

**26 October 2016**  
**[26–16]**

Approval report – Application A1115

## Irradiation of Blueberries & Raspberries

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Food Standards Australia New Zealand (FSANZ) has assessed an Application made by the NSW Department of Primary Industries (NSW DPI) to irradiate blueberries and raspberries for phytosanitary purposes.

On 29 June 2016, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received 35 submissions.

FSANZ approved the draft variation on 19 October 2016. The Australia and New Zealand Ministerial Forum on Food Regulation (Forum) was notified of FSANZ's decision on 25 October 2016.

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

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### Supporting document

The following document which informed the assessment of this Application is available on the FSANZ website at <http://www.foodstandards.gov.au/code/applications/Pages/A1115IrradiationBlueberriesandRaspberries.aspx>:

SD1 Risk and Technical Assessment Report (at Approval)

## 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 Applicant sought the same dose range (150 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).

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.

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

Thirty-four submissions, including a number of campaign submissions, were received on the proposed draft variation. FSANZ also received an online petition. The issues raised have been addressed in this Report. Based on data provided in the Application and information from other sources, consumption of irradiated fruits and vegetables is considered safe and nutritionally adequate for Australian and New Zealand consumers. Other irradiated foods have been assessed as safe through the evaluation of previous applications and evaluations by other countries. Previous World Health Organization (WHO) expert committees (1994 and 1999) concluded that irradiated food is safe to consume and nutritionally adequate. 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.

The FSANZ Board has approved the draft variation to Standard 1.5.3 to permit the irradiation of blueberries and raspberries 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. The current mandatory labelling of irradiated foods and record keeping requirements will apply to these irradiated fruits.

# 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 measure<sup>1</sup> 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 consistent 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 application A413)
- tropical fruits (mango, breadfruit, carambola, custard apple, litchi, longan, mangosteen, papaya and rambutan) (under application A443)
- persimmons (under application A1038)
- tomatoes and capsicums (under application A1069)
- apple, apricot, cherry, nectarine, peach, plum, honeydew, rockmelon, scallopini, strawberry, table grape, zucchini (courgette) (under application 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 was assessed under the General Procedure.

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<sup>1</sup> 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 findings

### 2.1 Summary of issues raised in submissions

Public submissions were invited on a draft variation which was released for public comment from 29 June to 10 August 2016. Thirty-four submissions were received (including a petition with 173 signatories from [Change.org](http://Change.org) against the proposed draft variation and from individuals as part of an online campaign, raising similar issues to the online petition). Two late comments received after the closing date.

During the public consultation, submitters also requested that FSANZ take note of issues that were previously raised in their submissions to A1092 – Irradiation of Specific Fruits & Vegetables. FSANZ has undertaken this comparison of submission issues between the two Applications. On the basis of this comparison, FSANZ has addressed the previous issues and has also given further consideration to other (new) issues in section 2.1.1.

#### 2.1.1 General issues raised by submitters

A number of submissions supported the draft variation: Steritech, Mountain Blue Farms, Horticulture New Zealand Incorporated, New Zealand Ministry for Primary Industries (MPI), NSW Food Authority, the Victorian Departments of Health and Human Services and Economic Development, Jobs, Transport and Resources, the Australian Food and Grocery Council and the New Zealand Food and Grocery Council. One submitter supported approval subject to proper enforcement of, and continuation of, the irradiation labelling requirements.

These submitters maintained that phytosanitary treatments that are safe and effective are important for Australian and New Zealand biosecurity purposes. Permitting the irradiation of blueberries and raspberries will allow for continued access to markets and may lead to increased domestic and international trade.

A number of submissions opposed the draft variation: Physicians and Scientists for Global Responsibility, Leah Bloomfield, Salome Argyropoulos, Christine Bennet, Consumers' Association of South Australia, Joe and Gaylene Thompson and Marsha Emerman. (See also section 2.1.2 below.)

The following general issues were raised by those opposing the draft variation:

- Food should not be processed by irradiation as a substitute procedure for good manufacturing practices.
- Irradiated food will not be fresh, and consumers may not even know because there is no guarantee of proper labelling.
- There is a conflict of interest by the NSW Government being both the applicant and one of the final arbiters of the decision on its own Application.

##### 2.1.1.1 FSANZ response

Although this Application is specifically for the purpose of pest disinfestation, not bacterial contamination, FSANZ agrees that food irradiation should not be used to clean up already spoiled food.

However, at phytosanitary doses of irradiation, there is no evidence that there are reductions in quality of fresh produce and there may be a dual benefit of increased shelf-life (although that is not the purpose of irradiating these fruits).

Any conflict of interest by the NSW Government is an issue for the Forum to consider.

### **2.1.2 Safety and nutritional impacts of irradiated foods**

Issues were raised by: Bob Phelps (Gene Ethics), Robert Ernest Tait (Friends of the Earth) , Janet Davies , Louise Davies , Robin Percy, Marsha Emerman, Physicians and Scientists for Global Responsibility, Vicki Wilson, Consumers' Association of South Australia, Janet Grevillea, Christine Bennett, Salome Argyropoulos, Peter Beetz, Ineke de Graaf, Phyllis Menos, Cathy Cheadle, Andrew James and Theodor Niemeyer.

The following specific issues were raised in relation to the safety and nutritional impacts of irradiated foods:

- Irradiation is a new technology with a limited history showing it is safe for human use.
- Irradiation has not been proven as safe and numerous scientific studies have shown the potential health risks posed by irradiated food. For example, in 2008-2009 up to one hundred Australian cats developed neurological disorders linked to the consumption of irradiated cat food. The risk to humans has not been ruled out.
- Irradiation produces free radicals in food and has been linked to health problems such as nutritional deficiencies, immune system disorders and genetic damage.
- There are no long-term studies on the safety of irradiated foods.
- Irradiation will destroy vitamin and nutritional content of blueberries and raspberries.

#### **2.1.2.1 FSANZ response**

After assessing the available evidence, FSANZ remains satisfied that food irradiated for human consumption does not pose a health or nutritional risk.

FSANZ assesses all applications to irradiate food on a case-by-case basis. When an applicant seeks approval for a new irradiated food, they must provide FSANZ with the evidence that supports the safety and nutritional adequacy of that irradiated food. This enables FSANZ to independently assess the data and reach a conclusion about the safety of the irradiated food. FSANZ also complements the data package provided by the Applicant with information from the scientific literature, other applications, other government agencies and the public. This and previous applications have had appropriate supporting data and information.

Before approvals are granted, FSANZ undertakes a comprehensive review of the safety and nutritional impacts on foods requested to be permitted to be irradiated. There is an extensive body of evidence demonstrating that the consumption of irradiated foodstuffs is safe for consumers.

This evidence is detailed in the risk assessments prepared in relation to the current and previous irradiation applications and in the range of worldwide permissions for irradiated foods (see SD1).

The 1999 WHO monograph on food irradiation prepared by the Joint FAO/IAEA/WHO Study Group evaluated an extensive database of long-term feeding studies conducted in laboratory animals (rats, mice, dogs, quails, hamsters, chickens, pigs and monkeys). These studies tested a range of foods that would have contained radiolytic compounds both naturally occurring and potentially unique to irradiated food. For example, 22 studies of at least two years' duration were conducted in rats, with many more studies conducted over shorter durations. In mice, 12 studies ranging up to 2 years were conducted, while long-term dog studies were conducted for 2–4 years. These studies found no evidence to indicate that the consumption of irradiated food is carcinogenic or caused any other adverse effects. Consistent with these long-term bioassays, the weight-of-evidence from an extensive battery of *in vitro* and *in vivo* genotoxicity assays indicated that irradiated foods are not mutagenic.

The formation of potentially novel compounds such as the 2 alkylcyclobutanones, or the production of increased concentrations of naturally-occurring compounds (e.g. furan, hydrocarbons) was considered as part of the risk assessments undertaken for previous applications and the current application. The conclusions of these risk assessments are that the formation of these compounds does not pose any public health and safety issues for consumers, including any genotoxic potential or increased risk of carcinogenicity.

Furan has either not been detected, or detected at only low levels, in a range of other fruits irradiated at 5 kGy (five times higher than the maximum dose sought in this application) and it is likely that furan levels are undetectable in blueberries and raspberries irradiated at doses up to 1 kGy. Furan is found in many non-irradiated foods (such as coffee and jarred baby foods) as a processing contaminant.

FSANZ is aware of publications suggesting that irradiated pet food is responsible for the development of a chronic neurological syndrome resulting in lameness and deaths in cats. However, FSANZ believes that this is a cat-specific effect. In summary, as reported in detail in the Risk Assessment (SD1), FSANZ does not consider that there are any implications for the safety of food irradiated for human consumption.

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

Irradiation of blueberries and raspberries at doses up to 1kGy appears to have no consistent effect on vitamins or provitamins that are potentially sensitive to irradiation. Reported reductions fall well within the range of vitamin losses that normally occur during the storage and processing of non-irradiated fruit. FSANZ's recent review concluded that phytosanitary doses of irradiation do not pose a nutritional risk to the Australian and New Zealand populations<sup>2</sup>.

In summary, one of the key considerations under the FSANZ Act is protection of public health and safety. FSANZ has always undertaken a robust and scientifically valid risk assessment on any food requested to be irradiated.

In regard to the fruits requested to be irradiated, FSANZ has concluded that there are no public health and safety risks from their consumption. In addition, reported vitamin loss falls well within the range that normally occurs during the storage and processing of non-irradiated fruit. Refer to section 2.2 for details on the safety and nutritional adequacy of irradiated foods.

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<sup>2</sup> <http://www.foodstandards.gov.au/publications/Pages/Nutritional-impact-of-phytosanitary-irradiation-of-fruits-and-vegetables.aspx>

### **2.1.3 Technological need to irradiate foods**

A number of submitters indicated that there was no technological need to irradiate foods and numerous chemical free alternatives existed: Louise Davies, Vicki Wilson, Janet Grevillea, Consumers' Association of South Australia, Salome Argyropoulos, Peter Beetz, Ineke de Graaf, Phyllis Menos and Cathy Cheadle.

#### **2.1.3.1 FSANZ response**

This issue was specifically addressed in the assessment summary for the call for submissions and in the related SD1. Food irradiation is an additional tool that can be used as a phytosanitary measure to alleviate pests such as fruit fly. There is now a need for an effective and cost efficient alternative to the two commonly used insecticides (dimethoate and fenthion) on specific fruits and vegetables. Reviews of these chemicals by the APVMA have resulted in their use being restricted, suspended or withdrawn.

FSANZ has been advised by the relevant quarantine authorities that irradiation is an internationally accepted quarantine measure for control of fruit fly and other insect pests and would provide an effective alternative to currently used disinfestation methods. It is currently considered by the quarantine agencies to be the preferred option to access markets in other countries.

FSANZ also notes that industry has advised that while other options exist, many of these are unsuitable for use in the fresh market due to potential phytotoxicity and quality issues, and require approval from quarantine authorities. There are costs and time delays associated with getting such approvals.

However, both the Australian Department of Agriculture and Water Resources (Agriculture) and the New Zealand Ministry for Primary Industries (NZ MPI) will independently perform an import risk assessment (for quarantine purposes) on irradiation of these fruits and vegetables specifically for food imported into Australia or New Zealand. These assessments are separate from the food standards approval process.

### **2.1.4 Labelling issues**

Labelling issues were raised in submissions from: Physicians and Scientists for Global Responsibility, Robert Ernest Tait (Friends of the Earth), Marsha Emerman, Christine Bennett, Bob Phelps (Gene Ethics), Consumers' Association of South Australia, Janet Grevillea.

The following labelling issues were raised:

- Food labels and displays containing labelling information need to be of a specific legibility and/or size
- Displays for irradiated food in supermarkets and grocery stores need to be mandated
- Labels on irradiated food must refer to the source of the irradiation (e.g. radio-isotope, electron beams etc)
- Food labelling information needs to be enforced more effectively.

FSANZ notes that many of the labelling issues mentioned in submissions to A1115 have been raised in previous Applications on the irradiation of certain foods.

No new evidence or material on these issues has emerged since the last Application (A1092), and so FSANZ considered that the following responses remain current for A1115:



1. Standard 1.2.1 requires any word, statement, expression or design on a food label (or the display of labelling information) to be legible and to be prominent so as to contrast distinctly with the background of the label. These requirements apply to the mandated statement on irradiated food.
2. If the food is not normally required to be labelled, then the mandatory labelling statement must be displayed on, or in connection with, the food. This would apply to foods such as whole fruit and vegetables sold loose by supermarkets.
3. FSANZ has not identified any evidence demonstrating how information on the source of irradiation (gamma rays from cobalt 60, e beam or x-ray) will influence consumer purchasing decisions. Therefore, we do not consider that there is a specific need to mandate a statement on the label relating to the source of irradiation, although there is no prohibition against the voluntary display of this information either.
4. Compliance and enforcement activities relating to the labelling requirements for irradiated food are the responsibility of the Australian state and territory jurisdictions and the NZ MPI.

Submissions also raised concerns about a FSANZ review that will remove the labelling requirements for irradiated food. Section 2.3.1 below provides an update on this review. It should be noted that this application is not proposing any changes to the labelling requirements for irradiated food.

Please see section 2.3.1 below for further details on how labelling requirements apply to irradiated foods.

## **2.2 Risk assessment**

Full details of the risk assessment prepared in relation to this Application are provided in **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 the previous considerations and includes an assessment of data on the safety and nutritional adequacy of irradiated foods that has become available since the assessments conducted in 2002, 2011, 2013 and 2014.

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

### 2.2.1.1 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 <sup>3</sup>	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
USA <sup>4</sup>	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, scallopini, 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

<sup>3</sup> In Canada, permission to irradiate beef, poultry, shrimp, prawns and mangoes is still in the process of Final Approval.

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

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 purpose<sup>5</sup>.

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 incorporate irradiation treatment into their supply chain with minimal impact on efficiency and profitability of the supply chain.

Both Agriculture and the NZ MPI have previously written to FSANZ endorsing irradiation as an effective quarantine treatment for fruit fly and other pests that are of quarantine concern to Australia and New Zealand.

However, both Agriculture and the NZ 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.

### 2.2.2 Safety and nutritional content of irradiated foods

FSANZ has previously assessed the technological need, safety and nutrient profile of various irradiated foods. These assessments were conducted in 2002<sup>6</sup>, 2011<sup>7</sup>, 2013<sup>8</sup>, and 2014<sup>9</sup>, 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 populations<sup>10</sup>.

There are negligible risks to public health and safety associated with the consumption of blueberries and raspberries which have been irradiated at 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)<sup>11</sup> in irradiated blueberries and raspberries because of their low lipid content.

<sup>5</sup> [http://www.codexalimentarius.net/download/standards/16/CXS\\_106e.pdf](http://www.codexalimentarius.net/download/standards/16/CXS_106e.pdf)

<sup>6</sup> <http://www.foodstandards.gov.au/code/applications/Pages/applicationa443irradiationoftropicalfruit/Default.aspx>

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

<sup>8</sup> <http://www.foodstandards.gov.au/code/applications/Pages/applicationa1069irra5511.aspx>

<sup>9</sup> <http://www.foodstandards.gov.au/code/applications/Pages/A1092-Irradiation.aspx>

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

<sup>11</sup> Alkylcyclobutanones are considered to be uniquely formed during food irradiation at levels dependent on the lipid content of the food.

- 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. Therefore, there is minimal potential for the consumption of irradiated blueberries and raspberries to affect the nutritional adequacy of the Australian and New Zealand populations.
- 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 25–50 times greater than that being proposed for irradiation of the currently specified 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 the European Food Safety Authority (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.

## **2.3 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.

### **2.3.1 Labelling of irradiated food in Australia and New Zealand**

#### **2.3.1.1 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 in 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.



### **2.3.1.2 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. The consultation paper and submissions received are available on the FSANZ website<sup>12</sup>. 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 assessment processes that include public consultation.

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

## **2.4 Decision**

The draft variation as proposed following assessment was approved without amendment. The variation takes effect on the date of gazettal. The approved draft variation is at Attachment A.

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

## **2.5 Risk communication**

### **2.5.1 Consultation**

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

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

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application. Every submission was considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

## **2.6 FSANZ Act assessment requirements**

### **2.6.1 Section 29**

#### **2.6.1.1 Cost benefit analysis**

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

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 approve the draft variation, FSANZ considered the following options:

### **Option 1: Approve the draft variation to Standard 1.5.3 to permit the use of irradiation blueberries and raspberries (with or without amendment)**

*Consumers:* Irradiated raspberries and blueberries have been assessed as being as safe and nutritionally adequate.

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

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 safe and nutritionally adequate.

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.

Potentially increases the range of food ingredients available to the food industry throughout the year.

### **Option 2 – Reject the draft variation**

*Consumers:* Possible restriction in the availability of raspberries and blueberries which have been infested with pests of quarantine concern.

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

*Government:* Potential effect as a lack of approval may be regarded as unnecessarily trade restrictive (if considered inconsistent with WTO obligations).

*Industry:* 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 safe and nutritionally adequate, not approving a draft variation would offer little benefit to consumers.



FSANZ decided to approve the draft variation without amendment, 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.

#### **2.6.1.2 Other measures**

During the public consultation period, some submitters claimed that other methods and alternatives exist to alleviate fruit fly infestation that is more effective.

FSANZ has been advised by the relevant quarantine authorities that irradiation is an internationally accepted quarantine measure for control of fruit fly and other insect pests and would provide an effective alternative to currently used disinfestation methods. FSANZ also notes that industry has advised that while other options exist, many of these are unsuitable for use in the fresh market due to potential phytotoxicity and quality issues, and require approval from quarantine authorities. There are costs and time delays associated with getting such approvals.

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

#### **2.6.1.3 Any relevant New Zealand standards**

Standard 1.5.3 is a joint Australia and New Zealand standard.

#### **2.6.1.4 Any other relevant matters**

Other relevant matters are considered below.

### **2.6.2. Subsection 18(1)**

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

#### **2.6.2.1 Protection of public health and safety**

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.

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

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

#### **2.6.2.3 The prevention of misleading or deceptive conduct**

No issues identified.

### **2.6.3 Subsection 18(2) considerations**

FSANZ has also had regard to:

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

FSANZ's risk analysis relied on 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 raspberries and blueberries 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 Forum on Food Regulation**

No Policy Guideline is applicable.

### 3 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 (1994) Safety and nutritional adequacy of irradiated food. Geneva.

WHO (1994) Safety and nutritional adequacy of irradiated food. Geneva.

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

## **Attachments**

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

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



### **Food Standards (Application A1115 – Irradiation of Blueberries & Raspberries) Variation**

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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 inserting each of the following into the table to subsection 1.5.3—3(2), in alphabetical order

blueberry

raspberry

## **Attachment B – Explanatory Statement**

### **1. Authority**

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

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

FSANZ accepted Application A1115 which seeks to permit the irradiation of raspberries and blueberries as a phytosanitary measure<sup>13</sup>. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation to Standard 1.5.3.

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

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

### **2. Purpose**

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

### **3. Documents incorporated by reference**

The variations to food regulatory measures do not incorporate any documents by reference.

### **4. Consultation**

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1115 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 29 June 2016 for a six-week consultation period.

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

### **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.

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<sup>13</sup> 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.

## 6. Variation

The variation amends the table to subsection 1.5.3—3(2) by inserting the words ‘blueberry’ and ‘raspberry’ into that table in alphabetical order. **By virtue of subsection 1.5.3—3(1), the** effect of this amendment is to permit the irradiation of raspberries and blueberries with a minimum dose of 150 Gy and a maximum dose of 1 kGy.