomatoes and capsicums has been considered by determining their nutrient profile and any changes in intake of radiation sensitive vitamins in Australia and New Zealand following irradiation.

3.1. Technological need and efficacy of the irradiation process

Disinfestation of tomatoes and capsicums by irradiation is a valid treatment for quarantine purposes and meets the requirements of a technological need (pest disinfestation) under the Standard. Insect pests of quarantine significance are a major barrier in gaining access to some markets. The International Plant Protection Convention (IPPC), Codex Alimentarius, quarantine agencies in Australia, New Zealand and the USA, endorse irradiation as a legitimate phytosanitary treatment.

Both Biosecurity Australia (now DAFF Biosecurity) and the NZ Ministry for Primary Industries (NZMPI) provided letters to FSANZ endorsing irradiation as an effective quarantine treatment for fruit fly and other pests that are of quarantine concern to Australia and New Zealand.

However, both DAFF Biosecurity and the NZMPI will still need to independently perform an import risk assessment (for quarantine purposes) on irradiation of tomatoes and capsicums, specifically for food imported into Australia or New Zealand. These assessments are separate from the food standards approval process.

3.2. Safety and nutritional content of irradiated foods

FSANZ has concluded that available studies indicate that irradiating tomatoes and capsicums does not pose a significant human health risk for Australian or New Zealand consumers due to the following reasons:

- No toxicological hazards have been identified with the use of food irradiation up to a maximum of 1 kGy.

⁶ <http://www.foodstandards.gov.au/srcfiles/A443%20FAR%20-%20Irradiation%20Tropical%20Fruit.pdf>
⁷ <http://www.foodstandards.gov.au/foodstandards/applications/applicationa1038irra4655.cfm>

- Differences in the levels of irradiation sensitive vitamins or provitamins (ie. vitamins A & C and β -carotene) in tomatoes and capsicums are within the range of the vitamin losses that normally occur during the storage or processing of non-irradiated fruit.
- Any potential effects of irradiation on vitamin levels are smaller than effects associated with other food handling or processing steps, such as cooking, drying, freezing, storage time and ripeness.
- Estimated mean dietary intakes of the irradiation-sensitive vitamins A and C following irradiation remain above Estimated Average Requirements even for the worst case scenario (loss of 15% following irradiation of fresh tomatoes, capsicums and tropical fruits (with existing irradiation permissions)).
- Assessment of the combined cumulative nutritional impacts of both the currently permitted irradiated foods and irradiated fresh tomatoes and capsicums on population intakes of vitamin A and C led to an estimated decrease of less than 2% for all scenarios.

3.3 Other relevant safety matters

FSANZ is aware of reports of adverse neurological effects (leukoencephalomyelopathy) in laboratory cats associated with the exclusive consumption of highly irradiated feed (~25-50 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 and high peroxide content may be responsible. FSANZ has previously discussed these findings in relation to Application A1038 – Irradiation of Persimmons concluding that the effects were cat-specific.

FSANZ is also aware that the US FDA is actively investigating the cause of illnesses in pets in association with the consumption of jerky pet treat products imported from China. While irradiation is being investigated as one of many potential causes, there is no evidence to date implicating irradiation as the causative agent. Further discussion of this issue is covered in Section 3.2.4 of SD2.

FSANZ has concluded that the safety of irradiated foods has been extensively examined in both long-term animal-feeding studies and in studies in humans (refer to Table 1). In addition, various regulatory authorities in other countries (e.g. the USFDA, Canada and European Union) approve the use of irradiation of specific foods following a safety assessment. Irradiated foods have also been consumed by humans in other countries without any known adverse effect (refer to section 2 of SD1). An FAO/IAEA/WHO expert committee examined the wholesomeness, safety and nutritional adequacy of irradiated food (WHO, 1999). The WHO (1999) concluded that food irradiated to any dose appropriate to achieve the intended technological objective is both safe to consume and nutritionally adequate.

4. Summary of submissions

Consultation is a key part of FSANZ's standards development process. FSANZ acknowledges the time taken by individuals and organisations to make submissions.

Every submission on an application or proposal is reviewed by FSANZ staff, who examine the issues identified and prepare a response. While not all comments can be taken on board during the process, they are valued and all contribute to the rigour of our assessment.

Public submissions were invited on a draft variation which was released for public comment between 26 September and 7 November 2012. Sixty three submissions were received; of which 32 were campaign letters opposed to irradiation.

Submitters' issues were addressed in Table 1.

Submissions in support of irradiation highlighted the following:

- Food irradiation is a safe and an effective technology against pests of quarantine concern, does not impact on food quality, leaves no chemical residues, is cost-competitive and consumer acceptance in New Zealand is high.
- Since the use of the pesticide dimethoate was restricted since October 2011, there has been no export of Australian tomatoes to New Zealand. Therefore, an alternative to dimethoate, such as irradiation, should be found immediately.

Other submitters, while supporting the approval of irradiated tomatoes and capsicums, suggested that FSANZ should have considered the following issues:

- An increase in the maximum energy level⁸ permitted in clause 3 (b) of Standard 1.5.3, consistent with other food safety regulators (these regulators were not identified).
- A generic approval of irradiation as a phytosanitary treatment for fruits and vegetables as has been done by Codex and the USFDA.
- Whether it is good policy that irradiated foods are required to be labelled, when other treatments (e.g. chemical) are not.
- A more adequate assessment of the costs to consumers, industry and the government of the requirement for labelling of irradiated tomatoes and capsicums should have been undertaken.
- An explanation why the application was deemed as deregulatory in nature, when there is a mandatory requirement to label irradiated foods.

Campaign letters were received from a range of consumers raising issues in relation to the safety of irradiated foods, the possibility of depletion of essential nutrients and that there is inadequate labeling of irradiated foods.

Submissions were also were received from:

- Physicians and Scientists for Global Responsibility
- Food Irradiation Watch (with support from Gene Ethics, MADGE, Friends of the Earth, GE Free NZ in Food and Environment, Food and Water Watch, Allergy, Sensitivity & Environmental Health Association Qld Inc, Green Party Aotearoa New Zealand, Soil & Health Association of NZ, and Safe Food Campaign)
- Food and Water Watch
- Horticulture New Zealand
- Green Party Aotearoa, New Zealand
- Sustainable Agriculture and Communities Alliance Inc.
- New Zealand Peasants Association.

⁸ The maximum energy level for x-rays generated by or from a machine source is set at 5 megaelectron volts

These submitters were all opposed to approval of irradiation of tomatoes and capsicums. FSANZ received no submissions from consumers who supported irradiation of tomatoes and capsicums.

An overview of submitters concerns is as follows:

Safety of irradiated foods

- Irradiation has not been proven as safe and numerous scientific studies have shown the potential health risks posed by irradiated food.
- Irradiation produces free radicals in food and has been linked to health problems such as nutritional deficiencies, immune system disorders, and genetic damage.
- There are no long-term studies on the safety of irradiated foods.
- FSANZ's scientific approach to the risk assessment of irradiated foods is not robust enough.
- The USFDA is now investigating whether irradiation is the cause of sickness and death in dogs in the USA, linked to irradiated chicken jerky treats. This suggests that the problem may not be unique to cats eating irradiated diets, as previously claimed. The risk to humans cannot be ruled out.
- Recent studies have shown new evidence of an allergenic effect from low doses of irradiation.
- Concerns that irradiation of fruits and vegetables that have had pesticides applied and then irradiated may produce toxic chemical pesticide residues in food.

Nutritional impacts of irradiated foods

- Plans to approve irradiation of further fruits and vegetables for irradiation will have a significant impact on the diets of Australian and New Zealand consumers. In particular, greater impacts on the nutrition and health of communities following Southern European diets for which tomatoes and capsicums are a larger part of their diet.
- Irradiation has been shown to deplete vitamin C, vitamin A, proteins, essential fatty acids and other nutrients in food. There could be a possible adverse cumulative effect on nutrition from eating a variety of irradiated foods.

Technological need

- There is no technological need to irradiate foods and numerous chemical free alternatives exist.
- FSANZ is making an assumption about the technical need for irradiation as a phytosanitary measure, without the expertise or even the jurisdiction to do so.

Labelling of irradiated foods

- Labelling requirements are weak and there is no way to visually distinguish between irradiated and non-irradiated foods. Therefore, consumers depend on the integrity and comprehensiveness of irradiation labelling.

- The Government has proposed a review of mandatory labelling with the aim of removing labelling requirements for irradiated foods.
- All irradiated food should be individually labelled “treated with radiation” or “irradiated.”

Cost/benefit analysis

- FSANZ has inflated the claimed benefits of approving A1069 while diminishing the impacts of the known hazards, risks and costs of irradiating tomatoes and capsicums. These are impacts that the whole community will bear.
- There have been inadequate assessments of (i) consumer resistance to irradiation which may have negative impacts on the market and share of sales of all tomatoes and capsicums; (ii) additional costs for growers not using irradiation to differentiate their products; (iii) additional costs for retailers to provide labelling at the point of sale; and (iv) additional costs for Government to enforce labelling requirements.

Consumers

- Despite FSANZ’s claim, there is no reliable and contemporary evidence that the Australian and New Zealand public are aware of, or will consent to, the widespread irradiation of the fresh fruit and vegetable supply.

General

- As there is no simple, reliable and affordable test for irradiated foods, it is difficult for state and local authorities to monitor them in the marketplace and to enforce the labelling requirements.
- There is a conflict of interest by the Queensland Government being both the applicant and one of the final arbiters of the decision on its own application.
- The Legislative and Governance Forum on Food Regulation (the Forum) has been derelict in its duty to canvass all potential management, chemical and technical replacement options to follow the final phase-out of fruit fly insecticides which have been under the Australian Pesticides and Veterinary Medicines Authority (APVMA) review since the mid-1990s because of their known toxicity to humans. A thorough process to review all fruit fly control options should precede any further approvals of food irradiation.
- No other countries expressly require or allow the irradiation of tomatoes and capsicums which FSANZ uses to strengthen the applicant’s case for approval.

Table 1: Issues raised in submissions

Abbreviations of submitters used in the Table

AFGC:	Australian Food and Grocery Council
BGGA:	Bowen Gumlu Growers Association Inc.
BFVG:	Bundaberg Fruit and Vegetables Growers
CONS:	Individual consumers opposed to irradiation of food. Includes campaign letters received by FSANZ opposed to approval of tomatoes and capsicums
DAFF:	Australian Department of Agriculture Fisheries and Forestry
FBI:	Food and Beverages Importers Association

FIW: Food Irradiation Watch with support from Gene Ethics, MADGE, Friends of the Earth, GE Free NZ in Food and Environment, Food and Water Watch, Allergy, Sensitivity & Environmental Health Association Qld Inc, Green Party Aotearoa New Zealand, Soil & Health Association of NZ (Organic NZ) and Safe Food Campaign

FoENZ: Friends of the Earth, New Zealand

FTAA: Food Technology Association of Australia

FWW: Food and Water Watch

GPANZ: The Green Party Aotearoa New Zealand

HAS: Horticultural Access Solutions

HNZ: Horticulture NZ

NZPA: New Zealand Peasants Association

MPINZ: Ministry for Primary Industries New Zealand

NZFGC: New Zealand Food and Grocery Council

NZFPPIA: New Zealand Fresh Produce Importers Association Inc.

PPL: Primor Produce Limited

PSGR: Physicians and Scientists for Global Responsibility

QH: Queensland Health

SACA: Sustainable Agriculture and Communities Alliance Inc.

SD: S&D Produce

STER: Steritech

VDPIH: Victorian Departments of Primary Industries and Health

Issue	Raised by	FSANZ Response (including any amendments to drafting)
Safety and nutritional adequacy of irradiated foods		
Irradiation is a safe and effective technology for use on pests of quarantine concern.	BGG STER DAFF FTAA NZFGC AFGC FBIA NZFP QH VDPIH MPINZ	No comment needed
Irradiation of food is unsafe, unique unsafe chemicals are produced in food following irradiation and there are no long-term studies on the safety of irradiated foods.	CONS FIW GPANZ FWW PSGR NZPA SACA FoENZ	<p>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 in relation to the current and previous irradiation applications. In addition, the range of current permission and consumption of irradiated foods (see section 2 of SD1).</p> <p>The formation of potentially novel compounds such as the 2-alkylcyclobutanones, or the production of increased concentrations of naturally-occurring compounds (e.g. furan, hydrocarbons) was considered as part of Application A1038 – Irradiation of persimmons. No supplementary published data was identified as part of the current application. 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.</p> <p>In response to the statement that there are no long term studies on the safety of irradiated foods, the 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. For example, 22 studies of at least 2 years duration were conducted in rats, with many more studies conducted over shorter durations. In mice, 12 studies ranging to 2 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.</p> <p>Consistent with these long-term bioassays, the weight-of-evidence from an extensive battery of <i>in vitro</i> and <i>in vitro</i> genotoxicity assays indicated that irradiated foods are not mutagenic.</p>

Issue	Raised by	FSANZ Response (including any amendments to drafting)
<p>The adverse neurological disorders in cats may not be cat-specific and is currently being investigated for death and illness in dogs in the US</p> <p>http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm319463.htm</p>	FIW	<p>FSANZ is aware that the USFDA is actively investigating the cause of illnesses reported in pets which may be associated with the consumption of jerky pet treat products</p> <p>FSANZ followed this issue up with the USFDA who responded that the USFDA is now expanding its testing to include irradiation by-products and is consulting with the National Aeronautics and Space Administration (NASA) experts to discuss this possibility further. To date, the USFDA does not have anything to link irradiation to the issue at this time. This information was added to SD2.</p> <p>In conclusion, serious health issues have been identified in dogs in the USA fed some batches of chicken jerky treats sourced from China. No problems have been found with treats from other sources and no differences have been found between the suspect treats and similar treats from other suppliers. The cause remains under investigation. Irradiation is being investigated as one of many potential causes but there is no evidence to hand implicating irradiation as the causative agent.</p>
<p>Recent studies have shown new evidence of an allergenic effect from low doses of irradiation</p> <p>http://www.sciencedirect.com/science/article/pii/S0278691512006849</p>	FIW	<p>The cited study by Vaz et al (2012) uses an experimental approach to induce mice to become immunologically responsive to a test protein (Con A). This experimental approach used by the investigators is not relevant to dietary exposure scenarios. Following irradiation of con A at either 1 or 25 kGy, some variation in immunologic markers was reported in mice but it should be noted that irradiation itself did not make con A allergenic. In fact, irradiation at the higher dose appeared to reduce the “allergenicity” and antinutritional properties of con A.</p> <p>The investigators also reported on the formation of insoluble amorphous aggregates and partially unfolded species following the irradiation of purified con A, suggesting some link with allergenicity potential. However, such a finding is not unique to irradiation and has already been described following the simple heating of Con A [Kudou et al 2004] Characterization of heat-induced aggregates of concanavalin A using fluorescent probes. Science and Technology of Advanced Materials 5:339-341.</p>

Issue	Raised by	FSANZ Response (including any amendments to drafting)
<p>FSANZ's scientific approach to the risk assessment of irradiated foods is not robust enough, the dietary exposure assessment was inadequate and FSANZ relied on unpublished pro-irradiation biased industry data.</p>	<p>FIW FWW</p>	<p>FSANZ's comprehensive search of the scientific literature did not identify any studies which revealed potential harmful effects from irradiated foods. The weight-of-evidence indicates that irradiated food is as safe as non-irradiated food when treated at doses necessary to achieve the intended technological function and in accordance with good radiation practice.</p> <p>The Applicant supplied the most up-to-date compositional studies on irradiated tomatoes and capsicums currently available and included data on key macronutrients, vitamins, minerals and fatty acids. FSANZ undertook a comprehensive assessment of that data (Refer to SD2) in conjunction with a review of published data (9 studies in total) on nutrient levels in irradiated tomatoes and capsicums.</p> <p>The weight-of-evidence of the existing database, plus data on the safety of irradiated foods that has become available since the FSANZ assessment conducted in 2002, indicated that there were no new public health or safety considerations that need to be addressed as part of the current Application.</p>
<p>Concerns over the irradiation of fruits and vegetables that have had pesticides applied and then irradiated.</p>	<p>FIW PSGR</p>	<p>There has been previous research undertaken into the effects of irradiation on agricultural chemical residues by the USFDA when they approved the irradiation of fruit and vegetables for disinfestation of pests up to a maximum dose of 1 kGy.</p> <p>Due to the minimal agricultural residues present in food and the low doses of irradiation (1 kGy) used on fruits and vegetables, there is a limited scope for a by-product of irradiation (referred to as a radiolytic product) to be produced. Moreover, if radiolytic products were formed they are more likely to be appreciably less toxic than the parent compound. The USFDA concluded that the potential toxicity of each radiolytic product from a pesticide residue on foods that are irradiated would be negligible and that such residues do not pose a hazard to health.</p> <p>FSANZ agrees with the conclusion from the USFDA that there is negligible risk from consuming irradiated foods that may also have residues of agricultural chemicals present. FSANZ also notes that residues of agricultural chemicals are kept low by good agricultural practice (GAP), in-field management practices and maximum residue limits (MRLs) that are set for each chemical. These practices limit the levels of agricultural residues that are present in irradiated food.</p>

Issue	Raised by	FSANZ Response (including any amendments to drafting)
<p>Irradiation decreases nutrients in tomatoes and capsicums and there could be a possible adverse cumulative effect on nutrition from eating a variety of irradiated foods. In particular, greater impacts on the nutrition and health of Southern European communities for which tomatoes and capsicums are a larger part of their diet.</p>	<p>CONS FIW HNZ FWW PSGR SACA</p>	<p>Before approvals are granted, FSANZ undertakes a comprehensive review of the nutritional impacts on foods requested to be permitted to be irradiated. This issue has been addressed in section 3.2 and SD 2.</p> <p>During the assessment on tomatoes and capsicums, FSANZ thoroughly investigated the nutritional impacts from irradiation of tomatoes and capsicums, taking previous irradiation permissions into account. This assessment drew on consumption data for all communities in Australia and New Zealand, including southern Europeans. Given that no discernible effects of irradiation were found on levels of vitamin C and beta carotene in tomatoes and capsicums, people who eat large amounts of these foods would continue to receive nutritional benefits from eating them.</p> <p>For more information on assessment of the cumulative effects on nutrition of irradiated foods, refer to section 5 (Dietary Exposure Assessment) of SD2. FSANZ will continue to assess cumulative impacts on nutrition, if more foods are requested to be irradiated.</p>
<p>Irradiation is designed to extend the shelf life of produce and allow it to be sold well past a time when it would otherwise be unfit to eat, therefore further negatively impacting on nutritional quality</p>	<p>FIW</p>	<p>Irradiation of tomatoes and capsicums at up to 1 kGy is a phytosanitary measure, to allow produce to be sold in certain markets, and is not sufficient to markedly increase shelf life of fresh produce. As the risk assessment found there is no discernible impact on levels of key nutrients in tomatoes and capsicums, there is no evidence to suggest that there could be additional losses in nutritional quality.</p>
Standard 1.5.3		
<p>In regard to clause 3 (b) of Standard 1.5.3 other food safety regulators have approved an energy level not exceeding 7.5 mEv. FSANZ may wish to consider amending 3 (b).</p>	<p>HAS</p>	<p>An increase to the energy limit was not requested by the Applicant. The current energy limit in clause 3 (b) of 5 mEv was adopted into Standard 1.5.3 by FSANZ following the review on the safety and nutritional adequacy of irradiated foods by the World Health Organisation in 1994. The limit was set by the WHO as a precaution against the possible production of short-lived radioactive isotopes that may be formed in food irradiated with electrons or x-rays of sufficient high energy.</p>

Issue	Raised by	FSANZ Response (including any amendments to drafting)
Labelling and information		
<p>The cost to industry for labelling of irradiated foods has been recognised as a “voluntary” cost. AFGC would argue that the cost will not be voluntary if manufacturers only have access to produce that has been irradiated.</p>	AFGC	<p>The requirement to label irradiated foods is not an additional requirement proposed by this application; it is a mandatory requirement for all irradiated food products. Labelling changes therefore apply to the introduction of any new irradiation permissions.</p> <p>FSANZ acknowledges that there may be labelling costs for some food manufacturers that accompany the benefits from increased phytosanitary options for tomatoes and capsicums. However, the irradiation of tomatoes and capsicums, or the use of irradiated tomatoes and capsicum in manufacturing (involving mandatory labelling), will primarily be a business decision. Businesses will still be able to choose the technology that produces the greatest return from amongst a range of technologies that are available for their circumstances. This application does not limit or restrict other methods of phytosanitary treatment.</p>
<p>The cost to Government from enforcing labelling requirements on irradiated tomatoes and capsicums has not been included in the assessment.</p>	HNZ	<p>Enforcement costs and how they are dealt with by jurisdictions will vary. Most jurisdictions do not incur additional costs for each minor variation in labelling requirements.</p>
<p>The proposal and assessment have failed to address the fact that a significant proportion of tomatoes (especially) are consumed via the catering, restaurant and institutional channels. No consideration has been given as to how these consumers will be informed that the products they are being offered/are eating are irradiated.</p> <p>FSANZ needs to extend the labelling requirements to menus and other consumer information (such as websites) in this situation to ensure the provision of adequate information relating to food to enable consumers to make informed choices.</p>	HNZ	<p>Standard 1.2.1 – <i>Application of Labelling and Other Information Requirements</i> of the Code requires information to be provided on foods permitted to be treated with ionising radiation throughout the food supply chain to ensure the end user receives adequate information about that food. For example subclause 2(2)(i) of Standard 1.2.1 requires that all food for retail sale meets the labelling requirements of Standard 1.5.3.</p> <p>The term ‘food for retail sale’ applies to food that is sold to the public (for immediate consumption) from a restaurant or other catering establishment or institution. Where a label is not physically present on an unpackaged food (e.g. a restaurant meal), then the labelling requirements of Standard 1.5.3 can be provided in material that is displayed on or in connection with the food (e.g. a menu).</p>

Issue	Raised by	FSANZ Response (including any amendments to drafting)
<p>FSANZ may wish to consider whether it is good policy, or enables consumers to make informed purchase decisions, to only require consumer labelling for irradiation and not require equivalent labelling for insecticides, fumigants or thermal treatments.</p>	<p>HAS AFGC</p>	<p>Labelling requirements for irradiated food were introduced along with the pre-market approval system on the basis that consumers would be able to identify that a food had been treated with this new technology, and could make informed food choices accordingly. This rationale was established for irradiated food in 1988 by an Australian House of Representatives Standing Committee on Environment, Recreation and the Arts.</p> <p>FSANZ has been asked by the Legislative and Governance Forum on Food Regulation (Government Response to Recommendation 34 of the Review of Food Labelling Law and Policy (2011)) to review the need to continue mandatory labelling of irradiated food. This work is expected to commence in 2014.</p>
<p>Although Standard 1.5.3, Clause 6 (3) requires adjacent labelling of the irradiation treatment for loose or unpacked commodity, there is little or no observed adherence or enforcement to this requirement in the market place, as per tropical fruits that are permitted to be irradiated. Has FSANZ conducted market surveys to establish the relevance of this Clause?</p>	<p>FTAA</p>	<p>FSANZ is responsible for developing and maintaining the Code, whereas Australian state and territory jurisdictions and the New Zealand government are responsible for enforcing the Code. Consequently, this application cannot address matters relating to compliance with the labelling requirements for irradiated food.</p> <p>FSANZ notes that, in their submission, Steritech has advised that irradiated mangoes are being sold in New Zealand with labels identifying that they are irradiated, according to the requirements in Standard 1.5.3.</p>
<p>Labelling requirements are weak and there is no way to visually distinguish between irradiated and non-irradiated foods. Thus shoppers depend on the integrity and comprehensiveness of irradiation labelling</p> <p>All irradiated food should be individually labelled “treated with radiation” or “irradiated –</p>	<p>FIW FWW</p>	<p>All food labelling information must comply with the legibility requirements in Standard 1.2.9 – Legibility Requirements. Standard 1.2.9 requires that all food labels present information so that it is legible, prominent (such as to afford a distinct contrast to the background), and in English.</p> <p>Standard 1.5.3 already requires that the labels of irradiated food display a statement to the effect that the food has been treated with ionising radiation. FSANZ is not proposing to change this requirement in respect to the labelling of irradiated tomatoes and capsicums.</p> <p>FSANZ has recently viewed some examples of labelled stickers collected from supermarkets and provided by industry on individual fruits. This demonstrates that industry is labelling individual tropical fruits (e.g. mangoes) when exported to New Zealand. In some circumstances, labelling on the stickers also includes the optional Radura symbol.</p>
<p>Labelling of irradiated foods in Australia and New Zealand is under threat. The government has proposed a review of mandatory labelling with the aim of removing labelling requirements.</p>	<p>FIW</p>	<p>In their response to Recommendation 34 of the Review of Food Labelling Law and Policy, the Legislative and Governance Forum on Food Regulation have requested FSANZ review the need to continue the mandatory labelling requirements for irradiated food. FSANZ expects to commence this review in 2014. The review will not affect the requirements for irradiated food to be subject to a pre-market safety assessment.</p>

Issue	Raised by	FSANZ Response (including any amendments to drafting)
Technological need to irradiate tomatoes and capsicums		
<p>There is no technological need to irradiate foods and numerous chemical free alternatives exist. FSANZ is making an assumption about the technical need for irradiation as a phytosanitary measure, without the expertise or even the jurisdiction to do so. The fact that the Australian industry has known for some time about the probable loss of the dimethoate treatment option and has failed to establish other options should not be used to justify the approval of this treatment.</p>	<p>FIW GPANZ HNZ FWW PSGR SACA</p>	<p>This issue has been previously addressed in section 3.1 and SD2.</p> <p>FSANZ has been advised by the relevant quarantine authorities that irradiation is an internationally accepted quarantine measure for control of fruit fly and other insect pests and would provide an effective alternative to currently used disinfestation methods. It is currently considered by the quarantine agencies to be the preferred option to access markets in other countries.</p> <p>There is now a need for an effective and cost efficient alternative to the two commonly used insecticides (dimethoate and fenthion) on tomatoes and capsicums. Reviews of these chemicals by the APVMA have resulted in their use on tomatoes and capsicums being restricted, suspended or withdrawn.</p> <p>Permitting the irradiation of tomatoes and capsicums will allow domestic and international trade in tomatoes and capsicums to continue without disruption.</p> <p>FSANZ was advised that the required bilateral export-import phytosanitary systems and documentation frameworks (e.g. New Zealand import standards and bilateral quarantine arrangements) are already in place to include the irradiation treatment option for tomatoes and capsicums.</p> <p>However, both DAFF Biosecurity and the NZMPI will still need to independently perform an import risk assessment (for quarantine purposes) on irradiation of tomatoes and capsicums, specifically for food imported into Australia or New Zealand. These assessments are separate from the food standards approval process.</p>
<p>While MPI supports irradiation as a phytosanitary measure against pests, as noted in the documents, further import risk assessments for quarantine purposes are required. When developing an import health standard to enable entry to New Zealand it is necessary to risk assess all organisms. MPI aims to complete this work within the FSANZ timeframes allowed for this application.</p>	<p>MPINZ</p>	<p>FSANZ supports this approach and no further comment is needed.</p>

Issue	Raised by	FSANZ Response (including any amendments to drafting)
Cost benefit analysis		
<p>In the cost/benefit statement, FSANZ inflates the claimed benefits of approving A1069 while diminishing the impacts of the known hazards, risks and costs of irradiating tomatoes and capsicums, which are impacts that the whole community will bear.</p>	<p>FIW</p>	<p>FSANZ has concluded that there are no safety concerns from irradiating tomatoes and capsicums. Disinfestation of insects on tomatoes and capsicums by irradiation is a safe and valid treatment for quarantine purposes. Insect pests of quarantine significance represent a major barrier in gaining access to some markets. The international Plant Protection Convention (IPPC), Codex Alimentarius, quarantine agencies in Australia, New Zealand and the USA endorse irradiation as a legitimate phytosanitary treatment.</p> <p>FSANZ was clear in the Call for Submissions Report that a consideration of the costs and benefits of the regulatory options is not intended to be an exhaustive, quantitative economic analysis of the options and, in fact, most of the impacts that are considered cannot be assigned a dollar value. Rather, the assessment seeks to highlight the qualitative impacts relevant to each option.</p> <p>These impacts are deliberately limited to those involving broad areas such as trade, consumer information and compliance. Moreover, since the irradiation of tomatoes and capsicums is a voluntary business decision that food producers will make, such a course of action will only be taken if there are financial dividends accruing to them.</p>
<p>Query the following statement on page 14 of the Call for Submissions document:</p> <p>“A Regulation Impact Statement (RIS) was not required because the proposed variation to Standard 1.5.3 is likely to have a minor impact on business and individuals and is deemed to be a de-regulation.”</p> <p>The AFGC query how this measure is deemed to be a “de-regulation”.</p> <p>The application is to add permissions to an existing regulation; however, the use of irradiated produce adds regulation due to the requirement to label products which have been irradiated.</p>	<p>AFGC</p>	<p>This assessment was made by the Office of Best Practice Regulator (OBPR) not FSANZ. FSANZ is not in a position to quantify the costs of labelling. This would require a full Regulatory Impact Statement and submission of full costings of labelling by the Applicant or industry bodies such as the AFGC and NZFGC. This would be an unnecessary burden to the Applicant, delay finalisation of the application and was not required by the OBPR.</p> <p>FSANZ acknowledges that approval to irradiate tomatoes and capsicums is deregulatory for producers of tomatoes and capsicums but not for manufacturers of foods with irradiated ingredients (as labelling would be required). However, the mandatory labelling of irradiated tomatoes and capsicums is a cost that businesses will have to consider before adopting irradiation. Because this is a voluntary business decision that food producers will make, it will only be taken if there are financial dividends accruing to them.</p>

Issue	Raised by	FSANZ Response (including any amendments to drafting)
<p>The assessment of the potential negative impacts on industry is cursory and inadequate. For example, the impacts on industry in terms of a negative consumer response to irradiated product and potential market share loss has not been researched or assessed.</p> <p>There have been inadequate assessments of the following:</p> <ul style="list-style-type: none"> • consumer resistance to irradiation may have negative impacts on the market share of sales of all tomatoes and capsicums • additional costs for growers not using irradiation to differentiate their products. • additional costs for retailers to provide labelling at the point of sale • additional costs for Government to enforce labelling requirements. 	HNZ	<p>The Office of Best Practice Regulation (OBPR), in a letter to FSANZ dated 15 May 2012 (reference 13845), provided a standing exemption from the need to assess if a Regulation Impact Statement (RIS) was needed for applications seeking permission to irradiate foods. The proposed variation to the Code is considered minor and machinery in nature.</p> <p>Therefore, a consideration of the costs and benefits of the regulatory options is not intended to be an exhaustive, quantitative economic analysis of the options and, in fact, most of the impacts that are considered cannot be assigned a dollar value.</p> <p>Rather, the assessment seeks to highlight the qualitative impacts relevant to each option. These impacts are deliberately limited to those involving broad areas such as trade, consumer information and compliance.</p> <p>Since the irradiation of tomatoes and capsicums is a voluntary business decision that food producers will make, they will have to decide whether to source and use irradiated tomatoes and capsicums.</p>
Consumer acceptance		
<p>AUSVEG, the Australian vegetable industry body, undertook research into consumer attitudes to fruit flies and fruit fly treatments in 2012. This research was presented to industry in April / May 2012 and can be found at http://ausveg.businesscatalyst.com/md/Dimethoate%20and%20Fenthion%20Road%20Show/AUSVEG%20D%20F%20Road%20Show%20%20Market%20Research.pdf</p>	HAS	<p>FSANZ has reviewed the AUSVEG commissioned study, and notes that findings on consumer awareness, understanding and acceptance are generally consistent with those presented in the peer reviewed literature. As there is insufficient methodological detail in the presentation/report to assess the validity and reliability of the study these findings have not been added to SD1.</p>
<p>Categorisation of food irradiation as just another food technology as per Cox et al 2007 (in SD1) is dismissive and misleading. Comparisons of food irradiation with canning and pasteurisation are invalid.</p>	FIW	<p>FSANZ does not suggest that food irradiation is a similar technology to canning or pasteurisation. FSANZ does suggest, based on the existing literature, that the responses of consumers to new food technologies are broadly similar. As Cox et al 2007 highlights, pasteurisation was viewed with suspicion when it was first introduced.</p>

Issue	Raised by	FSANZ Response (including any amendments to drafting)
Concern that not enough detail on the study samples and methods in key quoted studies was provided.	FIW	Additional detail has been incorporated on the key studies (Gamble et al (2002) and TNS Social Research (2008) in SD1.
Concern about using studies from outside Australia and New Zealand, older studies and studies that use products other than tomatoes and capsicums.	FIW	FSANZ agrees that the extent of literature on Australian and New Zealand consumers' responses to food irradiation is limited. However, as there are consistencies in human responses to new food technologies, evidence from outside Australia, New Zealand and on other products is relevant and has been included.
In terms of the methodology and context of this review, the keyword and search strategies are not disclosed. Therefore there is no way for the public to assess the comprehensiveness or narrowness of the review.	FIW	FSANZ's review draws on the literature provided by the Applicant, supplemented through a targeted literature search to identify additional relevant studies. The following electronic abstracts and databases were interrogated: SocINDEX; PsychINFO; Nutrition Abstracts and Reviews; and Food Science and Technology Abstracts. Additionally FSANZ drew on a recently published Evidence Review of Public Attitudes to Emerging Food Technologies commissioned in 2009 by the UK FSA. Search terms were "food irradiation" and "consumer". The search was limited to peer reviewed articles. Abstracts were reviewed and articles selected for the review based on their relevance to consumer awareness, values and behavioural response to food irradiation.
<p>Despite FSANZ's claim, there is no reliable and contemporary evidence that the Australian and New Zealand public are aware of, or will consent to, the widespread irradiation of the fresh fruit and vegetable supply.</p> <p>The FSANZ review document appears to have a substantial bias towards a permissive approach to food irradiation, rather than a critical approach.</p>	FIW	<p>FSANZ agrees that the extant literature on Australian and New Zealand consumers' responses to food irradiation is limited. FSANZ has summarised the relevant research related to consumer awareness, understanding and acceptance of food irradiation in Appendix 1 of SD1.</p> <p>As demonstrated by markets in various nations consumers are willing to purchase food that has been irradiated. 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.</p> <p>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.</p>
FSANZ disregards the potential for irradiation to undermine consumer views of fresh produce as being very healthy and general patterns of fruit and vegetable consumption, since fruit is perceived as a part of a healthy eating pattern.	FIW HNZ	FSANZ agrees that fruit and vegetables are important components of a healthy diet and that Australians and New Zealanders need to eat more of them. The risk assessment in SD2 found no discernible effects of irradiation on the levels of the major vitamins present in tomatoes and capsicums. Therefore, there should be no concern about the nutritional quality of irradiated tomatoes and capsicums.

Issue	Raised by	FSANZ Response (including any amendments to drafting)
General		
<p>Supports approval to irradiate tomatoes and capsicums as a phytosanitary measure in an environment where fruit fly disinfestation options are decreasing. Permitting the irradiation of tomatoes and capsicums will allow domestic and international trade in tomatoes and capsicums to continue without disruption.</p> <p>Irradiation is technologically justified and no public health or safety concerns were identified. Potential effects on vitamin levels may be smaller than those typically due to processes such as cooking, drying, storage or ripening. The recent restriction on the use of dimethoate as a post-harvest treatment has significantly impacted on the 2012 export season for tomatoes and capsicums and has resulted in no trade at all from Australia to New Zealand.</p>	BGGA BFVG PPL VDPIH NZMPI NZFGC AFGC FBIA S&D NZFPI QH DAFF	No comment needed.
<p>Approval will allow DAFF to propose irradiation as an alternative treatment to chemical treatments with an aim to gain market access to New Zealand.</p> <p>DAFF recognises the proposed dose ranges as an effective treatment dose for pests of quarantine concern.</p> <p>Other treatments (heat, cold and fumigation) have the potential to damage fruits and lower the quality</p>	DAFF	No comment needed.

Issue	Raised by	FSANZ Response (including any amendments to drafting)
<p>FSANZ should consider a generic approval of irradiation as a phytosanitary treatment for fruits and vegetables as has been done by Codex and the US FDA.</p> <p>With the recent loss of dimethoate and fenthion as market access tools, measures such as irradiation with a generic approval for all fruit and vegetable commodities will greatly assist in supplying food to the consumer.</p> <p>The workload associated with submitting individual case-by-case applications is likely to become unmanageable and delay access to this treatment for those waiting for assessment.</p> <p>The use of a generic approach will not only speed up the application process but will greatly reduce the cost to industry that is currently required to fund the case-by-case nutrient analysis work and assessment processes. The available data covering a range of produce types shows that the irradiation treatment of fresh produce for phytosanitary purposes has no detrimental impacts in terms of quality, nutrient content, nutrient composition or other food safety concerns.</p> <p>There is no technological reason, or regulatory justification, for continuing with the commodity-by-commodity assessment approach</p>	<p>HAS DAFF BFVG PPL S&D NZFPI</p>	<p>Codex and the USFDA recognise all fresh fruit and vegetables that have been treated by irradiation for insect pests at dosages of up to 1 kGy (US) and 10 kGy (Codex) as safe and wholesome for human consumption.</p> <p>FSANZ is aware of this generic dose approval and sought clarification from the USFDA in regard to the process and assessment that the USFDA undertook before establishing this maximum dose, in particular, how the USFDA conducted its safety and nutrition assessment for all fruits and vegetables.</p> <p>However, from the information supplied by the USFDA, it appears that under the current risk assessment practices that FSANZ uses, that the nutritional risk assessment may not be rigorous enough to address whether the consumption of specific irradiated foods would lead to any major nutrient depletion for consumers in the context of the whole diet.</p> <p>However, an Applicant, with appropriate supporting data, can currently apply to FSANZ for consideration of a generic approval as a phytosanitary treatment for fruits and vegetables.</p> <p>FSANZ notes the comments about the impacts of assessing permissions for irradiated foods on a case-by-case basis and that both DAFF Biosecurity and the NZMPI will still need to independently perform an import risk assessment (for quarantine purposes) on irradiation of tomatoes and capsicums, specifically for food imported into Australia or New Zealand. These assessments are separate from the food standards approval process.</p> <p>FSANZ will continue to explore the feasibility of a generic approval for all fruit and vegetables for a recognised phytosanitary requirement, subject to appropriate data.</p>

Issue	Raised by	FSANZ Response (including any amendments to drafting)
It appears that the current detection methods can detect irradiated foods, to check labelling compliance, but there may be additional costs for enforcement agencies adopting and validating these methods. There may be additional costs auditing records at irradiation facilities.	QH	These have been included as possible costs in the regulatory impact section but no quantitative figures are available.
As there is no simple, reliable and affordable test for irradiated foods, it is difficult for state and local authorities to monitor them in the marketplace and to enforce the labelling requirements	FIW PSGR	It is correct that there is no internationally recognised single method of detection for irradiated foods; rather there are various methods (Refer to SD1). Current detection methods for irradiated food are able to detect whether a food has been irradiated or not, but cannot accurately measure absorbed doses. The control of the dose is managed by proper validation of the process prior to routine processing and is established and controlled by accurate dosimetry and maintenance of records by irradiation facilities under the existing State/Territory or New Zealand irradiation licensing requirements.
The Legislative and Governance Forum on Food Regulation (the Forum) and FSANZ have been derelict in their duty to protect the public health and safety by failing to facilitate the much earlier and timelier phase out of highly toxic dimethoate and fenthion in which fresh fruits and vegetables are now dipped to control fruit fly larvae.	FIW	This is a matter for Australian Pesticides and Veterinary Medicines Authority (APVMA) as reviews of these chemicals has resulted in their use on tomatoes and capsicums being restricted, suspended or withdrawn. FSANZ acts in accordance with identified public health and safety issues at all times. FSANZ has moved to remove the associated maximum residue limits for dimethoate and fenthion in foods when advised by the APVMA in a timely manner.
The Forum has been derelict in its duty to canvass all potential management, chemical and technical replacement options to follow the final phase-out of fruit fly insecticides which have been under APVMA review since the mid-1990s because of their known toxicity to humans. A thorough process to review all fruit fly control options should precede any further hasty approvals of food irradiation.	FIW	There is now a need for an effective and cost efficient alternative to the two commonly used insecticides (dimethoate and fenthion) on tomatoes and capsicums. FSANZ does not compare the effectiveness of irradiation against other treatments such as chemicals; heat/cold etc. These are matters for other regulatory agencies such as DAFF and NZMPI.

Issue	Raised by	FSANZ Response (including any amendments to drafting)
The Queensland government has a clear conflict of interest in being both the applicant for A1069 and one of the final arbiters of the decision on its own application. This conflict also now extends to other states, such as NSW and Victoria that have fruit fly infestations as a result of poor phytosanitary regulation, monitoring and controls, and climate change.	FIW	This is an issue for the COAG Legislative and Governance Forum on Food Regulation (The Forum) to consider.
There are further plans to seek approval to irradiate up to 16 more fruit and vegetables, including zucchinis, honey dew melons, rockmelons, nectarines, strawberries, cherries, apricots, plum, peaches, table grapes, and apples. These foods are regularly consumed by the Australian and New Zealand public and these proposals will have a significant impact on their diets.	FIW	FSANZ will assess the nutritional impacts of these irradiated foods on a case-by-case basis as per the requirements of Standard 1.5.3, taking into account existing irradiation permissions.
No other countries expressly require or allow the irradiation of tomatoes and capsicums, which FSANZ uses to strengthen the applicant's case for approval.	FIW	FSANZ notes that the USFDA has a generic approval for irradiation of all fruit and vegetables for a phytosanitary need. Codex also permits the use of irradiation on any food up to a recognised technological dose use level. Therefore, if needed, tomatoes and capsicums could be irradiated.
The application is market and industry driven and ignores the principles enshrined in Codex that the food must be safe.	CONS	FSANZ has followed the usual FSANZ approach in its risk assessment of Application A1069 that is based on the Codex Alimentarius process.
Many consumers choose to eat fresh produce due to the positive health benefits and the industry invests a substantial amount of funding to promote these. It is critical that this aspect of our industry is protected.	HNZ	FSANZ agrees but found no evidence in the studies submitted by DAFF Queensland that at the doses used, there would be reductions in quality of fresh produce.

As a result of consideration of the submissions, FSANZ assessed the following new safety issues:

- illnesses reported in pets which may be associated with the consumption of jerky pet treat products (that may have been irradiated)
- Recent studies on possible allergenic effects from low doses of irradiation.

FSANZ also considered other matters and issues raised by submitters on the technological need, labelling, cost-benefits, consumer perceptions and other general matters.

In summary, and after consideration of all the submissions, FSANZ concludes the following:

- Irradiated tomatoes and capsicums are safe and nutritionally adequate for Australian and New Zealand consumers.
- Disinfestation of tomatoes and capsicums by irradiation is a valid treatment for quarantine purposes.
- Mandatory labelling of irradiated foods is a requirement of Standard 1.5.3 and there is no need to require additional labelling of irradiated tomatoes and capsicums. FSANZ acknowledges that there may be labelling costs for some food manufacturers that accompany the benefits from increased phytosanitary options for tomatoes and capsicums.
- A consideration of the costs and benefits of the regulatory options is not an exhaustive, quantitative economic analysis of the options and, in fact, most of the impacts that are considered cannot be assigned a dollar value.
- The extent of the literature on Australian and New Zealand consumers' responses to food irradiation is limited and may contribute to perception of increased risk. Information and education may assist in addressing the information gap.
- The other general matters raised in submissions have been considered and addressed by FSANZ (refer to Table 1) or are outside of FSANZ's remit.

5. Risk management

Based on the risk assessment and consideration of other matters, FSANZ recommends that irradiation of tomatoes and capsicums be permitted for inclusion in the Standard with the following requirements:

- irradiation of tomatoes and capsicums is permitted only for the purposes of pest disinfestation for a phytosanitary objective
- the permitted dose range should be a minimum dose of 150 Gy and a maximum of 1 kGy
- the current mandatory labelling of irradiated foods and record keeping requirements do not require amending (Refer to section 3.1 of SD1).

Other matters, such as general exposure to radiation, damage to the environment and occupational health issues for radiation workers are outside FSANZ's mandate and are covered by other agencies' legislation such as controls imposed by the assessment of radiation licence applications (Refer to section 3.2 of SD1).

There are a range of internationally accepted methods of detection for irradiated foods that could be used for enforcement purposes (Refer to section 3.3 of SD1). The current detection methods for irradiated food are able to detect whether a food has been irradiated or not, but cannot accurately measure absorbed doses.

The control of the dose is managed by proper validation of the process prior to routine processing and is established and controlled by accurate dosimetry and maintenance of records by irradiation facilities under the existing State/Territory or New Zealand irradiation licensing requirements.

6. Risk communication

FSANZ developed and applied a basic communication strategy to this Application. The call for submissions was notified via the FSANZ Notification Circular, media release and through FSANZ's social media tools and the Food Standards News.

Subscribers and interested parties were also notified about the availability of reports for public comment.

The process by which FSANZ considers standard development matters is open, accountable, consultative and transparent. Public submissions were called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options.

7. Decision

The draft variation to Standard 1.5.3 as proposed following assessment was approved with a minor editorial change.

On 26 September 2012, FSANZ called for submissions on a draft variation to Standard 1.5.3 to include permission to irradiate tomatoes and capsicums. Following consultation, no change is proposed to the risk management response.

At approval, FSANZ corrected the alphabetical listing to the entry for capsicum in the Table to Clause 4 of Standard 1.5.3. Capsicum is now listed after breadfruit and before carambola. This is a minor editorial change and does not impact on any parties.

The draft variation to the Standard is at Attachment A and an Explanatory Statement is at Attachment B.

7.1 Reasons for decision

The draft variation to Standard 1.5.3 as proposed following assessment was approved with a minor editorial change on the basis of the available evidence and for the following reasons:

- Irradiation of tomatoes and capsicums is suitable for the purposes of pest disinfection for a phytosanitary objective.
- The safety assessment did not identify any public health and safety concerns associated with the irradiation of tomatoes and capsicums.
- Mandatory labelling of irradiated foods and record keeping requirements will apply to irradiated tomatoes and capsicums.

- There were no measures that would be more cost-effective than a variation to Standard 1.5.3 and could achieve the same end.

FSANZ had regard to the following matters under section 29 of the 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
- whether other measures (whether available to FSANZ or not) would be more cost-effective than a food regulatory measure developed or varied as a result of the Application
- any relevant New Zealand standards. Standard 1.5.3 applies to New Zealand. There are no New Zealand standards.
- any other relevant matters.

There are no other measures that could achieve the same result other than an amendment to Standard 1.5.3.

Standard 1.5.3 applies to New Zealand. There are no relevant New Zealand-only standards.

8. Cost/benefit analysis

In a letter dated 15 May 2012 (referenced 13845), the Office of Best Practice Regulation (OBPR) stated it has assessed that applications for permission relating to the voluntary irradiation of fruits and vegetables be treated as machinery in nature and as such do not require the preparation of a Regulation Impact Statement (RIS). Therefore, this section is limited to a qualitative assessment of the costs and benefits accruing from the voluntary adoption of irradiation treatment for tomatoes and capsicums.

After preparing a draft variation and the call for submissions, the FSANZ Act requires FSANZ to do one of the following in relation to the draft variation:

1. approve the draft variation circulated in the call for submissions;
2. approve that draft variation subject to such amendments as FSANZ considers necessary;
3. reject the draft variation.

FSANZ considered the following options:

1. approve a draft variation to Standard 1.5.3 to permit the use of irradiation on tomatoes and capsicums (Option 1)
2. approve that draft variation to Standard 1.5.3 subject to such amendments as considered necessary (Option 2)
3. reject the draft variation to Standard 1.5.3 (Option 3).

8.1 Option 1 – Approve the draft variation to Standard 1.5.3

8.1.1 Consumers

The following were identified as potential benefits for consumers:

- possibly greater year-round availability of tomatoes and capsicums in some markets/regions in Australia and New Zealand
- possibly better quality fruit depending on the dose of irradiation, as other treatments (such as heat and cold) can affect fruit quality
- produce may be transported for longer periods while maintaining desirable sensory qualities for consumers
- provides choice to consumers wanting to avoid exposure to other treatments such as chemicals
- approval of irradiated tomatoes and capsicums may increase competition in the marketplace, improve seasonal availability and increase price competition.

A potential cost to consumers is that irradiated tomatoes and capsicums may cost more than non-irradiated ones. Additionally, a further additional cost that could be passed on to consumers could arise due to the requirement for labelling of irradiated tomatoes or capsicums as required under clause 6 of Standard 1.5.3. This requirement may add to cost by way of the requirement to provide product labels and the provision of signage at the point of sale for unpackaged produce.

8.1.2 Industry

DAFF Queensland considers trade in tomatoes and capsicums to be at risk of market disruption should phytosanitary uses of insecticide treatments be withdrawn or restricted. The combined value of tomato and capsicum production in 2006–07 was estimated at approximately A\$420 million, of which the value of the Queensland produce was approximately A\$282 million.

Approximately 70% of Queensland production was sent to markets in Australia with restrictions against the introduction of fruit fly. In addition, tomatoes and capsicums (value approximately A\$11 million) were exported in 2006–07. Approximately 90% of these exports went to New Zealand where demand for Australian produce is strong in the winter and spring months.

The following were identified as potential benefits for industry:

- availability of an alternative internationally-endorsed phytosanitary measure when the current chemical-based treatments are restricted
- increased shelf life and quality of fruit, depending on the dose
- assistance and maintenance of the economic viability of an important segment of the horticulture sector
- increased trade opportunities and increased markets available to growers due to an alternative treatment being available to meet quarantine requirements - permission to irradiate could facilitate market access to New Zealand
- introduction of 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.

Where producers opt to voluntarily adopt irradiation of tomatoes or capsicums, they could incur costs associated with the initial establishment of an irradiation facility, as well as the ongoing treatment of produce. Because the decision to adopt irradiation is voluntary, food businesses would only adopt such a course of action if there are financial gains in it for them.

The following were identified as costs for industry:

- Initial set-up costs in establishing an irradiation facility including building and capital may be significant.
- Costs to industry of treatment and transport irradiated foods.
- In a situation where manufacturers may have access to both irradiated and non-irradiated produce at different times of the year, there will also be a cost for maintaining 2 different label stocks – one declaring the use of irradiated produce and one without. This potentially makes Australian products using such ingredients less competitive when compared to imported equivalent products that are not irradiated.
- There may be added cost in the supply chain due to the requirements to track, and possibly segregate, irradiated produce to ensure that labelling requirements are met.
- Potential cost in ascertaining consumer acceptance of irradiated tomatoes and capsicums.

However, businesses wishing to use irradiation will decide to do so based on commercial gains they hope to create e.g. by reducing their cost or extending market access.

8.1.3 Government

The following were identified as benefits for Government:

- additional pest disinfestation treatment which may facilitate trade when some methods are not accepted or are being phased out e.g. some chemical treatments.
- possible enhanced economic development in rural and regional Australia.

State, territory and New Zealand government agencies may incur costs associated with the enforcing labelling requirements for irradiated tomatoes and capsicums. Such costs and how they are dealt with by jurisdictions will vary. It is suggested that for most jurisdictions, additional costs are not incurred for each minor variation in labelling requirements.

There may be additional costs for enforcement agencies adopting and validating methods to detect irradiated foods. There may be additional costs auditing records at irradiation facilities. However, no quantitative figures on these specific costs were available.

8.2 Option 2 – Approve the draft variation to Standard 1.5.3 subject to such amendments as considered necessary

Following consultation, as there was no change to the risk management response there are no impacts on consumers, industry or the government to consider.

8.3 Option 3 – Reject the draft variation to Standard 1.5.3

8.3.1 Consumers

There could be a benefit to consumers who prefer not to consume irradiated foods, due to a belief that such foods are potentially unsafe and/or nutritionally inadequate or that there is no technological justification to irradiate foods. However, irradiated food is required to be labelled, so consumers wishing to avoid it will be able to do so.

A potential cost to consumers was identified as the possible limitation of the supply of tomatoes and capsicums due to the phase out of chemicals that normally reduce fruit fly disinfestation. If there was not an efficacious alternative treatment, such as irradiation, there is a strong possibility that the tomato and capsicum supplies will decrease and prices may increase. It is also possible that vitamin intakes will reduce unless tomatoes and capsicums can be replaced with cheaper produce items of comparable nutrient content.

8.3.2 Industry

No benefits to industry were identified.

The following were identified as costs for industry:

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

8.3.3 Government

There are no benefits to Governments in maintaining a prohibition. No costs were identified, although lack of approval may be regarded as unnecessarily trade restrictive.

9. Addressing FSANZ's objectives for standards-setting

FSANZ has considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment of this Application as follows.

9.1 Protection of public health and safety

FSANZ concludes that approving irradiation of tomatoes and capsicums at a minimum dose of 150 Gy and a maximum of 1 kGy does not pose a significant human health risk for Australian or New Zealand consumers.

9.2 The provision of adequate information relating to food to enable consumers to make informed choices

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.

9.3 The prevention of misleading or deceptive conduct

No issues identified.

9.4 Subsection 18(2) considerations

FSANZ has also had regard to the objectives set out in subsection 18(2):

- the need for standards to be based on risk analysis using the best available scientific evidence

FSANZ has previously assessed and characterised the risk from consumption of irradiated foods. Collectively, these risk assessments have considered all available information (national and international), including animal toxicity and nutrition data, relevant to the safety of irradiated foods.

FSANZ evaluated the scientific literature published since previous assessments and concluded that there were no new publications indicating a potential for safety concerns in any population group consuming irradiated foods.

- the promotion of consistency between domestic and international food standards

Approval to irradiate tomatoes and capsicums will promote consistency with other countries that approve the irradiation of fruits and vegetables for a phytosanitary purpose. It also aligns with the Codex General Standard for Irradiated Foods which sets a maximum absorbed dose of 10 kGy. No specific foods are mentioned, although the Codex standard states that:

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.

- the desirability of an efficient and internationally competitive food industry

Approval of irradiation of tomatoes and capsicums may increase the international competitiveness of Australian and New Zealand growers gaining access to overseas markets for their produce, and it is also supportive of trans-Tasman trade.

- the promotion of fair trading in food

Not applicable.

- any written policy guidelines formulated by the Ministerial Council⁹.

No Policy Guideline is applicable.

10. Implementation

The variation will take effect on gazettal.

11. References

Cassidy et al (2007) Leukoencephalomyelopathy in specific pathogen-free cats. *Vet. Pathol* **44**: 912-916.

Caulfield CD et al (2009) The experimental induction of leukoencephalomyelopathy in cats. *Vet. Pathol.* **46**: 1258-1269.

European Food Safety Authority (2011) Scientific opinion on the chemical safety of irradiation of food. *EFSA Journal* **2011**;9(4). <http://www.efsa.europa.eu/en/efsajournal/pub/1930.htm>

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.

⁹ Now known as the COAG Legislative and Governance Forum on Food Regulation

Attachments

- A. Approved variation to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement

Attachment A – Approved variation to the Australia New Zealand Food Standards Code



Food Standards (Application A1069 – Irradiation of Tomatoes and Capsicums) Variation

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

Dated XXXX

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

1 Name

This instrument is the *Food Standards (Application A1069 – Irradiation of Tomatoes and Capsicums) Variation*.

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

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

3 Commencement

The variation commences **on the date of gazettal**.

SCHEDULE

[1] Standard 1.5.3 is varied by –

[1.1] omitting from the Table to clause 4 “Bread fruit” and substituting

“Bread fruit
Capsicum”

[1.2] omitting from the Table to clause 4 “Rambutan” and substituting

“Rambutan
Tomato”

Attachment B – Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

FSANZ accepted Application A1069 which seeks to permit the irradiation of tomatoes and capsicums as a phytosanitary measure¹⁰. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation to Standard 1.5.3.

Following consideration by COAG Legislative and Governance Forum on Food Regulation¹¹, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislative Instruments Act 2003*.

2. Purpose and operation

Tomatoes and capsicums are currently not permitted to be irradiated in Standard 1.5.3. The Authority has approved a draft variation to Standard 1.5.3 to include tomatoes and capsicums in the Table to clause 4. The variation in Standard 1.5.3 will permit irradiation of tomatoes and capsicums for the purpose of pest disinfestation for a phytosanitary objective in the Table to clause 4 of Standard 1.5.3.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1069 has included one round of public consultation following an assessment and the preparation of a draft variation to the Standard. A report (which included the draft variation) was released on 26 September 2012 for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variation to Standard 1.5.3 is likely to have a minor impact on business and individuals and is deemed to be a de-regulation.

¹⁰ 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.

¹¹ Previously known as the Australia and New Zealand Food Regulation Ministerial Council

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variations

The variation permits the irradiation of tomatoes and capsicums for the purpose of pest disinfestation for a phytosanitary objective by adding tomatoes and capsicums to the Table to clause 4 in Standard 1.5.3 with a minimum dose of 150 Gy and a maximum dose of 1 kGy.