

28 August 2014
[17–14]

Call for submissions – Application A1092

Irradiation of Specific Fruits & Vegetables

FSANZ has assessed an Application made by the Queensland Department of Agriculture, Fisheries & Forestry to seek permission to irradiate apple, apricot, cherry, nectarine, peach, plum, honeydew, rockmelon, scallopini¹, strawberry, table grape and zucchini (courgette) for phytosanitary purposes and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that is provided in-confidence, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 9 October 2014

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters. Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
CANBERRA BC ACT 2610
AUSTRALIA
Tel +61 2 6271 2222

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6143
NEW ZEALAND
Tel +64 4 978 5630

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

Table of Contents

EXECUTIVE SUMMARY	2
1 INTRODUCTION	3
1.1 THE APPLICANT	3
1.2 THE APPLICATION	3
1.3 THE CURRENT STANDARD.....	3
1.4 REASONS FOR ACCEPTING APPLICATION	4
1.5 PROCEDURE FOR ASSESSMENT	4
2 SUMMARY OF THE ASSESSMENT	4
2.1 RISK ASSESSMENT	4
2.1.1 <i>Technological need and efficacy of the irradiation process</i>	4
2.1.2 <i>Safety and nutritional content of irradiated foods</i>	5
2.2 RISK MANAGEMENT	6
2.3 RISK COMMUNICATION.....	6
2.3.1 <i>Consultation</i>	6
2.3.2 <i>World Trade Organization (WTO)</i>	7
2.4 FSANZ ACT ASSESSMENT REQUIREMENTS	7
2.4.1 <i>Section 29</i>	7
2.4.2 <i>Subsection 18(1)</i>	12
2.4.3 <i>Subsection 18(2) considerations</i>	12
3 DRAFT VARIATIONS	13
3.1 TRANSITIONAL ARRANGEMENTS	13
4 REFERENCES	14
ATTACHMENT A – DRAFT VARIATIONS TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE</i>	15
ATTACHMENT B – DRAFT EXPLANATORY STATEMENT	17

Supporting documents

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

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

Executive summary

Food Standards Australia New Zealand (FSANZ) received an Application from the Queensland Department of Agriculture, Fisheries & 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 tropical fruits, persimmons, tomatoes and capsicums in the *Australia New Zealand Food Standards Code* (the Code) are requested.

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

Relevant quarantine agencies in Australia and New Zealand provided advice on whether 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 efficacious 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 vegetable was not detected, with negligible levels in apples and strawberries. The low levels generated in table grapes are also unlikely to present a toxicological hazard.

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 and vegetables.

FSANZ has prepared a draft variation to the Code 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.

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 and seeks to amend an existing standard: Standard 1.5.3 – Irradiated Foods to provide for the safe use of irradiation as a phytosanitary measure² for apple, apricot, cherry, honeydew, nectarine, peach, plum, rockmelon, scallopini, strawberry, table grape and zucchini (courgette).

Zucchini (courgette³) and scallopini are members of the summer squash family. FSANZ clarified with the Applicant that they are seeking permissions to irradiate both scallopini and zucchini (courgette) and the general reference to summer squash in their application referred to both commodities. However, FSANZ did not see the need to list the common term summer squash in the proposed drafting for either scallopini or zucchini (courgette).

The Applicant has indicated that the edible portions of zucchini/scallopini are botanically fruits, but are usually classed as vegetables in nutritional tables. However, in the *Australia New Zealand Food Standards Code* (the Code) they are classified as fruiting vegetables, cucurbits in Schedule 4 of Standard 1.4.2 – Maximum Residue Limits. However, to prevent any confusion in the public domain, in this assessment summary, zucchini (courgette) and scallopini will be referred to as vegetables.

These fruits 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 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)⁴ approved two Applications to irradiate herbs, spices and herbal infusions (A413) and 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 and tomatoes and capsicums by the Legislative and Governance Forum on Food Regulation under Application A1069.

² A phytosanitary measure is any legislation, regulation or official procedure having the purpose to prevent the introduction and/or spread of quarantine pests, or to limit the economic impact of regulated non-quarantine pests.

³ The names zucchini and courgette are used interchangeably

⁴ Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (The Forum).

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 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 is being assessed under the General Procedure.

2 Summary of the assessment

2.1 Risk assessment

Full details of the risk assessment prepared in relation to 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 non-irradiated 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.

2.1.1 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 lost or restricted.

Disinfestation of fruits and vegetables 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 and quarantine agencies in Australia, New Zealand and the USA, endorse irradiation as a legitimate phytosanitary treatment.

Both the Commonwealth Department of Agriculture and the New Zealand Ministry for Primary Industries (NZMPI) have previously 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 the Department of Agriculture and the 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.

2.1.2 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 2002⁵, 2011⁶, and 2013⁷, 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 kGy.

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 populations⁸.

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 irradiated at 1 kGy but the amount of furan present would be expected to be lower. Dietary surveys in Europe show that many non-irradiated foods contain furans at levels comparable to grapes irradiated at 5 kGy.
- Available data indicate that the carbohydrate, fat, protein and mineral content of foods are unaffected by irradiation at doses up to 1 kGy.
- For irradiated and non-irradiated fruit 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 reported in cats and dogs following exclusive consumption of specific brands of pet foods irradiated at 50 kGy are unlikely to be relevant for humans.

⁵ <http://www.foodstandards.gov.au/code/applications/Pages/applicationa443irradiationoftropicalfruit/Default.aspx>

⁶ <http://www.foodstandards.gov.au/code/applications/Pages/applicationa1038irra4655.aspx>

⁷ <http://www.foodstandards.gov.au/code/applications/Pages/applicationa1069irra5511.aspx>

⁸ <http://www.foodstandards.gov.au/publications/Pages/Nutritional-impact-of-phytosanitary-irradiation-of-fruits-and-vegetables.aspx>

2.2 Risk management

Based on the risk assessment and consideration of other matters, FSANZ recommends that irradiation of these fruits and vegetables is 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
- 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 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.

2.3 Risk communication

2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process.

FSANZ has developed and applied a basic communication strategy to this Application. All calls for submissions are notified via the FSANZ Notification Circular, media release, FSANZ's social media tools and Food Standards News.

The process by which FSANZ considers standard development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by the Application and the impacts of regulatory options. The draft variation will be considered for approval by the FSANZ Board taking into account public comments received from this call for submissions.

The Applicant, individuals and organisations that make submissions on this Application will be notified at each stage of the assessment. Subscribers and interested parties are also notified via email about the availability of reports for public comment.

If the draft variation to the Code is approved by the FSANZ Board, that decision will be notified to the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council). 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.

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

2.3.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are relevant international standards, and amending the Code to include permissions to irradiate these commodities would have a trade enabling effect as it would permit these irradiated commodities to be sold in Australia and New Zealand and also allow imports into Australia and New Zealand and sold, where currently they would be prohibited. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade Agreement was not considered necessary.

2.4 FSANZ Act assessment requirements

When assessing this Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

2.4.1 Section 29

2.4.1.1 Cost benefit analysis

Paragraph 29(2)(a) of the FSANZ Act requires FSANZ to have regard to whether the costs arising from a food regulatory measure developed for this Proposal would outweigh the direct and indirect benefits to the community, Government and industry that arise from the measure.

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.

Information supplied by the applicant, has suggested that DAFF and the horticulture industry consider trade in these fruits and vegetables is at risk of market disruption. In Queensland the forecast value for total fruit and vegetables in 2012–13 was AUD\$2453 million with total fruit and nuts accounting for AUD\$1334 million and total vegetables AUD\$1119 million. Supplying the domestic market is the major focus of the horticulture industry in Queensland (overall approximately 70%). Therefore, access to interstate markets is vital to the ongoing economic viability of the state and industry.

In reaching its decision to prepare a draft variation, FSANZ considered the following options:

Option 1: Prepare a draft variation to Standard 1.5.3 to permit the use of irradiation on the requested fruits and vegetables.

Option 2 Reject the Application

Option 1: Prepare a draft variation to Standard 1.5.3 to permit the use of irradiation on the requested fruits

AFFECTED PARTY	BENEFITS	COSTS
<p>Government</p>	<p>Additional pest disinfection treatment which may facilitate trade when some methods are not accepted or are being phased out e.g. some chemical treatments.</p> <p>Possible enhanced economic development in rural and regional Australia.</p>	<p>State, territory and New Zealand government agencies may incur costs associated with enforcing labelling requirements for irradiated fruits and vegetables. 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.</p> <p>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.</p>
<p>Industry</p>	<p>Availability of an alternative internationally-endorsed phytosanitary measure when the current chemical-based treatments are restricted. Other postharvest options for example, heat treatments, cold disinfection, 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 frame needed to gain approval from quarantine authorities.</p> <p>Increased shelf life and quality of fruit and vegetables, depending on the dose.</p> <p>Assistance and maintenance of the economic viability of an important segment of the horticulture sector.</p> <p>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.</p>	<p>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.</p> <p>If needed the initial set-up costs in establishing a dedicated irradiation facility including building and capital may be significant.</p> <p>Costs to industry of treatment and transport of irradiated foods.</p> <p>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 less competitive when compared to imported equivalent products that are not irradiated.</p>

AFFECTED PARTY	BENEFITS	COSTS
	<p>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.</p> <p>Reduction in the costs of using pesticides</p>	<p>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.</p> <p>Potential cost in ascertaining consumer acceptance of irradiated commodities.</p>
Consumers	<p>Possibly greater year-round availability of these commodities in some markets/regions in Australia and New Zealand.</p> <p>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.</p> <p>Produce may be transported for longer periods while maintaining desirable sensory qualities for consumers.</p> <p>Provides choice to consumers wanting to avoid exposure to other treatments such as chemicals and the resulting residues in those foods.</p> <p>Approval of these commodities may increase competition in the marketplace, improve seasonal availability and increase price competition.</p>	<p>A potential cost to consumers is that irradiated fruits and vegetables may cost more than non-irradiated ones. Additionally, 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.</p>

Option 2: Reject the Application

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	No benefits to industry were identified.	<p>Loss of trade opportunities and access to markets where current disinfestation methods are not accepted.</p> <p>Costs in research and development incurred in an attempt to identify alternative treatments as existing chemical or other treatments are phased out.</p>
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.

FSANZ concluded that 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.

2.4.1.2 Other measures

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.

2.4.1.3 Any relevant New Zealand standards

Standard 1.5.3 is a Joint standard.

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2 Subsection 18(1)

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

2.4.2.1 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.

2.4.2.2 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.

2.4.2.3 The prevention of misleading or deceptive conduct

No issues identified.

2.4.3 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 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 and nutritional adequacy 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 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 Council⁹**

No Policy Guideline is applicable.

3 Draft variations

The draft variations to Standard 1.5.3 are at Attachment A. The draft variations are intended to take effect on gazettal.

A draft 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.

3.1 Transitional arrangements

3.1.1 *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 website¹⁰. 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 is expected to consider P1025 and the proposed changes to the Code in late 2014. If approved, it is 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, including the variations at Attachment A.

⁹ Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)

¹⁰ <http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx>

4 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.

Attachments

- A. Draft variations to the *Australia New Zealand Food Standards Code*
- B. Draft Explanatory Statement

Attachment A – Draft variations to the *Australia New Zealand Food Standards Code*



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

”

[1.2] inserting in the Table to clause 4

“

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

”

Attachment B – Draft 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 A1092 which seeks to permit the irradiation of fruits and vegetables as a phytosanitary measure¹¹. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation to Standard 1.5.3.

2. Purpose

Apple, apricot, cherry, nectarine, peach, plum, honeydew, rockmelon, scaloppini, strawberry, table grape and zucchini (courgette) are currently not permitted to be irradiated in Standard 1.5.3. Therefore, FSANZ is proposing to vary Standard 1.5.3 by including these commodities 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 A1092 will include one round of public consultation following an assessment and the preparation of a draft variation. A Call for Submissions (which includes the draft variation) will be released for a six-week consultation period.

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 deregulatory in nature.

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 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.

¹¹ 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.