

29 June 2016
[16–16]

Call for submissions – Application A1115

Irradiation of Blueberries & Raspberries

FSANZ has assessed an Application made by the NSW Department of Primary Industries (NSW DPI) to irradiate blueberries and raspberries for phytosanitary purposes and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

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

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

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

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

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

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 10 August 2016

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:

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Supporting documents

The following documents which informed the assessment of this Application are available on the FSANZ website at

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

SD1 Risk and Technical Assessment Report

Executive summary

Food Standards Australia New Zealand (FSANZ) has received an Application from the NSW Department of Primary Industries (NSW DPI) to irradiate blueberries and raspberries for phytosanitary purposes. The same dose range, 150 Gray (Gy) to 1 kGy, and conditions (including mandatory labelling) as currently prescribed for tropical fruits, persimmons, tomatoes and capsicums and a range of other fruits and vegetables in the *Australia New Zealand Food Standards Code* (the Code) is requested.

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

Relevant quarantine agencies in Australia and New Zealand have previously provided advice that irradiation is a valid treatment for quarantine purposes for the disinfestation of these fruits.

Permitting the irradiation of these fruits will allow increased domestic and international trade as there are rigorous requirements in place for an appropriate and efficacious treatment for fruit fly for quarantine purposes. In the past, phytosanitary measures for these foods have primarily involved the use of the chemicals dimethoate and/or fenthion. However, since the use of dimethoate and fenthion for this purpose has been restricted, other options such as irradiation need to be considered.

Food irradiation fulfils its intended technological function and is an appropriate and efficacious treatment for fruit fly for quarantine purposes.

There are negligible risks to public health and safety associated with the consumption of blueberries and raspberries which have been irradiated at up to a maximum of 1 kGy.

FSANZ has prepared a draft variation to the Code to permit the irradiation of these fruits by adding them to the table to subsection 1.5.3—3(2) with a minimum dose of 150 Gy and a maximum dose of 1 kGy.

1 Introduction

1.1 The Applicant

This Application was made by the NSW Department of Primary Industries (NSW DPI), a division of the NSW Department of Trade and Investment, Regional Infrastructure and Services.

1.2 The Application

The Application was lodged on 12 June 2015 and seeks to amend: Standard 1.5.3 – Irradiation of food to provide for the safe use of irradiation as a phytosanitary measure¹ for blueberries and raspberries.

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

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

1.3 The Current Standard

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

To date the following irradiated foods have been approved:

- herbs, spices and herbal infusions (under A413)
- tropical fruits (mango, breadfruit, carambola, custard apple, litchi, longan, mangosteen, papaya and rambutan) (under A443)
- persimmons (under A1038)
- tomatoes and capsicums (under A1069)
- apple, apricot, cherry, nectarine, peach, plum, honeydew, rockmelon, scallopini, strawberry, table grape, zucchini (courgette) (under A1092).

1.4 Reasons for accepting Application

The Application was accepted for assessment because:

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

1.5 Procedure for assessment

The Application is being assessed under the General Procedure.

¹ A phytosanitary measure is any legislation, regulation or official procedure having the purpose to prevent the introduction and/or spread of quarantine pests, or to limit the economic impact of regulated non-quarantine pests.

2 Summary of the assessment

2.1 Risk assessment

Full details of the risk assessment prepared for this Application are provided in **Supporting Document 1 (SD1)**.

The purpose of this risk assessment was to determine the technological (phytosanitary) need to irradiate blueberries and raspberries and whether these foods, irradiated up to a maximum dose of 1 kGy, are as safe and nutritious as non-irradiated foods. The risk assessment takes account of previous considerations and includes an assessment of data on the safety and nutritional adequacy of irradiated foods that has become available since the assessments conducted in 2002, 2011, 2013 and 2014.

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

Several approved options exist for phytosanitary treatments of these fruits. Among the most commonly used are pre and post-harvest treatments with insecticides. Following the review of dimethoate and fenthion use by the Australian Pesticides and Veterinary Medicines Authority (APVMA) many phytosanitary uses were lost or restricted (APVMA, 2011).

Disinfestation of blueberries and raspberries by irradiation is a valid alternative treatment for quarantine purposes as insect pests of quarantine significance are a major barrier in gaining access to some markets. The International Plant Protection Convention (IPPC), Codex Alimentarius and quarantine agencies in Australia, New Zealand and the USA, endorse irradiation as a legitimate phytosanitary treatment.

2.1.1.1 Worldwide permissions and consumption of irradiated foods

Permissions to irradiate a food 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 Table 1**).

Table 1: Summary of specific countries permissions for irradiated foods

Country	Food	Dose range (kGy)
European Union	Dried aromatic herbs, spices and vegetable seasonings	10
Canada ²	Onions	0.15
	Potatoes	0.15
	Wheat, flour, whole wheat flour	0.75
	Whole or ground spices and dehydrated seasonings	10
	Fresh Beef to control microbial decontamination	1.5 to 4.5
	Frozen ground beef to control microbial decontamination	2.0 to 7
	Poultry to control microbial decontamination	1.5 to 3
	Shrimp and Prawns to control microbial decontamination	1.5 to 5
	Mangoes (Disinfestation)	0.15 to 1

² In Canada, permission to irradiate beef, poultry, shrimp, prawns and mangoes are still in the process of Final Approval.

Country	Food	Dose range (kGy)
USA ³	Fruit and vegetables (to control insects and other arthropods and to inhibit maturation (e.g., ripening or sprouting))	1
	Poultry to control foodborne pathogens	4.5
	Beef (Refrigerated) to control microbial decontamination	4.5
	Beef and poultry (Frozen) to control microbial decontamination	7
	Dry or dehydrated aromatic substances (e.g., spices and seasonings) to control microorganisms	30
	Fresh foods to control microorganisms	1
	Eggs for control of salmonella	3.0
	Fresh iceberg lettuce and fresh spinach	4
Australia/New Zealand	Herbs, spices and herbal infusions (Disinfestation or decontamination)	2 to 30
	Tropical fruits (mango, breadfruit, carambola, custard apple, litchi, longan, mangosteen, papaya and rambutan) , persimmons and tomatoes and capsicums, apple, apricot, cherry, nectarine, peach, plum, honeydew, rockmelon, scallopin, strawberry, table grape, zucchini (courgette) to control pests of quarantine concern	0.15 to 1
Thailand	Selected tropical fruits (mango, mangosteen, lychee, longan, rambutan and pineapple) for disinfestation	0.4
Philippines	Mangoes for disinfestation	1
	Onions for sprout inhibition	0.3 to 1
	Garlic for disinfestation	0.3 to 1
Vietnam	Seafood for decontamination	2 to 7.5
	Frozen Fruits for decontamination	2 to 3
	Dragon fruits to control pests	1
Indonesia	Mango to control insects	0.75
	Papaya, mushroom, tomatoes, bananas and broccoli for shelf-life extension	1-2
	Fresh meat and chicken for decontamination of pathogens	5-7
India	Mangoes to control insects	0.25 to 0.75
	Fresh meat and chicken for decontamination of pathogens	2.5 to 4
	Spices for decontamination	6.0 to 14
	Raisins, figs and dried dates to control insects	0.25 to 0.75
	Fresh seafoods for shelf-life extension	1 to 3

The 1983 Codex standard for irradiated foods (revised 2003) requires that the maximum absorbed dose to a food should not exceed 10 kGy, except when necessary to achieve a legitimate technological purpose⁴. No specific foods are mentioned, although the standard states:

- *The irradiation of food is justified only where it fulfils a technological need or where it serves a food hygiene purpose and should not be used as a substitute for good manufacturing practices.*

Summary

Irradiation is already an approved phytosanitary treatment for many fruit and vegetables. The treatment would provide an alternative phytosanitary treatment for the raspberry and blueberry industries. It is anticipated that industry can commercially incorporate irradiation treatment into their supply chain with minimal impact on efficiency and profitability of the supply chain.

Both the Australian Government Department of Agriculture and Water Resources (Agriculture) and the New Zealand Ministry for Primary Industries (MPI) have previously provided letters to FSANZ endorsing irradiation as an effective quarantine treatment for fruit

³ In the USA, food irradiation is considered as a food additive under their legislation.

⁴ http://www.codexalimentarius.net/download/standards/16/CXS_106e.pdf

fly and other pests that are of quarantine concern to Australia and New Zealand.

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

2.1.2 Safety and nutritional content of irradiated foods

FSANZ has previously assessed the technological need, safety and nutrient profile of various irradiated tropical fruits, persimmons, tomatoes and capsicums and apple, apricot, cherry, nectarine, peach, plum, honeydew, rockmelon, scallopini, strawberry, table grape and zucchini (courgette).

These assessments were conducted in 2002⁵, 2011⁶, 2013⁷, and 2014⁸, respectively. FSANZ concluded that there was an established need to irradiate these foods and that there were no public health and safety issues associated with their consumption when irradiated up to a maximum dose of 1 kGy.

In February 2014, FSANZ published a review of the published literature on the nutritional impact of phytosanitary irradiation of fruits and vegetables and concluded that phytosanitary doses of irradiation do not pose a nutritional risk to the Australian and New Zealand populations⁹.

There are negligible risks to public health and safety associated with the consumption of blueberries and raspberries which have been irradiated up to 1 kGy. This conclusion is based on the following considerations:

- There is a low potential for the generation of 2-alkylcyclobutanones (2-ACBs)¹⁰ in irradiated blueberries and raspberries because of their low lipid content. The weight-of-evidence, supported by new published data, indicates that 2-ACBs are not genotoxic.
- Furan, a genotoxic carcinogen found in some non-irradiated foods, has been either not detected, or detected at only low levels in a range of other fruits irradiated at 5 kGy, which is five-times higher than the maximum dose sought in this Application. It is likely that furan levels are undetectable in blueberries and raspberries irradiated at doses of up to 1 kGy.
- Irradiation of blueberries and raspberries at doses of up to 1 kGy appears to have no consistent effect on the levels of vitamins or provitamins that are potentially sensitive to irradiation. There is limited and conflicting evidence of some losses of vitamin C in irradiated berries, but these reported reductions fall well within the range of vitamin losses that normally occur during the storage and processing of non-irradiated fruit. There is therefore minimal potential for the consumption of irradiated blueberries and raspberries to affect the nutritional adequacy of the Australian and New Zealand populations.

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

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

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

⁸ <http://www.foodstandards.gov.au/code/applications/Pages/A1092-Irradiation.aspx>

⁹ <http://www.foodstandards.gov.au/publications/Pages/Nutritional-impact-of-phytosanitary-irradiation-of-fruits-and-vegetables.aspx>

¹⁰ Alkylcyclobutanones are considered to be uniquely formed during food irradiation at levels dependent on the lipid content of the food.

- The safety of irradiated food has been extensively assessed by national regulators and international scientific bodies. The weight of scientific opinion is that irradiated food is safe for consumption when irradiated at doses necessary to achieve the intended technological function and in accordance with 'Good Practice in Food Irradiation'.

FSANZ is aware of publications and reports suggesting that irradiated pet foods are responsible for the development of adverse health effects in cats and dogs. Therefore, FSANZ has considered whether these reports raise any safety concerns of relevance to humans who consume irradiated foods.

FSANZ has previously considered reports of adverse neurological effects (leukoencephalomyelopathy) in specific pathogen-free cats associated with the exclusive consumption of dry feed that had been irradiated in the range of 26-54 kGy (Cassidy et al 2007; Caulfield et al 2009). While the exact aetiology of the leukoencephalomyelopathy remains to be determined, Caulfield et al (2009) suggested that the long-term, exclusive consumption of highly irradiated feed with a reduced Vitamin A content and a high peroxide content may have been responsible for the pathology.

Consumption of a specific brand of imported dry cat or dog food that had been irradiated at 50 kGy to comply with Australian quarantine requirements also resulted in neurological effects in cats involving movement (ataxia). The cause of the neurological effects for this one brand of dry pet food was not established, but dogs consuming the same dried food were unaffected. This product is no longer imported into Australia.

The levels of irradiation used for these dry pet food incidents are 25 to 50 times greater than that being proposed for irradiation of the currently approved fruits and vegetables for phytosanitary purposes. At high doses of irradiation (25-50 kGy), Vitamin A was shown to be reduced (Caulfield et al 2009). Since this highly irradiated food was the sole source of nutrition for cats, a nutritional deficiency occurred. However, FSANZ has previously concluded that low levels of irradiation (up to 1 kGy) do not appreciably reduce vitamin levels in fruits and vegetables and it is unlikely that the fruits requested to be irradiated would ever be the sole dietary sources of the affected nutrients.

These two studies (Cassidy et al 2007; Caulfield et al 2009) were also reviewed by EFSA in 2011 as part of its updated hazard assessment on the safety of irradiated foods. While EFSA expressed some uncertainty about the relevance of the observations in cats to humans, and noted the need for additional data, it also noted the lack of a similar effect in dogs fed the same irradiated diet or from observations in rodents or humans. EFSA's overall conclusion was that the weight-of-evidence indicates that consumption of irradiated food is safe for humans.

FSANZ is also aware that the United States Food and Drug Administration (USFDA) is actively investigating the cause of illnesses reported in dogs which may be associated with the consumption of irradiated jerky pet treat products¹¹.

These pet treat products are also irradiated up to 50 kGy to control microbes. To date, extensive testing by the USFDA has not identified a contaminant which could account for the pathology observed, but further testing is still under way. More recently (24 January 2014) it was reported that two of the top-selling brands of jerky treats for pets returned to US store shelves, a year after the nationwide recall.

¹¹ <http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm360951.htm>

FSANZ does not consider that these studies have implications for the safety of food irradiated at up to 1 kGy, and will continue to monitor any developments in this area and consider any related issues for irradiation of food for human consumption.

2.2 Risk management

Based on the risk assessment and consideration of other matters, FSANZ recommends that irradiation of these fruits is permitted for inclusion in Standard 1.5.3 with the following requirements:

- irradiation is permitted only for the purposes of pest disinfestation for a phytosanitary objective
- the permitted dose range should be a minimum dose of 150 Gy and a maximum of 1 kGy
- the application of current mandatory labelling and record keeping requirements for irradiated foods.

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

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

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

2.2.1 Labelling of irradiated food in Australia and New Zealand

2.2.1.1 Mandatory labelling requirements

Section 1.5.3—9 requires that if foods have been irradiated or the food has an ingredient or component that has been irradiated, then the label must carry a statement to the effect that the food, ingredient or component has been treated with ionising radiation. The statement may be on the statement of ingredients or elsewhere on the label. This requirement applies to foods available for retail sale in Australia or New Zealand.

If an irradiated food or food containing irradiated ingredients or components is exempt from bearing a label (e.g. unpackaged fruits or vegetables, or ready-to-eat foods) then section 1.2.1—9 (Standard 1.2.1 – Requirements to have labels or otherwise provide information) requires the statement to accompany the food or be displayed in connection with the display of the food.

The wording of the mandatory statement is not prescribed. Food suppliers and manufacturers can decide how to word the statement as long as it still indicates that the food has been treated with ionising radiation.

The mandatory labelling requirements would apply to blueberries and raspberries should the irradiation of these fruits be permitted. FSANZ is not proposing to make any exceptions or changes as part of this application.

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 is also 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.



2.2.1.2 Review of the mandatory labelling of irradiated food

In 2011, an independent review of food labelling law and policy was completed and a final report was published—*Labelling Logic: Review of Food Labelling Law and Policy (2011)* (Labelling Logic) (Blewett et al 2011).

The report made 61 recommendations including Recommendation 34 which states: *That the requirement for mandatory labelling of irradiated food be reviewed.*

In the government response, the Australia and New Zealand Ministerial Forum on Food Regulation (Forum) supported Recommendation 34 and requested that FSANZ review Standard 1.5.3 with a view to assessing the need for the mandatory labelling requirement for all irradiated food to continue, and assessing whether there is a more effective approach to communicating the safety and benefits of irradiation to consumers. While the Forum asked FSANZ to assess the current requirements, it did not ask for the Code to be changed, so no removal of the current labelling requirement for irradiated food is being proposed at this time. As such, the scope of this review means that existing labelling requirements will continue to apply to all foods that are permitted to be irradiated.

FSANZ is progressing work on this review in relation to Recommendation 34. A consultation paper was published on 18 January 2016 and was open for a ten-week comment period until 29 March 2016. The consultation paper and submissions received are available on the FSANZ website¹².

FSANZ expects to complete the review by late 2016, at which time FSANZ will provide a report to the Forum. The Forum may then request that FSANZ undertake further work or provide more advice. If the Forum asks FSANZ to consider making amendments to Standard 1.5.3, then this will occur through FSANZ's formal legislative processes, including public consultation.

¹² <http://www.foodstandards.gov.au/consumer/labelling/review/Pages/Labelling-review-recommendation-34irradiation-labelling.aspx>

2.3 Risk communication

2.3.1 Consultation

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

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

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

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

If the draft variation to the Code is approved by the FSANZ Board, that decision will be notified to the Forum. If the decision is not subject to a request for a review, the Applicant and stakeholders including the public, will be notified of the gazettal of the variation to the Code.

Every submission on an application is considered by the FSANZ Board. While not all comments may be taken on board during the process, they are valued and all contribute to the rigour of our assessment.

2.3.2 World Trade Organization (WTO)

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

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

2.4 FSANZ Act assessment requirements

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

2.4.1 Section 29

2.4.1.1 Cost benefit analysis

The Office of Best Practice Regulation (OBPR), in a letter to FSANZ dated 15 May 2012 (reference 13845), provided a standing exemption from the need to consider if a Regulation Impact Statement (RIS) was required for applications seeking permission to irradiate foods.

This standing exemption was provided as such changes are considered as minor, machinery and deregulatory in nature. The exemption relates to the introduction of a food to the food supply that has been determined to be safe.

Section 29 of the FSANZ ACT requires FSANZ to consider the costs and benefits arising from a food regulatory measure developed or varied as a result of the Application. FSANZ analysis found the direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the Application outweigh the costs to the community, Government or industry that would arise from the development or variation of that measure.

The below consideration of the costs and benefits of the regulatory options is not intended to be an exhaustive, quantitative financial analysis of the options as most of the impacts that are considered cannot be assigned a dollar value. Rather, the analysis seeks to highlight the qualitative impacts of criteria that are relevant to each option. These criteria are deliberately limited to those involving broad areas such as trade, consumer information and compliance.

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

Option 1: Prepare a draft variation to permit the use of irradiation for blueberries and raspberries

Consumers: Irradiated raspberries and blueberries have been assessed as being as safe and nutritionally adequate as non-irradiated berries.

Mandatory labelling will allow consumers wishing to avoid these foods to do so.

This permission may increase the range of produce available to consumers throughout the year.

Government: Approval would facilitate trade and market access in both domestic and international markets and avoid any conflict with WTO responsibilities. As mentioned above, irradiated raspberries and blueberries have been assessed as being as safe and nutritionally adequate as non-irradiated berries.

In the case of approved irradiated foods, monitoring is required to ensure compliance with the labelling requirements, and in the case of irradiated foods that have not been approved, monitoring is required to ensure they are not illegally entering the food supply.

Industry: Irradiated raspberries and blueberries would be permitted under the Code, allowing broader market access for domestic trade and importers and increased choice by businesses to use a proven quarantine treatment to alleviate 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.

Option 2 – Reject application

Consumers: There would be possible restriction in the availability of raspberries and blueberries which have been infested with pests of quarantine concern.

There would be no effect on consumers wishing to avoid irradiated raspberries and blueberries as these are not currently permitted in the food supply.

Government: Lack of approval may be regarded as unnecessarily trade restrictive (if considered inconsistent with WTO obligations) in which case there would be a potential effect on government however, this would be in terms of trade policy rather than on government revenue.

Industry: There would be possible loss of trade opportunities and access to markets where current disinfestation methods are not accepted.

As irradiated raspberries and blueberries have been found to be as safe and nutritionally adequate as non-irradiated raspberries and blueberries, not preparing a draft variation would offer little benefit to consumers.

FSANZ has prepared a draft variation to Standard 1.5.3 because the potential benefits of approving the variation outweigh the potential costs, and because no public health or safety concerns resulting from consumption of these foods were identified in the safety assessment.

2.4.1.2 Other measures

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

2.4.1.3 Any relevant New Zealand standards

Standard 1.5.3 is a joint standard.

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2 Subsection 18(1)

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

2.4.2.1 Protection of public health and safety

There are negligible risks to public health and safety associated with the consumption of blueberries and raspberries which have been irradiated at up to a maximum of 1 kGy.

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

The mandatory requirements under Standard 1.5.3 to label irradiated foods will provide information for consumers to make informed purchase decisions. Based on the risk assessment findings, no additional mandatory labelling requirements are proposed.

2.4.2.3 The prevention of misleading or deceptive conduct

No issues identified.

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

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

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

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

Approval to irradiate fruits and vegetables will promote consistency with other countries that approve the irradiation of fruits and vegetables for a phytosanitary purpose.

It also aligns with the Codex General Standard for Irradiated Foods which sets a maximum absorbed dose of 10 kGy. No specific foods are mentioned, although the Standard states that:

The irradiation of food is justified only where it fulfils a technological need or where it serves a food hygiene purpose and should not be used as a substitute for good manufacturing practices.

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

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

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

Not applicable.

- **any written policy guidelines formulated by the Ministerial Council¹³**

No Policy Guideline is applicable.

3 Draft variations

The draft variation to Standard 1.5.3 is at Attachment A. The draft variation is intended to take effect on gazettal.

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

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

APVMA (2011) Australian Pesticides and Veterinary Medicines Authority. Accessed September 2014 at 2011 Dimethoate Residues and Dietary Risk Assessment Report - August 2011.

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

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

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

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

WHO (1999) High-dose irradiation: Wholesomeness of food irradiated with doses above 10 kGy. Joint FAO/IAEA/WHO Study Group on High-Dose Irradiation. WHO Technical Report Series 890. Geneva.

Attachments

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

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



Food Standards (Application A1115 – Irradiation of Blueberries & Raspberries) 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 Standards Management Officer]

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

Note:

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

1 Name

This instrument is the *Food Standards (Application A1115 – Irradiation of Blueberries & Raspberries) Variation*.

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

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

3 Commencement

The variation commences on the date of gazettal.

Schedule

[1] Standard 1.5.3 is varied by adding each of the following to the table to subsection 1.5.3—3(2), in alphabetical order

blueberry

raspberry

”

Attachment B – Draft Explanatory Statement

1. Authority

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

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

FSANZ accepted Application A1115 which seeks to permit the irradiation of raspberries and blueberries as a phytosanitary measure¹⁴. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation.

2. Purpose

FSANZ has prepared a draft variation to the Code to include blueberries and raspberries in the table to subsection 1.5.3—3(2).

3. Documents incorporated by reference

The variation to a food regulatory measure 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 A1115 will include one round of public consultation following an assessment and the preparation of a draft variation.

A Regulation Impact Statement (RIS) was not required because the proposed variation to Standard 1.5.3 is likely to have a minor impact on business and individuals and is deemed to be deregulatory in nature.

5. Statement of compatibility with human rights

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

6. Variation

The variation permits the irradiation of raspberries and blueberries by adding these commodities to the table to subsection 1.5.3—3(2) with a minimum dose of 150 Gy and a maximum dose of 1 kGy.

¹⁴ A phytosanitary measure is any legislation, regulation or official procedure having the purpose to prevent the introduction and/or spread of quarantine pests, or to limit the economic impact of regulated non-quarantine pests.