

12 May 2021
155-21

Approval report – Application A1193

Irradiation as a phytosanitary measure for all fresh fruit and vegetables

Food Standards Australia New Zealand (FSANZ) has assessed an application made by the Queensland Government Department of Agriculture and Fisheries (QLD DAF) to permit the use of irradiation on fresh fruit and vegetables as a phytosanitary measure (pest disinfection), and has prepared a draft variation.

On 30 October 2020, FSANZ sought submissions on the draft variation and published an associated report. FSANZ received 480 submissions plus another three after the closing date.

FSANZ approved the draft variation on 28 April 2021. The Food Ministers' Meeting (formerly the Australia and New Zealand Ministerial Forum on Food Regulation) was notified of FSANZ's decision on 12 May 2021.

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

Table of contents

EXECUTIVE SUMMARY	4
1 INTRODUCTION	6
1.1 THE APPLICANT	6
1.2 THE APPLICATION	6
1.3 THE CURRENT STANDARD	7
1.3.1 <i>Permitted use</i>	7
1.3.2 <i>Record keeping</i>	7
1.3.3 <i>Labelling requirements</i>	7
1.4 INTERNATIONAL STANDARDS	7
1.5 REASONS FOR ACCEPTING APPLICATION	8
1.6 PROCEDURE FOR ASSESSMENT	8
1.7 DECISION	8
2 SUMMARY OF THE FINDINGS	8
2.1 SUBMISSIONS RECEIVED	8
2.2 SUMMARY OF ISSUES RAISED IN SUBMISSIONS	9
3 RISK ASSESSMENT	27
3.1 TECHNOLOGICAL NEED AND EFFICACY OF IRRADIATION	27
3.1.1 <i>Justification for use of irradiation as a phytosanitary measure</i>	27
3.1.2 <i>Worldwide permissions for food irradiation</i>	28
3.1.3 <i>Summary</i>	28
3.2 SAFETY AND NUTRITIONAL CONTENT OF IRRADIATED FOODS	29
4 RISK MANAGEMENT	29
4.1 LABELLING OF IRRADIATED FOOD.....	31
4.2 RISK MANAGEMENT CONCLUSION	32
5 RISK COMMUNICATION	32
5.1 CONSULTATION	32
5.2 WORLD TRADE ORGANIZATION (WTO).....	32
6 FSANZ ACT ASSESSMENT REQUIREMENTS	33
6.1 SECTION 29.....	33
6.1.1 <i>Consideration of costs and benefits</i>	33
6.1.2 <i>Other measures</i>	34
6.1.3 <i>Any relevant New Zealand standards</i>	34
6.1.4 <i>Any other relevant matters</i>	34
6.2. SUBSECTION 18(1).....	34
6.2.1 <i>Protection of public health and safety</i>	34
6.2.2 <i>The provision of adequate information relating to food to enable consumers to make informed choices</i> 34	
6.2.3 <i>The prevention of misleading or deceptive conduct</i>	34
6.3 SUBSECTION 18(2) CONSIDERATIONS	35
7 REFERENCES	36
ATTACHMENT A – APPROVED VARIATION TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE.....	38
ATTACHMENT B – EXPLANATORY STATEMENT	40
ATTACHMENT C – DRAFT VARIATION TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE (CALL FOR SUBMISSIONS)	42
APPENDIX 1: SUMMARY OF SPECIFIC COUNTRIES’ PERMISSIONS FOR IRRADIATED FOODS	44
APPENDIX 2: ISSUES RAISED IN SUBMISSIONS AND FSANZ RESPONSE.....	47
APPENDIX 3: ISSUES RAISED IN THE ‘SAMPLE LETTER’ AND ASSOCIATED WEBPAGES AND FSANZ RESPONSE.....	47
APPENDIX 4: FOOD IRRADIATION WATCH/GENE ETHICS QUESTIONS ON THE APPLICATION AND SD1 AND FSANZ RESPONSE	47

Supporting document

The [following document](#)¹ which informed the assessment of this application is available on the FSANZ website:

Supporting document 1 Risk and Technical Assessment Report (at approval)

¹ <https://www.foodstandards.gov.au/code/applications/Pages/A1193.aspx>

Executive summary

The Queensland Government Department of Agriculture and Fisheries (the applicant) submitted an application to Food Standards Australia New Zealand (FSANZ) in November 2019 to permit irradiation as a phytosanitary measure (i.e. pest disinfestation) for all types of fresh fruit and vegetables.

Irradiation is already approved for use on 26 fruits and vegetables in Standard 1.5.3 of the *Australia New Zealand Food Standards Code* (the Code). It has been approved for use in Australia and New Zealand for 20 years and internationally since the 1950s. Its use is endorsed by two internationally recognised standards-setting agencies for human and plant health – Codex Alimentarius (Codex) and the International Plant Protection Convention (IPPC) – and supported by relevant quarantine agencies in Australia and New Zealand.

This approval extends current permissions to cover all types of fruit and vegetables. Irradiation is one of a range of treatments used on food to stop the spread of regulated pests between quarantine zones in Australia and New Zealand. Most fresh produce in Australia and New Zealand is grown and consumed within the same quarantine zone and is not subject to any pest disinfestation. Despite this extension to the existing permissions, it is expected that only a small proportion of domestically produced and imported produce will be irradiated. For example, irradiation will be used as an alternative when other phytosanitary methods are not effective or if another traditional treatment is suspended. The Queensland Department of Agriculture and Fisheries has provided conservative estimates that between 0.3 – 8% of total fruit and vegetables consumed in Australia and New Zealand might be irradiated. Mandatory labelling requirements for irradiated foods will apply.

As part of the risk and technical assessment, FSANZ undertook a comprehensive review of the available evidence which demonstrates that:

- irradiation is an appropriate and effective treatment for regulated pests, including fruit fly, at the proposed dose range
- the use of irradiation as a treatment for pest disinfestation is technologically justified and effective in fulfilling its stated purpose
- there are no public health and safety concerns associated with the consumption of fresh fruit and vegetables that have been irradiated at doses of up to 1 kiloGray (kGy).

The toxicological assessment concluded that based on the available evidence there are no safety concerns with the consumption of fresh fruit and vegetables that have been irradiated at doses of up to 1 kGy. Radiolytic compounds generated through food irradiation are at levels generally comparable to those naturally present in cooked food and are not likely to result in harm. Further, there is no evidence that phytosanitary irradiation of fruit and vegetables at the proposed doses would increase the toxicity of any mycotoxin contamination, or increase the allergenicity of the produce, or result in additional dietary exposure to furan.

The nutrition risk assessment concluded that, based on the available evidence, the effect of irradiation on the micronutrient intake across the Australian and New Zealand populations from fruit and vegetables is minimal. The nutrition risk assessment was based on, among other things, nutrient impact data covering the most commonly consumed fruit and vegetables as well as those that provide the largest proportion of dietary intake from fruits and vegetables for the Australian and New Zealand populations. Some variability and higher losses in nutrient content due to irradiation were observed in a small number of commodities. These commodities contribute only a small amount to total dietary intake. Moreover, as outlined above, only a small proportion of fruit and vegetables in Australia and New Zealand

will be irradiated.

FSANZ received 480 eligible submissions in response to its public call for comment. Of these, 456 were unsupportive and 24 were supportive of the application.

Key issues raised by submitters related to the technological need to irradiate foods, the safety and nutritional quality of irradiated food and labelling of irradiated foods. FSANZ assessed and considered each individual submission and the issues raised – these are addressed in full at Section 2.2 and Appendix 2.

After careful consideration of submissions and based on the available evidence (including additional risk assessments), FSANZ's risk assessment conclusion and risk management response remained unchanged – irradiation of fresh fruit and vegetables as a phytosanitary measure at the proposed levels, is safe and suitable.

For the reasons summarised in this report, FSANZ approved the draft variation to the Code, with one minor amendment (see Section 1.7 of this report). The approved draft variation will amend section 1.5.3—3 to permit irradiation of fresh fruit and vegetables for the purpose of pest disinfestation for a phytosanitary objective. The current permission in section 1.5.3—3 for 26 fruits and vegetables will be replaced with a permission for fresh fruit and vegetables.

The scope of the permissions cover fresh fruit and vegetables presently described in Schedule 22 of the Code, and any other fresh commodity generally understood to be a fruit or vegetable. Commodities not in scope include dried pulses and legumes (classified as 'Vegetables' in Schedule 22), and nuts and seeds (classified as a separate food group 'Nuts and Seeds' in Schedule 22).

The applicant did not request any changes to the dose range, and it remains unchanged (150 Gray (Gy) to 1 kGy). Other existing conditions (including mandatory labelling and record keeping requirements) continue to apply. Use of irradiation on fresh fruit and vegetables is voluntary and only one of a number of existing phytosanitary treatment options. Its use for anything other than phytosanitary purposes is not permitted.

1 Introduction

1.1 The applicant

The application was made by the Queensland Government Department of Agriculture and Fisheries (QLD DAF). QLD DAF operates in the areas of policy development, biosecurity, fisheries and forestry management, research and development, and trade and export, to support the agriculture, fisheries and forestry sectors in that state.

1.2 The application

The application was received on 6 November 2019. It sought to change Standard 1.5.3 – Irradiation of food, of the *Australia New Zealand Food Standards Code* (the Code) to permit the use of irradiation on all fresh fruit and vegetables for the purpose of pest disinfection for a phytosanitary objective². This in effect was an extension to the existing permissions covering 26 fruits and vegetables, where the treatment is for a phytosanitary purpose only.

A phytosanitary treatment is used on food that is entering another quarantine region, when there is a requirement for that food to be free from regulated pests. This requirement can apply to interstate trade across different quarantine jurisdictions within Australia. It can also apply to imports into Australia and New Zealand.

The application sought the above permission for all fresh fruit and vegetables presently described in Schedule 22 of the Code, and any other fresh commodity generally understood to be a fruit or vegetable. The application excluded dried pulses and legumes (classified as 'Vegetables' in Schedule 22), and nuts and seeds (classified as a separate food group 'Nuts and Seeds' in Schedule 22). The application did not seek any change to the required dose range: that is, 150 Gray (Gy) to 1 kiloGray (kGy).

The application claimed that the above permission, if granted, would in practice apply to only a small proportion of domestically produced and imported produce that requires a phytosanitary treatment to permit its movement into another quarantine region. This was on the basis that most fresh produce in Australia and New Zealand is grown and consumed within the same quarantine jurisdiction and, as such, is not subject to any phytosanitary treatment for pest disinfection. For some produce that does cross quarantine borders, e.g. Australian-grown vegetables, an end point phytosanitary treatment is also unnecessary as harvesting and processing requirements result in soil and pest free commodities. In other cases, existing and well established phytosanitary treatments will continue to be used instead of irradiation. The application stated that irradiation as a phytosanitary treatment would be an alternative when other methods are not effective or if another traditional treatment has been suspended. In all, the applicant estimated 3% and 8% of total fruit and 1.2% and 0.3% of total vegetables consumed in Australia and New Zealand, respectively, might be irradiated.

The application stated that the above permission would bring Australian and New Zealand regulations into line with international standards and recommendations.

Standard 1.5.3 includes a number of other mandatory requirements for food irradiation, covering conditions for the re-irradiation of food, sources of radiation, record-keeping and labelling information requirements. The application did not propose any changes to these requirements.

² A phytosanitary measure includes any legislation, regulation or official requirement that prevents the introduction and/or spread of quarantine pests.

1.3 The current Standard

Australian and New Zealand food laws require that food for sale must comply with the Code. The requirements relevant to this application are summarised below.

1.3.1 Permitted use

Paragraphs 1.1.1—10(5)(d) and (6)(h) of the Code provide that a food for sale must not consist of, or have as an ingredient or a component, a food that has been irradiated, unless expressly permitted by the Code. Division 2 of Standard 1.5.3 of the Code contains the relevant permissions for the irradiation (and re-irradiation) of food. At present, 26 specific fruits and vegetables are permitted to be irradiated for the purpose of pest disinfection for a phytosanitary objective.

In addition, subsections 1.5.3—4 and 1.5.3—5 of the Code provides that herbs, spices and plant material for a herbal infusion may be irradiated for the purpose of controlling sprouting and pest disinfection, including the control of weeds.

1.3.2 Record keeping

Subsection 1.1.1—14(2) states that if the Code sets requirements for record-keeping in relation to food, those requirements must be complied with. Division 3 of Standard 1.5.3 details the record keeping requirements of the person irradiating the food (section 1.5.3—8).

1.3.3 Labelling requirements

Subsection 1.1.1—10(8) states that if a labelling requirement of the Code applies to the sale of food, the labelling must comply with the requirement.

Subsection 1.2.1—8 and 1.2.1—9 of the Code contains information requirements for foods that are required to bear a label, and for those not required to bear a label, respectively, including information relating to irradiated food.

Section 1.5.3—9 requires that if the food has been irradiated, or if an ingredient or component of the food has been irradiated, then there must be a statement to the effect that the food, or the ingredient or component of that food, has been treated with ionising radiation.

1.4 International standards

In developing food regulatory measures, FSANZ must have regard to the promotion of consistency between domestic and international food standards. The relevant international standard setting agencies are the Codex Alimentarius Commission (Codex) and the International Plant Protection Convention (IPPC). Both agencies endorse the use of food irradiation.

The relevant Codex standard is the [Codex General Standard for Irradiated Foods](#) (CXS 106-1983, Rev.1-2003) (CAC 2003). Under this standard, food may be irradiated to a maximum dose of 10 kGy, provided irradiation fulfils a technological requirement and/or is beneficial in protecting consumer health. This standard also states that irradiation must not be used as a substitute for good hygienic and good manufacturing practices or good agricultural practices.

The [Codex General Standard for the Labelling of Prepackaged Foods](#) (CXS 1-1985) includes specifications for the labelling of irradiated foods, including when an irradiated product is used as an ingredient in another food. This standard states the use of the international food

irradiation symbol (the Radura symbol) is optional, but specifies conditions for its use.

The IPPC sets internationally recognised protocols and standards for food irradiation including the International Standard for Phytosanitary Measures 18 (ISPM 18) – *Guidelines for the use of irradiation as a phytosanitary measure* (FAO IPPC 2003) and ISPM 28 – *Phytosanitary treatments for regulated pests*, with Part 7 being specific to fruit flies (FAO IPPC 2009). See Section 2.5 of SD1 for further details regarding these international standards.

In addition, the EU, as well as a number of countries worldwide, have specific, national regulations covering the irradiation of food, including fresh fruit and vegetables. Amending the Code as requested will bring Australian and New Zealand standards more into line with Codex and other countries' regulations. See Appendix 1 for a summary of specific countries' permissions for irradiated foods.

1.5 Reasons for accepting application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) and
- it related to a matter that might be developed as a food regulatory measure.

1.6 Procedure for assessment

The application was assessed as a General Procedure.

1.7 Decision

The draft variation as proposed following assessment was approved with an amendment. The variation takes effect on gazettal. The approved draft variation, as amended after consideration of submissions, is at Attachment A.

The related explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

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

The amendment made to the draft variation was a consequential amendment to Note 1 of Schedule 22. The amendment makes it clear that a purpose of Schedule 22 is to describe foods and classes of foods for the purposes of subsection 1.5.3—3(2). The need for this amendment was overlooked at the time the draft variation was prepared.

2 Summary of the findings

2.1 Submissions received

FSANZ called for submissions on a proposed draft variation to the Code on 30 October 2020. A total of 480 eligible submissions were received with private individuals making up the majority of submissions. Of the total, 456 were unsupportive and 24 were supportive of the application. Of those that were unsupportive, 156 were based on a 'sample letter' provided by Friends of the Earth on their website: https://www.foe.org.au/queensland_irradiation.

A copy of the 'sample letter' has also been saved to the FSANZ webpage for A1193: <https://www.foodstandards.gov.au/code/applications/Documents/A1193%20Campaign%20Letter.pdf?csf=1&e=pVD2WM>.

FSANZ had regard to all submissions received.

Table 1 provides a summary of the number of submissions received from various sectors of the community broken down by whether or not they supported the application. Table 2 categorises the main themes raised in the submissions, by the various submitter groups. The numbers reported in Table 2 are approximates, as the information contained in each submission could not always be clearly categorised into a single theme for the purposes of providing the summary below.

Table 1: Number of supportive and unsupportive submissions received by submitter group

Submitter group	Supportive	Unsupportive	Total
Private individuals	2	422	424
Industry	13	7	20
Government	4	-	4
Health practitioners	-	13	13
Community groups	1	10	11
Other	4	4	8
Total	24	456	480

Table 2: Main themes raised in submissions from the various submitter groups*

Theme	Number of submitters						
	Total	Private individuals	Industry	Govt	Health practitioners	Community group	Other
Safety	341	291	20	3	13	9	5
Nutritional impact	314	284	7	2	10	8	3
Technological justification	63	37	16	3	0	7	0
Labelling	250	227	8	2	6	7	0
Monitoring and enforcement	8	3	1	2	0	2	0
Other issues**	329#	--	--	--	--	--	--

*Both supportive and unsupportive submissions, as well as those based on the 'sample letter' were included in this compilation. Submissions can address multiple themes.

**These include Freshness/Quality, Horticultural industry, Harmonisation of regulations and trade, Scope of permissions, FSANZ process, Public opinion and legal.

#There were 329 submissions that raised at least one of the 'Other issues'.

2.2 Summary of issues raised in submissions

Table 3 below provides a high level summary of the submitters' issues and FSANZ's responses to these.

Supportive

Submitters in support of the draft variation indicated that:

- Irradiation as a phytosanitary treatment is safe, effective and important for Australian

and New Zealand biosecurity purposes.

- Permitting the irradiation of fruit and vegetables will bring Australia and New Zealand more into line with the legislative approach taken by countries that already trade in fresh fruit and vegetables irradiated for a phytosanitary purpose.
- Irradiation as a phytosanitary treatment will create opportunities for the domestic industry to access a range of new international markets for trade.

Although supportive, submitters stressed the importance of ensuring that existing labelling requirements remain and the need for close monitoring by regulators to ensure irradiation is not used for purposes other than pest disinfection, such as to prolong shelf life. See Appendix 2 – FSANZ’s responses to submissions for more details.

Unsupportive

In contrast, submitters opposed to irradiation raised concerns about:

- the technological need to irradiate foods
- the safety and nutritional quality of irradiated foods
- inadequate/poorly enforced labelling of irradiated foods
- other issues, some of which are outside of FSANZ’s remit.

For the purposes of providing this report, these issues have been summarised in Table 3 below, and further details are provided in Appendix 2 and Appendix 3. Appendix 3 contains a point by point rebuttal of specific issues raised in the ‘sample letter’. In addition, this appendix contains FSANZ’s responses to issues raised by Friends of the Earth on the following pages of their website:

1. Brief overview of food irradiation in Australia and New Zealand
https://www.foe.org.au/queensland_irradiation
2. Food Irradiation A1193 FAQ
https://www.foe.org.au/a1193_faq.

One joint submission from Food Irradiation Watch/Gene Ethics contained a separate attachment of 53 questions relating to various aspects of the application itself, and a further 11 questions relating to Supporting Document 1 (SD1) of the CFS report. The responses provided in Table 3 address the core issues contained in these questions, and more details are provided in Appendix 4.

FSANZ notes that many of the issues raised in submissions for A1193 have been raised in submissions and campaign letters for previous irradiation applications. This is particularly applicable to safety, labelling and technological purpose, where no new evidence or material has emerged since the last irradiation application in 2016. Nevertheless, FSANZ has reviewed these issues as part of A1193, and responded in Table 3 and Appendices 2-4, accordingly.

As a result of additional work to address concerns raised in submissions, a number of sections in SD1 have been amended to include further details, particularly Section 2 (Technological need and quarantine requirements) and Section 5 (Dietary intake assessment). Section 5 includes a new section that evaluates the coverage of the nutrient impact data compiled in the nutrition risk assessment against commonly consumed commodities and contributions to nutrient intakes. This section provides further support for the risk assessment conclusions. See Table 3 and/or Appendices 2-4 for details.

Table 3: Summary of key issues raised in submissions

No.	Issue	Raised by	FSANZ response
Safety assessment			
1	The safety of irradiated food has not been established. Multiple studies suggest there should be concerns about the effects of food irradiation on health.	Private individuals GE Free Northland Health practitioners Academia Sustainable Agriculture and Communities Alliance (SACA), Victoria GE Free NZ Food Irradiation Watch/Gene Ethics	For the reasons set out in this report and SD1, FSANZ remains satisfied that irradiation of fruit and vegetables as proposed will not pose a public health and safety risk. Submitters cited numerous studies or articles indicating that food irradiation is unsafe due to formation of radiolytic compounds, free radicals, carcinogens, and other toxic chemicals. FSANZ reviewed all the studies and articles and found that these have either been addressed in previous FSANZ risk assessments, are incorrect or irrelevant, have been misrepresented in the article, or actually support irradiation (see Appendix 2 for FSANZ comments on studies).
2	Irradiation can cause the accumulation of toxic radiolytic compounds that may be mutagenic and carcinogenic.	Food Irradiation Watch/Gene Ethics Private individuals Sustainable Agriculture and Communities Alliance (SACA), Victoria	Hazard assessment of the radiolytic products is included in SD1. It was concluded in this and previous FSANZ hazard assessments of radiolytic products, as well as by the World Health Organization (WHO), European Food Safety Authority (EFSA), US Food and Drug Administration (US FDA) and other regulatory authorities, that phytosanitary irradiation does not increase the risk of cancer. No new information was provided by submitters or located by FSANZ that would lead FSANZ to change its previous conclusions.
3	FSANZ should give consideration to conducting a dietary exposure assessment for furans to show that irradiation of food has no impact on exposure to furans through the diet.	New Zealand Food Safety	A review of the data from the New Zealand Dietary Furan Programme was undertaken and a summary of relevant concentration data and estimates of furan dietary exposure have been included in SD1 (Section 3.2.2.1). In addition, consideration of the potential worst case dietary exposure to furan from irradiated fruit and vegetables was estimated and a comparison made with total dietary exposure to furan. This showed that exposure to furan from irradiated fruits and vegetables is likely to be negligible.
4	Irradiation of pet food responsible for neurological disorders leading to paralysis and death in cats.	Private individuals Food Irradiation	The submitters refer to irradiation of cat food at very high doses (at least 50 times higher than the maximum dose sought by the applicant in the current application) which was found to have toxic effects in cats. The toxicity of

No.	Issue	Raised by	FSANZ response
		Watch/Gene Ethics Sustainable Agriculture and Communities Alliance (SACA), Victoria GE Free NZ Wiser Equity Pty Ltd Friends of the Earth NZ	highly irradiated cat food to cats was discussed in FSANZ's previous hazard assessment for Application A1092 ³ . The toxic effects are specific to cats and are not observed in other species.
Safety – nuclear industry and the environment			
5	Submitters raised a number of issues related to the nuclear industry, noting that food irradiation is a branch of the nuclear industry, and there are inherent safety issues regarding transport, commercial use and workplace health and safety. Impacts on the environment were also of concern. The depleted radioactive waste must be disposed of in a security-conscious manner.	Private individuals Academia	<p>Issues concerning the safety of this branch of the nuclear industry, including potential environmental issues, are outside FSANZ's regulatory mandate and are the responsibility of other agencies' legislation. These may include the relevant state/territory environment departments, environment protection authorities and the radiation health/safety areas of health departments.</p> <p>In both Australia and New Zealand, the nuclear industry is regulated with strict guidelines and standards on the establishment and routine operation of irradiation facilities, use and storage of radioactive material, and transport and disposal of radioactive material.</p> <p>In Australia, food irradiation is undertaken using the radionuclide ⁶⁰Co and, more recently, X-rays. The radionuclide ⁶⁰Co source does not produce radioactive waste material but decays over time to produce non-radioactive nickel. The sources can be returned to the supplier for reactivation or reuse in another application.</p>
Nutrition assessment			
6	Submitters expressed concerns about the effect of irradiation on the nutrient content of foods.	Academia Private individuals	The effect of irradiation on nutrients has been addressed in Section 4 of SD1. The FSANZ risk assessment (SD1) focussed mainly on vitamin C and β-carotene as these vitamins are most likely to be affected by irradiation, and fruit and vegetables are important sources of these nutrients in the diet. The

³ See A1092 Irradiation of specific fruits and vegetables Approval Report, SD2 Risk and technical report. [A1092-Irradiation-AppR-SD2.pdf \(foodstandards.gov.au\)](https://www.foodstandards.gov.au/foodstandards.gov.au)

No.	Issue	Raised by	FSANZ response
		Food Irradiation Watch/Gene Ethics Sustainable Agriculture and Communities Alliance (SACA), Victoria GE Free NZ Wiser Equity Pty Ltd GE Free Northland	weight of evidence which has been reviewed and evaluated by FSANZ in this application (as well as in previous applications and FSANZ's 2014 review) indicates that losses of vitamin C and β -carotene in fruit and vegetables that are irradiated are small.
7	Submitters expressed concerns about uncertainty in evidence about impact of irradiation on nutrient losses.	As above	FSANZ has indicated in SD1 where there was limited data on the effect of irradiation on nutrient content (e.g. vitamin E and thiamin). In cases where data on irradiation-sensitive vitamins was unavailable FSANZ noted that fruit and vegetables only make a relatively small contribution to population intakes of these nutrients and there are other food groups that are important dietary sources. Where nutrient losses due to irradiation were found in specific commodities, these contributed only small amounts to total dietary intakes. Specific comments related to nutrition issues are provided in Appendix 2 (see nos. 26 – 46). Therefore we reiterate the conclusion that based on the available evidence the effect of irradiation on the nutritional quality of fruit and vegetables is likely to be low.
8	Submitters were concerned that the amount of irradiated fruit and vegetables that are available for consumption will increase substantially following approval of this application, thus affecting nutrient intakes.	As above	Irradiation will remain a voluntary measure that can only be used for phytosanitary purposes. It also remains one of several phytosanitary treatment options available, and it would only be used for fresh fruit and vegetables that are being transported from one quarantine region into another. There are constraints to a substantial increase in the use of phytosanitary irradiation – such as cost, capacity, consumer acceptance and supply chain logistics. The applicant has provided conservative estimates that between 0.3 – 8% of total fruit and vegetables consumed in Australia and New Zealand might be irradiated. FSANZ concludes that the irradiation of fruit and vegetables would have minimal impact on population nutrient intakes, and this conclusion is valid in the context of the small proportion of fresh fruit and vegetables likely to be treated.

No.	Issue	Raised by	FSANZ response
9	Submitters were concerned about lower nutrient intakes due to irradiation of fruit and vegetables.	As above	Based on the number of factors considered in the dietary intake assessment, including that commodities where nutrient losses were shown only contribute small amounts to dietary intakes (i.e. 0.4% or less of vitamin C intakes from rocket and spinach), and that only a small proportion of fruit and vegetables will be irradiated (see response to no. 8 above), FSANZ concluded that there would be minimal impact on population nutrient intakes. In addition, see Section 5.2.6 in SD1 – a new section that evaluates the coverage of the nutrient impact data compiled in the nutrition risk assessment against commonly consumed commodities and contributions to nutrient intakes.
10	Submitters were concerned about potential health impacts from irradiation of fruit and vegetables	As above	From a nutrition perspective (see above for safety considerations), the risk associated with irradiation is that the nutritional quality of fruit and vegetables is reduced and may lead to nutrient inadequacies. Whilst some published studies indicated losses in nutrient content of some irradiation sensitive nutrients such as vitamin C and β -carotene in some commodities, other factors were considered in the dietary intake assessment. These factors included that fruit and vegetables contribute only a proportion of total dietary vitamin C and β -carotene intake (42 – 63% for vitamin C and 62 – 73% for β -carotene), a variety of foods contribute to the intake of individual nutrients, and only a small proportion of fruit and vegetables would be irradiated (conservative estimates being between 0.3 – 8%). The impact of vitamin losses in specific commodities was investigated by FSANZ (see Section 5.2.2 in the SD1) and were shown to contribute a small proportion to total dietary intakes of the nutrient (i.e. 0.4% or less of vitamin C intakes from rocket and spinach). Therefore, any impact of irradiation on nutrient content will have minimal impact on total dietary intakes. Responses to submissions in relation to other nutrients (e.g. folate, thiamin, vitamin E, vitamin A, vitamin K) are directly addressed in Appendix 2 (see nos. 26 – 46).
11	Submitters expressed concerns for specific sub-groups within the population from eating irradiated produce, including infants and children, and people with allergies.	As above Allergy and Anaphylaxis Australia	The dietary intake assessment conducted by FSANZ for this application and previous applications for phytosanitary irradiation considered the Australian and New Zealand populations, which includes all age groups including children, and sub-populations with varied eating habits including very high intakes of fruit and vegetables. Multi-generation studies in animal models show that there are no specific safety concerns for infants or children.
Technological justification			
12	There is no demonstrated technological need for using irradiation as a phytosanitary measure, as numerous chemical-free alternatives exist.	Food Irradiation Watch/Gene Ethics GE Free NZ	This issue has been addressed in Section 2 of SD1. Irradiation will not be a mandatory treatment under the Code. Rather, it will be only one of a number of existing phytosanitary treatment options from which the horticultural industry may choose, depending on their individual

No.	Issue	Raised by	FSANZ response
		<p>Sustainable Agriculture and Communities Alliance (SACA), Victoria</p> <p>Friends of the Earth NZ</p> <p>Private individuals</p> <p>Ceres Natural Foods</p> <p>GE Free Northland</p> <p>Organic Industries of Australia</p> <p>Wiser Equity Pty Ltd</p>	<p>circumstances.</p> <p>FSANZ's risk assessment demonstrates the technological justification and efficacy of treating fruit and vegetables with irradiation as a phytosanitary measure, whereby a minimum dose of 150 Gy can prevent the emergence of adult fruit flies in fruit and vegetables, and a minimum dose of 400 Gy is recognised as a generic treatment for all insects in all host fruit and vegetables (except adult Lepidoptera that pupate internally).</p> <p>FSANZ has been advised by the relevant quarantine authorities that irradiation is an internationally accepted quarantine measure for control of fruit fly and other insect pests and provides an effective alternative to other methods. FSANZ has been advised by industry that while other options exist (including chemical-free alternatives), these may be unsuitable for use in certain circumstances due to potential phytotoxicity and quality issues and require prior approval from quarantine authorities. In such circumstances irradiation is a feasible alternative. No credible evidence to the contrary was provided by submitters or located by FSANZ.</p>
13	Food irradiation will not eliminate the use of chemicals in crop production, rather, it will be used in conjunction with existing treatments.	<p>Food Irradiation Watch/Gene Ethics</p> <p>Private individuals</p> <p>Wiser Equity Pty Ltd</p>	The use of phytosanitary irradiation is not intended to eliminate all chemical use – it is simply another treatment option for quarantine purposes. FSANZ's SD1 states that ionising radiation can be a viable and effective alternative to chemical treatments, particularly in cases where such treatments have been restricted or are being phased-out. Examples include the insecticides dimethoate and fenthion, and the fumigant methyl bromide (MeBr).
14	There is no mechanism to ensure that industry will determine or use radiation dosages for particular purposes, products, and/or pests.	Food Irradiation Watch/Gene Ethics	<p>The processing of food by irradiation is one of the heaviest regulated and audited treatments available to industry. Correct dosages are managed by accurate dosimetry and maintenance of records under the requirements of Standard 1.5.3.</p> <p>The application is seeking permission to use irradiation at dosages ranging from 150 Gy to 1 kGy. There is no incentive for industry to use doses that fall outside the permitted range, noting that lower doses will likely be ineffective for pest disinfestation and higher doses may impair organoleptic properties.</p>
15	As microbial contamination is also treated and shelf-life is extended when produce is irradiated, what practical and routine processes exist to ensure that insect de-infestation is the sole purpose for such treatments? Are these collateral benefits of treatment not also incentives to use irradiation?	Food Irradiation Watch/Gene Ethics	See FSANZ's response to no. 14 above and no. 21 below. Permitted phytosanitary doses are insufficient to result in microbial decontamination or any marked increase in shelf life.

No.	Issue	Raised by	FSANZ response
	Labelling		
16	The requirement for labelling irradiated fruit should be removed since the public health and safety of such produce is now clearly established. Labelling is an unnecessary cost for both industry and consumers to bear.	New Zealand Food and Grocery Council	<p>The intent of mandatory labelling requirements for irradiated food is to enable consumers to make an informed choice. In 2011, an independent review of labelling recommended that the requirement for mandatory labelling of irradiated food be reviewed. In their response to the recommendation, Food Regulation Ministers asked FSANZ to review the need for the mandatory labelling of irradiated food, and assess whether there is a more effective approach to communicate the safety and benefits of irradiation to consumers. In April 2017, Food Regulation Ministers considered FSANZ's review report and agreed that no further action was required.</p> <p>Noting the findings of this 2017 review, and as the application is not seeking a change to the labelling requirements, removal of mandatory labelling requirements is therefore out of scope.</p>
17	<p>There is a lack of confidence around adequate labelling. Issues raised by submitters included:</p> <ul style="list-style-type: none"> • Labels and displays containing labelling information regarding irradiation need to be of a specific legibility and/or size. • The Radura symbol is not readily understood by consumers and should be mandated. • Labelling regulations should specify the wording for the required labelling statement. • The labelling of irradiated foods needs to be monitored and enforced more effectively. 	<p>Private individuals</p> <p>Friends of the Earth NZ</p> <p>Food Irradiation Watch/Gene Ethics</p> <p>Consumers SA</p>	<p>FSANZ has no evidence that consumers find the legibility of information relating to irradiated food to be problematic and considers existing generic legibility requirements that currently apply are appropriate.</p> <p>As noted in Section 4.1, use of the Radura symbol is voluntary. This is consistent with the Codex Standard for Labelling of Pre-Packaged Foods (CXS 1-1985), which permits the optional use of the Radura symbol.</p> <p>Similarly, the Code does not prescribe the wording of the mandatory statement. This is consistent with CXS 1-1985 which specifies a written statement indicating the food has been treated with ionising radiation, but does not specify the words to be used.</p> <p>Monitoring and enforcement of compliance with Code requirements is the responsibility of the relevant enforcement agencies in each Australian state and territory and New Zealand.</p>
18	One submitter recommends clarification of the term 'fresh' as it applies to fruits and vegetables, by way of a definition or reference to a definition [in the drafting]. In the absence of criteria that delineates 'fresh', there could be confusion amongst consumers and industry regarding what are the intrinsic or extrinsic physicochemical attributes of the specific fruits and vegetables that define them as fresh.	<p>Food Safety Standards and Regulation, Health Protection Branch, Department of Health, Queensland</p> <p>Food Irradiation Watch/Gene Ethics</p>	<p>The term 'fresh' has been used in this application to clarify the types of produce items that may be permitted for irradiation.</p> <p>The Code does not regulate the use of 'fresh' claims made on food labels. Suppliers can voluntarily provide this kind of information on the labels of their food products, as long as the information is not false, misleading or deceptive under consumer protection legislation. In Australia, the Australian Competition and Consumer Commission (ACCC) enforces the Competition</p>

No.	Issue	Raised by	FSANZ response
	Other submitters were of the view that the marketing and labelling of irradiated food as 'fresh' raises issues regarding false and misleading representations. Irradiated produce is intentionally and significantly altered and should not be described or marketed as fresh.	Private individual	and Consumer Act 2010 (Cth); and states and territories enforce their own consumer protection legislation. In New Zealand, the New Zealand Commerce Commission (NZCC) enforces the Fair Trading Act 1986 (NZ), which prohibits false and misleading conduct by businesses.
Monitoring, surveillance and enforcement			
19	There is scant evidence of any monitoring of the personal or public health impacts of the consumption of irradiated produce. Indeed, "consumption data are not available." Therefore, suggesting that food irradiation has been proven safe – without any kind of surveillance system – is scientifically indefensible.	Food Irradiation Watch/Gene Ethics Private individual	<p>There is a long history of safe use of ionising radiation for foodstuffs both in Australia and internationally. The outcomes of FSANZ's most recent assessment for Application A1193 indicate that there are no new public health or safety considerations that need to be addressed.</p> <p>Diets composed entirely of irradiated food have been consumed for protracted periods by astronauts and by patients with severe immunodeficiencies with no adverse effects.</p> <p>Nutrient intakes of the population are monitored over time via national nutrition surveys. Using a combination of consumption data obtained from survey respondents, and food composition data from national food composition databases, these surveys can be used to determine dietary intakes, the foods contributing to nutrient intakes and any inadequate or excess intakes of nutrients in the population. National food composition databases are compiled and updated over time, with updates focussing on commonly consumed foods that are major contributors to population nutrient intakes. National food composition databases contain the best available evidence of the nutrient content of the food supply at that point in time. Existing national food composition databases do not include a discrete set of nutrient data on irradiated produce for use in national nutrition surveys at this point in time, likely due to the limited availability of such produce. National food composition databases will continue to be updated over time with contemporaneous data that reflects changes in the nutrient content of fresh produce, including any changes resulting from more irradiated produce being part of that food supply.</p>
20	Without a strict monitoring and enforcement regime, there are no guarantees that food will not be irradiated for other than what is permitted, for example, to extend shelf life; to remove pathogenic microbial contamination; or to sterilize produce, for distributor	Food Irradiation Watch/Gene Ethics	As mentioned in FSANZ's response to no. 17 above, monitoring and enforcement of compliance with Code requirements is the responsibility of the jurisdictions.

No.	Issue	Raised by	FSANZ response
	convenience or marketing advantage.		
21	There is no simple, reliable and affordable test for irradiated foods and so it may be difficult for state and local authorities to monitor produce in the marketplace, to assess the dose used, or to enforce the labelling requirements.	Food Irradiation Watch/Gene Ethics	<p>Monitoring and enforcement of compliance with Code requirements is the responsibility of the jurisdictions.</p> <p>Various methods exist for detection of irradiated foods.</p> <p>Current detection methods for irradiated food are able to detect whether a food has been irradiated or not, but cannot accurately measure absorbed doses as the changes that irradiation induces in foods are minimal. However, the dose 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 and maintenance of records requirements under Standard 1.5.3 of the Code.</p>
	Freshness/Quality		
22	<p>Many submissions included comments about the impact that irradiation may potentially have on the produce, in terms of freshness and quality and, subsequently, on those consuming the treated food. Examples of some comments included:</p> <ul style="list-style-type: none"> • Irradiation will destroy all living enzymes. • Irradiation kills the goodness of fresh produce. • Food should be natural and the way it was intended to be consumed. • Evidence shows that the natural bacteria on the skins of fresh produce are important for the health of the human gut biome and irradiation also kills that good bacteria. • Irradiation does not kill viruses and all bacteria and it does not remove toxins in the fruit, giving consumers a false sense of security over the handling of fruits. 	<p>Private individuals</p> <p>Ceres Natural Foods</p>	<p>Treatment with the appropriate doses of irradiation, within the approved dose range of 150 Gy – 1 kGy is likely to minimise any impacts on the overall freshness and quality of fruit and vegetables. Optimal dosages for each commodity are determined through experience and experimental data.</p> <p>Irradiation is not proposed as an alternative to good agricultural practices and appropriate hygiene measures are still necessary to ensure that safe and suitable produce is provided to consumers. Food irradiation cannot be used to clean up already spoiled food.</p> <p>There is no evidence that irradiation has a detrimental impact on human health through destruction of enzymes or of beneficial bacteria.</p>
23	Many submissions included comments that fruit and vegetables should not be tampered with, that irradiation is a form of food tampering, and that fruit and vegetables should be available for purchase and consumption in their fresh, natural and unadulterated state.	Private individuals	<p>Irradiation does not constitute a form of food tampering. The irradiation of fruit and vegetables as proposed in the application has been assessed as an appropriate and efficacious treatment and there are no public health and safety concerns associated with its use.</p> <p>There are already a number of existing phytosanitary treatment options from which the horticultural industry may choose, to ensure safe and suitable produce is available to consumers in Australia and New Zealand. If the</p>

No.	Issue	Raised by	FSANZ response
			application is approved, irradiation will be another such option; its use will be voluntary and based on individual business requirements.
	Horticultural industry		
24	FSANZ should seek to communicate with the horticultural sector about the proposed new permission and consumers, noting there may be an increase in irradiated foods in the market.	Victorian Department of Health and Human Services and the Victorian Department of Jobs, Precincts and Regions	Noted. FSANZ will develop communication products post the Call for Submissions period to raise awareness and understanding of the application and food irradiation more broadly.
25	<p>A range of comments regarding how the use of phytosanitary irradiation will be of benefit to the horticultural industry were made, as follows:</p> <ul style="list-style-type: none"> • Current treatment options are not reliably effective and can cause damage to shelf life and product quality. This restricts the business from supplying some markets, with the market going underserved and prices for consumers rising. • Unlike chemical alternatives, which may remain a concern for workplace health and safety, irradiation is a feasible and ozone friendly alternative. • Phytosanitary irradiation is one of the most reliable and commercially effective biosecurity treatments available. • Irradiation remains extremely sustainable. It is a highly automated process, with an extreme level of process control. • Although the volumes of each approved crop treated remain very seasonal and make up a small percentage of total harvest, the treatment, when required, plays a critical role in the supply chain, ensuring a prosperous and sustainable fresh produce industry. • Irradiation has enabled effective market access where dosimetry has proven to be efficacious for broad spectrum pest control and maintenance of product quality. • Approval of the application will create opportunities for the industry to access a range of new markets for trade, enhance distribution, create greater access for 	<p>Apple & Pear Australia Ltd</p> <p>PM Fresh, NSW</p> <p>Southern Cross Produce, New Zealand</p> <p>Melissa's World Variety Produce, US</p> <p>Seeka, Fresh produce company, NZ</p> <p>Steritech, Queensland</p> <p>Momack Produce, Victoria</p> <p>Ontario Group, Dimbulah Queensland</p> <p>Australian Table Grapes Association, Victoria</p>	Noted.

No.	Issue	Raised by	FSANZ response
	<p>consumers, and thus support market growth.</p> <ul style="list-style-type: none"> • Generic approval of irradiation will not limit organic fruit and vegetable choices. • In terms of emergency preparedness and food security, there is already a generic irradiation treatment for almost any insect/crop combination. It is thus a viable treatment for many crops in the event of a foreign or exotic pest incursion. The inability to use it when needed could place the Australian horticultural industry at unnecessary and great risk. 		
26	<p>The extension to existing approvals to food irradiation is an import-enabling tool, which could facilitate the import of cheap, possibly over-sprayed and sub-standard irradiated food. This influx of cheap product will have a negative impact on the domestic horticultural industry.</p>	<p>Food Irradiation Watch/Gene Ethics</p> <p>Private individuals</p> <p>Wiser Equity Pty Ltd</p> <p>Consumers SA</p> <p>GE Free Northland</p> <p>Sustainable Agriculture and Communities Alliance (SACA), Victoria</p>	<p>Approval of this application will not facilitate the import of over-sprayed and sub-standard irradiated food. All imported food for human consumption must comply with the requirements of the <i>Imported Food Control Act 1992</i>, administered by Australian Government Department of Agriculture, Water and the Environment (DAWE), and is subject to the same requirements of the Code that cover domestically produced food. The sale of imported food in Australian and New Zealand is also subject to national, state and territory food laws that require food for sale to be safe and suitable.</p> <p>In terms of consultation with government, supportive submissions have been received from a number of government agencies. In particular, the two principle biosecurity agencies – DAWE and Biosecurity New Zealand – endorse the use of irradiation as an important quarantine measure for regulated pests. Biosecurity Tasmania endorses irradiation as a quality alternative to MeBr fumigation and use of certain insecticides that are becoming more restricted or being phased out.</p> <p>Numerous submissions from horticultural businesses indicate that phytosanitary irradiation can potentially benefit (as opposed to have a negative impact on) the domestic horticultural industry by allowing broader market access for domestic trade and increasing choice by businesses to use a proven quarantine treatment to eradicate fruit fly pests. In addition, phytosanitary irradiation will be a viable treatment for crops in the event of a foreign or exotic pest incursion, which would otherwise place the Australian horticultural industry at unnecessary risk.</p>
27	<p>The use of food irradiation could create problems for small farmers who either do not wish to or have the infrastructure/ finance to irradiate food.</p>	<p>Private individuals</p>	<p>If this application is approved, irradiation will not be a mandatory treatment under the Code. Rather, it will be only one of a number of existing phytosanitary treatment options from which the horticultural industry may choose. It will be up to individual fresh fruit and vegetable suppliers to decide</p>

No.	Issue	Raised by	FSANZ response
			on the phytosanitary treatment that is best for their particular circumstances, whilst ensuring that the produce they supply is safe and pest free.
28	The submitters request that proposed permissions be extended to include cut flowers, particularly roses. Current approved phytosanitary treatments for import of roses (including MeBr) have their disadvantages with regards to the environment and in particular the ozone layer. A more environmentally sensitive approach to pest management would be welcomed. The X-ray phytosanitary irradiation treatment facility in Melbourne is cold chain friendly, chemical free, and ozone friendly.	Mr Fresh, Victoria Fairtrade Australia New Zealand (FANZ)	Out of scope.
Harmonisation of regulations and trade			
29	<p>The applicant bases most of their argument on the need to access export markets. FSANZ's assessment on the need for irradiation should be made on the quality and safety of food, not on trade considerations and market disruption.</p> <p>Further, FSANZ should not try and justify approving Application A1193 to promote consistency with other international regulations because this is misleading – while some countries have general approvals for the irradiation of fruits and vegetables many others do not.</p>	<p>GE Free NZ</p> <p>Wiser Equity Pty Ltd</p> <p>Food Irradiation Watch/Gene Ethics</p> <p>Private individuals</p> <p>Health practitioner</p> <p>Consumers SA</p>	<p>Noted.</p> <p>FSANZ must assess this application in accordance with the FSANZ Act. As explained in Section 6 of this report, the Act requires FSANZ to have regard to a number of matters in that assessment. These include the protection of public health and safety, which remains FSANZ's primary objective in standards development and in this assessment. As explained in this report, FSANZ's assessment, based on the available evidence, is that permitting the irradiation of fruit and vegetables in the manner sought by the application would not pose a public health and safety risk.</p> <p>The Act also requires FSANZ to have regard to the promotion of consistency between domestic and international food standards and to the desirability of an efficient and internationally competitive food industry.</p> <p>Appendix 1 of this report provides a summary of specific countries' permissions for irradiated foods (focussing mainly on those in the Asia Pacific region and, as such, potential trading partners), including permissions for the irradiation of fresh fruit and vegetables as a phytosanitary measure. Of the 11 countries listed in Appendix 1, 8 have generic permissions for fresh fruit and vegetables.</p>
Concerns related to the scope of the permissions for irradiation			
30	<p>Submitters raised numerous issues relating to FSANZ's consideration of costs and benefits, including:</p> <ul style="list-style-type: none"> • The public will be exposed to further risks, costs and 	<p>Private individuals</p> <p>Ceres Natural Foods</p>	<p>If the application is approved, due to the voluntary nature of the permission, the horticultural industry will only use irradiation where they believe a net benefit exists and a cost benefit analysis of all the other alternative</p>

No.	Issue	Raised by	FSANZ response
	<p>hazards</p> <ul style="list-style-type: none"> • Irradiation of fresh fruit and vegetables will increase costs [to consumers] • Analysis of all the other alternative phytosanitary hasn't been undertaken • Analysis of the benefit of food irradiation. 		<p>phytosanitary measures is not necessary.</p> <p>In terms of the benefits of phytosanitary irradiation, this issue has been addressed in Section 2 of SD1, where FSANZ's risk assessment demonstrates the technological justification and efficacy of treating fruit and vegetables with irradiation as a phytosanitary measure.</p>
31	<p>Submitters were of the view that consumers should be given the choice as to whether or not they purchase irradiated foods.</p> <p>Some submitters expressed these views under the incorrect assumption that irradiation would be mandatory for all fresh produce and, as such, non-irradiated produce would no longer be available.</p>	Private individuals	<p>Mandatory labelling requirements for irradiated fruit and vegetables will enable consumers to make an informed choice.</p> <p>The application does not require the irradiation of all fruit and vegetables, rather it provides a safe post-harvest phytosanitary treatment option for industry to use.</p>
32	<p>FSANZ has not investigated Australian public resistance to irradiation and is forcing this upon consumers. There is no reliable evidence that the Australian and New Zealand public are aware of, or will consent to, the widespread irradiation of fresh produce.</p>	Private individuals	<p>Approval of the application will not force irradiation upon consumers. As explained in this report, irradiation will remain voluntary and only a small proportion of fruit and vegetables available in Australian and New Zealand will be irradiated. Specifically, the applicant has provided conservative estimates that between 0.3 – 8% of total fruit and vegetables consumed in Australia and New Zealand might be irradiated. Labelling requirements will continue to apply to enable consumers to make an informed choice.</p> <p>FSANZ acknowledges that consumers have limited exposure to irradiated food and labelling given the low numbers of irradiated food in the marketplace. This may also mean that consumer awareness and understanding of the food irradiation process and labelling requirements is low. See FSANZ's 2016 review of the mandatory labelling of irradiated food.</p> <p>FSANZ will continue to look for ways to raise awareness and understanding of the application and food irradiation more broadly.</p>
33	<p>Many in the general public are not aware of the foods already approved for irradiation and likely not aware of the proposed changes. Surveys have shown that even when educated, public opinion is negative towards irradiation and it is not a preferred treatment. For example, market research was conducted for an article that appeared in The Land, <i>"The survey results showed that even when informed, irradiation was not the preferred treatment method among consumers."</i></p>	Private individual	<p>Refer to response for no. 32.</p>

No.	Issue	Raised by	FSANZ response
	FSANZ process		
34	<p>Numerous submitters (including those submitting the 'sample letter') expressed concern regarding the expedited timeframe for this application, in particular, that they had not received adequate notice about the commencement of the CFS period, which was brought forward due to the applicant choosing to pay a fee to expedite the application.</p>	<p>Food Irradiation Watch/Gene Ethics</p> <p>Private individuals</p>	<p>Public notice given by FSANZ was legally valid and complied with the requirements imposed by the relevant sections of the FSANZ Act.</p> <p>FSANZ accepted the application on 27 November 2019 and this was publicly notified on 7 January 2020. As part of the notification, FSANZ published an indicative timeline, with a proposed start date of late November 2020. However, the applicant chose to expedite assessment of their application by paying the required fee. The assessment commenced on 12 May 2020, the date the fee was received. Accordingly, the application was publicly re-notified on 15 May 2020. The Call for Submissions period was subsequently also brought forward from early-April 2021 to 30 October 2020 to meet the 9 month statutory timeframe for General Level applications per the FSANZ Act.</p> <p>Updates to timelines for this and all applications and proposals are notified in the publically available FSANZ Work Plan. This is the key document regarding expected timetables for applications and proposals and is frequently updated.</p> <p>FSANZ also notes the following:</p> <ul style="list-style-type: none"> • The initial period given for public consultation was six weeks, the standard length for FSANZ public consultation, with the exception of eight week consultation periods released between March and June 2020 in response to the Covid pandemic. • Public notice was given in both Australia and New Zealand of the Call for Submissions and the dates for public comment in the following ways: <ul style="list-style-type: none"> - The revised dates for consultation were updated in the FSANZ Work Plan and published on 18 May 2020. - The Call for Submissions itself was notified on 30 October 2020 via a FSANZ Notification Circular (with 6,700 subscribers), media release, social media (with over 43,000 Facebook followers and 2,500 Instagram followers), and FSANZ Food Standards News (with 7,600 subscribers).

No.	Issue	Raised by	FSANZ response
			<ul style="list-style-type: none"> • The six week period for public consultation commenced on 30 October 2020, did not occur over a period with major public holidays and was eight weeks before Christmas. • The following options were available for those unable to make the deadline for submissions: <ul style="list-style-type: none"> - Submitters could ask to provide draft comments before the close of submissions, finalising their comments post the closing date by an agreed deadline. - Submitters were able to lodge a late submission after the period for public submissions had closed, to which the Board could still have regard in their decision making. - Submitters could request an extension to the Call for Submissions period as noted on the front page of all FSANZ Call for Submissions reports. • Following the consideration of a request for an extension to the consultation period for A1193, the Call for Submissions was extended by two weeks from 11 December 2020 to 24 December 2020. The extension was publically notified on 11 December 2020.
35	<p>Submitters expressed concern about the timing and expeditious nature of this application, with submitters questioning why it was being “rushed through”.</p> <p>Submitters suggested that the consultation period was deliberately set to coincide with the pre-Christmas rush so as to minimise public awareness and the number of submissions.</p>	<p>Health practitioners</p> <p>Consumers SA</p> <p>Private individuals</p>	<p>The application was not “rushed through”.</p> <p>The Call for Submissions was issued and publically notified on 30 October 2020 – eight weeks before Christmas, and any “pre-Christmas rush”.</p> <p>In terms of public awareness, the Call for Submissions was the subject of extensive public notification. See FSANZ’s response to no. 34 above.</p> <p>The application was assessed in accordance with the FSANZ Act. It requires FSANZ to assess each accepted application in accordance with that Act and within the timeframes set by that Act. The Act also provides that, where an applicant chooses to pay the prescribed application fee, assessment of the application must commence on the day that fee is received by FSANZ. This was the case with Application A1193. FSANZ did not have a discretion to defer or delay that assessment.</p> <p>The timeframe set by the Act for Application A1193 (via General Procedure</p>

No.	Issue	Raised by	FSANZ response
			<p>Level 5) was 9 months. This included a number of statutory major milestones, as set out in the publically available FSANZ Work Plan. To complete the assessment of this application within this required timeframe, an eight week public comment period was provided. A period of six weeks is typical for most applications. See also FSANZ's response to no. 34 above.</p>
36	<p>Submitters made a range of general comments regarding a lack of scientific rigour in FSANZ's assessment, the quality and amount of scientific evidence, bias, and FSANZ's scientific credibility.</p>	<p>Food Irradiation Watch/Gene Ethics</p> <p>Wiser Equity Pty Ltd</p> <p>Private individuals</p>	<p>FSANZ undertakes risk assessments in accordance with the most up-to-date international risk assessment procedures and using the available scientific evidence.</p> <p>FSANZ has previously assessed and characterised the risk from consumption of irradiated fruit and vegetables, as part of its assessment of applications submitted to the agency since 2002 (see SD1). Collectively, these risk assessments considered all of the relevant information that was available at the time (national and international), including animal toxicity and nutrition data relating to the safety and nutritional adequacy of irradiated foods. In addition, FSANZ undertook a dedicated review on the nutritional impact of irradiation of fruit and vegetables, published as a review in 2014.</p> <p>For this application, FSANZ conducted a comprehensive review of the scientific literature that has been published subsequent to the earlier risk assessments and the 2014 review of the literature. The weight of evidence indicates that there are no new public health or safety concerns that need to be addressed as part of the current application.</p>
37	<p>There is concern at the use of Schedule 22, noting its main application within the Code relates to Australia-only maximum residue limits (MRLs). These 'multipurpose' provisions should be stand-alone to avoid confusion and improve transparency of application.</p>	<p>New Zealand Food and Grocery Council (NZFGC)</p>	<p>This issue has been raised by NZFGC and responded to and addressed by FSANZ in previous applications and proposals. See, for example, Application A1163 – Food irradiation definition of herbs and spices.</p> <p>NZFGC has not provided, and FSANZ has not located, any evidence that would warrant a change in FSANZ's stated position on this issue to date.</p> <p>As previously stated:</p> <ul style="list-style-type: none"> • The fact that a law or a Standard exists for one purpose does not mean that that law or Standard, or a list in one part of it, cannot be referenced and used for and by another law or Standard. This is accepted and normal drafting and legislative practice. • Schedule 22 and its precursor has been referenced by the Irradiation Standard since 2001. The purpose statement in section 1.4.2—2 cannot

No.	Issue	Raised by	FSANZ response
			<p>of itself change that fact or the legal effect of section 1.5.3—3 and the definition in subsection 1.5.3—3(2).</p> <ul style="list-style-type: none"> • In any event, the proposed variation for Schedule 22 itself makes clear that a purpose of Schedule 22 is to describe foods and classes of foods for the purposes of subsection 1.5.3—3(2). See Note 1 of Schedule 22. • No evidence has been presented that the proposed references in section 1.5.3—3 to two small parts of Schedule 22 will in fact create confusion or reduce transparency of application.
38	The Queensland Government has a clear conflict of interest by being both the applicant for A1193 and having two representatives, namely the Hons Yvette D'Ath and Mark Furner, on the Forum, being one of the final arbiters of the decision on its own application.	Private individuals	<p>This issue – which relates to the Australia and New Zealand Ministerial Forum on Food Regulation (now the Food Ministers' Meeting) – is out of scope.</p> <p>As explained in this report, FSANZ made its own independent and evidence based assessment of the application in accordance with the FSANZ Act.</p>
Public opinion and legal aspects			
39	A number of submitters raised concerns that the application was highly controversial, misguided and unwise, scientifically, and legally. In terms of the legal aspects, submitters raised concerns regarding the liability of the government (including the Queensland government) and FSANZ in relation to any long-term consequences for the public's health.	Private individuals Health practitioner Wiser Equity Pty Ltd	<p>FSANZ's assessment, based on the available scientific evidence, is that irradiation of fruit and vegetables in the manner proposed does not pose any public health and safety concerns. That assessment was conducted in accordance with and complied with the FSANZ Act.</p> <p>Irradiation has been used since the late 1950s and is one of the most extensively studied methods of food processing. The safety of irradiated foods has been evaluated by international scientific bodies and regulatory agencies in other countries, as well as independently by FSANZ. FSANZ assessments have concluded that phytosanitary irradiation is technologically justified and effective in achieving its stated purpose, and that there are no public health and safety concerns.</p>

3 Risk assessment

The risk and technical assessment report investigated: the technological need for the irradiation of all fresh fruit and vegetables for phytosanitary purposes; whether, when irradiated to a maximum dose of 1 kGy they are as safe and nutritious as their non-irradiated counterparts; and whether there are any implications for the dietary intakes of Australians and New Zealanders.

In undertaking the hazard assessment, nutrition risk assessment and dietary intake assessment, the outcomes of previous assessments by FSANZ were considered, as was a FSANZ review (FSANZ 2014) of the impact of phytosanitary doses of irradiation (up to 1 kGy) on the nutritional quality of a range of fruit and vegetables. The review report is available from the FSANZ website at the following link:

<https://www.foodstandards.gov.au/publications/Documents/Nutritional%20impact%20of%20phytosanitary%20irradiation%20of%20fruit%20and%20vegetables/Nutritional%20impact%20of%20phytosanitary%20irradiation%20of%20fruit%20and%20vegetables.pdf>

The present risk assessment analysed data and information on the technological efficacy of irradiation as a phytosanitary measure, and the safety and nutritional impacts of food irradiation, which has become available since the last irradiation application was considered by FSANZ in 2016.

Further details on the risk and technical assessment can be found in SD1.

3.1 Technological need and efficacy of irradiation

FSANZ has previously assessed the technological need and efficacy of irradiation as a phytosanitary measure for a number of fruit and vegetables. These assessments were conducted in [2002](#), [2011](#), [2013](#), [2014](#) and [2016](#). In each case, FSANZ concluded that there was an established technological need to irradiate these foods, and that irradiation was an efficacious treatment option.

3.1.1 Justification for use of irradiation as a phytosanitary measure

Insect pests of quarantine significance such as fruit fly are a major barrier in gaining access to some markets. Therefore, effective treatments for such pests for quarantine purposes are essential.

Ionising radiation provides an effective quarantine treatment option that is well established in the international trade of horticultural products. As mentioned in Section 1.4 above, its use is endorsed by the relevant international standard setting agencies Codex and the IPPC.

Quarantine agencies in Australia and New Zealand, including the Australian Government Department of Agriculture, Water and the Environment (DAWE), Biosecurity Tasmania and Biosecurity New Zealand (in the New Zealand Ministry for Primary Industries (MPI)) endorse the use of irradiation as an important quarantine measure for regulated pests. Notably, in its submission to FSANZ, Biosecurity Tasmania advised that it considered irradiation to be an effective phytosanitary measure, which provides a quality alternative to MeBr fumigation and use of certain insecticides that are becoming more restricted or being phased out.

DAWE and Biosecurity New Zealand will still need to independently perform an import risk assessment (for quarantine purposes) on irradiation of fruit and vegetables specifically for

food imported into Australia or New Zealand. These assessments are separate from the food standards approval process.

There are certain advantages to using ionising radiation in that it is a broad-spectrum treatment useful for commodities that do not tolerate other options such as heat treatment or prolonged cold storage well, resulting in phytotoxicity or quality issues. At the low doses required to meet a phytosanitary objective (namely, pest disinfestation), irradiation is well-tolerated by the majority of fruit and vegetables. An absorbed minimum dose of 400 Gy is an effective quarantine treatment for the life stages of most arthropod pests associated with the movement of fresh horticultural commodities; 150 Gy is effective for fruit flies. These doses are consistent with international standards and those set by domestic quarantine agencies (See Section 2.5 of SD1 for further details).

The application stated that the permission, if granted, would in practice apply to only a small proportion of domestically produced and imported produce that requires a phytosanitary treatment to permit its movement into another quarantine region (between 0.3 – 8% of total fruit and vegetables consumed in Australia and New Zealand might be irradiated). Appendix 3 of the application provided further details regarding the potential of phytosanitary irradiation treatment for various produce items in the medium term, based on commercial significance and supply and demand influences. For many commonly consumed fresh produce items, including apples, oranges, carrots, broccoli, cauliflower, onions and salad leaf, the application stated that the use of irradiation to meet quarantine requirements and/or industry needs would be of low commercial significance. Likewise, the application also stated that the expected use of irradiation on these produce items to balance seasonal supply and demand will be on a rare or emergency trade need basis only. This information is based on the applicant's knowledge of phytosanitary treatments and commodity trade in general.

3.1.2 Worldwide permissions for food irradiation

Currently, food irradiation is approved in more than 60 countries (GHI 2018), including for fresh fruit and vegetables. Permissions vary considerably in different parts of the world, and they are based on either a case-by-case or a generic approach (without any foods specifically listed) as adopted by Codex (see Section 1.4). A generic approval for the irradiation of all fresh fruit and vegetables for pest disinfestation for a phytosanitary objective will bring Australian and New Zealand regulations more into line with international and other countries' standards. See Appendix 1 for a summary of specific countries' permissions for irradiated foods.

3.1.3 Summary

Irradiation is already approved for use in Australia and New Zealand as a phytosanitary treatment for 26 fruits and vegetables. It is globally recognised as being efficacious and cost-effective, and phytosanitary doses are well-tolerated by the majority of fruit and vegetables. DAWE, Biosecurity Tasmania and NZ MPI have provided advice to FSANZ endorsing irradiation as an effective quarantine treatment for regulated arthropod pests, including fruit flies, which are of quarantine concern to Australia and New Zealand.

The majority of fresh produce in Australia and New Zealand is grown and consumed in the same quarantine jurisdiction and, as such, is not subject to any phytosanitary treatment for pest disinfestation. A further proportion destined for different quarantine regions do not require phytosanitary treatment because the harvesting and processing requirements result in soil and pest free commodities, or else existing phytosanitary treatments remain the best option. Therefore, only a small proportion of the fresh produce available for consumption may be subjected to irradiation.

The irradiation of fresh fruit and vegetables for anything other than a phytosanitary purpose is not permitted under the Code and approval of this application will not change this.

In determining an appropriate phytosanitary treatment, individual businesses within the horticultural sector will have a number of options, one of which will be ionising radiation. The availability of this as an option will also depend on the permissions for use that apply in the jurisdiction receiving the goods; in Australia and New Zealand this involves a pre-market safety assessment. Ultimately, businesses will be able to choose the treatment option that is best for their particular circumstances, based on an assessment of all relevant factors including efficiency and cost.

3.2 Safety and nutritional content of irradiated foods

There are no public health and safety concerns associated with the consumption of fresh fruit and vegetables that have been irradiated at doses of up to 1 kGy. This conclusion is based on the best available evidence and includes the following considerations:

- Radiolytic compounds generated through food irradiation are not produced at levels that are likely to result in harm. The levels of these compounds are generally comparable to those naturally present in cooked food.
- There is no evidence to indicate that phytosanitary irradiation at the proposed doses would increase the allergenicity of food, or increase the toxicity associated with any mycotoxin contamination.
- FSANZ considers that based on the best available evidence the effect of irradiation on the micronutrient intake from fruit and vegetables is likely to be low. The range of fruit that has been assessed is comprehensive, accounting for most types of fruit consumed in Australia and New Zealand; however, the range of vegetables examined is not as comprehensive. An evaluation by FSANZ showed that for the commodities where nutrient impact data were available, they contributed to a large proportion of the dietary intakes from fruits and vegetables, and included the most commonly consumed commodities. While the body of evidence for fruit and vegetables suggests that irradiation-induced losses of micronutrients that are more sensitive to irradiation is small, some variability and higher losses in nutrient content were observed in a few foods.
- The few instances of higher losses in nutrient content are not of concern because there will only be a small proportion of domestically produced and imported fruit and vegetables in Australia and New Zealand treated by irradiation, with some commodities not requiring irradiation due to localised consumption and technological reasons. Therefore the dietary intake of nutrients is likely to come from a mix of non-irradiated and a small amount of irradiated produce over the course of a lifetime. This minimises any impact on population nutrient intakes from consuming irradiated produce.
- The drivers for phytosanitary irradiation are biosecurity requirements and trade patterns. Constraints include cost, capacity, consumer acceptance and supply chain logistics. These factors and the volumes of irradiated fruit and vegetables can be monitored. If the proportion of irradiated fruit and vegetables increased markedly over time, a revised risk assessment could be conducted to ensure current conclusions remain valid.

4 Risk management

The Risk and Technical Assessment Report (SD1) concluded that, on the basis of the best

available evidence, there are no public health and safety concerns associated with consuming fresh fruit and vegetables that have been irradiated at doses of up to 1 kGy. Based on this conclusion and a consideration of other relevant matters including the submissions received, FSANZ recommends that the existing permission for the irradiation of 26 fruits and vegetables in Standard 1.5.3 of the Code be replaced with a permission for all fresh fruit and vegetables (with a consequential amendment to Schedule 22). This is subject to the following requirements being met:

- Irradiation is to be used only for pest disinfection for a phytosanitary objective.
- Irradiation is to be used on fresh fruit and vegetables as presently described in Schedule 22 of the Code, and any other fresh commodity generally understood to be a fruit or vegetable, including crops grown overseas. Commodities that are not permitted under this variation to Standard 1.5.3 include dried pulses and legumes (classified as 'Vegetables' in Schedule 22), and nuts and seeds. Consistent with the approach taken by other provisions and permissions in the Code, the variation does not define what constitutes 'fresh'.
- The permitted dose range remains unchanged i.e. the minimum dose is 150 Gy and the maximum dose is 1 kGy.
- The existing mandatory labelling (see Section 4.1) and record keeping requirements for irradiated foods continue to apply.

In recommending this risk management measure, FSANZ notes that:

- This permission will apply to fresh fruit and vegetables entering another quarantine region that require a phytosanitary treatment to ensure that they are free from regulated pests. As such, this permission is likely to apply only to a proportion of produce available to Australians and New Zealanders that is not grown and consumed in the same quarantine region, depending also on its suitability for irradiation and the availability of other treatments.
- The permission will bring Australia and New Zealand more into line with existing standards and regulations in other parts of the world including the Codex General Standard for Irradiated Foods. This Standard states that irradiation must not be used as a substitute for good hygienic and good manufacturing practices or good agricultural practices.
- Irradiation as a phytosanitary measure will not be mandatory and is only one of a number of phytosanitary treatment options available.
- The labelling of irradiated food, as a risk management consideration for this application, is discussed in Section 4.1 below.
- The nutrition risk assessment concluded that the irradiation of fruit and vegetables would have minimal impact on population nutrient intakes, and these conclusions are valid in the context of the small proportion of fresh produce likely to be treated. A statutory mechanism exists by which permissions in the Code can be formally reviewed and amended by FSANZ should credible new information arise suggesting that a food standard may no longer be appropriate. This could be in relation to public health and safety, labelling or enforcement concerns. FSANZ has a strong track record of reviewing existing standards in this manner. It is not possible to pre-empt the likelihood or timing of any future reassessment of irradiated food only to state that it can be undertaken if necessary.

- Matters concerning minimising the risks of human exposure to unsafe levels of radiation generally, potential risks to the environment, and occupational health and safety risks to workers, are outside FSANZ's statutory remit. These risks are managed by or under different legislation such as that relating to the granting, management and oversight of radiation licences.

4.1 Labelling of irradiated food

The existing requirement for mandatory labelling of irradiated foods at section 1.5.3—9 of the Code will apply to fruit or vegetables permitted to be irradiated as a result of this application.

Section 1.5.3—9 requires that if the food has been irradiated, a statement to the effect that the food has been treated with ionising radiation is required. Similarly, if the food has as an ingredient or component a food that has been irradiated, a statement to the effect that the ingredient or component has been treated with ionising radiation is required. When an irradiated ingredient or component is used in a packaged food, the statement may be in the statement of ingredients or elsewhere on the label.

The wording of the mandatory statement is not prescribed. Food suppliers and manufacturers can decide how to word the statement as long as it indicates that the food has been treated with ionising radiation. Generic legibility requirements will apply, which require statements on a label to be legible and prominent so as to contrast distinctly with the background (section 1.2.1—24).

If an irradiated food or a food containing an irradiated ingredient or component is exempt from bearing a label (e.g. unpackaged fruit or vegetables or food sold in a restaurant) then section 1.2.1—9 of the Code requires that the statement accompany the food or be displayed in connection with the display of the food.

Food sold to caterers is required to have labelling information relating to irradiated food. This information must be on the label of the food required to bear a label (section 1.2.1—15), or provided to the caterer with the food if the food sold is not required to bear a label (section 1.2.1—13).

The Radura symbol (depicted in Figure 1 below) is described in the Codex Standard (CXS 1-1985) as an international food irradiation symbol for optional use on food labels. Codex specifies that when the Radura symbol is used, it shall be in close proximity to the name of the food (refer to Section 1.4 of this report). The Code does not mandate the display of this symbol on the labels of irradiated food, however there is no prohibition on its voluntary use. Even if the symbol is used, the food label must still display the mandatory labelling requirements for irradiated foods.



Figure 1 *The Radura symbol*

4.2 Risk management conclusion

Following consideration of the evidence and FSANZ Act assessment requirements (refer to Sections 3 and 6), including issues raised in submissions (refer to Section 2), FSANZ's decision is to permit the irradiation of fresh fruit and vegetables for phytosanitary purposes. The permitted dose range of 150 Gy to 1 kGy will remain unchanged, as will the existing mandatory labelling and record keeping requirements for irradiated foods.

5 Risk communication

5.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a communication strategy that was appropriate to ensure that all interested parties, including the relevant Commonwealth, New Zealand, and state/territory-based government agencies, the horticultural industry, exporters and importers, and members of the public, were aware of this application and kept up to date on progress. 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 approaches standards 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. FSANZ also engaged with key stakeholders including several consumer groups, Australian jurisdictions and the New Zealand government.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application. FSANZ had regard to all submissions made in making its decision. All comments are valued and contribute to the rigour of our assessment.

5.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO member nations 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.

The proposed amendments are consistent with the WTO Sanitary and Phytosanitary Agreement (SPS), which requires all measures to be the least restrictive to trade. However, FSANZ made a notification to the WTO for this application in accordance with the SPS agreement, as FSANZ acknowledged that this application seeks the generic use of the technology for fruit and vegetables, and it would be in the interests of improved transparency and to enable other WTO members to comment on the proposed amendments. The notification was published on 2 November 2020 by the Australian government (Notification G/SPS/N/AUS/508) and on 3 November 2020 by the New Zealand government (Notification G/SPS/N/NZL/640). The closing date for the notification was 10 January 2021.

No WTO member nation provided comment on this application.

6 FSANZ Act assessment requirements

6.1 Section 29

6.1.1 Consideration of costs and benefits

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement (RIS) for applications seeking permission to irradiate foods (OBPR correspondence dated 15 May 2012, reference number 13845). This standing exemption was provided as such changes are considered minor, machinery and deregulatory in nature. The exemption applies to the introduction of a food to the food supply that has been determined to be safe.

As this application sought permission to irradiate all types of fresh fruit and vegetables as a phytosanitary treatment, FSANZ contacted OBPR to confirm that the standing exemption (reference 13845) applied in this case given the wider scope than past irradiation applications. The OBPR confirmed that a RIS was not required as the application appeared likely to have only a minor economic impact (OBPR reference number 42788).

FSANZ, however, considered the costs and benefits that could arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (paragraph 29(2)(a)).

The purpose of this consideration was to determine if the community, government, and industry as a whole is likely to benefit, on balance, from a move from the status quo (i.e. rejecting the application). This analysis considered either approving or rejecting the application. A consideration of costs and benefits was included in the CFS report based on the information and data held at that time. No further information was received during the consultation process that changed the findings from the analysis of costs and benefits in the CFS.

The consideration of the costs and benefits outlined in this section is not intended to be an exhaustive, quantitative economic analysis of the measure and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment sought to highlight the likely positives and negatives of moving away from the status quo by permitting a broader range of fruit and vegetables to be irradiated for a phytosanitary purpose.

FSANZ's conclusions regarding impacts of the proposed measure are set out below.

Industry

Approving the use of irradiation for all fresh fruit and vegetables as a phytosanitary measure would allow broader market access for domestic trade and importers and increased choice by businesses to use a proven quarantine treatment to eradicate fruit fly pests.

The segregation of irradiated foods from non-irradiated will be driven by industry (e.g. retailers) based on market and consumer preferences.

Consumers

As mentioned above, no public health or safety concerns resulting from consumption of these foods were identified in the safety assessment. Mandatory labelling will allow consumers wishing to avoid irradiated foods to do so.

Government

There may be incremental but likely inconsequential costs to government in terms of monitoring and enforcement to ensure compliance with the labelling requirements. As the permission relates only to fresh fruit and vegetables, monitoring is also required to ensure that irradiated foods that are not approved under Standard 1.5.3 are not illegally entering the food supply.

Conclusions from cost benefit considerations

FSANZ's assessment is that the potential benefits of approving the variation outweigh the potential costs.

6.1.2 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.

6.1.3 Any relevant New Zealand standards

Standards 1.1.1, 1.2.1, 1.5.3 and Schedule 22 apply in both Australia and New Zealand and there are no relevant New Zealand only standards.

6.1.4 Any other relevant matters

Other relevant matters are considered below.

6.2. Subsection 18(1)

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

6.2.1 Protection of public health and safety

FSANZ undertook a safety assessment (see SD1) and concluded that based on the best available evidence there are no public health and safety concerns associated with the consumption of fresh fruit and vegetables that have been irradiated at doses of up to 1 kGy.

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

Labelling issues have been addressed in Table 3 and Appendices 2-4 to this report. The mandatory requirements under Standard 1.5.3 to label irradiated foods (as discussed in Section 4.1 above) provide adequate information to enable consumers to make informed choices.

6.2.3 The prevention of misleading or deceptive conduct

This issue is addressed in Table 3 (see issue 18 of that Table).

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 used the best available scientific evidence to conduct the risk analysis detailed in SD1 – the Risk and Technical Assessment Report. The applicant submitted a dossier of information and scientific literature as part of the application. FSANZ also referred to a substantial amount of other technical and scientific information in assessing the application.

In particular, FSANZ has previously assessed and characterised the risk from consumption of irradiated fruit and vegetables, as part of its assessment of applications submitted to the agency since 2002 and its 2014 review. Collectively, these risk assessments considered all of the relevant information that was available at the time (national and international), including animal toxicity and nutrition data relating to the safety and nutritional adequacy of irradiated foods.

For this application, FSANZ evaluated the scientific literature published subsequent to previous assessments and the 2014 review. The current assessment focussed on two irradiation-sensitive micronutrients relevant to fruit and vegetables – vitamin C and β -carotene, and on three categories of vegetables that were not previously assessed by FSANZ – Brassicas, leafy vegetables and roots and tubers.

During the public consultation period, submitters provided references to a number of studies and other literature on various safety and nutritional aspects of food irradiation, for the consideration of FSANZ. These have been addressed in Table 3 and Appendices 2-4. FSANZ has determined that the additional studies and information do not alter the conclusions of the risk and technical assessment. FSANZ has however clarified that the risk assessment conclusions are valid in the context of the small proportion of fresh fruit and vegetables likely to be irradiated.

- **the promotion of consistency between domestic and international food standards**

Permitting irradiation of fresh fruit and vegetables for phytosanitary purposes will promote consistency between domestic and international food standards. Specifically, this generic approval will bring Standard 1.5.3 of the Code more into line with the Codex General Standard for Irradiated Foods and with regulations that already exist in other countries that participate in the international trade of irradiated produce.

Internationally, food irradiation is approved in more than 60 countries. The applicant indicates that there are now at least 15 countries trading in irradiated produce. Permissions vary considerably in different parts of the world and are based on either a case-by-case approach or the generic approach established by Codex (see Section 1.4 above). Many countries that permit irradiation of foods have taken the generic approach of permitting irradiation as a phytosanitary measure for all fresh fruit and vegetables on the basis that it is a proven safe and efficacious treatment. As shown in Appendix 1, Australia and New Zealand's major trading partners have permitted the irradiation of fresh fruit and vegetables.

- **the desirability of an efficient and internationally competitive food industry**

As noted above, permitting irradiation of fresh fruit and vegetables for phytosanitary purposes will promote consistency between Australian and New Zealand regulations with

those of current and potential trading partners. This will strengthen Australia's and New Zealand's positions as international trading partners, support trade negotiations, and reduce barriers to trade. This in turn will increase the efficiency and international competitiveness of the respective horticultural industries. Approval will also support trans-Tasman trade with irradiation as an important alternative quarantine measure.

Several significant benefits to the horticultural industry that can be achieved through a harmonised approach are as follows:

- The use of some phytosanitary treatments involving chemicals such as MeBr or insecticides such as dimethoate is becoming more restricted or is being phased-out; MeBr is listed as an ozone-depleting substance subject to phase-out provisions in the Montreal Protocol. By harmonising regulations, Australia and New Zealand will be able to employ irradiation as a suitable and effective substitute for these treatments that meets rigorous quarantine requirements.
- There will be more capacity to enter into reciprocal trading arrangements and, as such, better access to new markets. It is not helpful to trade negotiations if trading partners accept certain irradiated fresh products from Australia (as one of the main exporters of irradiated produce), when Australia does not, especially if the crops they seek to import into Australia are of economic importance to their country.
- A consistent approach to domestic and international food standards will enable irradiation to be rapidly employed as a temporary emergency measure when a pest incursion is suspected.
- Operating under harmonised regulations, Australia and New Zealand will have the capacity to deliver a more timely response to new trade opportunities.

The conclusion of the risk assessment is that based on the best available evidence there are no public health and safety concerns associated with the consumption of fresh fruit and vegetables that have been irradiated at doses of up to 1 kGy. It is therefore appropriate that the Australian and New Zealand horticultural industry be given the opportunity to benefit from the use of this alternative phytosanitary measure. Ultimately, horticultural businesses will make their own economic decisions, taking into account the costs and benefits of using irradiation as a treatment option, to determine if it is of overall benefit to their particular business.

- **the promotion of fair trading in food**

FSANZ identified no issues relevant to this objective.

- **any written policy guidelines formulated by the Forum on Food Regulation**

There is no policy guideline for irradiated foods.

7 References

- CAC, Codex Alimentarius Commission (2003) General standard for irradiated foods (CXS 106-1983, Rev.1–2003). Codex Alimentarius, FAO/WHO, Rome.
- CAC, Codex Alimentarius Commission (1985) General standard for the labelling of prepackaged foods (CXS 1-1985, Rev 2018). Codex Alimentarius, FAO/WHO, Rome.
- FAO IPPC, Food and Agriculture Organization International Plant Protection Convention. (2009) 2016 version published. International standards for phytosanitary measures, ISPM No. 28, Annex 07.

Irradiation treatment for fruit flies of the family Tephritidae (generic). Secretariat of the IPPC. FAO of the UN, Rome, Italy.

https://www.ippc.int/static/media/files/publication/en/2016/06/PT_07_2009_En_2016-04-22_PostCPM11_InkAm.pdf

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

GHI, Global Harmonization Initiative (2018) Consensus document on food irradiation.

Attachments

- A. Approved draft variation to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement
- C. Draft variation to the Australia New Zealand Food Standards Code (Call for Submissions)

Appendices

- Appendix 1: Summary of specific countries' permissions for irradiated foods
- Appendix 2: Issues raised in submissions and FSANZ response
- Appendix 3: Issues raised in the 'sample letter' and associated webpages and FSANZ response
- Appendix 4: Food Irradiation Watch/Gene Ethics questions on the application and SD1 and FSANZ response

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



Food Standards (Application A1193 – Irradiation as a phytosanitary measure for all fresh fruit 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 variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by Delegate]

[Insert name of and title of Delegate]

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 A1193 – Irradiation as a phytosanitary measure for all fresh fruit and vegetables) Variation*.

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

The Schedule varies Standards 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 omitting section 1.5.3—3 and inserting

1.5.3—3 Irradiation of fresh fruit and vegetables

- (1) Fresh fruit and fresh vegetables may be irradiated for the purpose of pest disinfestation for a phytosanitary objective, if the absorbed dose is:
 - (a) no lower than 150 Gy; and
 - (b) no higher than 1 kGy.
- (2) In this section:

fruit includes (but is not limited to) a fruit described in Schedule 22; and

vegetables includes (but is not limited to) a vegetable described in Schedule 22.
- (3) Despite subsection (2), any of the following is not a fruit or a vegetable for the purposes of this section: dried pulses; legumes; nuts; or seeds.

[2] **Schedule 22** is varied by omitting Note 1 and inserting

Note 1 This instrument is a standard under the *Food Standards Australia New Zealand Act 1991* (Cth). The standards together make up the *Australia New Zealand Food Standards Code*. See also section 1.1.1—3.

This Standard describes foods and classes of foods for subsection 1.4.1—2(2), subsection 1.4.2—3(4), subsection 1.5.3—3(2), subsection 1.5.3—4(3), paragraph S5—4(2)(b), section S19—4 and section S19—5, and portions of food for subsection 1.4.2—3(2).

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 A1193 which seeks permission to use irradiation as a phytosanitary measure (pest disinfestation) for all types of fresh fruit and vegetables. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation to the Code.

Following consideration by the Food Ministers' Meeting (formerly the Australia and New Zealand Ministerial Forum on Food Regulation), section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

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

2. Purpose

The Authority has approved a draft variation amending section 1.5.3—3, replacing the existing permission for the irradiation of 26 fruits and vegetables, with a permission for the irradiation of all fresh fruit and vegetables for the purpose of pest disinfestation for a phytosanitary objective. Excluded from scope are dried pulses, legumes, nuts and seeds. The approved draft variation also amends Note 1 of Schedule 22 to explain that a purpose of Schedule 22 is to describe foods and classes of foods for the purposes of subsection 1.5.3—3(2) of the Code.

3. Documents incorporated by reference

The variation does 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 A1193 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary.

The Office of Best Practice Regulation (OBPR) granted the Authority a standing exemption from the requirement to develop a Regulatory Impact Statement (RIS) for proposed variations to the Code permitting the irradiation of foods (OBPR correspondence dated 15 May 2012, reference 13845). This standing exemption was provided as such changes are considered minor, machinery and deregulatory in nature. The exemption applies to the introduction of a food to the food supply that has been determined to be safe.

The use of irradiation as a phytosanitary measure is not compulsory and individual

growers/suppliers will make their own decision as to its use, based on a consideration of the costs and benefits to their business.

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

Item [1] amends Standard 1.5.3 by omitting section 1.5.3—3 and substituting a new section 1.5.3—3.

New subsection 1.5.3—3(1) will provide that fresh fruit and/or fresh vegetables may be irradiated for the purpose of pest disinfestation for a phytosanitary objective provided that in each case the absorbed dose is: no lower than 150 Gray (Gy) and a maximum dose is 1 kiloGray (kGy).

New subsection 1.5.3—3(2) will provide that, for the purposes of new subsection 1.5.3—3(1): the term ‘vegetable’ includes (but is not limited to) a vegetable described in Schedule 22; and the term ‘fruit’ includes (but is not limited to) a fruit described in Schedule 22. Both are an inclusive definition. The effect will be that:

- the term ‘fruit’ in subsection 1.5.3—3(1) includes (but is not limited to): plant material that meets the general description of a ‘fruit’ in Schedule 22; and/or plant material that is listed in the list of commodities provided in Schedule 22 for ‘fruit’; and
- the term ‘vegetable’ in subsection 1.5.3—3(1) includes (but is not limited to): plant material that meets the general description of a ‘vegetable’ in Schedule 22; and/or plant material that is listed in the list of commodities provided in Schedule 22 for ‘vegetables’.

The use of the phrase ‘includes (but is not limited to)’ makes clear that a ‘fruit’ or ‘vegetable’ for the purposes of subsection 1.5.3—3(1) also includes any plant derived material that is not covered by the latter description or list but which falls within the commonly accepted and ordinary meaning of ‘fruit’ and ‘vegetable’.

New subsection 1.5.3—3(3) provides that the permission granted by new subsection 1.5.3—3(1) does not apply to any of the following: dried pulses; legumes; nuts; seeds.

Item [2] amends Schedule 22 by omitting Note 1 and inserting a new Note 1.

New Note 1 will, among other things, explain that a purpose of Schedule 22 is to describe foods and classes of foods for the purposes of subsection 1.5.3—3(2) of the Code.

Attachment C – Draft variation to the Australia New Zealand Food Standards Code (Call for Submissions)



Food Standards (Application A1193 – Irradiation as a phytosanitary measure for all fresh fruit 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 variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by Delegate]

[Insert name of and title of Delegate]

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 A1193 – Irradiation as a phytosanitary measure for all fresh fruit and vegetables) Variation*.

2 Variation to 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 omitting section 1.5.3—3 and inserting

1.5.3—3 Irradiation of fresh fruit and vegetables

- (1) Fresh fruit and fresh vegetables may be irradiated for the purpose of pest disinfestation for a phytosanitary objective, if the absorbed dose is:
 - (a) no lower than 150 Gy; and
 - (b) no higher than 1 kGy.
- (2) In this section:

fruit includes (but is not limited to) a fruit described in Schedule 22; and

vegetables includes (but is not limited to) a vegetable described in Schedule 22.
- (3) Despite subsection (2), any of the following is not a fruit or a vegetable for the purposes of this section: dried pulses; legumes; nuts; or seeds.

Appendix 1: Summary of specific countries' permissions for irradiated foods

Country	Food	Dose/Dose range (kGy)
European Union	Dried aromatic herbs, spices and vegetable seasonings (contamination and/or infestation)	10
Canada	Onions (inhibit sprouting during storage)	0.15
	Potatoes (inhibit sprouting during storage)	0.15
	Wheat, flour, whole wheat flour (control insects)	0.75
	Whole or ground spices and dehydrated seasonings (reduce microbial load)	10
	Fresh raw ground beef (reduce microbial load)	1.5 to 4.5
	Frozen raw ground beef (reduce microbial load)	1.5 to 7
USA ⁴	Pork carcasses and cuts (control of <i>Trichinella spiralis</i>)	0.3 to 1
	Growth and maturation inhibition of fresh foods	1
	Disinfestation of arthropod pests in food	1
	Dry or dehydrated enzyme preparations (microbial disinfestation)	10
	Dry or dehydrated aromatic substances (e.g., spices and seasonings) (microbial disinfestation)	30
	Poultry (control foodborne pathogens)	4.5 to 7.0
	Refrigerated and frozen uncooked meat and meat products (foodborne pathogens and extension of shelf-life)	4.5 to 7.0
	Eggs (control of <i>Salmonella</i>)	3.0
	Fresh or frozen molluscan shellfish (control of <i>Vibrio</i> bacteria)	5.5
	Fresh iceberg lettuce and fresh spinach (control of foodborne pathogens, extension of shelf-life)	4.0
	Unrefrigerated (as well as refrigerated) uncooked meat and meat products (foodborne pathogens)	4.5
	Crustaceans (food-borne pathogens and extension of shelf-life)	6.0
Thailand	Roots and tubers (prevent germination)	1
	Slow down ripeness	2
	Control insect disinfestation	2
	Decrease amount of parasites	4
	Prolong shelf life	7
	Decrease amount of microorganisms and pathogens	10
Philippines	Mangoes for disinfestation	1
	Onions for sprout inhibition	0.3 to 1
	Garlic for disinfestation	0.3 to 1
Vietnam	Fresh fruit and vegetables (delay ripening, pest control, extend preservation)	0.2 to 2.5
	Cereals, beans, seeds, dried fruit (exterminate insects and parasites, minimise bacteria, inhibit germination)	0.1 to 5.0
	Aquatic animals (reduce pathogens, extend preservation, control parasites)	0.1 to 7.0
	Meat (cattle and poultry) (minimise pathogen, extend preservation, control parasites)	0.5 to 7.0

⁴ In the USA, food irradiation is considered as a food additive under their legislation.

Country	Food	Dose/Dose range (kGy)
	Dried vegetables and herbs (minimise pathogens, exterminate insects and pests)	0.3 to 10.0
	Dried animal foodstuffs (exterminate insects and parasites, control fungi, minimise pathogens)	0.3 to 7.0
Indonesia	Bulb and tuber roots (inhibit sprouting)	0.15
	Fresh fruit and vegetables (delay maturation, insect disinfestation, quarantine, shelf-life extension)	1.0 to 2.5
	Processed vegetables and fruit products (extend shelf-life)	7.0
	Mango (extend shelf-life)	0.75
	Mangosteen Insects (insect disinfestation/quarantine treatment)	1.0
	Cereals and products, nuts, oil seeds (insect disinfestation, reduce microbes)	1.0 to 5.0
	Fish and seafood (fresh and frozen) (reduce pathogens, extend shelf-life, control of parasitic infections)	2.0 to 5.0
	Processed fish products and seafood (reduce pathogens, extend shelf-life)	8.0 to 10.0
	Meat, poultry and dairy (fresh or frozen) (reduce pathogens, extend shelf-life, control of parasitic infections, control infection by certain parasites, eliminate <i>Salmonella</i> bacteria)	2.0 to 7.0
	Herbs, spices and herbal tea (reduce pathogens, insect disinfestation)	1.0 to 10.0
	Dried foods of animal origin (eradicate microbes, fungi and yeast, sterilization, extend shelf life, insect disinfestation)	1.0 to 5.0
	Certain prepared foods (for commercial sterilisation, eradicate microbial pathogens, including spore microbes, extend shelf life)	60
India	Bulbs, stem and root tubers (inhibit sprouting)	0.02 to 0.2
	Fresh fruits and vegetables (delay ripening, insect disinfestation, extend shelf-life, quarantine)	0.2 to 2.5
	Cereals and pulses and their milled products, nuts, oil seeds, dried fruits and their products (insect disinfestation, reduce microbes)	0.25 to 5.0
	Aquatic products (fresh and frozen) (eliminate pathogens, extend shelf-life, control of parasites)	0.3 to 7.0
	Meat and meat products, poultry (fresh and frozen) and eggs (for pathogenic microorganisms, shelf-life extension, control of parasites)	0.3 to 7.0
	Dry vegetables, herbs, spices, tea, coffee, cocoa and plant products (eliminate pathogens, insect disinfestation)	0.3 to 14.0
	Dried food of animal origin (insect disinfestation, control of molds, pathogenic microorganisms)	0.3 to 7.0
	Ethnic foods, military rations, space foods, RTC and RTE foods (quarantine, reduce microbes, sterilise)	0.25 to 25.0
Malaysia	Bulbs, roots and tubers (sprout inhibition)	0.05 to 0.2
	Fresh fruits and vegetables (delay ripening, shelf life extension, quarantine control)	0.15 to 2.5
	Cereal and their milled products, nuts, oil seeds, pulses, dried fruits and their products (insect disinfestation, to reduce microbial load, sprout inhibition)	0.1 to 5.0
	Fish and fish products and frog legs (reduction of pathogens,	0.1 to 7.0

Country	Food	Dose/Dose range (kGy)
	shelf-life extension, control of infection by parasites, insect disinfestation)	
	Meat and meat products (reduction of pathogens, shelf life extension, control of infection by parasites)	0.3 to 7.0
	Dried vegetables, spices, condiments, dry herbs, tea (reduction of pathogens, insect disinfestation)	0.3 to 10.0
	Cocoa and cocoa products (reduction of microbial load, insect disinfestations)	0.3 to 5.0
	Dried food of animal origin (for insect disinfestations, control of moulds, reduction of pathogens)	0.3 to 7.0
	Other food not specified above (reduction of pathogens, reduction of microbial load)	1.0 to 10.0
China	Poultry, livestock, cooked	≤8.0
	Pollen	8.0
	Dried nuts, preserved fruits	0.4 to 1.0
	Spices, dried	≤10.0
	Fruits, vegetables, fresh	≤1.5
	Pork, fresh	0.65
	Poultry, livestock, frozen & packaged	≤2.5
	Beans	≤0.2
	Cereals, grains and products	0.4 to 0.6
	Sweet potato wine	≤4.0
Singapore	Ionising radiation to be conducted according to the requirements of the Codex General Standard for Irradiated Foods (CXS 106-1983, Rev.1–2003)	10

Appendix 2: Issues raised in submissions and FSANZ response

Provided as a separate document.

Appendix 3: Issues raised in the 'sample letter' and associated webpages and FSANZ response

Provided as a separate document.

Appendix 4: Food Irradiation Watch/Gene Ethics questions on the application and SD1 and FSANZ response

Provided as a separate document.