

16 December 2014 [26–14]

Approval Report – Application A1092

Irradiation of Specific Fruits & Vegetables

Food Standards Australia New Zealand (FSANZ) has assessed an application made by the Queensland Department of Agriculture, Fisheries and Forestry to irradiate apple, apricot, cherry, nectarine, peach, plum, honeydew, rockmelon, scallopini¹, strawberry, table grape and zucchini (courgette) for phytosanitary purposes.

On 28 August 2014, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received forty six submissions.

FSANZ approved the draft variation on 4 December 2014. The Australia and New Zealand Ministerial Forum on Food Regulation² (Forum) was notified of FSANZ's decision on 15 December 2014.

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

¹ Scallopini and zucchini (courgette) are members of the summer squash family

² convening as the Australia and New Zealand Food Regulation Ministerial Council

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Supporting documents

The following documents which informed the assessment of this Application are available on the FSANZ website at <u>http://www.foodstandards.gov.au/code/applications/Pages/A1092-Irradiation.aspx</u>

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

Executive summary

Food Standards Australia New Zealand (FSANZ) received an Application from the Queensland Department of Agriculture, Fisheries and Forestry to seek permission to irradiate apple, apricot, cherry, nectarine, peach, plum, honeydew, rockmelon, scallopini, strawberry, table grape, zucchini (courgette) for phytosanitary purposes. The same dose ranges (150 Gy to 1 kGy) and conditions (including mandatory labelling) as currently prescribed for other produce in the *Australia New Zealand Food Standards Code* (the Code) were requested.

FSANZ has reviewed the rationale for the Application and current scientific evidence on the safety of irradiated fruits and vegetables and the effect of irradiation on their nutritional composition.

Relevant quarantine agencies in Australia and New Zealand confirmed in their advice that irradiation is a valid treatment for quarantine purposes for the disinfestation of these fruits and vegetables. Permitting the irradiation of these fruits and vegetables will allow increased domestic and international trade as there are rigorous requirements in place for an appropriate and effective treatment for fruit fly for quarantine purposes. In the past, phytosanitary measures for these foods have primarily involved the use of the chemicals dimethoate and/or fenthion. However, since the use of dimethoate and fenthion for this purpose has been restricted, other options such as irradiation need to be considered.

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-alkylcyclobutanones (2-ACBs). Furan formation in the majority of the fruits and vegetables was not detected, with negligible levels in apples and strawberries. Low furan levels were detected in table grapes only but these levels are unlikely to present a toxicological hazard.

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 attributable to irradiation. 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.

Forty four submissions were received following the Call for Submissions and the issues raised have been addressed in the Approval Report. Based on data provided in the Application and information from other sources, consumption of irradiated fruits and vegetables is considered safe and nutritionally adequate for Australian and New Zealand consumers. Other irradiated foods have been assessed as safe through permissions and consumption in other countries and previous World Health Organization (WHO) expert committees (1994 and 1999) concluded 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 these fruits and vegetables by adding them 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. The mandatory requirements for labelling of irradiated foods will apply to allow for informed consumer choice.

1 Introduction

1.1 The Applicant

The Application was made by the Queensland Department of Agriculture, Fisheries and Forestry (QLD DAFF).

1.2 The Application

The Application was lodged on 25 October 2013. It sought to amend Standard 1.5.3 – Irradiated Foods to provide for the safe use of irradiation as a phytosanitary measure³ for apple, apricot, cherry, honeydew, nectarine, peach, plum, rockmelon, scallopini, strawberry, table grape and zucchini (courgette).

Zucchini (courgette⁴) and scallopini are members of the summer squash family. FSANZ clarified with the Applicant that they were seeking permissions to irradiate both scallopini and zucchini (courgette) and the general reference to summer squash in their application referred to both commodities. The Applicant indicated that the edible portions of zucchini/scallopini are botanically fruits, but are usually classed as vegetables in nutritional tables. In the Code, they are classified as fruiting vegetables, cucurbits in Schedule 4 of Standard 1.4.2 – Maximum Residue Limits. However, to prevent any confusion zucchini (courgette) and scallopini will be referred to as vegetables.

These fruits and vegetables are potential hosts to fruit flies and other pests. The Queensland fruit fly is considered one of the world's worst pests of fruiting crops and is listed as a pest requiring treatment by most international and interstate markets trading in the movement of fresh fruit.

The minimum dose requested for phytosanitary purposes is 150 Gray and the maximum 1 Kilogray (kGy). These doses are commensurate with dose ranges approved for quarantine purposes of other fruits and vegetables in the Code and in other countries.

1.3 The current Standard

Standard 1.5.3 prohibits the sale of irradiated foods unless permitted in the Standard. FSANZ is required to undertake a pre-market assessment before irradiated fruits and vegetables can be sold in Australia or New Zealand. There are currently permissions for irradiation of herbs, spices and herbal infusions; a range of tropical fruits (mango, breadfruit, carambola, custard apple, litchi, longan, mangosteen, papaya and rambutan); persimmons and tomatoes and capsicums.

Under Standard 1.5.3, irradiation facilities must keep records of the irradiation treatment. The Standard also requires that the label on a package of irradiated food or food containing irradiated ingredients or components include a statement to the effect that the food, ingredient or component has been treated with ionising radiation. Food containing irradiated food as an ingredient or component must include this statement either as part of the declaration of that ingredient or component in the ingredient list, or elsewhere on the label. Standard 1.5.3 also requires irradiated food, or a food containing an irradiated food as an ingredient or component, which is sold unpackaged, including ready to eat foods,

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

⁴ The names zucchini and courgette are used interchangeably

to display on or in connection with the food a statement that the food has been treated with ionising radiation.

While the use of a labelling statement is mandatory for irradiated food, FSANZ notes that the international Radura symbol⁵ could be used voluntarily in addition to the mandatory labelling requirements.

For more information on current permissions and consumption of irradiated foods in a range of countries, current requirements for 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)**.

1.4 Reasons for accepting the 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.

1.5 **Procedure for assessment**

The Application was assessed under the General Procedure.

2 Summary of the findings

2.1 Summary of issues raised in submissions

Public submissions were invited on a draft variation which was released for public comment from 28 August to 9 October 2014.

Forty-four submissions were received, plus two submissions received after the closing date. Thirty-one of these supported the proposed draft variation to the Code, whilst 14 did not support the draft variation and one submitter was non-committal. Some of the submitters who did support the draft variation indicated that this was based on the application of the labelling of irradiated foods in order to provide informed choice for consumers.

Submitters in support indicated that food irradiation is a safe and effective treatment for disinfestation of fruit fly and other pests of quarantine concern. Approval of the requested foods will allow enhanced access to Australian domestic markets and open up international markets. One submitter suggested that because of the extent of the safety data-base on irradiated foods that it is now appropriate that FSANZ considers fast tracking of future applications and considers a generic approval approach for food irradiation of fruits and vegetables for phytosanitary treatment purposes.

In contrast, submitters opposed to irradiation suggested that there is no technological need to irradiate foods as other alternatives exist. They also raised issues in relation to the safety of irradiated foods, the possibility of depletion of essential nutrients, inadequate or poorly enforced labelling requirements, the adequacy of the cost-benefit analysis and other general issues some of which are outside of FSANZ's remit.

Submitters' issues are addressed in Table 1.

⁵ The Radura is the international symbol indicating a food product has been irradiated.

Table 1: Summary of issues

Issue	Raised by	FSANZ response
The technological need for irradiation of the requested fruits and vegetables has not been established and there are numerous alternatives.	Individual consumers Food Irradiation Watch (supported by Gene Ethics, Friends of the Earth, MADGE, GM-Free Australia Alliance)	 This issue was addressed in the Call for Submissions Report and in SD2. Food irradiation is an additional tool that can be used as a phytosanitary measure to alleviate pests such as fruit fly. There is now a need for an effective and cost efficient alternative to the two commonly used insecticides (dimethoate and fenthion) on specific fruits and vegetables. Reviews of these chemicals by the APVMA have resulted in their use being restricted, suspended or withdrawn. 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. FSANZ also notes that industry has advised that while other options exist many of these are unsuitable for use in the fresh market due to potential phytotoxicity and quality issues, and require approval from quarantine authorities. There are costs and time delays associated with getting such approvals. However, both the Australian Department of Agriculture and the New Zealand Ministry for Primary Industry (NZMPI) will still need to independently perform an import risk assessment (for quarantine purposes) on irradiation of these fruits and vegetables specifically for food imported into Australia or New Zealand. These assessments are separate from the food standards approval process.
Support the application as these approvals will allow all producers, exporters and supply chain operatives enhanced access to Australian domestic markets under the ICA- 55 protocol ⁶ , as well as export markets, and that Irradiation provides an efficacious and sustainable additional post – harvest disinfestation option.	Fruit growers Tasmania Inc. Sunray Strawberries Fruits of Byron Low Chill Australia Ltd AusVeg Harrosmiths international Barkers Nutrafruit Apple and Pear Australia Ltd Cherry Growers Australia	FSANZ notes the support and specific reasons for approval of the requested fruits and vegetables. Furthermore, in regard to New Zealand, FSANZ was advised by one submitter 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 irradiation as a treatment option for many of the requested commodities.

⁶ www.daff.qld.gov.au/ data/assets/pdf_file/0008/69578/ICA-55.pdf

Issue	Raised by	FSANZ response
Irradiation is an effective, reliable and	INC.	
sustainable tool to manage fruit fly which is	Sunny Ridge Strawberry	
critical to the economic future of the	Farm	
horticulture industry and other pests of	Bowen Gumlu Growers	
quarantine concern.	Association	
Will provide another option to ensure fruit is	Queensland Strawberry	
free of fruit fly and reduce the use of	Growers Association	
chemicals (pre and post-harvest) on fruits	Victorian Departments of	
and vegetables, while maintaining quality	Environment and Primary	
and shelf-life of produce.	Industries (DEPI) and	
	Health (DH)	
Postharvest options other than irradiation do	Bundaberg Fruit and	
exist, for example heat treatments and cold	Vegetable Growers	
disinfestation, fumigants and new	Association	
insecticides, but many of these are	Costa Group	
unsuitable for use in the fresh market due to	Fruitmaster	
potential phytotoxicity and quality issues,	Lanteri Pty Ltd	
and require approval from quarantine	YoungSun Fruits	
authorities. There are costs and time delays	New Zealand Ministry for	
associated with getting such approvals.	Primary Industries (NZMPI)	
	Total Food Network	
Identifying alternative treatments for export	Steritech Pty Ltd	
produce, such as irradiation, is a high	J&R Produce	
priority for Australian horticulture,	New Zealand Fresh Produce	
particularly as an increasing range of	Importers Association	
chemical treatments become unavailable.	New Zealand Food and	
Ineretore, irradiation is a valuable method of	Grocery Council (NZFGC)	
pest disinfestation that can facilitate trade	Food and Beverage	
and market access to a number of countries	Importers Association	
- New Zealand, China, USA, Talwan,	Australian Melon Association	
Malaysia, Thalland and Vietnam.	Nexas Agriculture	
Irradiction is a sofe and effective technology	Food Technology	
for biococytic purposes and the application	ASSOCIATION OF AUSTRALIA	
requesting the same data range (450 Cuts 4		
requesting the same dose range (150 Gy to 1		
key) and conditions (including mandatory		
fruite percimments temptees and		
nuits, persiminons, tomatoes and		
capsicums in the Code.		

Issue	Raised by	FSANZ response
 Request for FSANZ to fast track all future phytosanitary related applications and give consideration to a generic approval approach for phytosanitary treatment purposes. 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 show 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. There is no technological reason, or regulatory justification, for continuing with the commodity-by-commodity assessment approach 	New Zealand Fresh Produce Importers Association	 FSANZ's recent review concluded that phytosanitary doses of irradiation do not pose a nutritional risk to the Australian and New Zealand populations. It was recommended that the data requirements for applications to irradiate fruits and vegetables can be streamlined to focus on data for vitamin C, with requirements for other nutrients to be determined on a case-by-case basis http://www.foodstandards.gov.au/publications/Pages/Nutritional-impact-of-phytosanitary-irradiation-of-fruits-and-vegetables.aspx. Although this has now streamlined the data requirements for Applicants, with a focus on vitamin C, more extensive data may be required under certain circumstances. For example, fruits or vegetables that have atypical compositions (e.g. a food that may not have nutritional properties representative of its specific class) may require a case-by-case consideration of the data required for a comprehensive nutrition assessment. 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. FSANZ will continue to explore the feasibility of a generic approval with a potential applicant for all fruit and vegetables for a recognised phytosanitary requirement, subject to appropriate data.
Supports the application to permit the irradiation of the requested fruits and vegetables and recommends that consumer education is needed to promote the awareness of irradiated foods, the benefits of irradiation and how health risks related to irradiation are managed. (This specifically relates to possible consumer fears about whether irradiation can make food radioactive).	The Dietitians Association of Australia (DAA)	 FSANZ has provided a number of fact sheets and other information in order to promote the consumer awareness of irradiated foods http://www.foodstandards.gov.au/consumer/foodtech/irradiation/Pages/default.aspx Irradiation by gamma rays, X-rays or electrons does not make food radioactive. Where a radioactive Cobalt 60 source is used, the gamma rays do not have enough energy to make food radioactive. Also, the food does not come in contact with the energy source during food irradiation, so it cannot become contaminated by radioactive material.

Issue	Raised by	FSANZ response
 Recognises that irradiation has potential to deliver benefits to consumers in terms of food safety, convenience, greater availability and reduced use of herbicides and pesticides. However, a precautionary approach must be taken to reduce the impact of any unknown and negative consequences of irradiation and provide information in order that consumers can make informed choices. 	CHOICE	To date FSANZ's risk assessments have not identified any unknown or adverse effects from irradiation of the currently permitted foods or the foods requested to be irradiated in this application. For each application, FSANZ evaluates any supplementary data published since its previous evaluations covering the safety of food irradiation in general, and specifically, the potential hazard of radiolytic compounds generated by the irradiation of foods.
Irradiation is a tool of large agri-business – and supports mass production systems that diminish the power of local food producers and destroy local markets.	Individual consumers	This issue is outside of FSANZ's remit but is a business decision for industry (e.g. farmers) based on the need to use food irradiation for a specific purpose. However, FSANZ notes that a range of both small and large businesses made a submission in support of food irradiation as a quarantine measure for the requested foods.
Irradiation covers up potential bacterial contamination of food (e.g. meat and poultry) and does not provide clean food	Individual consumers	Although this application is specifically for the purpose of pest disinfestation, not bacterial contamination, FSANZ agrees that food irradiation should not be used to clean up already spoiled food. However, at phytosanitary doses of irradiation, there is limited evidence that there are reductions in quality of fresh produce.
Irradiation using radioactive sources is an environmental hazard. Concerns that there are no guarantees that an accident will not occur during the transport of Cobalt 60 or within irradiation facilities.	Individual consumers	 These issues are not unique to food irradiation but equally apply to other more extensive uses of irradiation e.g. for medical sterilisation within a hospital environment. However, the transport, operation or disposal of radioactive materials are outside FSANZ's remit but are considered by relevant state/territory and New Zealand authorities under their radiation protection legislation as detailed in section 4.1 of SD1.
The general description for scallopini is not the common or well-known name in Australia and New Zealand. Suggest adding squash in brackets or the specific botanical name for the varieties included in the term 'Scallopini'.	FTAA	FSANZ understands that Scallopini and zucchini (courgette) are members of the summer squash family. However, after further liaison with the Applicant, FSANZ did not see the need to list the common term summer squash or a specific botanical name in the proposed drafting for scallopini.

Issue	Raised by	FSANZ response
Concerns about the impartiality of the approval process as the Queensland government is both the applicant for A1092 and a member of the decision-making Ministerial Forum.	Individual consumers Food Irradiation Watch (supported by Gene Ethics, Friends of the Earth, MADGE, GM-Free Australia Alliance)	This is an issue for the Forum to consider.
FSANZ has failed to take into account consumer concerns over the safety of irradiated foods, preferring an industry bias which has trade harmonisation as its main criteria, at the expense of public health.	Individual consumers Food Irradiation Watch (supported by Gene Ethics, Friends of the Earth, MADGE, GM-Free Australia Alliance)	One of the key considerations under the FSANZ Act is protection of public health and safety. FSANZ has always undertaken a robust and scientifically valid risk assessment on any food requested to be irradiated. In regard to the fruits and vegetables requested to be irradiated, FSANZ has concluded that there is no public health and safety risks from their consumption.
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 Australian Pesticides and Veterinary Medicine 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 to irradiate fresh fruits and vegetables.	Food Irradiation Watch (supported by Gene Ethics, Friends of the Earth, MADGE, GM-Free Australia Alliance)	 Whether or not the Forum has been derelict in its duties is not a matter for FSANZ. 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 Queensland DAFF and NZMPI when they assess the suitability of irradiation as a phytosanitary measure for the requested fruits and vegetables. Industry has advised FSANZ that although other options exist to control fruit fly infestation, many are unsuitable due to potential phytotoxicity and quality issues, and require approval from quarantine authorities. There are costs and time delays associated with getting such approvals and this makes them not as cost effective when compared to irradiation.
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 were dipped to control fruit fly larvae.	Food Irradiation Watch (supported by Gene Ethics, Friends of the Earth, MADGE, GM-Free Australia Alliance)	This is a matter for the APVMA as reviews of these chemicals has resulted in their use being restricted, suspended or withdrawn. FSANZ acts in accordance with identified public health and safety issues at all times. FSANZ removes the maximum residue limits for any chemicals (e.g. dimethoate and fenthion) in foods when advised by the APVMA in a timely manner.

Issue	Raised by	FSANZ response
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 (The submitter's referenced recent surveys, industry reports and media acknowledging consumer opposition or concern with food irradiation).	Food Irradiation Watch (supported by Gene Ethics, Friends of the Earth, MADGE, GM-Free Australia Alliance)	 FSANZ agrees that the 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. As demonstrated by markets in various nations, some consumers purchase food that has been irradiated. Australian and New Zealand consumers are generally aware of the term irradiation, but hold concerns about the application of the technology to food. The response to food irradiation is not dissimilar to their response to other new food technologies, where perceived risks and benefits of the technology will inform subsequent decisions made by consumers. While aware of irradiation, consumers' objective understanding of the technology has not been reported in the literature located by FSANZ, and self-reported understanding appears limited. This situation may contribute to consumer perceptions of increased risk. Information and education may assist in addressing the information gap.
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	Food Irradiation Watch (supported by Gene Ethics, Friends of the Earth, MADGE, GM-Free Australia Alliance)	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 before 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. There is no evidence provided or identified that these requirements are not being met.
No other countries (or states) expressly require the irradiation of apples, apricots, cherries, nectarines, peaches, plums, honeydew, rockmelon, strawberries, table grapes, zucchini and squash; therefore, approval of A1092 cannot be claimed to be a mechanism for harmonisation of trade regulations.	Food Irradiation Watch (supported by Gene Ethics, Friends of the Earth, MADGE, GM-Free Australia Alliance)	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, these fruits and vegetables could be irradiated under either the US or Codex regulations (e.g. where a country recognises and implements Codex regulations for irradiated foods).

Issue	Raised by	FSANZ response
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	Food Irradiation Watch (supported by Gene Ethics, Friends of the Earth, MADGE, GM-Free Australia Alliance) Individual consumers	Standard 1.5.3 requires mandatory labelling of irradiated food with a statement to the effect that the food has been treated with ionising radiation. This requirement also applies to irradiated ingredients and components, when present in food, as well as to foods not required to be labelled e.g. unpackaged foods.
Strongly support either product or point of sale labelling of irradiated products to provide consumer choice. The proposal and assessment have failed to address the fact that a significant volume of these products are consumed via the catering, restaurant and institutional channels in foods like fruit salads, juices and smoothies. No consideration has been given to how consumers of these foods will be informed that the products they are being offered/are eating are irradiated.	Horticulture New Zealand	All irradiated food, or food containing an irradiated ingredient, must be labelled with a statement that the food or ingredient has been treated with ionising radiation, including food that is sold from restaurants and catering institutions. If the food is not required to be labelled (e.g. unpackaged foods) this information must be displayed on or in connection with the display of the food.
Commented that regarding the enforcement of labelling of irradiated foods, it seems that mandated labelling is very rarely used when required. There appears to have been very few breaches and subsequent enforcement reported.	FTAA	FSANZ notes the comments about compliance with the labelling requirements for irradiated food. Compliance and enforcement activities relating to the labelling requirements for irradiated food are the responsibility of the Australian state and territory jurisdictions and the New Zealand Ministry for Primary Industries.

Issue	Raised by	FSANZ response
 FSANZ needs to clearly explain and communicate that the current rules extend to labelling on menus and other information provided to consumers e.g. websites. Is also concerned about the current level of enforcement of existing labelling requirements in New Zealand, particularly at weekend markets and small retailers. There is a need for additional resource to monitor and enforce these scenarios. 	Horticulture New Zealand	 FSANZ has indicated in the current information for consumers on irradiated foods that: if the food is not normally required to be labelled, then the mandatory labelling statement must be displayed on or in connection to the food. This would apply to foods such as: whole fruit and vegetables sold loose by supermarkets a take away pizza with an irradiated herb as an ingredient. <u>http://www.foodstandards.gov.au/consumer/foodtech/irradiation/Pages/default.aspx</u>
Recommends that Australia and New Zealand mandate irradiated food labels to include the following words: Irradiated (name of the food), Treated with radiation, or Treated by irradiation.	Food Irradiation Watch (supported by Gene Ethics, Friends of the Earth, MADGE, GM-Free Australia Alliance)	Subclause 6(1) of Standard 1.5.3 does not prescribe the wording to be used to identify irradiated foods, only that the label must include a statement to the effect that the food has been treated with ionising radiation. This arrangement is consistent with the current International Codex Standard for Labelling of Pre-Packaged Foods (CODEX STAN 1-1985), which requires a statement on the label of irradiated foods, but does not specify the words to be used. Changing the current requirements for the display of a statement on the label is not supported, given that this would make the labelling requirements inconsistent with international practice.
The government has initiated a 'review' of mandatory labelling which will likely lead to the removal of labelling requirements. Supports the continuation of the mandatory labelling requirements for irradiated food	Individual consumers (multiple submissions) Food Irradiation Watch (supported by Gene Ethics, Friends of the Earth, MADGE, GM-Free Australia Alliance) Individual consumers CHOICE	 Standard 1.5.3 requires the labelling of irradiated foods, which will apply to the fruits and vegetables in this application. A review into food labelling in 2011 (titled <i>Labelling Logic - Review of Food Labelling Law and Policy</i>) recommended that the requirement for mandatory labelling of irradiated food be reviewed (Recommendation 34). The then Legislative and Governance Forum on Food Regulation supported the recommendation and requested FSANZ to review Standard 1.5.3, specifically with a view to assessing the need for the mandatory labelling requirement for all irradiated food to continue. FSANZ expects to undertake this review during 2015 and will consult broadly with
Urges FSANZ to ensure labelling of irradiation continues to be a requirement.	DAA	stakeholders on the current labelling requirements for irradiated foods.

Issue	Raised by	FSANZ response
The source of irradiation is not listed on the label.	Individual consumer	FSANZ has not identified any evidence demonstrating how information on the source of irradiation (gamma rays from cobalt 60, e beam or x-ray) will influence consumer purchasing decisions. Therefore, we do not consider that there is a specific need to mandate a statement on the label relating to the source of irradiation, although there is no prohibition against the voluntary display of this information either.
Positive statements about irradiation, such as 'to protect New Zealand's environment' and 'to destroy harmful micro-organisms' should be prohibited on the labels of irradiated food.	Food Irradiation Watch (supported by Gene Ethics, Friends of the Earth, MADGE, GM-Free Australia Alliance)	FSANZ does not consider that the use of positive statements that indicate the purpose of food irradiation should be prohibited (e.g. a positive statement such as 'Treated with irradiation – to protect the New Zealand environment'), provided they are not false, misleading or deceptive or likely to mislead or deceive. The <i>Competition and</i> <i>Consumer Act 2011</i> (Australia) and the <i>Fair Trading Act 1986</i> (New Zealand) already prohibit misleading and deceptive conduct, which applies to food labels.
Opposes the use of the Radura symbol on irradiated food, and calls for FSANZ to disallow its use as it is misleading and deceptive. The Radura symbol has clearly been designed to lead the public to believe that the [irradiated] process is "clean and green".	Food Irradiation Watch (supported by Gene Ethics, Friends of the Earth, MADGE, GM-Free Australia Alliance)	 The Radura is the international symbol indicating a food product has been irradiated. See SD 1 for further details on the Radura symbol and how it relates to the labelling requirements of Standard 1.5.3. Standard 1.5.3 does not require the use of the Radura symbol on the labels of irradiated foods, however its voluntary use is not prohibited either. This arrangement is consistent with international practice as the Codex Standard for Labelling of Pre- Packaged Foods (CODEX STAN 1-1985) permits the optional use of the Radura symbol.
The 'Radura' symbol might be considered by the food industry and consumers as a more acceptable manner of conveying the mandated message regarding irradiated food. An education program would also be required if this suggestion was adopted.	FTAA	FSANZ has no evidence that the Radura symbol would be more acceptable to consumers, as consumers who oppose irradiation may not be influenced by the symbol.
Concerns over link between irradiated cat food and neurological effects and deaths in cats. Until these adverse effects in cats are fully explored and understood there should be no further approvals of irradiated foods.	Individual consumers Food Irradiation Watch (supported by Gene Ethics, Friends of the Earth, MADGE, GM-Free Australia Alliance)	 FSANZ has been aware of publications suggesting that irradiated pet food is responsible for the development of a chronic neurological syndrome resulting in lameness and deaths in cats. However, FSANZ believes that this is a cat-specific effect. In summary, as reported in detail in the Risk Assessment (SD 2), FSANZ does not consider that there are any implications for the safety of food irradiated for human consumption.

Issue	Raised by	FSANZ response
General concerns over the safety of irradiated foods and that there is no absolute guarantee that food will be safe. Submitted a number of studies and quotations demonstrating the adverse effects of food irradiation in animals and humans. Unique unsafe chemicals are produced in food following irradiation.	City of Gold Coast Environmental Health Policy and Program Development Individual consumers	 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 and in the range of worldwide permissions for irradiated foods (see section 2 of SD1). Many of the cited studies were published prior to 1994 when the World Health Organization included them in their 1994 and 1999 reviews of the safety and nutritional adequacy of irradiated foods. The WHO reviews considered that many of the submitted studies and the findings were considered to be either not scientifically valid, repeatable or did not have relevance to consumption of irradiated foods by humans. FSANZ has previously reviewed these submitted studies in previous risk assessments or relied on the conclusions from the World Health Organization. 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 the risk assessments undertaken for previous applications and 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.
There has been no assessment of the impacts of irradiation of fruits and vegetables on folate and flavonoids. The Applicant should provide direct, published and peer-reviewed studies that folate is not affected by irradiation doses.	Food Irradiation Watch (supported by Gene Ethics, Friends of the Earth, MADGE, GM-Free Australia Alliance)	 In the FSANZ (2014) review of the nutritional impact of phytosanitary irradiation of fruits and vegetables, folate was considered to have a low sensitivity to irradiation and it is unlikely that phytosanitary doses of radiation of the requested fruits and vegetables would lead to a significant reduction in folate status for Australian and New Zealand consumers http://www.foodstandards.gov.au/publications/Pages/Nutritional-impact-of-phytosanitary-irradiation-of-fruits-and-vegetables.aspx. Fruits and vegetables are rich sources of non-vitamin bioactive compounds such as flavonoids. These compounds do not have recommended daily intakes and less is known about the level of intake within Australia and New Zealand. Similarly, less is known about the sensitivity of these compounds to irradiation, but given the diversity of compounds the degree of sensitivity is likely to be varied. For example, there are reports that the concentrations of some flavonoids, such as quercetin in onions, are actually increased following irradiation at 0.8 kGy (Nemeth K & Piskula (2007) Food content, processing, absorption and metabolism of onion flavonoids. Crit Rev Food Sci Nutr, 47:397–409)

Issue	Raised by	FSANZ response
Failure to address issue that irradiation has the potential to modify tertiary structure of proteins and increase allergenicity	Food Irradiation Watch (supported by Gene Ethics, Friends of the Earth, MADGE, GM-Free Australia Alliance)	 This issue relates to a study that suggested new evidence of an allergenic effect from low doses of irradiation (Vaz et al, 2012) http://www.sciencedirect.com/science/article/pii/S0278691512006849 This study used an experimental approach to induce mice to become immunologically responsive to a test protein (Concanavalin 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. The investigators also reported 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 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. In summary, consumption of irradiated or heated protein does not necessarily make them allergenic in humans. In addition, FSANZ notes that animal models are known to be poor predictors of likely allergenicity in humans.
Irradiation will reduce the nutritional value of food.	Individual consumers Food Irradiation Watch (supported by Gene Ethics, Friends of the Earth, MADGE, GM-Free Australia Alliance)	 Before approvals are granted, FSANZ undertakes a comprehensive review of the nutritional impacts on foods requested to be permitted to be irradiated. In February 2014, FSANZ published a review of the published literature on the nutritional impact of phytosanitary irradiation of fruits and vegetables and concluded that phytosanitary doses of irradiation do not pose a nutritional risk to the Australian and New Zealand populations. For more information refer to section 2.2.3 and SD2.

Issue	Raised by	FSANZ response
The research quoted (section 4.1 of SD2) shows a potential reduction in water soluble irradiation-sensitive vitamins (e.g. thiamine, vitamins C and E and B-carotene) yet this does not appear to have been addressed in the risk assessment. While we accept that similar variations in vitamin C levels result from processing it should be noted that most of the products covered by this application are consumed raw. The variation in other vitamins has not been addressed. Just because vitamin C levels vary with cooking does not automatically mean that others do too.	Horticulture New Zealand	 In the FSANZ (2014) review of the nutritional impact of phytosanitary irradiation of fruits and vegetables, fruits and vegetables generally were found to have high levels of carotenes and vitamin C but were not major contributors to intakes of vitamin E or thiamin, therefore the review focused on vitamin C and carotenes. Of those vitamins potentially more affected by irradiation, vitamin C and vitamin A (from pro-vitamin A carotenoids such as β-carotene) were the only nutrients present in the specified fruits and vegetables at nutritionally relevant levels. The literature review and current risk assessment for this application conducted by FSANZ found β-carotene levels were not significantly reduced by irradiation and there were no significant losses of vitamin C in irradiated fruits and vegetables.
There is a lack of long-term studies on irradiated foods.	Individual consumers Food Irradiation Watch (supported by Gene Ethics, Friends of the Earth, MADGE, GM-Free Australia Alliance)	 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. Consistent with these long-term bioassays, the weight-of-evidence from an extensive battery of <i>in vitro</i> and <i>in vivo</i> genotoxicity assays indicated that irradiated foods are not mutagenic.

Issue	Raised by	FSANZ response
Given the proposed larger number of irradiated products and that many of them are a key part of the New Zealand and Australian diet, there is potential for a greater impact on the nutritional adequacy provided by these products from both a combined and cumulative perspective. There is no evidence presented to support the conclusion that nutritional adequacy from consumption of both the currently permitted foods and the requested foods will not be significant.	Horticulture New Zealand	FSANZ assessed 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 the requested fruits and vegetables in A1092. Vitamin C was the main focus of the assessment and levels were similar between irradiated and non-irradiated fruits and vegetables, indicating that there would not be a cumulative loss of vitamin C across the diet.
FSANZ has not assessed the nutritional impacts on high consumers of raw fruit and vegetables.	Horticulture New Zealand	The majority of the data on the requested fruits and vegetables assessed was in the raw state; in particular the unpublished studies provided by the Applicant and showed that irradiation would not lead to adverse nutritional impacts for any consumer. Furthermore, FSANZ's review on phytosanitary doses of irradiation showed that vitamin C intakes exceed the recommended daily intake (RDI) in 95% of Australian and New Zealand populations, indicating that irradiation of fruits and vegetables does not pose a risk to adequate vitamin C intakes.
FSANZ's risk assessment of irradiated foods lacks scientific rigour	Food Irradiation Watch (supported by Gene Ethics, Friends of the Earth, MADGE, GM-Free Australia Alliance)	 FSANZ's comprehensive search of the scientific literature did not identify any studies which revealed potential harmful effects to humans from consumption of irradiated foods. FSANZ reviewed both unpublished data submitted by the Applicant and published studies. 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.

Issue	Raised by	FSANZ response
Section 4.2.2 of SD2 references unpublished papers presented by the applicant. FSANZ should not rely on these papers that have not been subjected to normal peer review processes. We believe any information in unpublished papers should be discounted.	Horticulture New Zealand Food Irradiation Watch (supported by Gene Ethics, Friends of the Earth, MADGE, GM-Free Australia Alliance)	The responsibility for demonstrating the safety of any new food product on the market lies with the developer of that product. This is also the case for new chemicals and drugs. When an applicant seeks approval for a new irradiated food, they must provide FSANZ with the evidence that supports the safety and nutritional adequacy of that irradiated food. It is a requirement that this data be generated according to internationally accepted protocols (i.e. validated methodology and procedures that are consistent with Good Laboratory Practice (GLP)) and stand up to external scrutiny (i.e. independent audits and documentation trails). In the case of data on nutrition, to achieve this, the applicant submits to FSANZ a comprehensive dossier of quality-assured raw experimental data for each food that is requested to be irradiated. This enables FSANZ to independently assess the data and reach a conclusion about the safety of the irradiated food. FSANZ also complements the data package provided by the applicant with information from the scientific literature, other applications, other government agencies and the public.
Concerns that FSANZ ignored the issues raised for previous Applications (A1038 and A1069) in regard to the process employed to demonstrate the safety of irradiated foods and that legitimate concerns were ignored. This is also reflected in FSANZ's consideration of A1092. This relates to FSANZ's general approach to the safety assessment and dietary modelling in previous assessments and the current assessment.	Food Irradiation Watch (supported by Gene Ethics, Friends of the Earth, MADGE, GM-Free Australia Alliance)	 FSANZ values and takes into consideration all submissions made during the public comment period. For any assessment on the safety of irradiated foods, FSANZ undertakes a risk-based approach based on available data before making a conclusion on the safety of irradiated foods. In regard to the current application, 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.

Issue	Raised by	FSANZ response
 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. The cost-benefit analysis makes dubious claims in regards to the benefits and costs to consumers, industry and government 	Horticulture New Zealand Food Irradiation Watch (supported by Gene Ethics, Friends of the Earth, MADGE, GM-Free Australia Alliance)	 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. 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. 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. Since the irradiation of these fruits and vegetables is a voluntary business decision that food producers will make, they will have to decide whether to source and use these fruits and vegetables. However, FSANZ has received a number of submissions from industry supporting approval of these foods.
FSANZ has inflated the claimed benefits of approving draft variations arising from A1092 while diminishing the impacts of the known hazards, risks and costs of irradiating the requested fruits and vegetables. These are impacts that the whole community will bear.	Food Irradiation Watch (supported by Gene Ethics, Friends of the Earth, MADGE, GM-Free Australia Alliance)	FSANZ has concluded that there are no safety concerns from irradiating the requested fruits and vegetables. Disinfestation of insects 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, and quarantine agencies in Australia, New Zealand and the USA endorse irradiation as a legitimate phytosanitary treatment.

2.2 Risk assessment

2.2.1 Risk assessment

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

The purpose of this risk assessment was to determine the technological (phytosanitary) need to irradiate the fruits and vegetables in the current application and whether these foods, irradiated up to a maximum dose of 1 kGy, are as safe and nutritious as nonirradiated foods. The risk assessment takes account of the previous considerations and includes an assessment of data on the safety and nutritional adequacy of irradiated foods that has become available since the assessments conducted in 2002, 2011 and 2013.

2.2.2 Technological (phytosanitary) need and efficacy of the irradiation process

Several approved options exist for phytosanitary treatments of these fruits and vegetables. Among the most commonly used are pre and post-harvest treatments with insecticides. Following the review of dimethoate and fenthion use by the Australian Pesticides and Veterinary Medicines Authority (APVMA), many phytosanitary uses were removed or restricted.

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

Both the Plant Biosecurity Division of the Australian Government Department of Agriculture (previously Biosecurity Australia) and the New Zealand Ministry for Primary Industries (NZMPI) have previously provided letters to FSANZ endorsing irradiation as an effective guarantine treatment for fruit fly and other pests that are of guarantine concern to Australia and New Zealand.

However, both the Plant Biosecurity Division of the Australian Government Department of Agriculture and the NZMPI will still need to independently perform an import risk assessment (for guarantine purposes) on irradiation of these fruits and vegetables specifically for food imported into Australia or New Zealand. These assessments are separate from the food standards approval process.

2.2.3 Safety and nutritional content of irradiated foods

FSANZ has previously assessed the technological need, safety and nutrient profile of various irradiated tropical fruits, persimmons, tomatoes and capsicums. These assessments were conducted in 2002⁷, 2011⁸, and 2013⁹, respectively. FSANZ concluded that there was an established need to irradiate tropical fruits, persimmons and tomatoes and capsicums and that there were no public health and safety issues associated with their consumption when irradiated up to a maximum dose of 1 kGv.

⁷ <u>http://www.foodstandards.gov.au/code/applications/Pages/applicationa443irradiationoftropicalfruit/Default.aspx</u> <u>http://www.foodstandards.gov.au/code/applications/Pages/applicationa1038irra4655.aspx</u>

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

In February 2014, FSANZ published a review of the published literature on the nutritional impact of phytosanitary irradiation of fruits and vegetables and concluded that phytosanitary doses of irradiation do not pose a nutritional risk to the Australian and New Zealand populations. The review recommended that the data requirements for applications to irradiate fruits and vegetables be streamlined to focus on data for vitamin C, with requirements for other nutrients to be determined on a case-by-case basis¹⁰.

The assessment of the potential toxicological hazard and nutritional adequacy for this application demonstrated that there are negligible risks to public health and safety associated with the consumption of the specified fruits and vegetables 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 and vegetables.
- 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 and vegetables (Limit of Quantitation=1 ppb). No data was available for fruit and vegetables irradiated at only 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 and vegetables, 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 were reported in cats and dogs following exclusive consumption of specific brands of pet foods irradiated at doses from 25 to 50 kGy. Low levels of irradiation (up to 1 kGy) do not appreciably reduce vitamin levels in the requested fruit and vegetables. Therefore, FSANZ does not consider that these studies have implications for the safety of fruits and vegetables irradiated for human consumption at up to 1 kGy.

¹⁰ <u>http://www.foodstandards.gov.au/publications/Pages/Nutritional-impact-of-phytosanitary-irradiation-of-fruits-and-vegetables.aspx</u>

2.3 Risk management

Based on the risk assessment and consideration of other matters, FSANZ recommends that irradiation of these fruits and vegetables are permitted for inclusion in the Standard with the following requirements:

- irradiation 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
- application of the current mandatory labelling of irradiated foods to enable consumers to make an informed choice.

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 4.0 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 4.2 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 before 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.

2.4 Decision

The draft variation as proposed following assessment was approved with amendments taking effect from P1033 Code Maintenance Proposal¹¹. This has resulted in a correction to the alphabetical order for the relevant entry for two food commodities into the Code being amended as "Litchi, Longan" and not "Longan, Litchi". The variation takes effect on the date of gazettal.

The approved draft variation is at Attachment A. The explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislative Instruments.

The draft variation on which submissions were sought is at Attachment C.

2.5 Risk communication

2.5.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application. Every submission on the Application was considered and reviewed by FSANZ staff, who examined the issues identified and prepared a response (see Table 1). All comments are valued and contribute to the rigour of our assessment.

¹¹ <u>http://www.foodstandards.gov.au/code/proposals/Pages/P1033CodeMaintenanceXII.aspx</u>

FSANZ called for public comment from 28 August to 9 October 2014 after assessing the Application.

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

The FSANZ Board's decision has been notified to the Forum. If the decision is not subject to a request for a review, the Applicant and stakeholders, including the public, will be notified of the gazettal of the variation to the Code in the national press and on the FSANZ website.

2.6 FSANZ Act assessment requirements

2.6.1 Section 29

2.6.1.1 Cost benefit analysis

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 consider if a Regulation Impact Statement (RIS) was required for applications seeking permission to irradiate foods. The proposed variation to the Code is considered minor and machinery in nature.

FSANZ undertook a cost benefit analysis of the regulatory options for the purposes of section 29. This 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 that are relevant to each option. These impacts are deliberately limited to those involving broad areas such as trade, consumer information and compliance.

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:

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

FSANZ considered the following options:

- approve a draft variation to Standard 1.5.3 to permit the use of the requested fruits and vegetables (Option1)
- approve that draft variation to Standard 1.5.3 subject to such amendments as considered necessary (Option 2)
- reject the draft variation to Standard 1.5.3 to permit the use of irradiation on the requested fruits and vegetables (Option 3).

Option 1: Approve the draft variation to Standard 1.5.3	to permit the use of irradiation on	the requested fruits and vegetables
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Affected party	Benefits	Costs
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 such as dimethoate and fenthion. The government is contributing to a possible enhanced economic development in rural and regional Australia.	There may be a potential cost to any government-enhanced development of domestic markets via competition with imported irradiated foods or with the other industries (e.g. organics industry which does not allow for irradiation). State, territory and New Zealand government agencies may incur costs associated with enforcing labelling requirements for irradiated fruits and vegetables. This applies to irradiated foods for sale in Australia, New Zealand and any imported produce. 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; however, it is likely that the methods available for currently permitted foods, are applicable to these. There may be additional costs auditing records at irradiation facilities. However, no quantitative figures on these specific costs were available.
Industry	 Availability of an alternative internationally-endorsed phytosanitary measure when the current chemical-based treatments are restricted. Other postharvest options such as heat treatments, cold disinfestation, fumigants, new insecticides are available, although unsuited for use for particular fresh produce due to possible phytotoxicity and quality issues, length of treatment time, as well as costs or the time needed to get approval from quarantine authorities. Although the specific purpose of approval of irradiation for the fruits and vegetables is for pest disinfestation (i.e. a quarantine purpose), there may be a parallel benefit of increased shelf life and quality of fruit and vegetables, depending on the dose of irradiation used on the produce. Potential for 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. 	 There may be potential future costs to Australian and/or New Zealand businesses (e.g. Australian and/or New Zealand growers) by a reduction in profits due to future competition from imported irradiated foods. Where producers opt to voluntarily adopt irradiation of fruits and vegetables, 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. If needed the initial set-up costs in establishing a dedicated irradiation facility including building and capital may be significant. Costs to industry of treatment and transport of 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.

Affected party	Benefits	Costs
	Permission to irradiate could facilitate market access to New Zealand.	This potentially makes Australian products less competitive when compared to imported equivalent products that are not irradiated.
	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 these other treatments may cause.	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.
	Reduction in the costs of using pesticides depending on whether irradiation is used to totally replace a pesticide or used in parallel during the post-harvest period.	Potential cost in ascertaining consumer acceptance of irradiated commodities.
Consumers	Possibly greater year-round availability of these commodities in some markets/regions in Australia and New Zealand.	A potential cost to consumers is that irradiated fruits and vegetables may cost more than non-irradiated ones.
	Possibly better quality fruit and vegetables depending on the dose of irradiation, as other treatments (such as heat and cold) can affect fruit and vegetable quality.	A further additional cost that could be passed on to consumers could arise due to the mandatory requirement for labelling as required under clause 6 of Standard 1.5.3. This cost arises from the requirement to provide product labels and the provision of signage at the point of sale for unpackaged
	Produce may also be transported for longer periods while maintaining desirable sensory qualities for consumers due to the parallel benefit of an increased shelf-life.	produce.
	Where food irradiation is used to replace a chemical treatment, it may provide choice to consumers wanting to avoid exposure to chemicals and the resulting residues in those foods.	
	Approval of these commodities may increase competition in the marketplace, improve seasonal availability and increase price competition.	

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. However, FSANZ has made a minor amendment to the drafting at the Call for Submissions stage as a result of amendments taking effect from Proposal P1033¹² – Code Maintenance Proposal. This has resulted in a correction to the alphabetical order for the relevant entry for two food commodities into the Code being amended as "Litchi, Longan" and not "Longan, Litchi".

¹² <u>http://www.foodstandards.gov.au/code/proposals/Pages/P1033CodeMaintenanceXII.aspx</u>

Affected party	Benefits	Costs
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.
Industry	There would be a benefit to local producers who do not wish to sell irradiate foods but would still have to compete with irradiated produce (either domestically produced or imported) in the market place.	Loss of trade opportunities and access to markets where current disinfestation methods are not accepted.
	Opportunities to invest in and develop non-chemical/non-radiation quarantine treatments for some industry sectors (e.g. organics industry).	Costs in research and development incurred in an attempt to identify irradiation as an alternative treatment as existing chemical or other treatments are phased out.
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 some fruits and vegetables 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 fruit and vegetable supplies will decrease and prices may increase.

Option 3: Reject the draft variation to Standard 1.5.3 to permit the use of irradiation on the requested fruits and vegetables

In summary, FSANZ undertook a limited impact analysis and concluded that permitting the irradiation of these fruits and vegetables would benefit consumers, industry and government by a reduction in pests of quarantine concern. This would lead to greater availability of produce and access to interstate and export markets for industry, thus assisting to ensure the ongoing economic viability of the horticultural industry. There are no specific costs to other stakeholders that override these benefits. There are no benefits in rejecting the draft variation.

The direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the application outweigh the costs to the community, government or industry that would arise from the development or variation of the food regulatory measure.

2.6.1.2 Other measures

During the public consultation period, some submitters claimed that other methods and alternatives exist to alleviate fruit fly infestation that are more effective. FSANZ has addressed these issues in Table 1 of section 2.1. In summary, 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. FSANZ also notes that industry has advised that while other options exist, many of these are unsuitable for use in the fresh market due to potential phytotoxicity and quality issues, and require approval from quarantine authorities. There are costs and time delays associated with getting such approvals.

Therefore, FSANZ concludes that there are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the Application.

2.6.1.3 Any relevant New Zealand standards

Standard 1.5.3 applies to New Zealand as a joint standard and there are no other relevant New Zealand Standards.

2.6.1.4 Any other relevant matters

There are no other relevant matters.

2.6.2. Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.6.2.1 Protection of public health and safety

FSANZ concludes that approval of irradiation of fruits and vegetables 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.

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

During the public consultation period some submitters claimed that the current labelling requirements are weak, not adequately enforced and raised issues in regard to the optional use of the Radura symbol. These issues have been addressed in Table 1 of section 2.1.

FSANZ has concluded that the mandatory requirements under Standard 1.5.3 to label irradiated foods will provide adequate information for consumers to make informed purchase decisions.

2.6.2.3 The prevention of misleading or deceptive conduct

No issues identified.

2.6.3 Subsection 18(2) considerations

FSANZ has also had regard to:

• 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 consuming irradiated foods. Collectively, these risk assessments have considered all available information (national and international), including animal toxicity and nutrition data, relevant to the safety and nutritional adequacy of irradiated foods.

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

• the promotion of consistency between domestic and international food standards

Approval to irradiate fruits and vegetables 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 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 these commodities 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 Council¹³

FSANZ has had regard to the Policy Guideline on Labelling of foods produced or processed using new technologies¹⁴.

¹³ Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)

¹⁴ <u>http://www.health.gov.au/internet/main/publishing.nsf/Content/foodsecretariat-policy-guidelines</u>

3 Transitional arrangements

3.1 Transitional arrangements for Code Revision

FSANZ is reviewing the Code in order to improve its clarity and legal efficacy. This review is being undertaken through Proposal P1025 – details of which are on the FSANZ website¹⁵. FSANZ released a draft revision of the Code for public comment in May 2013. The draft revision has changed the Code's structure and format. A further draft revision of the Code and call for submissions was released in July 2014.

The FSANZ Board approved the proposed changes to the Code in December 2014. The new Code will commence in March 2016 and will repeal and replace the current Code. The new Code will then need to be amended to incorporate any outstanding changes made to the current Code, including the variations at Attachment A if not rejected by the Forum. The new Code will then need to be amended to incorporate any outstanding changes made to Chapters 1 and 2 of the current Code. The amendment to the new Code resulting from Application A1092 is provided at Attachment D.

4 References

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

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.

Attachments

- A. Approved draft variation to the Australia New Zealand Food Standards Code
- B. Explanatory Statement
- C. Draft variations to the Australia New Zealand Food Standards Code at Call for Submissions
- D. Draft variation to the Australia New Zealand Food Standards Code in March 2015 following P1025

¹⁵ <u>http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx</u>

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



Food Standards (Application A1092 – Irradiation of Specific Fruits and vegetables) 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 [To be completed by Standards Management Officer]

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

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the Food Standards (Application A1092 – Irradiation of Specific Fruits and vegetables) 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	Minimum: 150 Gy	Pest disinfestation for a phytosanitary
Capsicum	Maximum: 1 kGy	objective.
Carambola		
Custard apple		
Litchi		
Longan		
Mango		
Mangosteen		
Papaya (Paw paw)		
Persimmon		
Rambutan		
Tomato		
		-

[1.2] inserting in the Table to clause 4

u		
Apple	Minimum: 150 Gy	Pest disinfestation for a phytosanitary
Apricot	Maximum: 1 kGy	objective.
Bread fruit		
Capsicum		
Carambola		
Cherry		
Custard apple		
Honeydew		
Litchi		
Longan		
Mango		
Mangosteen		
Nectarine		
Papaya (Paw paw)		
Peach		
Persimmon		
Plum		
Rambutan		
Rockmelon		
Scallopini		
Strawberry		
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.

The Authority accepted Application A1092 which seeks to permit the irradiation of fruits and vegetables as a phytosanitary measure¹⁶. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft Standard.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation¹⁷, 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 sunsetting under the *Legislative Instruments Act 2003*.

2. Purpose

The Authority has approved the irradiation of apple, apricot, cherry, nectarine, peach, plum, honeydew, rockmelon, scaloppini, strawberry, table grape and zucchini (courgette) in Standard 1.5.3. This will permit irradiation only for the purposes of pest disinfestation for a phytosanitary objective within the permitted dose range of 150 Gy and a maximum of 1 kGy.

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 A1092 included one round of public consultation following an assessment and the preparation of a draft Standard and associated report. Submissions were called for on 28 August 2014 for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variations to Standard 1.5.3 are likely to have a minor impact on business and individuals and is a broadening of food regulations to permit other foods to be irradiated.

¹⁶ 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.

¹⁷ convening 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. Variation

The variations permit the irradiation of apple, apricot, cherry, nectarine, peach, plum, honeydew, rockmelon, scaloppini, strawberry, table grape, zucchini (courgette) by adding these commodities 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.

Attachment C – Draft variations to the *Australia New Zealand Food Standards Code* (call for submissions)



Food Standards (Application A1092 – Irradiation of Specific Fruits and vegetables) 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 [To be completed by Standards Management Officer]

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

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the Food Standards (Application A1092 – Irradiation of Specific Fruits and vegetables) 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

"

	N/: : 450.0	
Bread fruit	Minimum: 150 Gy	Pest disinfestation for a phytosanitary
Capsicum	Maximum: 1 kGy	objective.
Carambola	-	
Custard apple		
Longan		
Litchi		
Mango		
Mangosteen		
Papaya (Paw paw)		
Persimmon		
Rambutan		
Tomato		

[1.2] inserting in the Table to clause 4

и		
Apple	Minimum: 150 Gy	Pest disinfestation for a phytosanitary
Apricot	Maximum: 1 kGy	objective.
Bread fruit	_	
Capsicum		
Carambola		
Cherry		
Custard apple		
Honeydew		
Litchi		
Longan		
Mango		
Mangosteen		
Nectarine		
Papaya (Paw paw)		
Peach		
Persimmon		
Plum		
Rambutan		
Rockmelon		
Scallopini		
Strawberry		
Table Grape		
Zucchini (courgette)		

Attachment D – Draft variation to the Australia New Zealand Food Standards Code in 2015 following P1025

Background

FSANZ is reviewing the Australian New Zealand Food Standards Code in order to improve its clarity and legal efficacy. This review is being undertaken through Proposal P1025. FSANZ released a draft revision of the Code for public comment in May 2013. The draft revision has changed the Code's structure and format. The draft instrument below reflects those changes. A further draft revision of the Code and call for submissions will be released in the near future.

The FSANZ Board is expected to consider P1025 and the proposed changes to the Code in late 2014. If approved, it expected that the new Code will commence in 2015 and will repeal and replace the current Code. The new Code will then need to be amended to incorporate any outstanding changes made to the current Code, such as the variations to Standard 1.3.3 proposed by A1096. This is the rationale for the draft variation below.

This draft variation is provided for background only. Its content and structure may change as P1025 progresses.

Draft instrument

Food Standards Code—Variation

Made under the Food Standards Australia New Zealand Act 1991

1 Name of instrument

This instrument is the Food Standards Australia New Zealand Code — Revocation and Transitional Variation 2015 (No. 1).

2 Commencement

This instrument commences on the day after it is registered.

3 Variation of Standard 1.5.3

Schedule 1 varies the Australia New Zealand Food Standards Code — Standard 1.5.3 — Irradiation of food.

Schedule 1 Variation of Standard 1.5.3

(section 3)

[1] Insert in the table to subsection (2) in alphabetical order –

"Apple Apricot Cherry Honeydew Nectarine Peach Plum Rockmelon Scallopini Strawberry Table Grape Zucchini (courgette)"