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[140–20]

Call for submissions – 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 Department of Agriculture and Fisheries to permit the use of irradiation as a phytosanitary measure for all types of fresh fruit and vegetables, and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

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

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

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

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

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

DEADLINE FOR SUBMISSIONS HAS BEEN EXTENDED TO: 6pm (Canberra time) 24 December 2020

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

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

Food Standards Australia New Zealand
PO Box 5423
KINGSTON ACT 2604
AUSTRALIA
Tel +61 2 6271 2222

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

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Supporting documents

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

SD 1 Risk and Technical Assessment Report

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

Executive summary

Food Standards Australia New Zealand (FSANZ) has received an application from the Queensland Government Department of Agriculture and Fisheries (QLD DAF) to permit irradiation as a phytosanitary measure (i.e. pest disinfection) for all types of fresh fruit and vegetables. This would extend the current permissions in place for 26 fruits and vegetables in Standard 1.5.3 of the *Australia New Zealand Food Standards Code* (the Code). The same dose range, 150 Gray (Gy) to 1 kiloGray (kGy), and conditions (including mandatory labelling) as currently prescribed for permitted fruit and vegetables in the Code would apply.

FSANZ reviewed the technological justification for the use of irradiation as specified in the application; the current scientific evidence on its safety; and its effects on the nutrient composition of fruit and vegetables. FSANZ also investigated whether there would be any impact on the nutrient intake of Australians and New Zealanders, as a result of potential changes to nutrient levels in fresh produce post-irradiation.

The applicant's stated technological purpose for irradiation is pest disinfection. The evidence demonstrates that irradiation is an appropriate and efficacious phytosanitary treatment for regulated pests, including fruit fly, at the proposed dose range. 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. The evidence provides adequate assurance that irradiation as a phytosanitary treatment for pest disinfection is technologically justified and effective in fulfilling its stated purpose.

A toxicological assessment concluded that on the basis of the available evidence there are no safety concerns associated with the consumption of fresh fruit and vegetables that have been irradiated with doses of up to 1 kGy. 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. Further, there is a lack of 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.

FSANZ conducted a nutrition risk assessment and considers that, based on the available evidence, the effect of irradiation on the nutritional quality of fruit and vegetables is likely to be low. However it is noted that in undertaking the nutrition risk assessment, not all vegetables were assessed for potential changes in nutrient content due to a lack of data. The effects of irradiation on the nutrient composition of those commodities remain uncertain. However, where small losses in nutrient content were identified in the nutrition risk assessment, the commodities in question made minor contributions to nutrient intakes. Therefore any impact on population intakes would be minimal. This dietary intake assessment also took into account that there will only be a proportion of imported and domestically produced fruit and vegetables treated with irradiation for phytosanitary purposes. The risk and technical assessment concluded that 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.

FSANZ has prepared a draft variation to the Code to permit the irradiation of all fresh fruit and vegetables. The draft variation amends section 1.5.3—3, replacing the existing permission irradiating 26 fruits and vegetables with a generic permission for all fresh fruit and vegetables. The proposed permission excludes dried pulses, legumes, nuts and seeds. The dose range (150 Gy – 1 kGy) and technological purpose (pest disinfection for a phytosanitary objective) remains unchanged.

1 Introduction

1.1 The applicant

This 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

Food Standards Australia New Zealand (FSANZ) received an application on 6 November 2019 seeking permission to irradiate all types of fresh fruit and vegetables for the purpose of pest disinfection for a phytosanitary objective². This would require an amendment to Standard 1.5.3 – Irradiation of food, of the *Australia New Zealand Food Standards Code* (the Code), which would replace the existing permission for the irradiation of 26 fruits and vegetables, with a generic permission for the irradiation of all fresh fruit and vegetables. Existing permissions cover use of irradiation solely for the purpose of pest disinfection for a phytosanitary objective; this will not change if this application is approved.

A phytosanitary treatment is used on food that is entering another quarantine region, when there is a requirement that the food is free from regulated pests. This requirement can apply to inter-state trade across different quarantine jurisdictions within Australia. It can also apply to imports into Australia and New Zealand. 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. The permission to irradiate all fruit and vegetables will therefore apply to the small proportion of domestically produced and imported produce that requires a phytosanitary treatment to permit its movement into another quarantine region.

The scope of the application covers 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 that are 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). There is no current permission, nor is the applicant seeking permission to irradiate these commodities for a phytosanitary objective. The same dose range, 150 Gray (Gy) to 1 kiloGray (kGy), currently prescribed for permitted fruit and vegetables in the Code would continue to apply if this application is approved.

The applicant states that a generic approval for the irradiation of all fresh fruit and vegetables for pest disinfection for a phytosanitary objective will bring Australian and New Zealand regulations more into line with numerous international and national standards.

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 does not propose any changes to these requirements.

1.3 The current standard

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

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

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.

The following fruit and vegetables are permitted to be irradiated for the purpose of pest disinfection for a phytosanitary objective:

- tropical fruit (breadfruit, carambola, custard apple, litchi, longan, mango, mangosteen, papaya (paw paw) and rambutan) (Application A443)³
- persimmons (Application A1038)⁴
- tomatoes and capsicums (Application A1069)⁵
- other specific fruit and vegetables (apple, apricot, cherry, nectarine, peach, plum, honeydew, rockmelon, scallopini, strawberry, table grape, zucchini (courgette)) (Application A1092)⁶
- blueberries and raspberries (Application A1115)⁷.

In addition, 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 (Application A413)⁸.

FSANZ is required to undertake a pre-market safety assessment prior to granting a generic permission for the irradiation of all fresh fruit and vegetables, so that they can be legally sold in Australia or New Zealand. Approval of this application will eliminate the need for any further applications for specific commodities being submitted and assessed by FSANZ on a case-by-case basis, as has been the situation since the first of six applications was received in 2002.

1.3.2 Record keeping

Subsection 1.1.1—14(2) provides 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 contains record keeping requirements for irradiated foods (section 1.5.3—8).

1.3.3 Labelling requirements

Subsection 1.1.1—10(8) of the Code provides that food for sale must comply with all relevant labelling requirements imposed by the Code for that food. 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.

Division 3 of Standard 1.5.3 of the Code contains requirements for labelling and other information – retail and catering. 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.

³ <http://www.foodstandards.gov.au/code/applications/Pages/applicationa443irradiationoftropicalfruit/Default.aspx>

⁴ <http://www.foodstandards.gov.au/code/applications/Pages/applicationa1038irra4655.aspx>

⁵ <http://www.foodstandards.gov.au/code/applications/Pages/applicationa1069irra5511.aspx>

⁶ <http://www.foodstandards.gov.au/code/applications/Pages/A1092-Irradiation.aspx>

⁷ <http://www.foodstandards.gov.au/code/applications/Pages/A1115IrradiationBlueberriesandRaspberries.aspx>

⁸ <https://www.foodstandards.gov.au/code/applications/Pages/applicationa413irradiationofherbsandspices/index.aspx>

1.4 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.

1.5 Procedure for assessment

The application is being assessed under the General Procedure.

2 Summary of the assessment

2.1 Risk assessment

The risk assessment investigated the technological need for the irradiation of all fresh fruit and vegetables for phytosanitary purposes, specifically 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 intake of Australians and New Zealanders.

In undertaking this risk assessment, the outcomes of previous assessments by FSANZ were considered, as was a 2014 FSANZ review 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>

In addition to earlier work, 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 SD 1.

2.1.1 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 need to irradiate these foods.

2.1.1.1 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 a highly effective quarantine treatment option that is well established in the international trade of horticultural products. Its use is endorsed by the international standards setting agencies Codex Alimentarius (Codex) and the International Plant Protection Convention (IPPC). Notably, the [Codex General Standard for Irradiated](#)

[Foods](#) (CODEX STAN 106_1983, Rev.1-2003) (CAC 2003) states that irradiation must not be used as a substitute for good hygienic and good manufacturing practices or good agricultural practices. Quarantine agencies in Australia and New Zealand, namely, the Australian Government Department of Agriculture, Water and the Environment (DAWE), and Biosecurity New Zealand (in the New Zealand Ministry for Primary Industries (MPI)) also endorse its use as an important quarantine measure for regulated pests.

Ionising radiation has a number of advantages over other existing treatment options. Irradiation is a broad-spectrum treatment useful for commodities that do not tolerate other options such as heat treatment or prolonged cold storage well. At the low doses required to meet a phytosanitary objective (namely, pest disinfection), 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 efficacious for fruit flies. These doses are consistent with international standards and those set by domestic quarantine agencies. See Section 2.5 of SD 1 for further details.

2.1.1.2 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. A generic approval for the irradiation of all fresh fruit and vegetables for pest disinfection for a phytosanitary objective will help bring Australian and New Zealand regulations more into line with international and national standards. See Appendix 1 for a summary of specific countries' permissions for irradiated foods.

2.1.1.3 Summary

Irradiation is already approved for use in Australia and New Zealand as a phytosanitary treatment for many fruit 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. Both DAWE and NZ MPI have provided advice to FSANZ endorsing irradiation as an effective quarantine treatment for regulated arthropod pests, including tephritid 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 disinfection. Therefore, only a small amount of the fresh produce available for consumption may be subjected to irradiation. The applicant has stated that even if a generic permission to irradiate all fresh fruit and vegetables is granted, a conservative assessment indicates that 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 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 may 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 decide on the treatment option that is best for their particular circumstances, based on an assessment of all relevant factors including efficiency and cost.

2.1.2 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 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.
- Irradiation of fruit and vegetables at doses of up to 1 kGy causes very small losses in the levels of micronutrients that are potentially sensitive to irradiation. There is evidence of losses of vitamin C and β -carotene in irradiated fruit and vegetables but these losses are, with few exceptions (i.e. spinach and rocket), small and of negligible impact to overall population nutrient intakes.
- There will only be a relatively small proportion of both imported and domestically produced fruit and vegetables treated by irradiation, with some commodities not requiring irradiation due to localised consumption and technological reasons. There may be some variation by state in Australia. 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.

2.2 Risk management

The Risk and Technical Assessment Report (SD 1) concluded that 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. Based on this conclusion and a consideration of other relevant matters, FSANZ recommends that the existing permission to irradiate 26 fruits and vegetables in Standard 1.5.3 be replaced with a generic permission to irradiate all fresh fruit and vegetables, provided the following requirements are met:

- Irradiation is permitted to be used only for pest disinfestation for a phytosanitary objective.
- Irradiation is permitted for use on 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, 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 2.2.1) 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 small proportion of produce available to Australians and New Zealanders that is not grown and consumed in the same quarantine region.
- 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 phytosanitary measure will be voluntary and only one of a number of other phytosanitary treatment options available.

The labelling of irradiated food, as a risk management consideration for this application, is discussed in Section 2.2.1 below. Other matters concerning minimising the risks of human exposure to unsafe levels of radiation, potential risks to the environment, and occupational health and safety risks to workers, are outside FSANZ's statutory functions. These and other controls are covered by different legislation such as those imposed as a result of an assessment of radiation licence applications.

2.2.1 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, 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.

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) 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.

The Radura symbol (below) is a standard international symbol indicating that a food product has been irradiated. The Code does not mandate the display of this symbol on the labels of irradiated food. However, there are also no restrictions in the Code regarding its voluntary use. Even if the symbol is included on the food label, it must still display the mandatory labelling requirements for irradiated foods.



Figure 1 *The Radura symbol*

2.2.2 Risk management conclusion

FSANZ proposes to replace the existing permission to irradiate 26 fruits and vegetables in Standard 1.5.3 with a generic permission to irradiate all fresh fruit and vegetables.

Permission to irradiate is for pest disinfestation for a phytosanitary objective only. This permission will apply only to the relatively small amount of the total fresh fruit and vegetables consumed in Australia and New Zealand, which are not produced and consumed in the same quarantine region. 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.

2.3 Risk communication

2.3.1 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, horticultural industry, exporters and importers, and general public, are aware of this application and are 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.

The draft variation will be considered for approval by the FSANZ Board taking into account public comments received from this call for submissions.

2.3.2 World Trade Organization (WTO)

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

The applicant indicates that there are now at least 15 countries trading in irradiated produce. With the exception of Australia and New Zealand, countries that are presently trading in irradiated fruit and vegetables grant a generic approval for the phytosanitary irradiation of all fruit and vegetables.

The relevant international standard is the [Codex General Standard for Irradiated Foods](#). 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.

Amending the Code to extend the use of irradiation from 26 fruits and vegetables to all fresh fruit and vegetables has the potential to bring Australian and New Zealand standards more into line with Codex and existing regulations in other countries that cover all fresh fruit and vegetables (see Appendix 1). As such, the proposed amendment may have an enabling effect on international trade, as it will allow imports of fresh produce into Australia and New Zealand to be sold, where currently they are prohibited; it will also facilitate reciprocal trade arrangements with target markets for Australian horticultural exports. This is consistent with the WHO Sanitary and Phytosanitary Agreement (SPS), which requires all measures to be the least restrictive to trade.

The applicant indicates that some developing countries are already trading in fruit such as salaka, guava, dragon fruit, pomegranate and star apple to the US. In particular, salaka and dragon fruit are commodities of potential trade importance to Asian neighbours and there is a likelihood that such countries will seek to increase further the range of produce that they

export to Australia and New Zealand using irradiation as the phytosanitary treatment. Even so, the introduction of such fruit would be a very minor part of the overall market.

A notification to the WTO under Australia's and New Zealand's obligations with respect to the SPS Agreement has been made as the application represents a significant extension of use of the technology, and in the interests of improved transparency and to enable other WTO members to comment on the proposed amendments.

2.4 FSANZ Act assessment requirements

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

2.4.1 Section 29

2.4.1.1 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 seeks 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) still applies in this case given the wider scope than past irradiation Applications. The OBPR confirmed that a RIS was not required as the Application appears likely to have only a minor economic impact (OBPR reference number 42788).

FSANZ, however, has given consideration to the costs and benefits that may 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 is 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 considers permitting the use of irradiation as a phytosanitary measure for all fresh fruit and vegetables.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures. In fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks 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.

Retailers may be able to offer a broader range of domestic and imported foods.

This permission potentially increases the range of food ingredients available to the food industry throughout the year.

Consumers

This permission may increase the range of safe produce available to consumers throughout the year. 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 any irradiated foods that do not fall within this definition and that are not approved, 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.

2.4.1.2 Other measures

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

2.4.1.3 Any relevant New Zealand standards

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

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2 Subsection 18(1)

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

2.4.2.1 Protection of public health and safety

FSANZ has undertaken a safety assessment (SD1) and concluded there are no public health and safety concerns associated with the consumption of fresh fruit and vegetables that have been irradiated with doses of up to 1 kGy.

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

The mandatory labelling of irradiated foods as discussed in Section 2.2.1 above provides

information to enable consumers to make informed choices.

2.4.2.3 The prevention of misleading or deceptive conduct

There were no issues identified with this application relevant to this objective.

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ used the best available scientific evidence to conduct the risk analysis detailed in SD 1 – 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 FSANZ since 2002. 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 has evaluated the scientific literature published since previous assessments and a 2014 review of the literature were conducted. The current assessment focussed on two irradiation-sensitive micronutrients that are 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.

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

Internationally, food irradiation is approved in more than 60 countries. 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 2.1.1.2 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 irradiation of fresh fruit and vegetables.

A generic approval will promote consistency between domestic and international food standards. Specifically, a generic approval will bring Standard 1.5.3 of the Code more into line with the Codex General Standard for Irradiated Foods. In addition, it will bring Standard 1.5.3 more into line with regulations that already exist in other countries that participate in the international trade of irradiated produce.

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

As noted above, a generic approval for all fruit and vegetables will bring the Australian and New Zealand regulations into line with the regulations 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 their horticultural industries. Approval of

irradiation will also support trans-Tasman trade, as an important alternative quarantine measure.

Several important benefits to the horticultural industry that can be achieved through a harmonised approach are described further below:

- The use of some phytosanitary treatments involving chemicals such as methyl bromide (MeBr) or insecticides such as fenthion and 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.
- By harmonising 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 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 is 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.

3 Draft variation

The draft variation to the Code is at Attachment A and is intended to take effect on gazettal.

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

4 References

CAC, Codex Alimentarius Commission (2003) General standard for irradiated foods (CODEX STAN 106_1983, Rev.1–2003). 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

Follett PA and Sanxter SS (2000) Comparison of rambutan quality after hot forced-air and irradiation quarantine treatments. HortScience 35(7) 1315–1318.

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

ICA, Interstate Certification Assurance (2011). National protocol number 55. Irradiation treatment. ICA 55 in Qld. <https://www.interstatequarantine.org.au/wp-content/uploads/2016/05/QLD-ICA-55.pdf>

USDA, US Department of Agriculture (2006) Animal and Plant Health Inspection Service. Treatments for fruit and vegetables. Federal Register 71(18) 4451–4464. <https://www.govinfo.gov/content/pkg/FR-2006-01-27/pdf/06-746.pdf>

Attachments

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

Attachment A – Draft 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 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.

Attachment B – Draft Explanatory Statement

1. Authority

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

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

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

2. Purpose

The Authority has prepared a draft variation amending section 1.5.3—3, replacing the existing permission for the irradiation of 26 fruits and vegetables, with a generic permission for the irradiation of all fresh fruit and vegetables. Excluded from scope are dried pulses, legumes, nuts and seeds.

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 will include 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.

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 ⁹	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 salmonella)	3.0
	Fresh or frozen molluscan shellfish (control of vibrio 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

⁹ 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)
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, shelf-life extension, control of infection by parasites, insect		0.1 to 7.0

Country	Food	Dose/Dose range (kGy)
	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 (CODEX STAN 106-1983)	10