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FINAL ASSESSMENT REPORT
(INQUIRY – SECTION 17)

AND

REGULATORY IMPACT STATEMENT

APPLICATION A413

REQUEST TO INCLUDE HERBS, SPICES, HERBAL INFUSIONS, PEANUTS, CASHEW NUTS, ALMONDS AND PISTACHIO NUTS IN STANDARDS A17 AND 1.5.3 – IRRADIATION OF FOODS IN THE *FOOD STANDARDS CODE*

The Final Assessment Report and Regulatory Impact Statement is the Inquiry Report of Application A413 for the purposes of section 18 of the Australia New Zealand Food Authority Act 1991.

TABLE OF CONTENTS

Executive summary **5**

Background **6**

Table 1 – Changes to the application **8**

The toxicological safety of irradiated foods **10**

The microbial safety of irradiated foods **11**

Technological justification and efficacy **11**

Nutritional impact of irradiation **13**

The problem **13**

The objective **13**

Options **14**

Impact analysis of affected parties **14**

Impact analysis of costs and benefits **14**

Consultation **22**
Views of stakeholders – first round of public consultation 22
What was the process used to arrive at the recommended options? 24

Conclusions **25**

Recommendation **27**

Implementation and review **28**
Communications 28
Broader regulatory framework 28

Table 2: Regulatory framework for irradiation facilities **28**
Monitoring and enforcement 29
Irradiation processing 30
Accompanying Documentation 30
Labelling 31
Prevention of misleading and deceptive conduct 31
Detection methods 31
Consistency between domestic and international food standards. 32
Maximum dosage of 30kGy for decontamination of herbs and spices 32

Food Standards-Setting in Australia and New Zealand **33**

Attachment 1 .... **35**
List of approvals for the use of herbs and spices, herbal infusions and nuts in other countries 35
Type of clearance 38

Scientific Assessment Report **39**
Summary 40
The toxicological safety of irradiated foods 40
The microbial safety of irradiated foods 40
Technological justification and efficacy 40
Nutritional impact of irradiation 42
The safety of food irradiation 43
Toxicological safety and the concept of chemiclearance 43
Summary of previous toxicological studies on herbs, spices and nuts 45

Specific studies on spices and nuts **45**
The concept of toxicological equivalence as it applies to irradiation 48
Production of radiolytic products 48
Conclusions 49
References 51
Technological justification and efficacy 55
Microbiological decontamination 55
Reductions of micro-organisms following irradiation and comparison with other techniques for decontamination 58
Other techniques currently used to decontaminate plant material 59
Justification for decontamination 59
Disinfestation 59
Justification and Efficacy for nuts 59
Justification and Efficacy for herbs and spices 60
Justification for disinfestation, inhibition of sprouting and control of weeds 61
Microbiological Safety concerns with Irradiated Foods 61
References 62

Nutrition report **65**
Nutritional implications for irradiated food 65
Conditions under which irradiation is conducted 65
Specific nutrients 65
Dietary Modelling 67
Conclusions 75
References 76

Attachment 3 .... **78**
A413 – Submissions from 1st Round of Public Consultation 78
A413 – Submissions from 2nd Round of Public Consultation 79

Attachment 4 .... **81**
Issues Raised in Public Comments 81
SAFETY 81
TECHNOLOGICAL NEED 86
EFFICACY OF FOOD IRRADIATION 88
MICROBIOLOGICAL 89
NUTRITION 92
OTHER ISSUES 93
MONITORING AND ENFORCEMENT 95
DOSAGES 96
LABELLING 98
INTERNATIONAL PRACTICES 99
COSTS VS BENEFITS 100
IRRADIATION FACILITIES 102
ISSUES RAISED AT SECOND ROUND OF PUBLIC CONSULTATION 104
References 106

Attachment 5 .... **109**
World Trade Organization implications 109

DRAFT VARIATION TO THE *FOOD STANDARDS CODE* **110**

EXECUTIVE SUMMARY

The applicant applied to the Australian New Zealand Food Authority for permission to amend the *Food Standards Code* to permit the irradiation of herbs, spices, nuts, oilseeds and teas for particular technological and food safety purposes. The applicant subsequently altered the application. Details of the changes to the application are provided at Table 1, page 7, of the Report.

While irradiation has not been used in Australia or New Zealand for foods for human consumption, it has been used elsewhere for this purpose for many decades. A large body of scientific evidence is available to assess the safety of the technology for the purposes, the products and the dosages outlined in the application.

A scientific risk assessment of the application was undertaken to examine whether there were any significant public health and safety risks in relation to the application. The assessment examined the toxicological safety, technological justification and efficacy, microbiological safety and the nutritional implications for the diets of the Australian and New Zealand populations.

The scientific risk assessment concludes that the irradiated foods named in the amended application are safe to consume. These irradiated foods will not have any significant impact on the average dietary intakes of essential vitamins and minerals. The dietary modelling notes that nuts are not the primary dietary source of vitamin E for the general population or for vegetarians.

However, the public is genuinely concerned that there may be public health and safety risks in relation to the use of this technology, in particular its use in treating food. Evidence to this effect has not been demonstrated in the scientific risk assessment.

Approval of this application will bring significant benefits to consumers, industry and governments.

Benefits for consumers include the delivery of safe foods, as irradiation is proven to be more effective as a decontamination treatment for micro-organisms than existing chemical treatments such as ethylene oxide and at least as effective for disinfestation as methyl bromide. This will mean lower chemical residues in food and no loss of flavour or volatile oils in the treated herbs, spices and herbal infusions.

To enable those consumers who do not wish to consume foods treated with this technology to make an informed choice, irradiated foods will be labelled.

Benefits for industry include an alternative technology for treatment of herbs, spices, herbal infusions, peanuts, cashew nuts, almonds and pistachio nuts. This is particularly important because some of the currently widely used technologies may not be available in the longer term due to their potential damage to health and the environment. In addition, this technology should enhance trade. However, an approval of this application may cause an increased cost to industry because of labelling requirements, if no alternative technologies to irradiation exist.

The main benefit for governments is a new food technology for Australia and New Zealand that can provide improved public health and safety outcomes, compared with some of the existing technologies.

BACKGROUND

What is food irradiation?

Food irradiation is a food processing technology that involves treating certain types of food with ionising energy or radiation. Ionising radiation can be used to preserve food, to extend shelf life or to ensure food safety.

Apart from food safety, ionising radiation can be used to destroy or inactivate insects, moulds and yeasts that can destroy food; to slow the ripening process in fresh fruit and vegetables; to prevent the sprouting of root and other tuber vegetables; and to prevent, for quarantine purposes, the sprouting of weeds and other seeds.

Food is irradiated by exposing it to a source of ionising radiation. The ionising radiation is in the form of gamma rays from a cobalt-60 irradiation source, or from an 'electron beam' generated from electricity. The current application proposes the use of gamma rays. Gamma rays are similar to ultraviolet light or microwaves, but are of much shorter wavelength and greater energy. Gamma rays pass energy through food in the same way that microwaves pass through food, but the food remains cool.

The irradiation process involves passing the food through a radiation field at a set speed to control the amount of energy or dose absorbed by the food. The food itself never comes into contact with the radiation source. Irradiation does not make food radioactive.

Irradiation cannot enhance deteriorated or inferior quality food. Nor can it prevent contamination from improper handling after the irradiation.

What foods are included in the application?

The Australia New Zealand Food Authority (ANZFA) received an application on 3 May 2000 to amend Volume 1 and Volume 2 of the *Food Standards Code* to permit the irradiation of herbs, spices, nuts, oilseeds and teas for particular purposes and doses.

The application seeks to achieve certain technological and food safety requirements including (as described in the application) microbial decontamination[1], pest disinfestation[2] and the prevention of sprouting[3] and germination of weed seeds[4] inadvertently present in the foods.

The applicant seeks approval for the use of the technology on the specified products for quarantine and non-quarantine treatments.

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[1] Reduction in numbers of spoilage and disease causing microorganisms.
[2] Control of quarantine insects, weeds and plant pathogens.
[3] Control of sprouting in plant foods.
[4] Control of non-quarantine weeds.

A quarantine treatment is one that is applied in order to prevent the introduction and establishment of quarantine pests[5] from one area to another. Non-quarantine treatments are applied for other reasons, for example, to improve food safety, quality or storage. Non-quarantine treatments may also be directed against pests and weeds that are not regarded as a quarantine risk, such as storage pests, which may need to be removed from products for non-quarantine reasons.

Other authorities, such as Biosecurity Australia, the New Zealand Biosecurity Authority, the Australian Quarantine Inspection Service (AQIS), the New Zealand Ministry of Health and State and Territory quarantine regulatory bodies, have responsibility for the development and implementation arrangements for the import of plant products and, in the case of Australia, the interstate trade of plant products.

ANZFA accepted the application and circulated an Issues Paper for public comment over an eight-week period from October to December 2000.

After the initial consultation period, ANZFA requested the applicant to provide further data to support the application. The final data was received in April 2001. The applicant has amended the application to include herbs, spices and herbal infusions for the purposes outlined in the original application namely, for decontamination, disinfestation, control of weeds and sprout inhibition. The application was also amended to delete all oilseeds, green and black teas and nuts, with the exception of peanuts, cashew nuts, almonds and pistachio nuts. In addition, the applicant amended the application to exclude decontamination of nuts as a proposed technological purpose.

The definition of herbs and spices has been clarified to be consistent with the *Food Standards Code* and the dosage for the control of weeds has been changed from a minimum of 3.0 kiloGray (kGy) to a maximum of 6.0kGy.

Following the second round of public consultation the application was amended to exclude the control of weeds, of a quarantine or non-quarantine nature, as a proposed technological purpose. The maximum dosage for the control of sprouting and pest infestations (excluding weed seeds) in peanuts, almonds, cashews and pistachio nuts has been changed to 1kGy.

Table 1 outlines the changes to the application.

[5] The International Plant Protection Convention has defined a quarantine pest as a ‘pest of potential economic importance to the area endangered thereby and not yet present there, or present but not widely distributed and being officially controlled’. The term ‘pest’ includes insects, diseases and weeds.

Table 1 – CHANGES TO THE APPLICATION

Initial application	**Amended application**	**Purpose**	**Dosage requested**
Herbs and spices: a category described in Standard A14, Schedule 3 (and Standard 1.4.2, Schedule 4 being identical to A14) of the *Food Standards Code* and including: fresh or dehydrated herbs, spices and vegetable seasonings used for flavour, aroma, texture or colour or for their other properties. Other than being all from plant origins, this grouping is not scientifically defined but instead, is defined by use. It includes, but is not limited to, spices from seeds (pepper, nutmeg, mustard), berries (allspice), buds (capers, cassia), bark (cinnamon), flowers (saffron, dill), pods (chilli, nasturtium), herbs from leaves (oregano, basil, parsley), roots (garlic, onion) or rhizomes (ginger, turmeric). The herbs, spices and vegetable seasonings may be pure, blended with other herbs and spices, or fractions or extracts. This category also includes sodium chloride and other minor amounts of dry ingredients (such as starch) ordinarily used in herbs and spice blends.	**Herbs and spices:** products deemed to comply with the definition given in Standard 1.4.2, Schedule 4 of the *Food Standards Code* **Herbs:** including leaves, flowers, stems and roots from a variety of herbaceous plants, used in relatively small amounts as condiments to flavour foods or beverages. They are used either in fresh or naturally dried form. Herbs include angelica, balm leaves, basil, bay leaves, burnet (great), burnet (salad), burning bush, catmint, celery leaves, chives, curry leaves, dill, fennel, hops, horehound, hyssop, kaffir lime leaves, lavender, lemon balm, lemon grass, lemon verbena, lovage, marigold flowers, marjoram, mints, mizuna, nasturtium leaves, parsley, rosemary, rue, sage, sassafras leaves, savoury (summer, winter), sorrel, sweet cicely, tansy, tarragon, thyme, winter cress, wintergreen leaves, woodruff and wormwoods.	Sprout inhibition Disinfestations Decontamination Control of weeds	Min 0.20kGy Min 0.30kGy Min 2.0kGy Min 3.0kGy(**amended to max of 6.0kGy)** Overall max dose of 30kGy (this would apply to decontamination)

	Spices: consist of the aromatic seeds, roots, berries or other fruits from a variety of plants, which are used in relatively small quantities to flavour foods. Spices include: angelica seed, anise seed, calamus root, caper buds, caraway seed, cardamom seed, cassia buds, celery seed, cinnamon bark, cloves, coriander seed, cumin seed, dill seed, elecampane root, fennel seed, fenugreek seed, galangal (rhizomes), ginger (root), grains of paradise, juniper berry, licorice root, lovage seed, mace, nasturtium pods, nutmeg, pepper (black, white), pepper (long), pimento (fruit), tonka bean, turmeric (root), vanilla beans		
Nuts: Includes the category described in Standard A14, Schedule 3 of: Almond; Beech nut, Brazil nut; Cashew nut: Chestnut; Coconut; Hazelnut; Hickory nut; Japanese horse-chestnut; Macadamia nut; Pecan; Pine nut; Pili nut; Pistachio nut; Sapucaia nut; and Walnut and also peanut -ground nut	**Peanuts, cashew nuts, almonds and pistachio nuts. All other nuts have been deleted from the application**	Sprout inhibition Disinfestation **Decontamination deleted from application**. **Control of weeds deleted from application**	Overall Max dose of 1kGy. Deleted Deleted

Oilseeds: category described in Standard A14, Schedule 3	**Deleted from application**	**Deleted**	**Deleted**
Teas: category defined in Standard A14, Schedule 3 and also including herbal teas composed of the fermented, dried or fresh leaves, flowers and other parts of plants used to make beverages for various purposes	**Herbal infusions:** composed of fermented, dried or fresh leaves, flowers and other parts of plants used to make beverages but excluding varieties and cultivars of *Camellia sinensis (L.) O. Kuntz*	Disinfestation Decontamination Control of weeds	Min 0.30kGy Min 2.0kGy Min 3.0kGy (amended to **Max 6.0kGy)** Overall Max of 10kGy (this would apply to decontamination)

Any approval granted under this application would apply to the relevant foods produced in Australia and New Zealand and the relevant foods imported by either country. The foods would be required to meet the relevant Standards in the *Food Standards Code.* Any approval granted under this application would allow not only the applicant but also any other approved irradiation facility to treat these particular foods with ionising radiation from gamma rays, X-rays from machine sources or electrons from machine sources as permitted by the Standard.

What other countries permit the irradiation of these foods?

Attachment 1 provides a detailed listing of approvals of these foods in other countries including details of the date approved, purpose approved and maximum dose approved. Twenty-four countries approve the irradiation of herbs and forty-two countries approve the irradiation of spices.

Conclusion of the scientific assessment report

The Scientific Assessment Report undertaken on the application is at Attachment 2. The following provides a summary of the outcomes of the report, which examined the toxicological safety, microbial safety, technological justification and efficacy and the nutritional impact of irradiation of the foods.

The toxicological safety of irradiated foods

International reviews of the scientific literature on the toxicological effects of irradiated foods concluded that there are conditions under which food irradiation may be safely applied. Extensive studies undertaken in animals and in humans on irradiated foods concluded that food irradiated at doses necessary to perform a technological function and in accordance with good manufacturing practice is safe. Two World Health Organization (WHO) reports (1994 and 1999) on the safety and nutritional adequacy of irradiated foods, the second focused on irradiation of foods at high doses (>10kGy), support the safety of this technology.

When food is irradiated, several compounds (radiolytic products) are formed. The concentration of each individual compound is extremely low. Virtually all the radiolytic products that have previously been found in irradiated foods are either naturally present in food or produced in thermally processed foods. Any radiolytic products must also have been present in the animal and human toxicology tests that showed no adverse effects.

The numerous toxicological studies on plant materials indicate there is no evidence that irradiated plant material in the diet leads to toxicological concerns. Therefore, by applying the concept of chemi-clearance, there is no evidence to suggest a toxicological concern following irradiation of spices, herbs and herbal infusions.

The analysis of the toxicological effects of irradiation on herbs, spices, herbal infusions and selected nuts indicates that the treatment does not produce adverse health effects beyond those arising from conventional treatments.

The microbial safety of irradiated foods

Irradiation of herbs, spices, herbal infusions and nuts presents no microbiological safety concerns and will not result in the increased induction of particular mutant bacterial species with increased pathogenicity or virulence.

Irradiation in common with other decontamination procedures, including cooking, cannot inactivate bacterial toxins and manufacturers must ensure that toxins and micro-organisms responsible for producing them are absent prior to irradiation.

Technological justification and efficacy

Microbiological decontamination

Herbs and Spices

The pathogens identified as commonly present in herbs and spices, and therefore likely to pose a public health and safety issue for consumers are *Salmonella*, *Escherichia coli*, *Bacillus cereus*, and *Clostridium perfringens*. *Salmonella* is found infrequently, but in a wide variety of spices. The incidence of contamination with potentially undesirable bacteria is, therefore, high.

Irradiation (at a variety of dose levels) has been shown to significantly reduce levels of micro-organisms present on herbs and spices. In addition, irradiation has been shown to be more effective than ethylene oxide at reducing microbial populations on herbs and spices.

Radiation doses required for microbial decontamination of spices have shown no major effect on the volatile oils that determine flavour quality.

In conclusion, the available research suggests that irradiating herbs and spices is an efficacious technique for the control of microbial decontamination and offers an alternative to more traditional techniques.

Nuts

There is evidence of the presence of moulds such as *Aspergillus flavus* on nuts; however, the presence of moulds does not present a public health problem unless poor storage conditions allow for aflatoxin production. Although the efficacy of irradiation at reducing mould levels on nuts has been demonstrated, no adequate technological need for the use of irradiation to reduce mould levels on nuts has been established.

There is evidence of the occasional presence of *Salmonella* on peanuts and almonds. There is no evidence of the presence of any pathogens (including *Salmonella*) on cashew nuts or pistachio nuts and there is no evidence of the efficacy of irradiation in reducing pathogen levels on nuts.

In conclusion, there is no technological justification for the use of irradiation for the control of micro-organisms on nuts.

Herbal infusions

Microbial contamination of herbal infusion raw materials has been reported and there is some evidence that the micro-organisms present in plant materials are able to survive the procedures used to prepare infusions. This potential for survival represents a public health problem especially given that infusions may be prepared using warm or even cold water.

The efficacy of irradiation in decreasing microbial contamination levels when applied to tea herbs has been demonstrated at doses from 1kGy to 10kGy.

In conclusion, although, the evidence supporting the technological need for decontamination of herbal infusions is less extensive than the evidence supporting the need for the irradiation of herbs and spices, the technological need and efficacy for control of microbial pathogens has been established.

Control of pests, weeds and inhibition of sprouting

Nuts

Pests and diseases associated with nuts are numerous including at least four species of arthropod that are of quarantine concern to Australia.

Irradiation efficacy data indicates that a dose of 0.5kGy to 2.0kGy (dependent upon species) would be sufficient to either kill or sterilise these pests.

Herbs, spices and herbal infusions

Herbs and spices may contain a wide variety of plants, plant products, insects and weed seeds sourced from many areas of the world, many of which are exotic to Australia and require quarantine treatment. The efficacy data cited for control of pests, weeds and inhibition of sprouting for nuts equally apply to herbs and spices.

In conclusion, the technological justification and efficacy has been established for the use of irradiation on herbs and spices for control of pests (particularly arthropod insects) and for the control of weeds and the inhibition of sprouting.

Nutritional impact of irradiation

The analysis of the nutritional impact of irradiation is based around dietary patterns where the specified foods may potentially make a significant contribution to the total diet.

The scientific literature indicates that carbohydrates, protein and saturated fats experience little change during irradiation.

The effects of irradiation on the unsaturated fatty acids in herbs and spices is relatively insignificant due to the minimal content of these nutrients and their minimal contribution to dietary patterns. The issue of unsaturated fatty acids is of more significance in nuts where the content is higher. However, the contribution of nuts to total unsaturated fatty acid intake is relatively insignificant.

Dietary modelling indicates that the foods covered by this application are insignificant sources of vitamins sensitive to irradiation (vitamin C, vitamin A, thiamin, folate and vitamin E). It is notable that the dietary modelling indicates that nuts are not the primary dietary source of vitamin E for the general population or for vegetarians. Consequently, the effects of irradiation on dietary vitamin E intake are relatively insignificant.

Available research on the irradiation effects of herbs, spices, herbal infusions, peanuts, almonds, cashew nuts and pistachio nuts, together with an analysis of dietary intake and dietary modelling, indicate that the irradiation of the foods covered by this application will not have a significant effect on the nutritional adequacy of the diet of the Australian and New Zealand populations.

The problem

Standard A17 - Irradiation of Food under Volume 1 of the *Australian Foods Standards Code, Regulation 264* in the New Zealand Food Regulations and an identical Standard in Volume 2 of the *Food Standards Code*, Standard 1.5.3, provide the framework agreed to by health ministers in 1999 to enable the consideration of applications on a case by case basis for the irradiation of foods.

The problem arises due to consumers not having sufficient information to determine the safety of irradiated food products. This leads to a tension between the perceived risks and the real risks of irradiated products and their safety.

The objective

The Standard prohibits the irradiation of food, or ingredients or components of food, unless a specific permission is given. The specific permission may impose conditions relating to matters such as dose, packaging materials, approved premises or facilities.

The objectives of the assessment of this application are to:

- examine the safety of these products when irradiated relative to their non-irradiated counterparts;
- provide sufficient information to enable consumers to make informed judgements against what they value and understand; and
- examine consistency with international standards.

Options

The Issues Paper raised on this matter in October 2000 outlined two potential regulatory options to be considered given that a regulatory Standard exists under which approval may be given under certain circumstances. These options were to not approve or to approve an application under the Standard. A third option would be to approve the application with conditions attached. The proposed options are to:

1. not approve the application and rely on existing approved methods to decontaminate, disinfest, stop sprouting, and ensure control of weeds;

2. approve the application to irradiate these products under prescribed conditions in the Table to Clause 4 of the Standard where there is a demonstrated technological or food safety need. The prescribed conditions would include dosage, use of the technology for defined purposes and food to be handled before and after irradiation according to good manufacturing; or

3. approve the application to irradiate these products without prescribed conditions in the Table to Clause 4 of the Standard, and with no minimum and/or maximum doses or conditions, provided a technological or food safety need has been demonstrated.

Impact analysis of affected parties

The affected parties in relation to the application are:

- consumers of foods and food ingredients;
- industry – food manufacturers, processors and growers, importers and irradiation facilities; and
- government agencies that regulate the food industry in Australia and New Zealand and those with an interest in food policy and regulation relevant to this application.

Impact analysis of costs and benefits

Option 1

Rely on existing approved methods to decontaminate, disinfest, stop sprouting and ensure control of weeds.

Benefits

Consumers

Some consumers will see this as a benefit as they will be able to avoid consuming irradiated foods. There is a view, not supported by the scientific evidence, that there are significant public health and safety issues associated with the consumption of irradiated foods. Although some of the more commonly used chemical methods may not be available in the longer term, and there are safety and environmental concerns associated with them, some consumers may prefer existing methods to achieve the food safety and technological outcomes required.

Industry

This option would benefit existing treatment facilities that already treat these foods for these purposes. However, as above, some of these methods may not be available in the longer term and this option will not provide the food industry with an alternative and more effective technology for use in the longer term.

Governments

This option would not entail any additional monitoring or enforcement by government agencies. However, there are no other expected benefits from this option. There could be negative consequences due to the possible reduction in alternate quarantine and non-quarantine (including food safety) treatment measures.

Costs

Consumers

Some of the most widely used existing methods to treat these products may not be available in the longer term, in particular, to assure food safety. This could mean that unless other technologies are available, consumers may not have the choice of purchasing these foods or ingredients if safety cannot be assured. While alternatives for the decontamination of herbs and spices, such as steam sterilisation, exist their use for herbs and some spices is limited because of the flavour and colour changes caused by the heat processing.

Existing technologies such as the use of methyl bromide are known to deplete the ozone layer and are being phased out globally under the Montreal Protocol and ethylene oxide is banned in many countries because it is a known carcinogen.

Industry

In the longer term, there may not be a suitable technology available for safety and quarantine treatments. For example, the current Australian permission for the use of ethylene oxide (ETO), used for the decontamination of herbs and spices, will expire at the end of September 2001. In New Zealand, the use of ETO is not time limited but is subject to ongoing monitoring. In any case, treatment with ETO often needs to be repeated and causes consequent delays for industry before the products can be used.

Methyl bromide, currently the principle post-harvest insect disinfestation treatment for quarantine and pre-shipment, is known to deplete the ozone layer and is globally being phased out under the Montreal Protocol. Although the use of methyl bromide is not under immediate threat, it cannot increase and its future use, availability and cost are uncertain.

To be able to assure food safety, food processors and manufacturers will require technologies that can replace the older chemical technologies, particularly where these products are used in ready-to-eat foods and there is no further microbial kill step prior to consumption by the consumer.

Most herbs and spices used in food processing in Australia and New Zealand are imported. Herbs and spices are used in a wide variety of processed and ready-to-eat foods. Without access to these commodities, Australian and New Zealand industry would need to undertake considerable reformulation of their products. In 2000, the sale of wet and dry herbs and spices in Australian grocery stores was valued at A$119.8m. In the period January 2000 – January 2001, Australia imported 3,800,000 kg of herbs and 8,400,000 kg of spices.

In the year to March 2001, 48,000 kg of herbs were exported from New Zealand whilst a significant quantity is imported.

Total Australian nut production in 2000 had a retail value estimated by the Nut Industry Council to be A$400m. Australia is a net exporter of almonds but has a fledgling cashew nut industry. Almost all cashews and fifty percent of pistachio nuts consumed in Australia are imported. The retail value of the peanut market in Australia is currently estimated by the Peanut Company of Australia to be between A$150 and A$200m per annum. Approximately twelve percent of peanuts consumed in Australia are imported.

All nuts grown in New Zealand are consumed locally whilst many more are imported. Nonetheless, this is a growth horticultural industry in New Zealand recording the 7^{th} highest areas planted of all horticultural products since 1994.

Governments

If existing technologies are no longer available, potential risks to public health and safety and quarantine protection may be raised for Australia and New Zealand governments, food industries and economies unless suitable alternative technologies are established.

Option 2

> **Approve the application to irradiate these products under prescribed conditions in the Table to Clause 4 of the Standard, where there is a demonstrated technological or food safety need. The prescribed conditions would include dosage, use of the technology for defined purposes and food to be handled before and after irradiation according to good manufacturing practice.**

Benefits

Consumers

Consumers will have access to safe foods by the use of irradiation for microbial control in herbs, spices and herbal infusions. The scientific assessment of the application concludes that irradiating these products for this purpose is justified and safe and that there will not be any significant effect on the nutritional contribution of these foods to the diets of Australian and New Zealand consumers.

Evidence also exists that irradiating herbs and spices for food safety purposes is a more effective technique than the use of the chemical fumigant, ethylene oxide, that is widely used for this purpose. Some herbs, spices and herbal infusions will have better sensory quality after irradiation than after treatment with some methods, such as steam sterilisation, which leads to loss of the volatile flavour compounds that are an essential function of herbs and spices.

Other benefits include the provision of another quarantine and non-quarantine method for the prevention of sprouting and control of insects and weeds for the products in question.

One of the benefits of irradiation as a technology is the ability to irradiate packaged food and thus help to ensure that there is no further contamination of the food prior to consumption.

Consumers will be able to make an informed choice in relation to the purchase of foods containing these products. Because irradiated foods will be labelled, consumers will be able to choose whether or not to consume these foods.

In addition, this option provides consumers with an enhanced level of assurance in relation to the control of irradiation for food safety or other technological purposes by the specification of any minimum or maximum doses required to achieve the food safety outcome and any other specific conditions attached to the approval.

Industry

This option would provide industry with an alternative technology for these products. Industry would be able to produce these products with a more effective, cleaner and safer technology than some of the existing technologies. In the longer term, these currently used technologies may not continue to be available and an alternative technology to ensure the safety of these foods and control infestations, sprouting and weeds will be needed.

This option would enhance trade with other countries that permit the irradiation of these products.

Many international standards and codes are available as guides for industry to use for the irradiation of foods. These include the standards of the *Codex Alimentarius Commission*, the *International Standards Organisation*, codes of practice of the *International Consultative Group on Food Irradiation* and the standards of the *American Society of Testing and Materials*.

Governments

Adoption of this option will provide additional quarantine and non-quarantine (including food safety) control options at a time when, internationally, current methods of control are being phased out. Effective minimum dose rates of irradiation for quarantine purposes will need to be determined on a country, pest and commodity basis. Each application will have to be considered and effective minimum irradiation dose rates for a particular quarantine application will have to be negotiated between respective quarantine authorities. However, the benefits related to these costs will be appropriate levels of protection for quarantine purposes.

This option will enable governments to continue to achieve public health and safety objectives. It will also enable governments to provide a higher level of assurance to consumers that this technology is being adequately regulated, particularly given that this will be a new food technology in Australia and New Zealand.

Costs

Consumers

It is not expected that the inclusion of minimum or maximum doses will add any costs to consumers for these goods. The greater the dose of irradiation, the greater is the cost to the food manufacturer or food importer. This is an incentive to use the lowest dose necessary to achieve the food safety outcome or technological purpose being sought.

However, if consumers are not able to assess the level of safety of these products they are likely to lose confidence in the products and this means they may not have an effective choice of these foods.

Industry

Commercial-in-confidence data received by ANZFA indicates that the cost of irradiating these products at a facility would be less than the costs of some of the alternative technologies. It is likely there would be similar costs for the transportation of foods for the purpose of alternative treatments - for example ethylene oxide and steam sterilisation.

Food businesses regularly change labels for a variety of reasons, including their own purposes and regulatory reasons. However, an approval under the Standard will mean that if a business irradiates foods, it will be required to immediately change its labels. Therefore, this option will have some cost impact on industry, depending on whether it has a reasonable period to manage this change.

Industry will choose the technology it requires for the technological or food safety purpose it is trying to achieve. If there is a range of technologies available for the product of similar efficacy, then it would be a commercial decision for the company to choose irradiation which will involve increased labelling costs.

The applicant notes that most of the packaging materials used for the foods included in the application are well suited for irradiation, with the exception of oriented polypropylene. It is also noted that normal glass may discolour.

The products related to this application are dry, dehydrated or surface-dry and present the least opportunity for reaction with packaging material. It is not expected that packaging materials for irradiated foods will be a significant cost to industry.

This option would provide industry with conditional approval. However, industry may consider this option a constraint on their commercial irradiation options. Such conditions are not inconsistent with good practice internationally. Hence, the cost of this impact is considered to be small.

Governments

Effective minimum doses for quarantine purposes will need to be determined by quarantine authorities. There would be considerable cost and time delays to government, industry and the economy as a whole if food authorities, rather than quarantine authorities, were to set the appropriate level of phytosanitary protection that would be required for foods to ensure Australia and New Zealand were protected from quarantine pests.

The cost to food safety enforcement agencies of monitoring any approval under the Standard for these products would be small and, in Australia, comprise inspection to assess compliance with the *Foods Standards Code*, including compliance with the Irradiation Standard and the Food Safety Standards. In New Zealand, this would include compliance with the relevant Standard and the Food Regulations.

Costs for quarantine authorities to assess the quarantine risks and appropriate level of protection (ALOP) are the same as any request to import produce into Australia or New Zealand. A full Import Risk Analysis (for Australia) or a full risk assessment (for New Zealand) examining the risk of introduction of quarantine pests must be conducted. If the risks associated with the proposed import were deemed above the Australian or New Zealand ALOP, risk mitigation factors would then be examined to reduce this risk. Irradiation may be considered as a risk mitigation factor if the efficacy for the quarantine pests of concern and the proposed imported commodity supports this approach. Additional costs may be incurred if irradiation efficacy data for the quarantine pests and commodity of concern is not available and additional research is required. This process also applies to interstate trade in Australia.

Option 3

Approve the application to irradiate these products without prescribed conditions in the Table to Clause 4 of the Standard, no minimum and/or maximum doses or conditions, provided a technological or food safety need has been demonstrated

Benefits

Consumers

Consumers will have access to safer foods by the use of irradiation for microbial control in herbs, spices and herbal infusions. The scientific assessment of the application concludes that irradiating these products for this purpose is justified and safe and that there will not be any significant effect on the nutritional contribution of these foods to the diets of Australian and New Zealand consumers.

Evidence also exists that irradiating herbs and spices for food safety purposes is a more effective technique than the use of the chemical fumigant, ethylene oxide, that is widely used for this purpose. Some herbs, spices and herbal infusions will have better sensory quality after irradiation than after treatment with alternate methods, such as steam sterilisation, which lead to loss of the volatile flavour compounds that are an essential function of herbs and spices.

Other benefits include the provision of another quarantine and non-quarantine method for the prevention of sprouting and control of insects and weeds for the products in question.

One of the benefits of irradiation as a technology is the ability to irradiate packaged food and thus help to ensure that there is no further contamination of the food prior to consumption.

Consumers will be able to make an informed choice in relation to the purchase of foods containing these products. Because irradiated foods will be labelled, consumers will be able to choose whether or not to consume these foods.

Industry

This option would provide industry with an alternative technology for these products.

This option gives industry the maximum flexibility and the least regulatory burden. Industry would be required to conform to the pre-existing requirements in the Standard for permitted sources of irradiation, record keeping (including the recording of minimum and maximum doses), minimum durable life of the product, the process used and compliance with the process used, the nature and quantity of food, lot identification, date of irradiation and whether the product has been previously irradiated and, if so, the details of the treatment.

Industry would be able to produce these products with more effective, cleaner and safer technologies than some of the existing technologies.

This option would enhance trade with other countries that permit the irradiation of these products.

Governments

Adoption of this option will provide additional quarantine and non-quarantine (including food safety) control options at a time when, internationally, current methods of control are being phased out. Effective minimum dose rates of irradiation for quarantine purposes will need to be determined on a pest, country and commodity basis by the relevant quarantine agencies. Non-specification of the maximum or minimum dose rates may provide more flexibility for quarantine applications, provided food safety and quality is not adversely affected.

Many international standards and codes are available for regulators, the food industry or irradiation industry to use as guidance for the irradiation of foods such as the standards of the *Codex Alimentarius Commission*s and the *International Standards Organisation*, codes of practice of the *International Consultative Group on Food Irradiation* and the standards of the *American Society of Testing and Materials*.

Costs

Consumers

Consumers are unlikely to accept no minimum and maximum dosages or conditions in the Table to Clause 4 of the Standard, given their concerns about the safety of this technology. If consumers are not able to assess the level of safety of these products they are likely to lose confidence in the products and this means they may not have an effective choice of these foods.

Industry

Commercial-in-confidence data received by ANZFA indicates that the cost of irradiating these products at a facility would be less than the costs of some of the alternative technologies. It is likely there would be similar costs for the transportation of foods for the purpose of alternative treatments, for example, ethylene oxide and steam sterilisation.

Food businesses regularly change labels for a variety of reasons including their own purposes and regulatory reasons. However, an approval under the Standard will mean that if a business irradiates foods, it will be required to immediately change its labels. Therefore, this option will have some cost impact on industry, depending on whether it has a reasonable period to manage this change.

Industry will choose the technology it requires for the technological or food safety purpose it is trying to achieve. If there is a range of technologies available for the product of similar efficacy, then it would be a commercial decision to choose irradiation which will involve increased labelling costs.

The applicant notes that most of the packaging materials used for the foods included in the application are well suited for irradiation, with the exception of oriented polypropylene. It is also noted that normal glass may discolour. The products related to this application are dry, dehydrated or surface-dry and present the least opportunity for reaction with packaging material.

There may also be risks for industry in relation to this option. If approval were to be granted for the application, consumers may choose not to purchase foods that have been treated with ionising radiation.

Governments

Effective minimum doses for quarantine purposes will need to be determined by quarantine authorities. There would be considerable cost and time delays to government, industry and the economy as a whole if food authorities, rather than quarantine authorities, were to set the appropriate level of phytosanitary protection that would be required for foods to ensure Australia and New Zealand were protected from quarantine pests.

The cost to food safety enforcement agencies of monitoring any approval under the Standard for these products would be small and, in Australia, comprise inspection to assess compliance with the *Foods Standards Code*, including compliance with the Irradiation Standard and the Food Safety Standards. In New Zealand, this would include compliance with the relevant Standard and the Food Regulations.

Costs for quarantine authorities to assess the quarantine risks and appropriate level of protection (ALOP) are the same as any request to import produce into Australia or New Zealand. A full Import Risk Analysis (for Australia) or a full risk assessment (for New Zealand) examining the risk of introduction of quarantine pests must be conducted. If the risks associated with the proposed import were deemed above the Australian or New Zealand ALOP, risk mitigation factors would then be examined to reduce this risk. Irradiation may be considered as a risk mitigation factor if the efficacy for the quarantine pests of concern and the proposed imported commodity supports this approach. Additional costs may be incurred if irradiation efficacy data for the quarantine pests and commodity of concern is not available and additional research is required.

Consultation

Views of stakeholders – first round of public consultation

ANZFA received 303 submissions as a result of the advertisement of the Issues Paper on the application. Thirty-five submissions were received from government authorities, professional associations, industry associations and other groups. Two hundred and twenty-five campaign submissions were received and forty-three submissions were received from other individuals. Further details are at Attachment 3.

A broad and comprehensive range of issues has been raised in the submissions received on this matter. In broad terms these include:

- safety, regulation and control of irradiation facilities;
- safety of irradiated foods including toxicological, nutritional, microbiological and efficacy issues;
- detection methods and monitoring and enforcement issues;
- justification of technological or food safety purposes;
- issues about the Standard, particularly how the Table to Clause 4 in the Standard would operate in relation to the foods, doses of ionising radiation for the foods, purposes described and conditions that would apply to any approval;
- international practice in relation to the irradiation of similar foods;
- labelling issues; and
- costs and benefits of the application.

The issues raised in the public consultation process are detailed and addressed at Attachment 4 in a question and answer format. A copy of the summary of submissions is available on request.

Overall the views of the community in relation to the application were negative (94%). A small range of governments, industry and professional organizations supported the application on the basis of the food safety outcomes and quarantine measures that can be achieved.

An analysis of the submissions received indicated that by far the most significant concern raised by submitters was in relation to the safety of irradiated foods and any impact on human health (80.1%). The next most significant issue raised by submitters related to the control and regulation of irradiation facilities, including issues related to the environment and the occupational health and safety of workers in the facilities (16.3%).

The issues raised by the application in relation to the nutritional impact on the diets of the Australian and New Zealand populations and justification of the technological need for certain products were resolved with the amendments to the application in relation to oilseeds, green and black teas and the decontamination of nuts. In the initial application, the inclusion of oilseeds raised issues about the capacity of the Australian and New Zealand populations to achieve the appropriate dietary intakes of Vitamin E if these products were irradiated. In addition, the technological justification of green and black teas and the decontamination of nuts were raised as issues. Following discussions on these matters with the applicant, the application has been amended as outlined in Table 1at page 7.

Views of stakeholders – second round of public consultation

As a result of the second round of public consultation 721 submissions were received. These included thirty-five submissions from government authorities, industry associations and business and other groups. Six hundred and sixteen campaign submissions were received and seventy submissions from individuals.

Again the overall the majority of community views on the application were negative (99%). A small group of government, professional and industry groups supported the application, although with some qualifications. The views of submitters are discussed below.

While a wide range of issues have been raised, the majority of the submitters who opposed the application did so on the basis of concerns over the safety of irradiated foods for human consumption (including nutritional issues) and the control of irradiation facilities including environmental safety concerns. Many of these issues were raised in the first round of public consultation and have been addressed in the Draft Assessment.

Related to these concerns, in the second round of public consultation, submitters have questioned the validity and independence of the studies and review of safety data on food irradiation conducted by the World Health Organization (WHO). Submitters have also questioned the concept of chemiclearance that is used to refer to the toxicological analysis and wholesomeness assessment of irradiated foods.

On microbiological issues, submitters have raised issues about the control of *Clostridium botulinum* and *Bacillus cereus* as well as aflatoxins. Concerns have also been expressed about the effect of irradiation on folate, the ANZFA DIAMOND dietary modeling and unsaturated fatty acids

The nut and peanut industry in Australia, including growers, processors, importers and exporters and industry associations have questioned the technological need for the use of irradiation to control the sprouting of weed seeds in peanuts, cashew nuts, almonds and pistachio nuts. Following further examination of the issues, the applicant has amended the application to exclude the proposed purpose of treating weed seeds in peanuts, almonds, cashews and pistachios.

A significant number of submitters are of the view that food acts require that food only be processed in dedicated food processing facilities and this is not the case.

A range of stakeholders raised issues about the international approvals at Attachment 1 and further clarification has now been provided in the attachment.

There appears to be some confusion about the dosages currently used for irradiating non-food products and that this either indicates that irradiation facilities would not be able to irradiate at lower doses, which is also not the case.

A number of submitters support Option 3, rather than Option 2 and these same submitters and one other also requested there be an exemption to the labelling requirement in the Standard so that labelling not be required in mixed irradiated foods unless there was a certain percentage of irradiated ingredients in the food. This is not a matter that can be dealt with in relation to this application as it was not a matter raised in the application nor has there been any consultation on the matter with the spectrum of stakeholders concerned.

The above array of issues have been addressed in the relevant parts of the final assessment report, clarified above or are separately identified in the question and answer section at Attachment 4 which deals with new issues raised in public comments. A separate section titled, ‘Issues Raised in Second Round Public Consultation” at the end of Attachment 4 has been created for this purpose.

What was the process used to arrive at the recommended options?

This application was used as a pilot of a new process to enhance ANZFA’s consultation processes in accordance with feedback received from stakeholders. Given the likely public interest in this application, ANZFA developed an Issues Paper in consultation with a Steering Group representative of the broad range of stakeholders with an interest in this application. This Group comprises Australian and New Zealand representatives from consumer organisations, the food industry and health and agriculture portfolios, as well as an expert in the field of radiation. The Group has assisted and guided ANZFA in developing the Issues Paper, considering the public response to the first round of public consultation and developing of this Draft Assessment Report.

The Issues Paper was intended to seek early input on a range of specific issues known to be of interest to various stakeholders, to seek input on the likely regulatory impact at an early stage and to seek input from stakeholders on any other matter of interest to them in relation to the application.

Given the nature of the application, it was important to ensure that other regulatory authorities were involved on the Steering Group and there was liaison with the regulators of irradiation facilities.

Represented on the Steering Group are:

- Health Departments (WA, Qld, Vic, NSW, Commonwealth and New Zealand)
- Agriculture and quarantine agencies (Agriculture, Forestry and Fisheries Australia, the Australian Quarantine Inspection Service and the Ministry of Agriculture and Forestry, NZ)
- Australian Consumers' Association
- New Zealand Consumers' Institute
- Australian Food and Grocery Council
- New Zealand Grocery Marketers Association Inc
- a radiation expert
- ANZFA staff

All stakeholders that made a submission in relation to the development of the Standard for Food Irradiation were included on the mailing list for the Issues Paper. In addition, other likely stakeholders with an interest in the application were added to this list including public health organisations, consumer groups, regulatory authorities and the food industry. Other interested parties as they came to the attention of the Authority, and as they have contacted the Authority through becoming aware of the application, have also been added to the mailing list for the Draft Assessment Report.

The purpose of this Report is to:

- convey information on the independent scientific assessment of the application;
- communicate about the broad range of issues raised by the community at large – consumers, industry and governments in relation to this application;
- convey information about the processes used to arrive at a recommended course of action in relation to the application; and
- seek your views as a stakeholder on this Draft Assessment Report which makes recommendations in relation to the application.

The Draft Assessment Report will be sent to all parties who have indicated an interest in this application for comment on the proposed recommendations.

The previous discussion in this Report on options has considered each option's costs and benefits. In the next section of the Report, conclusions are drawn by comparing the costs and benefits of the options.

Conclusions

While this technology has not been used in Australia and New Zealand for foods for human consumption, it has been used overseas for many decades and a large body of scientific evidence is available to assess the safety of the technology for the purposes, the products and dosages outlined in the application.

The technology has been safely used for many years in Australia and New Zealand for other purposes such as sterilising medical equipment and food containers and for quarantine and other therapeutic purposes.

A scientific risk assessment (Attachment 2) of the amended application was undertaken to examine whether there were any significant public health and safety risks in relation to the application. The assessment examined the toxicological safety, technological need, microbiological safety (including public health risks) and the nutritional implications for the diets of the Australian and New Zealand populations.

The scientific risk assessment concludes that the irradiated foods named in the amended application are safe to consume. These irradiated foods will not have any significant impact on the average dietary intakes of essential vitamins and minerals. The dietary modelling notes that nuts are not the primary dietary source of vitamin E for the general population or for vegetarians.

However, the public is genuinely concerned that there may be public health and safety risks in relation to the use of this technology, in particular its use in treating food. Evidence to this effect has not been demonstrated in the scientific risk assessment.

Overall there are no significant costs related to the application and there are some significant benefits to be gained by consumers, industry and governments with an approval of this application.

Such benefits for consumers include another technology to deliver safe foods, as irradiation is proven to be more effective as a decontamination treatment for micro-organisms, and is at least as efficacious for some arthropods of quarantine/non-quarantine concern, than existing chemical treatments such as ethylene oxide or methyl bromide. This will mean less chemical residues in food and a technology that results in no loss of flavour or volatile oils in the treated herbs and spices.

To enable choice for those consumers who do not wish to consume foods treated with this technology, irradiated foods will be labelled as required by the Standard.

Benefits for industry include an alternative technology for treatment of herbs, spices, herbal infusions, peanuts, cashew nuts, almonds and pistachio nuts. This is particularly important because some of the currently widely used technologies may not be available in the longer term due to their potential damage to health and the environment. In addition, this technology should enhance trade. However, an approval of this application may cause an increased cost to industry because of labelling requirements, if no alternative technologies to irradiation exist.

It should be noted that while there are alternative technologies currently available for use for the technological and food safety purposes applied for in this application, many have only limited use for the foods related to this application, for example, the use of steam sterilisation for herbs and spices (food safety) and methyl bromide fumigation for herbs and spices (quarantine). The use of irradiation as a technology generally has broader application than some existing technologies.

Any approval under the Standard would enhance trade and aid importers by providing an alternative technology for treatment of the products. Refer to Attachment 5 for World Trade Organisation implications.

For governments, this new food technology for Australia and New Zealand may provide improved public health and safety outcomes compared with some of the alternative technologies.

It is considered that the risks associated with Option 1, the status quo, far outweigh any benefits both in terms of cost and public health and safety for consumers, industry and governments.

It is not expected that the inclusion of minimum or maximum doses under Option 2 will add to the cost of production of these foods compared to option 3. Because the cost of irradiating rises as the dosage increases, there is an incentive to use the lowest dose necessary to achieve the food safety outcome or technological purpose being sought. However, requirements around dosage and special conditions provides a superior level of assurance to consumers that the process will be well regulated and provide better guidance to industry on the regulatory requirements. In addition, there are far greater benefits to be achieved under Option 2 than just cost, including significant public health and safety benefits. The overall benefits to be gained under Option 2 are considered to be greater than the overall benefits to be achieved under Option 3.

In conclusion, Option 2 is to be preferred.

Recommendation

It is recommended that the application, as amended by the applicant, be approved. The recommendation based on the analysis of relevant scientific evidence that demonstrates that the treatment of these foods with irradiation is safe. Overall, public health and safety benefits may be achieved through the use of this technology as an alternative to existing technologies. It is recommended that approval be made on the following conditions:

1. Approval be granted for the foods and food safety and technological purposes requested in the amended application.
2. A minimum dose of 2.0kGy and a maximum of 30kGy are approved for the decontamination of herbs and spices.
3. A minimum dose of 2.0kGy and a maximum dose of 10kGy are approved for the decontamination of herbal infusions.
4. Approval be granted for disinfestations (defined as the control of quarantine insects, weeds and plant pathogens), control of weeds (non quarantine) and control of sprouting for herbs and spices, with no minimum dose specified, as the minimum effective dose for these purposes should be based on the appropriate level of protection determined by quarantine authorities. A maximum dose of 6kGy for these purposes should be approved.
5. Approval be granted for disinfestation and control of sprouting for peanuts, almonds, cashews and pistachio nuts, with no minimum dose specified as the minimum effective doses for these purposes will be determined by quarantine authorities. A maximum dose of 1kGy for these purposes should be approved.
6. Approval be granted in all cases based on the condition that the food is to be handled before and after irradiation according to good manufacturing practice (GMP).

The proposed drafting for an amendment to the Standards is at Attachment 6.

Implementation and review

Communications

ANZFA will undertake communication activities to assist consumers, industry and governments to access information about any approval, the process of assessing the application, the outcomes of the scientific assessment of the application and other factual information about food irradiation relevant to the application.

Broader regulatory framework

Community concern has been expressed about the regulatory framework that exists for facilities that would irradiate food. An effective framework for the regulation of irradiation facilities exists in Australia and New Zealand. This is shown in further detail in Table 2.

Table 2: Regulatory framework for irradiation facilities

National level	State or Territory level	Local government level
Australia:		
Australian Radiation Protection and Nuclear Safety Agency (regulates Commonwealth radiation facilities)	Departments of Health or Environment Protection Authority in all Australian States and Territories for licensing and regulation of radiation use, planning, occupational health and safety and food laws	Local government authorities for local planning approvals, enforcement of food laws and standards and registration of food businesses
Department of Environment (environmental considerations depending on the size of the plant).		
Australian Quarantine and Inspection Service (approved quarantine treatment of imports, monitoring under the Imported Food Inspection Program and approval for exports).		
Therapeutic Goods Administration (approval for therapeutic goods).		
Australia New Zealand Food Authority (treatment of food).		
Australian Customs Service (approval for import of radioactive substances).		

New Zealand:		
Ministry of Health through the National Radiation Laboratory (regulates radiation facilities and import/export of radioactive substances)		Local government (planning approvals under the Resource Management Act)
Ministry of Health and Public Health Units (enforces food law, including food standards)		
Ministry of Agriculture and Forestry (Biosecurity), (approval of quarantine treatments)		
Ministry for the Environment (can issue national policy statements, provides guidance to local government)		

This framework can provide a high level of assurance to the community that the products will be produced using best radiation practice. In relation to food, the relevant irradiation Standards will ensure that the food is produced in accordance with good manufacturing practice and that a technological or food safety need is required to be demonstrated by the applicant before any permission to amend the Standard in the *Food Standards Code* is considered.

Monitoring and enforcement

Any approval under the Standard is subject to requirements related to ensuring proper treatment and documentation. In addition, food producers in Australia are required to comply with the *Food Standards Code*, including the requirements of the Food Safety Standards and Microbiological Standards. The States and Territories undertake enforcement. Breaches of the Code will result in significant penalties for individuals and companies, as proposed in the new Food Acts. Similar provisions apply in New Zealand under the Food Regulations and relevant Standard.

For any approval under the Standard, records must be kept for a period of time that exceeds the durable life of the product by one year at the facility where the food is irradiated. The records must identify the nature and lot identification of the food. The manufacturer, wholesaler or importer under the Australian Food Safety Standards must have in place a written food recall plan to enable them to recall food if the need arises.

In Australia, irradiation facilities already must keep adequate records as part of the regulatory requirements surrounding their licensing and operation and also as part of their registration requirements with other bodies such as the Australian Quarantine Inspection Service and the Therapeutic Goods Administration.

Irradiation processing

The requirement for the maintenance of Good Manufacturing Practice at all stages of the process will be made mandatory in the Standard. In Australia, the requirements of the Food Safety Standards will apply to ensure processing control requirements are satisfied at each step of the food handling process. In New Zealand, the Food Regulations and the Food Hygiene Regulations or food safety programmes will apply to these aspects.

Irradiation procedures (known as dosimetry) are well established after their use for over thirty years in the irradiation sterilisation of medical products. The record keeping required under any approval includes sufficient information for the dose delivered to any batch of product to be independently assessed.

There are now methods available that can determine whether foods have been irradiated. However, such methods are not appropriate as part of an enforcement method for proper dosimetry. At this time, detection methods cannot determine the dose to which a food has been irradiated with sufficient accuracy. Even if dose determination were possible by a detection method, such as a post-treatment method that samples only a small fraction of the food treated, this would not be a suitable enforcement method.

Accompanying Documentation

When the treated food leaves the irradiation plant, the shipment must be accompanied by clear documentation that specifies the dose applied, date of irradiation, facility address and lot number.

Irradiated products imported into Australia and New Zealand will also be required to comply with the requirements of the Standard. For irradiated foods moving in international trade, there has been rapid progress related to the development of certification systems for irradiated food to ensure irradiated food is properly processed, documented and meets the regulatory requirements of the importing country.

Guidelines for a certification system and a model certificate have been developed for the use of import/export authorities for foods irradiated for both phytosanitary and other purposes. These are based on the Codex Committee on Food Import and Export Inspection and Certification Systems (CCFICS) Draft Guidelines for Generic Official Certificate Formats and the Production and Issuance of Certificates. The certification system and certificates for phytosanitary treatments are based on the system and certificates, which are in international use for other phytosanitary treatments.

While specific certification requirements for irradiation treatments of food products for phytosanitary purposes have not yet been determined by quarantine authorities in Australia or New Zealand, consideration would be given to these by the relevant authorities in both countries once an application for this technological need was received.

Labelling

The Standard requires that food must be labelled with a statement that the food has been treated with ionising radiation. The Standard provides three examples of such statements. These include 'Treated with ionising radiation', 'Treated with ionising electrons' and 'Irradiated (name of food). The ANZFA document, *Irradiated Food - Information to Applicants,* states that the use of the international radura symbol is optional and, if used, should be in close proximity to the name of the food. However, the use of the symbol would be in addition to the statement that the food has been treated with ionising radiation.

An indication of the benefit of food irradiation would also be permitted to be placed on the label provided that is was not false, misleading or deceptive.

The Standard requires that where an irradiated food, or a food containing irradiated components, is displayed for retail sale other than in a package then that display must have on it, or in connection with the display, a label stating that the food or its ingredients have been treated with ionising radiation. Any change to this requirement would require an application to change the Standard.

Point of sale food, such as in restaurants, would not be covered. However the consumer has the right to ask if the food contains irradiated ingredients. This is consistent with the general labelling provisions in the *Food Standards Code*. Food businesses, in these circumstances, would be obligated to advise truthfully about whether the food has been irradiated or be at risk of breaching both food law and trade practices legislation. It is generally an offence under food legislation to sell food that is falsely or misleadingly described. It is generally an offence under trade practices legislation to engage in misleading or deceptive conduct.

It will be important for industry to have sufficient time to manage the changeover to new labels for irradiated products.

Prevention of misleading and deceptive conduct

Significant penalties exist for misleading or deceptive conduct under the Australian *Trade Practices Act*, State and Territory *Fair Trading Acts* and the New Zealand *Fair Trading Act*. For example, if it was claimed a product was irradiated to eliminate micro-organisms when in fact this was not the case or a lesser dose was used.

Food producers will be required to comply with the *Food Standards Code*. There are significant penalties for individuals and companies proposed in the food law for breaches of these requirements.

Detection methods

The value of methods to detect whether a food has been irradiated are:

- a check on whether foods have been correctly labelled;
- a means to ensure labelling regulations can be enforced;
- protection of the rights of consumers to be informed about the food they purchase and eat; and
- a discouragement of false claims, either that the food has or has not been irradiated.

The very low concentration of individual chemical changes in irradiated food has resulted in difficulty in devising detection methods. There is still no single test that can detect all potentially irradiated foods. However, intensive international effort has devised a successful series of detection methods for irradiated foods. European Union Standards produced between 1996 and 2000 allow for detection of food containing fat, bone, cellulose, for example nuts, and food from which silicate minerals can be isolated such as herbs and spices. These include methods suitable for the foods that are the subject of the application.

The Codex Alimentarius Commission Committee on Methods of Analysis and Sampling is proposing to adopt these methods as general Codex analytical methods. The European Union Standard methods are considered to have a very low failure rate. They are suitable for detection of the food as treated and will be useful in enforcing original shipping documentation. Some difficulties may result if the irradiated food is subsequently further processed, especially by heat, or blended with large amounts of irradiated food.

Detection methods are applied after the treatment. As discussed earlier, they are not used as a way to control the irradiation process. Process control must be carried out at the time of treatment using internationally accepted dosimetry and documentation methods.

The techniques and capability to use the abovementioned detection methods exist in Australia and New Zealand but not, at this stage, specifically for testing foods. The necessary set up and quality control systems would need to be established to specifically test for irradiated foods.

Consistency between domestic and international food standards.

An approval to irradiate these products would be consistent with international standards given that the international Codex Alimentarius Commission Standard allows irradiation of foods (not specified), up to a maximum overall dose of 10kGy, but only where irradiation of food justifies a technological need or where it serves a food hygiene purpose and should not be used as a substitute for good manufacturing practice.

The World Trade Organisation implications of an approval under the Standard are addressed at Attachment 5.

Maximum dosage of 30kGy for decontamination of herbs and spices

Based on the scientific evidence, the use of 30kGy to decontaminate herbs and spices is safe. The major concern of stakeholders is in relation to the possible use of this technology to replace good manufacturing practice. The Standard, however, would require the use of good manufacturing practice before and after irradiation.

It should be noted that the foods in question are not sterile products – they are naturally occurring and may be contaminated by soil, air, water and pests or animals in their surrounding environment, including during production, harvesting, processing and transportation. This is particularly so with spices and herbs.

While the international Codex standard for food irradiation is currently set at a maximum of 10kGy, Codex is considering raising this limit, based on the World Health Organization studies on high dose irradiation, so as to ensure food safety outcomes.

A number of countries currently permit the irradiation of herbs and spices for microbial control up to a maximum dose of 30kGy, including the US, Argentina and Croatia. Most other countries approve up to 10kGy, mainly for consistency with the current Codex Standard.

Steritech has two irradiation plants designed to sterilise large packs of medical products. Such plants often have a Dose Uniformity (DU) ratio around 3. Treatment to sterilise medical products are concerned with the minimum dose of 25kGy and not the maximum dose as the product is nearly always very stable at very high doses. This is not to say that the applicant is unable to sterilise at the lower doses requested in the application, as there are a variety of ways of controlling the required treatment.

Advice to ANZFA is that in irradiation plants designed specifically for food, a lower DU ratio allows better control of the minimum and maximum doses imparted to food, as food is sensitive (from a quality perspective) to the maximum dose. Overseas plants, for example one in France for de-boned chicken, are treating meat in packs about 7cm thick, and may have a DU ratio much lower than 3. Food facilities treating pallet loads, however, would find it difficult to get much below a DU ratio of 2.5. The WHO (1999) report states that most commercial facilities operate in a way that produces a dose spread (DU ratio) of 2 to 3.

The reason for wanting a maximum dose of 30kGy for herbs and spices is only partly because of the DU ratio. Some herbs and spices can be so heavily contaminated with micro-organisms that a dose of between 3kGy to 30kGy is required to ensure food safety. Previously, there have been concerns that the maximum dose of 10kGy may not be efficacious in reducing microbial numbers.

Food Standards-Setting in Australia and New Zealand

The Governments of Australia and New Zealand entered an Agreement in December 1995 establishing a system for the development of joint food standards. On 24 November 2000, Health Ministers in the Australia New Zealand Food Standards Council (ANZFSC) agreed to adopt the new *Australian New Zealand Food Standards Code*. The new Code was gazetted on 20 December 2000 in both Australia and New Zealand as an alternate to existing food regulations until December 2002 when it will become the sole food code for both countries. It aims to reduce the prescription of existing food regulations in both countries and lead to greater industry innovation, competition and trade.

Until the *Australia New Zealand Food Standards Code* is the sole Code between Australia and New Zealand, the following arrangements for the two countries apply:

- **Food imported into New Zealand other than from Australia** must comply with either Volume 1 (previously known as Australian *Food Standards Code)* or Volume 2 (also known as the *Australia New Zealand Food Standards Code)* of the *Food Standards Code*, as gazetted in New Zealand, or the New Zealand *Food Regulations 1984,* but not a combination thereof. However, in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the New Zealand *(Maximum Residue Limits of Agricultural Compounds) Mandatory Food Standard 1999.*

- **Food imported into Australia other than from New Zealand** must comply solely with Volume 1 (previously known as Australian *Food Standards Code)* or Volume 2 (also known as the *Australia New Zealand Food Standards Code)*, of the *Food Standards Code,* but not a combination of the two.

- **Food imported into New Zealand from Australia** must comply with either Volume 1 (previously known as Australian *Food Standards Code)* or Volume 2 (also known as the *Australia New Zealand Food Standards Code)* of the *Food Standards Code*, as gazetted in New Zealand, but not a combination thereof. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the New Zealand *Food Regulations 1984.*

- **Food imported into Australia from New Zealand** must comply with Volume 1 (known as Australian *Food Standards Code)* or Volume 2 (known as *Australia New Zealand Food Standards Code)* of the *Food Standards Code*, but not a combination of the two. However, under the provisions of the Trans-Tasman Mutual Recognition Arrangement, food may **also** be imported into Australia from New Zealand provided it complies with the New Zealand *Food Regulations 1984.*

- **Food manufactured in Australia and sold in Australia** must comply solely with Volume 1 (previously known as Australian *Food Standards Code)* or Volume 2 (also known as the *Australia New Zealand Food Standards Code)*, of the *Food Standards Code,* but not a combination of the two. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the New Zealand *Food Regulations 1984.*

In addition to the above, all food must comply with relevant food legislation. Further, all food sold in New Zealand must comply with the New Zealand *Fair Trading Act 1986* and all food sold in Australia must comply with the Australian *Trade Practices Act 1974,* and the respective Australian State and Territory *Fair Trading Acts.*

Any person or organisation may apply to ANZFA to have the *Food Standards Code* amended. In addition, ANZFA may develop proposals to amend the *Food Standards Code* or to develop joint Australia New Zealand food standards. ANZFA can provide advice on the requirements for applications to amend the *Food Standards Code*.

Attachment 1

List of approvals for the use of herbs and spices, herbal infusions and nuts in other countries[6]

Explanation for codes: 1Delay Ripening/physiological growth 2 Disinfestation 3 Microbial control 4 Quarantine treatment 5 Shelf life extension 6 Sprouting inhibition 7 Trichina/parasite control 8 Sterile meals for hospital patients 9 Sterilisation 10 Unstated

Herbs

Country	Code	Type of Clearance	Date	Dose max (kGy)
BELGIUM	3	Conditional	29.9.83	10.00
BRAZIL	2, 3	Unconditional	30.01.01	**
CANADA	3	Unconditional	03.10.84	10.00
DENMARK	3	Unconditional	23.12.85	15.00
EGYPT	3	Unconditional	22.10.97	10.00
FRANCE	3	Unconditional	22.05.90	10.00
GHANA	2	Unconditional	15.01.98	1.00
GHANA	3	Unconditional	15.01.98	10.00
ITALY	10	Unconditional	18.07.96	10.00
MEXICO	3	Unconditional	07.04.95	10.00
MEXICO	2	Unconditional	07.04.95	1.00
NETHERLANDS	3	Unconditional	01.08.92	15.00
NORWAY	3	Unconditional	16.07.82	10.00
PAKISTAN	3	Unconditional	07.03.96	10.00
PAKISTAN	2	Unconditional	07.03.96	1.00
SOUTH AFRICA	2	Conditional	04.10.85	1.00
USA	3	Unconditional	18.04.86	30.00

Herbs (dried)

Country	Code	Type of clearance	Date	Dose max (kGy)
AUSTRIA	10	Unconditional	20.09.00	10.00
FINLAND	10	Unconditional	20.09.00	10.00
GERMANY	10	Unconditional	20.09.00	10.00
GREECE	10	Unconditional	20.09.00	10.00
IRELAND	10	Unconditional	20.09.00	10.00
LUXEMBOURG	10	Unconditional	20.09.00	10.00
PORTUGAL	10	Unconditional	20.09.00	10.00
SPAIN	10	Unconditional	20.09.00	10.00
SWEDEN	10	Unconditional	20.09.00	10.00
UNITED KINGDOM	10	Unconditional	20.09.00	10.00

[6] ICGFI Database on Clearances of Irradiated Foods

Spices

Country	Code	Type of clearance	Date	Dose max (kGy)
ARGENTINA	3	Unconditional	09.12.90	10.00
ARGENTINA	3	Unconditional	09.12.90	30.00
AUSTRIA	10	Unconditional	20.09.00	10.00
BANGLADESH	3	Unconditional	29.12.83	10.00
BANGLADESH	2	Unconditional	29.12.83	1.00
BELGIUM	3	Conditional	29.09.83	10.00
BRAZIL	3	Unconditional	08.03.85	10.00
CANADA	3	Unconditional	03.10.84	10.00
CHILE	3	Unconditional	29.12.82	10.00
CHINA	3	Unconditional	10.06.97	10.00
CROATIA	3	Unconditional	21.06.94	30.00
CUBA	2	Unconditional	01.08.90	5.00
CZECH REPUBLIC	3	Conditional	24.08.92	10.00
DENMARK	3	Unconditional	23.12.85	15.00
EGYPT	3	Unconditional	22.10.97	10.00
FINLAND	3	Unconditional	13.11.87	10.00
FRANCE	3	Unconditional	10.02.83	11.00
GERMANY	10	Unconditional	20.09.00	10.00
GHANA	3, 4, 6	Unconditional	01.01.97	10.00
GHANA	2	Unconditional	01.01.97	1.00
GREECE	10	Unconditional	20.09.00	10.00
HUNGARY	3	Unconditional	19.08.86	6.00
INDIA	3	Unconditional	09.08.86	14.00
INDONESIA	3	Unconditional	29.12.87	10.00
IRAN	3	Unconditional	09.07.90	10.00
IRELAND	10	Unconditional	20.09.00	10.00
ISRAEL	10	Unconditional	17.02.87	10.00
ITALY	3	Unconditional	18.07.96	10.00
KOREA, REPUBLIC OF	3	Unconditional	13.09.88	10.00
LUXEMBOURG	10	Unconditional	20.09.00	10.00
NETHERLANDS	3	Unconditional	01.08.92	15.00
NORWAY	3	Unconditional	16.07.82	10.00
PAKISTAN	2	Unconditional	07.03.96	1.00
PAKISTAN	3	Unconditional	07.03.96	10.00
PHILIPPINES	3	Conditional	28.04.92	0.00
POLAND	3	Unconditional	01.10.90	10.00
PORTUGAL	10	Unconditional	20.09.00	10.00
SOUTH AFRICA	3	Conditional	04.10.85	10.00
SPAIN	10	Unconditional	20.09.00	10.00
SWEDEN	10	Unconditional	20.09.00	10.00
SYRIA	3	Unconditional	02.08.86	10.00
THAILAND	3	Unconditional	04.12.86	10.00
THAILAND	2	Unconditional	04.12.86	1.00
TURKEY	2, 3	Unconditional	06.11.99	10.00

UNITED KINGDOM	3	Unconditional	01.01.91	10.00
USA	3	Unconditional	18.04.86	30.00
YUGOSLAVIA	3	Unconditional	17.12.84	10.00

Vegetable seasonings (dried)

Country	Code	Type of clearance	Date	Dose max (kGy)
AUSTRIA	10	Unconditional	20.09.00	10.00
BELGIUM	10	Unconditional	20.09.00	10.00
BRAZIL	3	Unconditional	**	10.00
CANADA	10	Unconditional	03.10.84	10.00
DENMARK	10	Unconditional	20.09.00	10.00
FINLAND	10	Unconditional	20.09.00	10.00
FRANCE	10	Unconditional	20.09.00	10.00
GERMANY	10	Unconditional	20.09.00	10.00
GREECE	10	Unconditional	20.09.00	10.00
IRELAND	10	Unconditional	20.09.00	10.00
ISRAEL	2, 3	Unconditional	17.02.87	10.00
ITALY	10	Unconditional	20.09.00	10.00
KOREA, REP. OF	3	Unconditional	19.05.95	10.00
LUXEMBOURG	10	Unconditional	20.09.00	10.00
NETHERLANDS	10	Unconditional	20.09.00	10.00
NORWAY	3	Unconditional	16.07.82	10.00
PORTUGAL	10	Unconditional	20.09.00	10.00
SPAIN	10	Unconditional	20.09.00	10.00
SWEDEN	10	Unconditional	20.09.00	10.00
UNITED KINGDOM	3	Unconditional	01.01.91	10.00

Herbal infusions

Country	Code	Type of clearance	Date	Dose max (kGy)
BELGIUM	3	Conditional	30.11.88	10.00
BRAZIL	3	Unconditional	30.01.01	**
CROATIA	3	Unconditional	21.06.94	10.00
GHANA	2	Unconditional	01.01.97	1.00
GHANA	3	Unconditional	01.01.97	10.00
MEXICO	3	Unconditional	07.04.95	10.00
YUGOSLAVIA	3	Unconditional	17.12.84	10.00

Tea, rooibus

Country	Code	Type of clearance	Date	Dose max (kGy)
SOUTH AFRICA	2	Conditional	16.01.85	10.00

Tea, comfrey

Country	Code	Type of clearance	Date	Dose max (kGy)
SOUTH AFRICA	2	Conditional	20.09.92	10.00

Tea, black seed

Country	Code	Type of clearance	Date	Dose max (kGy)
SOUTH AFRICA	2	Conditional	12.10.93	10.00

Almonds

Country	Code	Type of clearance	Date	Dose max (kGy)
SOUTH AFRICA	3	Conditional	07.05.82	10.00

Peanuts

Country	Code	Type of clearance	Date	Dose max (kGy)
BRAZIL	2,3	Unconditional	30.01.01	**
CHINA	2	Unconditional	30.11.84	0.40
SOUTH AFRICA	3	Conditional	16.10.90	10.00

Nuts

Country	Code	Type of clearance	Date	Dose max (kGy)
BRAZIL	2, 3	Unconditional	30.01.01	**
GHANA	2	Unconditional	15.01.98	1.00
GHANA	3	Unconditional	15.01.98	5.00
ISRAEL	2	Unconditional	17.02.87	1.00
PAKISTAN	2	Unconditional	07.03.96	1.00
SOUTH AFRICA	3	Conditional	22.04.91	10.00

** Any food can be treated by radiation when the following conditions are observed:

a) The minimum absorbed dose must be sufficient to achieve the intended objective;
b) The maximum absorbed dose must be less than that which would compromise the functional properties or the organoleptic attributes of the food.

Unconditional clearance: Refers to the national regulation permitting irradiation processing and marketing of a particular food for human consumption.

Conditional clearance: Refers to national regulation permitting irradiation processing of a particular food for test marketing, consumer acceptance studies etc that may be for a limited or unlimited period.

Note Code 10 is used when a country does not specify the purpose for which the process is authorised, for example, EC Directive 1999/3/EC on the establishment of a community list of foods and food ingredients treated with ionising radiation states in the Annex only the category of foodstuff and the maximum overall average absorbed dose, whereas regulations in other countries e.g. the USA state the purpose which a particular food or class of foods is authorised.

Attachment 2

Scientific Assessment Report

Application A413

Request to include herbs, spices, herbal infusions and peanuts, almonds, cashews and pistachio nuts in the *Food Standards Code*

Summary

The toxicological safety of irradiated foods

International reviews of the scientific literature on the toxicological effects of irradiated foods concluded that there are conditions under which food irradiation may be safely applied. Extensive studies undertaken in animals and in humans on irradiated foods concluded that food irradiated at doses necessary to perform a technological function and in accordance with good manufacturing practice is safe. Two World Health Organization (WHO) reports (1994 and 1999) on the safety and nutritional adequacy of irradiated foods, the second of which focused on irradiation of foods at high doses (>10kGy), support the safety of this technology.

When food is irradiated, several compounds (radiolytic products) are formed but their total concentration is low. The concentration of each individual compound is extremely low. Virtually all the radiolytic products that have previously been found in irradiated foods are either naturally present in food or produced in thermally processed foods. Any radiolytic products must also have been present in the animal and human toxicology tests that showed no adverse effects.

The numerous toxicological studies on plant materials indicate there is no evidence that irradiated plant material in the diet leads to toxicological concerns. Therefore, by applying the concept of chemi-clearance, there is no evidence to suggest a toxicological concern following irradiation of spices, herbs and herbal infusions.

The analysis of the toxicological effects of irradiation on herbs, spices, herbal infusions and selected nuts indicates that the treatment does not produce adverse health effects beyond those arising from conventional treatments.

The microbial safety of irradiated foods

Irradiation of herbs, spices, herbal infusions and nuts presents no microbiological safety concerns and will not result in the increased induction of particular mutant bacterial species with increased pathogenicity or virulence.

Irradiation in common with other decontamination procedures, including cooking, cannot inactivate bacterial toxins and manufacturers must ensure that toxins and micro-organisms responsible for producing them are absent prior to irradiation.

Technological justification and efficacy

Microbiological decontamination

Herbs and spices

The pathogens identified as commonly present in herbs and spices, and therefore likely to pose a public health and safety issue for consumers are *Salmonella*, *Escherichia coli*, *Bacillus cereus*, and *Clostridium perfringens*. *Salmonella* is found infrequently**,** but in a wide variety of spices. The incidence of contamination with potentially undesirable bacteria is, therefore, high.

Irradiation (at a variety of dose levels) has been shown to significantly reduce levels of micro-organisms present on herbs and spices. In addition, irradiation has been shown to be more effective than ethylene oxide at reducing microbial populations on herbs and spices.

Radiation doses required for microbial decontamination of spices have shown no major effect on the volatile oils that determine flavour quality.

In conclusion, the available research suggests that irradiating herbs and spices is an efficacious technique for the control of microbial decontamination and offers an alternative to more traditional techniques.

Nuts

There is evidence of the presence of moulds such as *Aspergillus flavus* on nuts; however, the presence of moulds does not present a public health problem unless poor storage conditions allow for aflatoxin production. Although the efficacy of irradiation at reducing mould levels on nuts has been demonstrated, no adequate technological need for the use of irradiation to reduce mould levels on nuts has been established.

There is evidence of the occasional presence of *Salmonella* on peanuts and almonds. There is no evidence of the presence of any pathogens (including *Salmonella*) on cashew nuts or pistachio nuts and there is no evidence of the efficacy of irradiation in reducing pathogen levels on nuts.

In conclusion, there is no technological justification for the use of irradiation for the control of micro-organisms on nuts.

Herbal infusions

Microbial contamination of herbal infusion raw materials has been reported and there is some evidence that the micro-organisms present in plant materials are able to survive the procedures used to prepare infusions. This potential for survival represents a public health problem especially given that infusions may be prepared using warm or even cold water.

The efficacy of irradiation in decreasing microbial contamination levels when applied to tea herbs has been demonstrated at doses from 1kGy to 10kGy.

In conclusion, although, the evidence supporting the technological need for decontamination of herbal infusions is less extensive than the evidence supporting the need for the irradiation of herbs and spices, the technological need and efficacy for control of microbial pathogens has been established.

Control of pests, weeds and inhibition of sprouting

Nuts

Pests and diseases associated with nuts are numerous including at least four species of arthropod that are of quarantine concern to Australia.
Irradiation efficacy data indicates that a dose of 0.5kGy to 2.0kGy (dependent upon species) would be sufficient to either kill or sterilise these pests.

Herbs, spices and herbal infusions

Herbs and spices may contain a wide variety of plants, plant products, insects and weed seeds sourced from many areas of the world, many of which are exotic to Australia and require quarantine treatment. The efficacy data cited for control of pests, weeds and inhibition of sprouting for nuts equally apply to herbs and spices.

In conclusion, the technological justification and efficacy has been established for the use of irradiation on herbs and spices for control of pests (particularly arthropod insects) and for the control of weeds and the inhibition of sprouting.

Nutritional impact of irradiation

The analysis of the nutritional impact of irradiation is based around the dietary patterns where the specified foods may potentially make a significant contribution to the total diet.

The scientific literature indicates that carbohydrates, protein and saturated fats experience little change during irradiation.

The effects of irradiation on the unsaturated fatty acids in herbs and spices is relatively insignificant due to the minimal content of these nutrients and their minimal contribution to dietary patterns. The issue of unsaturated fatty acids is of more significance in nuts where the content is higher. However, the contribution of nuts to total unsaturated fatty acid intake is insignificant.

Dietary modelling indicates that the foods covered by this application are insignificant sources of vitamins sensitive to irradiation (vitamin A, vitamin C, Vitamin E, thiamine, folate) and unsaturated fatty acids, when considered in the context of the total diet. It is notable that the dietary modelling indicates that nuts are not the primary dietary source of vitamin E for the general population or for vegetarians. Consequently, the effects of irradiation on vitamin E intake are relatively insignificant.

Available research on the irradiation effects of herbs, spices, herbal infusions, peanuts, almonds, cashew nuts and pistachio nuts, together with an analysis of dietary intake and dietary modelling, indicates that the irradiation of the foods covered by this application will not have a significant effect on the nutritional adequacy of the diet of the Australian and New Zealand populations.

Scientific Assessment Report

The safety of food irradiation

The toxicological safety of food irradiation has been demonstrated by numerous animal and human feeding studies performed over a number of years. These have been performed in a range of animal species, namely, rats, mice, dogs and monkeys, and have consisted of acute, subchronic, reproductive, developmental, genotoxicity and long-term carcinogenicity studies. These have enabled numerous expert committees to evaluate and determine whether there are any toxicological concerns following consumption of irradiated foods.

The following sections are a concise review of the studies that have been performed and the subsequent safety issues in relation to the foods that are requested to be irradiated under Application A413 (herbs, spices, herbal infusions and selected nuts). It is not a comprehensive list of all possible toxicological studies undertaken on irradiated foods; these are available in the World Heath Organization reports (1994 and 1999).

Toxicological safety and the concept of chemiclearance

Chemiclearance is the term used to refer to the toxicological analysis and wholesomeness assessment of irradiated foods that is linked to the chemistry occurring during the irradiation process. Chemical analysis of irradiated foods and sophisticated probe technologies have enabled scientists to predict the types and amounts of either radiolytic[7] products that can be formed or constituents that can be changed in foods irradiated at a given dose under specified conditions (Lagunas-Solar 1995). Such changes are minor, but could have an impact on wholesomeness, which is defined as safe to consume and nutritionally adequate.

This concept arose in the early considerations of toxicological aspects of irradiated foods by expert international Committees (JECFI, 1964). It suggested at that time that as experience in irradiating a range of foods became more complete it would be possible to extrapolate data regarding the wholesomeness of treated classes of foods to related members of that class. This concept was further considered by JECFI (1969) and it was recommended that, based on the extensive work at that time on the identification and production of radiolytic products following irradiation, foods could be grouped into broad classes with regard to the uniformity of their behaviour in response to irradiation (Elis and Cohen, 1983).

The term chemiclearance was initially proposed by Basson (1977) and was applied in evaluating the wholesomeness of irradiated fruits (Elias and Cohen; 1983; Diehl, 1995). The 1980 meeting of JECFI (1981) reconfirmed the usefulness of the chemiclearance approach in its recommendation of the 10 kGy upper limit for irradiation of food.

An overview of the literature was undertaken whereby a comparison was made of the radiolytic products produced following irradiation of starches, meats and fruits (Basson, 1983; Basson et al, 1983; Merrit and Taub, 1983). It was concluded that foods with similar chemical composition would yield a similar spectrum of predictable radiolytic products.

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[7] A radiolytic product is defined as a chemical compound that originates during irradiation of food and can increase in yield with increasing dose (WHO, 1999).

Hence, within classes of food the results of toxicological studies (eg animal feeding studies or genotoxicity tests) on individual foods could be extrapolated to members of the same class (Basson, 1983).

Applying the concept to irradiated meats, it was observed that the same type of protein-derived and lipid derived radicals are observed following irradiation (Taub et al, 1980; Taub, 1981; Merrit and Taub, 1983). These authors found commonality in the electron spin resonance (ESR) spectra from pork, ham, beef and chicken when irradiated to 50 kGy and concluded that chemical data could be used to clear classes of meats (beef, pork, ham, bacon and chicken) on the basis of commonality in the chemistry. Studies on volatile and non-volatile products derived from fatty acids, fatty acid esters and oils also show a consistency and commonality in chemistry (Nawar, 1978) and that products formed in cereals are the same as those formed in pure starches and have the same ESR spectral characteristics (Raffi et al, 1981). Results also demonstrate that dry products such as spices are less affected chemically following irradiation than high moisture foods (Eiss, 1984).

In 1979 an FDA advisory committee concluded that any foods irradiated at levels up to 1 kGy or foods comprising no more than 0.01% of the daily diet irradiated up to 50 kGy are safe for human consumption without any toxicological testing (USFDA, 1986; Murano, 1995; Pauli and Tarantino, 1995). In 1980, the WHO joint committee concluded that the irradiation of any food commodity up to an overall average dose of 10 kGy presents no toxicological hazard; hence, toxicological testing of foods so treated is no longer required (WHO, 1994). Current WHO recommendations impose no upper dose limit, because doses required to eliminate biological hazards are below doses that might compromise the sensory quality of food (WHO, 1999).

There is also a microbiological counterpart to this assessment of safety that is based on the principle that microorganisms irradiated in similar foods will show a common response, as reflected in their D_{10}-values[8] (Thayer, 1995 and 1997).

In summary, animal and human feeding studies have not been conducted on every possible food. However, studies on a wide range of foods have established that foods of similar class and composition react similarly following irradiation. This concept is termed chemi-clearance (WHO, 1994 and 1999).

The principle of chemiclearance is based on two findings.

1. Foods of similar composition that are irradiated under similar conditions have similar chemical responses and they are, accordingly, toxicologically equivalent; and
2. If a food in a class of similar foods is safe and adequate for consumption following irradiation, then other members of that class are considered, correspondingly, wholesome.

[8] The D value is the time in minutes at a specific temperature required to destroy 90% of the organisms in a population Potter (1986) Food Science 4th Edition, Chapman and Hall, London

Therefore, the results of studies on a particular class of food can be extrapolated to others. From a toxicological point of view, foods of animal origin such as beef, pork, chicken and fish are quite similar in macronutrient composition so toxicological data on them can be viewed as being relevant to the whole class of foods and constituting a single database. Similarly, plant products such as vegetables and grains, herbs and spices and other plant products can be viewed as constituting a single class (WHO 1994).

On the basis of the commonality in the chemistry of proteins, lipids and starches, it has been concluded that radiolytic products produced even at doses above 10kGy (WHO 1999) are similar to those already detected at doses below 10kGy (WHO 1994). Therefore, irradiation of foods, for example, spices at high doses, either alone or as ingredients in another food will not lead to the formation of chemical entities that have not previously been identified (WHO 1999). As such, comparable food products reflecting similar chemical profiles should not need to be separately tested for safety and nutritional adequacy.

Overall conclusions

- Following irradiation, radiolytic products are produced which follow predictable pathways;
- Due to this uniformity in chemistry, it has been found that irradiation of specific classes of foods (eg meats, fats and starches) produces a similar spectrum of products;
- This has allowed extrapolation of toxicological studies performed on individual foods to be extrapolated to other members of the same class; and
- The commonality in the chemistry among food groups and the resulting products produced has been termed chemi-clearance and has been used by International Expert Committees to clear foods that are similar in chemical makeup to others which have had an extensive toxicological evaluation previously performed without further toxicological testing of that individual food.

Summary of previous toxicological studies on herbs, spices and nuts

Specific studies on spices and nuts

Food	**Toxicological study**	**Duration**	**Dose (kGy)**	**Effects**	**References***
Spices					
Spice mixture	Genotoxicity studies	Bacterial assay	50	Negative	Farkas, Andrassy and Incze (1981)
Paprika	Genotoxicity studies	In vivo assay	30	Negative	Chaubey et al (1979)
Paprika	Genotoxicity studies	In vitro bacterial assay and in vivo mouse study	50	Negative	Central Food Research Institute (1977)
Spice mixture	Teratology study in rats	15 days	15	No teratological effects in offspring of treated groups.	IFIP (1979)
Mixed spices	Teratological study in rats	10 days	15	No adverse effects noted	Lorand (1979)

Nuts					
Nuts	Geno-toxicity studies	56 days	2	No adverse effects noted	Baev et al (1981)
Nuts	Reproduction study in *mice*	240 days	2	No adverse effects noted	Baev (1980)

* These studies were cited in 1994 or 1999 WHO reports.

Long-term animal feeding studies

Species and Food	**Toxicological study**	**Duration**	**Dose (kGy)**	**Effects**	**References**
Rat					
Irradiated beef, pork, cheese, milk powder, oils	Long-term carcinogenesis	2 years	Up to 88kGy	No carcinogenicity observed	Teply and Kline (1959)
Irradiated pork and laboratory diets	Long-term carcinogenesis and reproduction	2.5 years	Up to 74kGy	No carcinogenicity observed	Van Logten (1983)
Mice					
Irradiated beef stew, codfish, chicken stew, green beans, peaches, flour	Long-term carcinogenesis	2 years	56kGy	No carcinogenicity observed	Calandra and Kay (1961)
Irradiated chicken	Long-term carcinogenesis	2 years	59kGy	No carcinogenicity observed	Raltech Scientific Services (1984)
Dogs					
Irradiated fish (tuna)	Chronic	2 years	Up to 56kGy	No adverse effects noted	McCay and Rumsey (1960)
Irradiated pork	Chronic	4 years	Not specified	No adverse effects noted	Cheng and Zhang (1983)
Monkeys					
Irradiated peaches	Chronic	2 years	Up to 55.8kGy	No adverse effects noted	Blood et al (1963)

* These studies were cited in 1994 or 1999 WHO reports.

Human studies

Food	**Duration**	**Dose (kGy)**	**Effects**	**References***
Fifty four items of various foods	Periods of 15 days, separated by control diet and washout intervals	25-40kGy	No toxic effects observed nor change in clinical parameter	Bierman (1958)
Canned pork	Two periods of 15 days separated by a 5 day washout interval	30kGy	No adverse effects noted	Plough (1957)
Variety of foods (potatoes, flour and oranges)	Short-term study but absolute time interval not stated in WHO (1999) report	25-40kGy	No clinical abnormalities	Bierman (1958)

Thirty-five different kinds of irradiated foods-grains, beans, vegetable and fruits, meat, fish, eggs, poultry and flavourings	90 days	1-8kGy	No adverse effects. No chromosomal abnormalities.	Shao and Feng (1988).

* These studies were cited in 1994 or 1999 WHO reports.

The tables above summarise some of the available studies on spices and nuts - a sample of the available long-term feeding studies on rats, mice, dogs and monkeys and studies on humans, where a broad range of irradiated foods have been administered in the diet. These studies have not shown any significant toxicological effects. The WHO (1994, 1999) reports do not cite any references for animal feeding studies specifically on herbs and herbal infusions, and, extensive searching of various toxicological databases by ANZFA, and also on request from the applicant (Steritech), has not revealed specific studies on irradiated herbs and herbal infusions.

However, herbs are edible plant materials and plant materials have been subjected to numerous safety studies to assess effects of irradiation in the diet of both animals and humans. Therefore, under the concept of chemi-clearance, the numerous safety studies that used other plant materials can be considered. There is no evidence that irradiated plant material in the diet leads to toxicological concerns and there is no reason to suggest a toxicological concern from irradiation of herbs and herbal infusions. Therefore, the studies on chemistry of irradiated foods in conjunction with the toxicological studies cited above for spices and nuts within this class justify extrapolating the conclusions about safety and nutritional adequacy to all members of this class.

The studies cited above and other available studies led to the adoption of a 10kGy limit by the Codex Alimentarius Commission in 1983, following the recommendations of a 1981 Joint Expert Committee on Food Irradiation Report. This was, at that time, the level at or below which the toxicological safety of irradiated foods had been established.

At that time the anticipated applications (eg inhibition of sprouting, insect disinfestation, extension of shelf life and control of microbes in meat, poultry, fish) for irradiation of food would require doses of less than 10kGy. At that stage the Committee concluded that irradiation of any commodity up to an overall average dose of 10kGy presented no toxicological hazard; hence testing of foods so treated was no longer required.

Since that time the safety of high dose irradiated foods (above 10kGy) has been evaluated in many feeding studies with a variety of diets in animals and humans as detailed in the 1999 WHO Report. The 1999 Study Group on High Dose (WHO 1999) does not mention a specific high dose up to which food is safe. It specifically talks about irradiated foods being wholesome throughout the technologically useful dose range. It indicates that high dose irradiated food will be unsaleable through loss of quality prior to any onset of concerns about toxicity. Codex is now considering removal of the 10kGy limit from its General Standard as a result of the 1999 WHO Report’s conclusions.

In summary, the data derived from animal studies are especially relevant to humans because of the composite nature of the food material used and the manner in which the diets were administered (WHO, 1999). Furthermore, humans in many countries have consumed irradiated herbs and spices for some time without any known adverse health effects. These include a number of patients in hospitals (organ transplant recipients and immunocompromised patients) who have been fed irradiated foods. Since 1974, at a particular Cancer Research Centre in the USA, twenty five percent of foods in the diet of some patients have been irradiated (Diehl, 1995). There have been no reports of adverse effects although the testing was not aimed at specifically determining safety; rather, the purpose was that administration of irradiated food could decrease susceptibility to bacterial or viral infections.

The concept of toxicological equivalence as it applies to irradiation

Although there has been extensive toxicological testing of irradiated foods, the concept of irradiated foods being toxicologically equivalent to non-irradiated foods, which may have been treated with other food processing techniques, is appropriate and has been previously considered by international organisations (WHO 1994, 1999).

Irradiation of food can be considered analogous or equivalent to other processes used to improve food safety and quality, namely, heating, canning, steam sterilisation and freezing. In other words, irradiation shares the common function of eliminating biological hazards in food without the formation of physical or chemical constituents that may constitute a hazard, that is, a toxicological effect following consumption in the diet (WHO 1999). Data indicate that irradiated foods do not contain either measurable levels of radioactivity or significant levels of radiolytic products distinct from non-irradiated foods.

Production of radiolytic products

When food is irradiated, a large number of new compounds (radiolytic products) are formed but at a small total concentration. The concentration of each individual compound is extremely low. The majority of these compounds have been shown to be present in either some unprocessed foods or in thermally processed foods. The remainder are similar in chemical structure and expected toxicity to chemicals found in either unprocessed foods or in thermally processed foods. A few could conceivably be unique to the irradiation process but, if so, they are present in miniscule amounts at the boundaries of analytical detection. Any radiolytic products must also have been present in the animal and human toxicology tests that showed no adverse effects.

The three major macronutrients, carbohydrates, proteins and lipids, give rise to different types of radiolytic products following irradiation. However, previous research has found that these compounds are not unique to irradiation but similar compounds are formed during ordinary cooking, steaming, roasting or thermal processing, pasteurisation and freezing or are naturally present in food (Diehl, 1995). Furthermore, at the cellular level, some radiolytic products (for example, hydrogen peroxide and the free radical superoxide) are produced within human cells. Biochemical mechanisms exist for neutralisation of free radicals.

A recent study suggested that a unique radiolytic product 2-dodecyclcyclobutanone (2-DCB) caused mutation to cells from the large bowel of rats when they were incubated *in vitro* with 2-DCB (Delincee and Pool-Zobel 1998).

This study was reviewed in the 1999 WHO Report on High Dose Irradiation. This study suggested a unique radiolytic product 2-DCB, formed from food containing fat, had possible mutagenic activity. The study indicated that 2-DCB in the concentration range 0.3-1.25 mg/ml produces cytotoxicity and an associated weak effect in DNA. However, the concentrations used were far greater (about three order of magnitude) than the 17µg/g reportedly present in the extracted lipid of chicken meat irradiated to 59kGy.

A note added in the WHO report states:

'In a subsequent *in vivo* study, as yet unpublished, the researchers claim to have found a small positive effect when six rats were administered an extremely high level of the synthetically prepared 2-DCB. Limitations of the experiment, particularly the exclusive reliance on the unvalidated comet assay technique, call into question the significance of this finding.' WHO (1999)

Furthermore, two other negative tests for mutagenicity on 2-DCB, namely, the Ames test, demonstrate that irradiated foods pose no health risk to consumers. In the absence of reliable data to the contrary, the WHO, as well as the Food and Agriculture Organization (FAO) of the United Nations and the International Atomic Energy Agency (IAEA), continue to concur with the conclusion of the Joint FAO/IAEA/WHO Study Group on High Dose Irradiation of Food that foods irradiated throughout the technologically appropriate dose range are safe and nutritionally adequate.

In addition to 2-DCB, concerns have been raised about the formation of trans fatty acids, fatty acid peroxides and epoxides following irradiation of food and their roles as possible carcinogens. These concerns are once again not unique to irradiated foods but also apply to heating of fatty foods. The United States Food and Drug Administration (USFDA) (1986) considered that peroxides and epoxides were formed in non-irradiated foods and were thermally and chemically unstable, decomposing to various aldehydes, ketones, alcohols and hydrocarbons which constitute end products of both unprocessed and conventionally processed foods. They concluded that the yields of these products are sufficiently low to raise no concerns about safety. Furthermore, these concerns were raised in relation to irradiation of nuts above a dose of 10kGy, which the applicant has not requested. Additionally, numerous studies at high dose were reviewed by the WHO Study Group in 1999 and there has been no evidence of carcinogenesis in the various animal studies.

In summary, over thirty years of research have shown that virtually all the radiolytic products that have previously been found in irradiated foods are either naturally present in food or produced in thermally processed foods (WHO 1994, 1999). All reliable scientific evidence, based on animal feeding tests and consumption by humans, has indicated that these products pose no risk to humans.

Conclusions

Research supports the safety of irradiated foods when processed under Good Manufacturing Practices. This conclusion has been reached by a number of independent organisations, namely, the World Health Organization (WHO), Codex Alimentarius, the US Food and Drug Administration (FDA), American Dietetic Association, Institute of Food Science and Technology, Institute of Food Technologists and the Council for Agricultural Science and Technology (Doyle 1999).

The 1994 WHO Report addressed the application of food irradiation, induced chemical changes, the detection, toxicology, microbiology and nutritional quality of irradiated food as well as responding to the commonly expressed concerns about irradiated food.

The final Report concluded that:

A review of the available scientific literature indicates that food irradiation is a thoroughly tested food technology. Safety studies have so far shown no deleterious effects. Irradiation will help to ensure a safer and more plentiful food supply by extending shelf life and by inactivating pests and pathogens. As long as requirements for good manufacturing practices are implemented, food irradiation is safe and effective. Possible risks resulting from disregard of good manufacturing practice are not basically different from those resulting from abuses of other processing methods, such as canning, freezing and pasteurisation.'

A more recent 1999 WHO Report of the previous toxicological data related to irradiated foods concluded with the following:

- food irradiation is, toxicologically, perhaps the most thoroughly investigated food processing technology;
- animal studies are suitable models and predictions from them are supported by human studies;
- a large number of toxicological studies, including carcinogenicity bio-assays and multigeneration reproductive toxicology evaluations, did not demonstrate any short-term or long-term toxicity related to the irradiation process; and
- foods that are appropriately prepared, packaged and, under proper conditions, irradiated to high doses for sterilisation should be deemed safe.

In addition to the WHO Reports, irradiated foods have been previously evaluated for safety by national and international expert panels (SCF 1986, NFA Denmark 1986, JECFI 1964, 1969, 1976, 1980) and individuals (Diehl 1990).

The overall safety conclusions are as follows:

- previous expert committees have evaluated the toxicological data and determined that irradiated foods are safe for consumption;
- there are chemical changes in foods following irradiation (albeit limited); referred to as radiolytic products. However, these products are not always unique to irradiation and are also present following more traditional processing of food, namely, heating;
- irradiated foods can be considered toxicologically equivalent to non-irradiated foods;
- although there are no specific animal or human feeding studies on herbs and herbal infusions, the concept of chemi-clearance allows the conclusion that they can be considered to be safe for consumption based on the similar plant class properties of both compared to other studies on irradiated plant materials; and
- scientific opinion currently suggests that food irradiated at dose levels necessary to achieve the intended technological function and, in accordance with good manufacturing practice, is safe.

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Technological justification and efficacy

Standard A17 Vol.1 of the *Food Standards Code*, Regulation 264 in the New Zealand Food Regulations and Standard 1.5.3 in Vol. 2 of the *Food Standards Code* state that where irradiation is permitted, food may only be processed by irradiation where such processing fulfils a technological need or is necessary for a purpose associated with food hygiene.

The need for improved ingredient sanitation is growing due to a move towards higher standards of processing control, such as Hazard Analysis Critical Control Points (HACCP) or International Standards Organisation (ISO); exporters ensuring their products meet or exceed the quality standards of the importing countries; and prevention of contamination of food processed or prepared in Australia or New Zealand.

It is recognised that removing contamination at the source is preferable and steps should be taken to reduce contamination at all stages of the production process. However, preventing contamination is not always possible. Despite all efforts at good agricultural practice, certain raw foodstuffs may still become contaminated with pathogenic organisms. Irradiation may provide a decontamination procedure that does not damage the intrinsic characteristics, for example aroma and flavour, associated with the food.

This section discusses in detail the public health risks of microbiologically contaminated foods, justification for irradiation of herbs, spices, nuts and herbal infusions and the efficacy of irradiation compared to other processes currently employed to decontaminate microbes in food. A subsequent section discusses the justification and efficacy of irradiation for the purposes of disinfestation, control of weeds and inhibition of sprouting.

Microbiological decontamination

Sources, nature and frequency of microbial contamination

Foods of plant origin can become contaminated with potentially dangerous micro-organisms because of the way they are grown and handled. Many spices in particular are obtained mainly from areas where diverse agricultural activities are occurring in the same location. Sources of contamination may be dust, insects, faecal material from birds and rodents, and possibly processing water. Contamination can occur at any stage during harvesting, drying and preparation, transport and storage of products. Preventing contamination is not always possible, and despite all efforts at good agricultural practice, plant products may still become contaminated with pathogenic micro-organisms.

The number and types of contaminating micro-organisms found will depend on factors such as crop, climatic conditions, harvesting technology, processing and storage technology. During drying of the spices a considerable part of the population of bacteria and fungi are killed off but many will survive. For example a survey in New Zealand has found Bacillus sp present in 40% of imported spices tested and at levels above 1000/g in 36/87 samples. In the same survey 5/140 samples contained Salmonella (ESR, 2000).

In addition to the bacteria that cause food-borne illness such as Salmonella, other bacteria such as spore formers Bacillus sp and Clostridium sp can be found in soil and dust and are naturally associated with plant material.

These bacteria form resistant spores that survive will in dried material. They can cause food poisoning if present in large numbers, more than 1 million per gram of the food to which they are added.

In addition to harmful (pathogenic micro-organisms), plant material may be contaminated with a variety of micro-organisms that, while not harmful to consumers, will cause spoilage and other quality defects in food and, thus, have an adverse effect on the shelf life of the foods themselves or, if used as ingredients, the foods to which they are added. These species are often also spore-forming bacteria.

Herbs and spices

Most of the microbes present on herbs and spices are aerobic spore forming bacteria, predominantly *Bacillus* species. However a wide variety of non-sporing bacteria and fungi may also be present (ICMSF 1998; Baxter and Holzapfel 1982). Coliforms and *Escherichia coli*, which indicate the presence of environmental and faecal contamination, are also often found. These bacteria include both spoilage and pathogenic species. Some of the pathogenic species may produce toxins.

The incidence of contamination with potentially undesirable bacteria is high. For example, Pafumi (1986) reported *E. coli* in approximately thirty percent of peppercorns and in forty-two percent of a range of herbs and spices that were tested (Roberts *et al*, 1982). The presence of *Salmonella* spp. is particularly common in pepper and paprika (D'Aoust, 1994). Pepper, paprika and cinnamon are currently stopped by Customs and tested for the presence of *Salmonella*. Herbs and spices imported into Australia and New Zealand often fail to meet microbial standards. Peppercorns and paprika have been found to have the highest level of microbial contamination (Hudson and Hasell 1998; Pafumi 1986). Peppercorns are the spices most commonly sent for ethylene oxide fumigation (Australian Bureau of Statistics, 2000). *Clostridium perfringens,* a spore-forming pathogenic species is also commonly present in herbs and spices.

In summary, the pathogens identified as commonly present in herbs and spices, and therefore likely to pose a public health and safety issue for consumers, are *Salmonella*, *Escherichia coli*, *Bacillus cereus*, and *Clostridium perfringens*. *Salmonella* is found infrequently**,** but in a wide variety of spices (ICMSF, 1986)

Nuts

Although nuts are not known as common hosts of the usual microbial contaminants, moulds such as *Aspergillus flavus* are commonly present and some strains may produce aflatoxins if allowed to grow to high levels. Bacterial contamination of nuts is unusual. However there are occasional reports of the presence of *Salmonella* spp. on peanuts and almonds. There is no evidence of the presence of any pathogens on cashew nuts or pistachio nuts.

Peanuts have occasionally been identified as a source of *Salmonella* infections. Several outbreaks have been traced to peanut butter (AIFST 1997). However, it is not always apparent as to whether the source of the problem is the nuts themselves, the processing plant, or a combination of both. The FDA has identified nuts and nut products (which do not undergo a bactericidal step) as a *Salmonella* hazard. As a result, nuts are included in the FDA sampling plan for *Salmonella*.

In summary, there is no technological justification for the use of irradiation against aflatoxins from moulds on nuts or for the control of micro-organisms on nuts.

Herbal infusions

Tea is defined as 'the product made from leaves and buds of one or more of *Camellia sinensis*'. There are no bacterial or microbial problems associated with true tea (green and black) as the firing and drying process by which the teas are prepared, together with Good Manufacturing Practice, would normally destroy micro-organisms and result in a product that exhibits low levels of microbial contamination. Therefore, there is no technological need for the irradiation of true tea. The applicant has formally withdrawn the request for permission to irradiate tea from *Camellia sinensis.*

Microbial contamination of herbal infusion raw materials such as juniper, peppermint, sage, St John's wort, horse chestnut, liquorice root, chamomile flowers, mint leaves, linden flowers, dog-rose hips and sage leaves has been reported (Kedzia 1997; Katusin-Razem et al 1988). Micro-organisms present on these herbs include aerobic bacteria, yeasts and moulds, *Enterobacteriaceae*, enterococci, *Bacillus* and *Clostridium* spores (Kedzia 1997). In recent years, *Salmonella* has increasingly been isolated from plant material intended for infusions. There is some evidence that the micro-organisms present in plant materials are able to survive the procedures used to prepare infusions (Baxter and Holzapfel 1982). This was confirmed by Katusin-Razem et al (1985, 1988) who reported that thermoresistant and spore-forming bacteria present on some tea herbs (mint leaves and dog-rose hip) were able to survive hot water infusion. This potential for survival represents a public health problem especially given that infusions may be prepared using warm or even cold water.

Public health risks from consumption of contaminated plant foods

Pathogens contaminating foods can be hazardous when these foods are used as ingredients in processed foods. For herbs and spices, the risk of food-borne illness is greatest when contaminated herbs and spices are used as ingredients in foods that are not subjected to any further treatment step, such as cooking.

A lesser risk of food-borne illness exists when contaminated herbs and spices are added to foods that are then subjected to a cooking or heating step. Although some spore-forming bacteria, such as *Bacillus* species can survive this step, large numbers of toxin producers must be present in food for illness to occur. *Bacillus* spp. can only grow to high levels if cooked foods are not cooled or stored correctly.

The public health risk associated with the consumption of nuts is due to the presence of aflatoxins or, less commonly, the presence of pathogenic bacteria, in particular *Salmonella*.

There is some evidence, as detailed above, that the micro-organisms present in tea herbs are able to survive the procedures used to prepare infusions. This potential for survival represents a public health problem especially given that infusions may be prepared using warm or even cold water.

Incidences of food poisoning associated with the consumption of various spices have been reported. *Bacillus cereus* food poisonings have been associated with the consumption of meat and meat dishes seasoned with spices (AIFST, 1997).

In New Zealand in 1998, imported peppercorns, contaminated with *Bacillus subtilis,* and used to produce peppered steak were found to be the cause of a food poisoning incident. Outbreaks of salmonellosis have been traced to several spices including chilli powder and peppercorns (D'Aoust, 1994). The paprika on paprika powdered potato chips was found to be the causative agent in a large outbreak of salmonellosis in Germany in 1993 (Lehmacher et al 1995).

Recently an outbreak of more than 100 cases of *Salmonella* Mbandaka in Australia and New Zealand resulted from the consumption of peanut butter (AIFST, 1997). However, in outbreaks such as this, it is not always apparent as to whether the source of the problem is the nuts themselves, or the processing plant, or a combination of both. Almonds exported from California to Canada were recalled after they were found to contain *Salmonella* which affected more than 100 people (Canadian Food Inspection Agency 2001).

An outbreak of salmonellosis due to consumption of *Salmonella* contaminated rooibos tea occurred in South Africa (Niemand 1985).

Reductions of micro-organisms following irradiation and comparison with other techniques for decontamination

Irradiation, at a variety of dose levels, has been shown to significantly reduce levels of micro-organisms present on herbs and spices (Vajdi and Pereira 1973; Kedzia 1997; Kiss and Farkas 1988; Farkas and Andrassy 1988). In addition, irradiation has been shown to be more effective than ethylene oxide at reducing microbial populations on herbs and spices (Farkas and Andrassy 1988; Vajdi and Pereira 1973; Kiss et al 1978; Szabad and Kiss 1979). Radiation doses required for microbial decontamination of spices have shown no major effect on the volatile oils that determine flavour quality. Antioxidant properties of spices remain unaltered by irradiation.

Irradiation is more commonly applied to nuts as a disinfestation method (refer to section on disinfestation) than a decontamination method. As such, there is limited evidence available on the efficacy of irradiation when applied to nuts. However, irradiation has been shown to be effective at reducing the amount of mould present on peanuts (Chiou et al 1990). Evidence of the efficacy of irradiation at reducing moulds on almonds, cashew nuts, and pistachio nuts is not readily available in the literature, nor is there evidence of the efficacy of irradiation at reducing pathogen levels on nuts.

The efficacy of irradiation when applied to tea herbs has been demonstrated. Kedzia (1997) reported that irradiation at doses from 1kGy to 10kGy was effective in decreasing microbial contamination levels on herbal raw materials such as juniper, peppermint, sage, St John's wort, horse chestnut, and liquorice root.

Mycotoxins (the toxins produced by fungi) such as aflatoxins are produced by some mould species which commonly contaminate nuts. Irradiation (even at high levels) has very little effect on these preformed toxins. A study by O'Neill et al (1993) found irradiation at 50kGy effective in destroying only ten to twenty percent of toxins present on infected corn.

Viruses and bacterial toxins, like the mycotoxins, are unlikely to be inactivated by irradiation.

Bacterial spores are more resistant to radiation and to heat and chemicals than are bacteria that are not spore formers or when they are in the non-sporing vegetative state. This where large numbers of spores are present in spices and herbs, there may still be detectable levels remaining after irradiation, although this will depend on the initial concentration and the level of irradiation applied. There are significant differences in the types of spores that are highly resistant to heat and chemical and irradiation treatment. Spores that have survived irradiation appear to be more susceptible to subsequent processing than spores that have not been treated (WHO, 1999)

Other techniques currently used to decontaminate plant material

The microbiological safety of herbs and spices imported into Australia and New Zealand is currently ensured through different technologies including steam sterilisation and treatment with ethylene oxide. In July 2000, the Australia New Zealand Food Standards Council granted permission for the use of ethylene oxide for decontaminating herbs and spices. This permission expires on 30 September 2001.

The safety of Australian grown nuts is currently ensured through roasting, steam treatment, chlorine dipping and good manufacturing practice.

Some herbs intended for use in infusions are currently sterilised using steam sterilisation techniques. However this method removes some of the flavour and aroma volatiles of the products. As a result of the *Salmonella* outbreak in the 1980s, rooibos tea is now pasteurised during processing.

Justification for decontamination

The evidence discussed above demonstrates that there is a technological justification for decontamination of spices, herbs and herbal infusions and that this can be achieved effectively by the use of irradiation. However, the need for decontamination of nuts has not been established.

Disinfestation

Justification and Efficacy for nuts

Quarantine Pests

There is some evidence of a technological need for the disinfestation of nuts, particularly, for control of arthropod pests of peanuts, cashews, almonds and pistachio nuts (Wallingford, 2000).

Arthropod pests of nuts are numerous. Many fall into the category of stored produce pests and, as such, if not controlled can cause major damage to stored food supplies worldwide. Existing treatments for nut shipments upon arrival include:

- methyl bromide fumigation at atmospheric pressure;
- methyl bromide fumigation under vacuum;
- phosphine fumigation; or
- cold storage.

If Khaphra beetle is detected, the consignment must be fumigated with methyl bromide at the required rate to kill Khaphra beetle (Australian Quarantine Inspection Service 2001). However, methyl bromide is to be phased out due to environmental and occupational health and safety issues. Research on irradiation of pests of stored products indicates the majority of these pests can be effectively treated at doses of 0.3kGy to 2.0kGy (Personal communication, Agriculture Fisheries and Forestry Australia).

Sprout inhibition in nuts

Agriculture Fisheries and Forestry Australia (AFFA) has indicated that there is a technological need to irradiate nuts to control sprouting. AFFA has also suggested that irradiation has been shown to inhibit or slow sprouting of various seeds, the effectiveness varying with seed type (Personal communication, AFFA).

Dry and uniform seeds of *Vigna unguiculata cv*. were gamma irradiated at doses of 10 to 80 krad. Compared with non-irradiated controls, seed germination percentage, shoot length, root length, seedling fresh and dry weights and seedling vigour index decreased with increasing irradiation dose (Thimmaiah et al 1998).

The percentage germination of maize irradiated with 0, 0.5, 1.0, 2.0 or 4.0kGy and stored at 5-30°C was reported. Germination after three months was generally decreased by all irradiation levels other than 0.5kGy. After twelve months, percentage germination was highest after 0.5kGy treatment, and was decreased by 2kGy or 4kGy irradiation (Tasnim et al 1999).

Currently, the above data and other studies (Suss et al 1977; Bebawi et al 1984; Moskalenko et al 1993) would suggest control of sprouting could be achieved using irradiation. However, further work needs to be conducted to determine specific required doses for specific species.

Justification and Efficacy for herbs and spices

Herbs and spices may contain a wide variety of plants, plant products, insects and weed seeds sourced from many areas of the world, many of which are exotic to Australia and require quarantine treatment. Current treatments include hot air, hot moist air, ethylene oxide, methyl bromide or re-export of the products (Personal communication, AFFA). The efficacy data cited for pests, weeds and inhibition of sprouting for nuts equally apply to herbs and spices (Personal communication, AFFA).

Investigation into the use of irradiation and efficacy as a phytosanitary tool is well advanced, with most pests of quarantine concern being controlled using irradiation doses well below those required for microbial decontamination (Padwal-Desai et al 1987; Personal communication, AFFA).

Whole and prepacked ground spices from local retailers in Maharashtra, India, were surveyed for infestation by insects. No adult insects emerged from spices that had been treated with gamma radiation at 1kGy and stored at 28-30°C (Padwal-Desai et al 1987).

Methyl bromide is one of the main decontamination methods employed by AQIS. The phasing out of the use of methyl bromide will require development of alternative decontamination methodologies. Scientific data indicate that irradiation is a viable alternative for phytosanitary use without compromising food quality (Personal communication, AFFA).

Justification for disinfestation, inhibition of sprouting and control of weeds

From the available advice ANZFA has received from the relevant quarantine agencies, for example AFFA and AQIS, and the available scientific literature, there is a justification for the use of irradiation for control of pests, weeds and inhibition of sprouting on herbs, spices, herbal infusions and for the disinfestation (excluding quarantine weeds) and control of sprouting in nuts. Additionally, its efficacy is equivalent to, or better than, techniques presently employed for these functions.

Microbiological Safety concerns with Irradiated Foods

A key question is whether irradiating food leads to increased microbiological hazards via the suppression of spoilage micro-organisms which, through ‘off’ odours or discolouration, warn consumers that the food may be bad or unsafe to eat. Concerns also have been raised that irradiation will result in the increased induction of mutants that may possess increased pathogenicity, virulence, or radiation resistance.

In 1982, at the request of the FAO of the United Nations and the WHO, the Board of the International Committee on Food Microbiology and Hygiene considered the evidence for the microbiological safety of food irradiation. They concluded that irradiation does not present any increased microbiological hazards (ICGFI 1991). Additionally, it was noted that irradiation is not the only process technique which suppresses micro-organisms signalling spoilage. Heat pasteurisation, chemical treatments and certain packaging methods have the same effect (ICGFI 1991). More recently, it was concluded that irradiation presents no microbiological problems and is of lesser concern, or considered irrelevant, at doses of radiation higher than 10kGy (WHO 1999).

Micro-organisms, resistance to radiation and increased pathogenicity/virulence.

In a laboratory environment, bacteria can be ‘trained’ over time to become more resistant to factors such as antibiotics or irradiation by exposing the bacterium to low (sub-lethal) levels. By gradually increasing the dose level over time the bacteria can develop increased resistance. In contrast, irradiation of food exposes micro-organisms to a single lethal dose of irradiation.

WHO (1994) stated that although both irradiation and conventional processing techniques have the potential to increase the rate of mutation in micro-organisms, there is no evidence of increased pathogenicity or virulence of pathogenic organisms as a result of these techniques. The USFDA agrees with these findings (United States General Accounting Office 2000).

In addition, the International Consultative Group on Food Irradiation (ICGFI 1999), and the International Atomic Energy Agency (IAEA), concluded that proper irradiation can neither increase virulence of pathogens nor increase their ability to grow better in irradiated food.

WHO (1999) established that micro-organisms that survive irradiation are likely to be more sensitive than untreated cells to environmental conditions such as temperature, pH, and nutrients. Therefore, micro-organisms that survive irradiation will be destroyed at a lower cooking temperature than those that have not been irradiated (United States General Accounting Office 2000). In many cases, the foods being irradiated will be heated before being consumed thereby destroying surviving micro-organisms.

Bacterial toxins, viruses and moulds

Irradiation cannot inactivate formed toxins. Therefore, manufacturers must ensure that toxins, and the micro-organisms responsible for producing them, are absent prior to irradiation. This same requirement already exists for other food preservation processes. Irradiation is, however, effective in destroying the moulds that can produce aflatoxins during storage of plant material.

All decontamination methods, including cooking, will destroy most of the micro-organisms that produce toxins, but not all toxins are destroyed. Some toxins, for example, the staphylococcal toxin, will survive even in canned products.

Plant products susceptible to aflatoxin formation, for example peanuts, are currently tested for levels of aflatoxins, not for the moulds that produce them. Products exceeding the permitted aflatoxin level would not be considered suitable for consumption and could not be made safe by irradiation, as the toxin, would not be fully inactivated.

Viruses (such as hepatitis) and prions do not multiply in food. Irradiation has been shown to be effective against the organisms of concern for the foods listed in the application. In addition, the foods listed in the application are usually too dry to support the growth of micro-organisms, therefore, there is no opportunity for the recovery and growth of either pathogens or spoilage bacteria. Growth of surviving pathogenic bacteria would only be possible if the irradiated product was added to a food which supported microbial growth and which was subjected to temperature and/or time abuse.

Regrowth of surviving pathogenic bacteria would need to be considered if the foods proposed for irradiation in this application were able to support the growth of bacteria.

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Nutrition report

Nutritional implications for irradiated food

Irradiation potentially causes both macro and micro nutrient changes in foods. The effect of irradiation on the nutritional quality and flavour characteristics of foods depends on the level of irradiation dose, the food's composition, and environmental conditions (Diehl 1981). Several organizations, for example the World Health Organization and the United States Food and Drug Administration, have concluded that various irradiated foods are nutritionally comparable to non-irradiated foods treated with other food processing techniques (WHO 1981, ACINF 1986, Diehl 1991). Research indicates that any irradiation decomposition or degradation of macronutrients increases in a dose-dependent relationship, and nutrient losses are comparable to other food processing techniques, for example, drying and heating (Diehl 1981, WHO 1999, Diehl 1995). Research has also indicated that further food processing techniques on irradiated foods may have a synergistic and significant effect on some nutrients in some foods (Diehl 1991, Diehl 1995).

The public health significance of irradiation induced nutritional losses in food depends on several factors, particularly the contribution that a particular food makes to the total diet.

Conditions under which irradiation is conducted

Temperature conditions, exposure to oxygen and storage conditions affect the nutrient content of irradiated foods (Diehl 1995, WHO 1994). Low-temperature food irradiation in the absence of oxygen assists in minimising the direct and indirect nutrient degradation in foods during storage (Diehl 1995, WHO 1994). Investigations into the irradiation effects on nutrient losses may measure the actual effects (direct effects) or, alternatively, longer term effects (indirect effects). The conditions, under which food is irradiated and stored has an influence on both these irradiation-induced effects (Diehl 1995).

Specific nutrients

Macronutrients

The available scientific research indicates that the exact effect of irradiation on the nutritional value of proteins, carbohydrates and fats will depend on the composition of the food, the irradiation conditions, for example low temperature environments and oxygen-free conditions, and the storage conditions, for example oxygen-free packaging, low temperature and storage duration (Diehl 1991, Diehl 1995, Olson 1998). The effect of irradiation on the nutritional quality of proteins, carbohydrates and saturated fats is minimal, however a direct effect on unsaturated fatty acids has been observed (Diehl 1991, WHO 1999, Diehl 1995). Research indicates that these nutritional effects are comparable to other food processing techniques, for example drying and heating (Diehl 1981, WHO 1999, Diehl 1995).

Some unsaturated fatty acids form an essential nutritional component in human health (WHO, 1994). Irradiation causes a direct dose-dependent modification of unsaturated fatty acids in various foods, including whole grains, for example rye, wheat and rice, as well as animal fats, fish and vegetable oils (Diehl 1995, Uthman et al 1998, Narvaiz et al 1992).

Foods which are composed primarily of unsaturated fatty acids, for example vegetable oils, have a particularly high susceptibility to oxidation processes, such as the direct effects that can be observed following various food processing techniques, including heating and irradiation. Nuts, being composed primarily of unsaturated fatty acids, are subject to these oxidation processes.

Furthermore, the absence or limitation of oxidation inhibiting compounds, for example proteins and natural antioxidants, in foods composed primarily of unsaturated fatty acids renders them susceptible to oxidisation processes, which may include the indirect effects of irradiation (Diehl, 1995). A main factor in the modification of unsaturated fatty acids to radiolytic compounds is peroxidation, which in turn produces discolouration, rancidity and changes to flavours and odours in foods (Olson 1998, Uthman et al 1998, Narvaiz et al 1992). The irradiation affected food components can, in turn, affect other nutrients, for example, fat soluble vitamins, in foods, especially during storage (Diehl 1995, Olson 1998, Hau et al 1992, Diehl and Kim 1981). Research indicates that these alterations in the food may have significant long-term effects on the nutritional quality, for example, unsaturated fatty acid stability and vitamin E, and palatability of the food (Diehl 1995, Olson 1998, Hau et al 1992, ICGFI 1999).

Minerals

From the available scientific literature there is a lack of evidence that irradiation, regardless of the dose, has an effect on the minerals and trace elements in foods (WHO 1994). In addition, the bioavailability of these elements is not affected by current irradiation techniques (WHO, 1994; 1999).

Water-soluble vitamins

The effects of irradiation on the retention and destruction of water-soluble vitamins varies from food to food and is dependent on several factors. These include irradiation dose, irradiation environment, for example, low temperature and an oxygen-free environment, storage conditions and the presence of oxygen.

The available research indicates the order of vitamin sensitivity to irradiation, from most sensitive to least sensitive, is (WHO 1999, Diehl 1995):

Vitamin B_1 →
Vitamin C →
Vitamin B_6 →
Vitamin B_2 →
Folic acid→
Cobalamin→
Nicotinic acid

The primary sources of vitamin B_1, vitamin B_2, vitamin B_6, folic acid and associated derivatives and vitamin C in the human diet are collectively: fruits; vegetables; grains; wheat-based products; yeast-based products; meat and dairy products (WHO 1999, Diehl 1995). Although herbs, spices, herbal infusions, peanuts, cashew nuts, almonds and pistachio nuts are sources of these vitamins, the dietary modelling indicates that these foods are insignificant contributors in the context of the total diet due to low consumption levels (Diehl 1995, WHO 1994). Refer to section on dietary modelling for further information.

Fat-soluble vitamins and associated pre-cursors

As is the case for water-soluble vitamins, the sensitivity to radiation of fat-soluble vitamins varies according to the specific food, irradiation dose, irradiation environment, storage conditions and the presence of oxygen. In general, the order of sensitivity to irradiation, from most sensitive to least sensitive, for fat-soluble vitamins is (Diehl 1995, WHO 1994):

Vitamin E →
β-carotene →
Vitamin A →
Vitamin K →
Vitamin D

The primary sources of vitamin E, β-carotene, vitamin A, and vitamin K in the human diet are collectively: oils; red and yellow fruits; red and green vegetables; wholegrains; yeast-based products; meat and dairy products. Although herbs, spices, herbal infusions, peanuts, cashew nuts, almonds and pistachio nuts are sources of these vitamins and associated precursors, the dietary modelling indicates that these foods are insignificant contributors in the context of the total diet due to low consumption levels (Diehl 1991, Diehl 1995). Refer to section on dietary modelling for further information.

Anti-oxidants

Anti-oxidants occur in foods in a variety of forms and have a multifaceted function in foods, one of which is lipid peroxidation. Anti-oxidants act directly with free radicals to form innocuous compounds. The scientific literature on the effects of irradiation on anti-oxidising compounds in foods that are the subject of this application is relatively limited and not conclusive. The antioxidants vitamins A, C and E and associated precursors in relation to this application have been addressed in the previous section and next two sections of the nutrition report.

The presence of anti-oxidants in herbs, spices and herbal infusions is highly variable and dependent on an array of botanical and compositional characteristics. Consequently, the dietary intake of anti-oxidants from these foods will vary significantly across the population and depends on an individual’s consumption level and dietary pattern. It is difficult to determine intake through dietary modelling on a population basis because limited representational data on which to model. However the dietary modelling indicates that these foods are likely to be insignificant dietary sources due to a low consumption.

Dietary Modelling

ANZFA has conducted dietary modelling, using ANZFA’s dietary modelling software package DIAMOND, to determine the potential dietary effects that irradiating all herbs, spices, herbal infusions and nuts (including the associated products where these foods are ingredients) will have on the consumption of vitamin A, vitamin C, vitamin E, thiamin and folate by the New Zealand and Australian populations. Therefore the dietary modelling provides worse-case estimates.

DIAMOND is based on the 1995 Australian National Nutrition Survey (NNS) and the 1997 New Zealand NNS (New Zealand Ministry of Health 2000; McLennan and Podger 1999). The 1995 Australian NNS surveyed 13 858 people aged two years and above, using a 24-hour food recall methodology (New Zealand Ministry of Health 2000). The 1997 New Zealand NNS surveyed 4 636 respondents, aged fifteen years and above (consequently, dietary consumption data for respondents under fifteen years is not available), using a 24-hour food recall methodology (McLennan and Podger 1999).

DIAMOND provides access to aggregates of individual dietary records from the most recent national surveys, derived from 24-hour recall records, as well as records of individual body weights. Thus, DIAMOND provides information about the distribution of food and nutrient consumption. This information provides more detail than is possible using point estimates of population consumption, apparent consumption or food production data.

It should be noted that the range of food consumption data reported in 24-hour recall surveys will tend to be far greater than those reported in 7-day surveys or food frequency surveys because these two survey methods report dietary patterns averaged over a number of days or months respectively. For foods that are frequently consumed, there may be little difference between the range of consumption reported over 24 hours and that averaged over a longer time period. However, for occasionally consumed foods the range and amounts of food consumed reported from 24-hour recall data may be much higher than that from surveys that reported over a long period of time.

Dietary modelling for Vitamin A, Vitamin C, Thiamin and Folate

DIAMOND was used to estimate consumption of vitamin A, vitamin C, thiamin and folate from herbs, spices, herbal infusions and nuts in the total diet. These results are indicated in tables 1 to 5.

Table 1: Estimated consumption of selected foods from the 1995 Australian National Nutrition Survey and the 1997 New Zealand National Nutrition Survey

Food	Number of consumers (% of total respondents)		Estimated consumption: All respondents mean (grams per day)		Estimated consumption: Consumer mean (grams per day)		Estimated consumption: 95^{th} percentile (grams per day)	
	Australia	New Zealand	Australia	New Zealand	Australia	New Zealand	Australia	New Zealand
Herbal infusions	436 (3.1)	118 (2.5)	15.6	10.2	494.8	398.8	1268.8	913.5
Nuts and nut products	1733 (12.5)	569 (12.3)	3.8	3.4	30.3	27.8	101.1	108.0

Herbs and spices	494 (3.6)	66 (1.4)	0.2	0.1	6.2	3.2	20.2	9.9

Table 2: Percent contribution to the total estimated intakes of vitamin A from selected foods from the 1995 Australian National Nutrition Survey and the 1997 New Zealand National Nutrition Survey

Food	Percent contribution: Whole population		Percent contribution: Children aged 2-6 years	
	Australia	**New Zealand**	**Australia**	**New Zealand**
Herbal infusions	0.0	0.0	0.0	n/a
Nuts and nut products	0.0	0.0	0.0	n/a
Herbs and spices	0.0	0.0	0.0	n/a
Total	**0.0**	**0.0**	**0.0**	**n/a**

Table 3: Percent contribution to the total estimated intakes of vitamin C from selected foods from the 1995 Australian National Nutrition Survey and the 1997 New Zealand National Nutrition Survey

Food	Percent contribution: Whole population		Percent contribution: Children aged 2-6 years	
	Australia	**New Zealand**	**Australia**	**New Zealand**
Herbal infusions	0.0	0.0	0.0	n/a
Nuts and nut products	0.0	0.0	0.0	n/a
Herbs and spices	0.0	0.0	0.0	n/a
Total	**0.0**	**0.0**	**0.0**	**n/a**

Table 4: Percent contribution to the total estimated intakes of thiamin from selected foods from the 1995 Australian National Nutrition Survey and the 1997 New Zealand National Nutrition Survey.

Food	Percent contribution: Whole population		Percent contribution: Children aged 2-6 years	
	Australia	New Zealand	Australia	New Zealand
Herbal infusions	0.1	0.0	0.0	n/a
Nuts and nut products	0.8	0.6	0.4	n/a
Herbs and spices	0.0	0.0	0.0	n/a
Total	**0.9**	**0.6**	**0.4**	**n/a**

Table 5: Percent contribution to the total estimated intakes of folate from selected foods from the 1995 Australian National Nutrition Survey and the 1997 New Zealand National Nutrition Survey.

Food	Percent contribution: Whole population		Percent contribution: Children aged 2-6 years	
	Australia	New Zealand	Australia	New Zealand
Herbal infusions	0.1	n/a	0.0	n/a
Nuts and nut products	0.7	0.8	0.7	n/a
Herbs and spices	0.0	0.0	0.0	n/a
Total	**0.8**	**0.8**	**0.7**	**n/a**

The dietary modelling indicates that herbs, spices, herbal infusions and nuts are minor contributors of vitamin A, vitamin C, thiamin and folate in the total diet. The consumption of foods that may be treated with irradiation may cause a small, but insignificant, reduction in the intake of vitamin A, vitamin C, thiamin and folate for the populations of Australia and New Zealand, due to the low consumption levels.

Dietary Modelling for Unsaturated Fatty Acids

As previously indicated nuts, but not herbs and spices, are composed of a significant level of unsaturated fatty acids. These unsaturated fatty acids are potentially damaged by irradiation however, the precise extent of this effect is dose-dependent and depends on several conditions.

DIAMOND was also used to estimate consumption of unsaturated fatty acids from nuts and nut products in the diet of the Australian population: these results are indicated in table 6. DIAMOND is currently unable to model similar data for the New Zealand population because compositional data is currently not available.

Table 6: Estimated consumption of unsaturated fatty acids from the 1995 Australian National Nutrition Survey

Unsaturated fatty acid intake	Whole population: All respondents mean (grams per day)	Whole population: 95th percentile (grams per day))
Total mono-unsaturated fatty acid	10.5	23.8
Nuts and nut products	0.3	0.8
Total poly-unsaturated fatty acid	11.9	26.4
Nuts and nut products	0.8	1.1
Total Unsaturated fatty acid	**22.4**	**50.2**
Nuts and nut products	**0.8** **(3.6%)**	**1.9** **(3.8%)**

The DIAMOND dietary modelling estimates that nuts and nut products are minor contributors to the unsaturated fatty acid, both mono-unsaturated and poly-unsaturated, intake for the whole population. Unsaturated fatty acids from nuts provide less than 4 percent of total mean unsaturated fatty acid intake in the diet. The consumption of foods that may be treated with irradiation may cause a small, but not significant, reduction in the intake of unsaturated fatty acids.

Vitamin E

Vitamin E is a key component in human cell membranes where its primary role is to act as an anti-oxidant, protecting the membranes' integrity. Vitamin E also acts as an anti-oxidant in foods preventing the oxidation and degradation of unsaturated fatty acids (Lonn and Yusuf 1997; Vaca and Harms-Ringdahl 1986).

Vitamin E stability

The effect of irradiation on vitamin E losses is comparable to other food processing techniques (Diehl 1994). WHO reports (1994, 1999) have indicated that foods irradiated within a safe dosage range have substantially equivalent nutritional properties to foods treated with other processing techniques. The effect of a number of food processing techniques may have a synergistic and significant effect on vitamin E levels in foods (Diehl 1995). Table 7 indicates the comparative changes in vitamin E levels in hazelnuts when exposed to irradiation and heat as food processing techniques (Diehl 1994; Diehl 1995).

Table 7: Comparative effects of irradiation and heat on vitamin E levels in hazelnuts.

Food processing technique		Whole Hazelnuts (mg vitamin E) [λ]	Ground Hazelnuts (mg vitamin E) [λ]
Untreated	No additional processing	26.1	26.0
	Cooked 10 minutes at 100°C	25.4 (2.7%↓)	23.5 (9.6%↓)
	Baked 30 minutes at 200°C	22.7 (13.0%↓)	12.6 (51.5%↓)
Treated with Irradiation (1kGy)	No additional processing	21.4 (18.0%↓)	18.0 (30.7%↓)
	and cooked 10 minutes at 100°C	20.0 (23.4%↓)	14.5 (44.0%↓)
	and baked 30 minutes at 200°C	8.5 (67.4%↓)	7.4 (71.5%↓)

λ – Vitamin E levels provided as mg of α-tocopherol per 100 grams

Of particular nutritional relevance to this application are the irradiation effects on peanuts, cashew nuts, almonds and pistachio nuts. Whole hazelnuts treated with irradiation at 1kGy, in the presence of air, contained 18.0 percent less vitamin E than the non-irradiated controls after one day. Ground hazelnuts contained 30.7 percent less vitamin E than the non-irradiated controls under the same conditions (Diehl 1981; Diehl 1991). It is also worth noting that ground hazelnuts baked for 30 minutes at 200°C contained 30.0 percent less vitamin E than ground hazelnuts irradiated at 1kGy.

Following irradiation, vitamin E degradation and the production of vitamin E degrading factors have been observed in vegetable oil research (ICGFI 1999; Vaca and Harms-Ringdahl 1986). The sensitivity of vitamin E during storage depends largely on the storage conditions, for example the presence of air and the surface area exposed, and the initial concentration of radiolytic compounds (Diehl 1995). Radiolytic compounds readily interact with anti-oxidants or reducing agents in order to form more stable compounds. This is an important consideration given that increased radiolytic compounds have been detected in various species of irradiated nuts. The irradiation-induced production of radiolytic compounds degrades vitamin E during the initial food processing treatment phase and the storage of the food (Diehl 1991; Diehl 1995; Diehl and Kim 1981).

Vacuum packaging and nitrogen packaging of food typically assist in reducing the vitamin E loss following the irradiation (Diehl 1991; Diehl 1995; WHO 1994).

Dietary modelling for Vitamin E

Dietary modelling was conducted to determine the potential effect that irradiation may have on the vitamin E sources in the total diet. The modelling process assessed the intakes of vitamin E for the whole population and for vegetarians. For the purpose of this nutrition report, vegetarian means either lacto-ovo or vegan vegetarian. Dietary modelling for vegetarians was conducted on the assumptions that this specific population group had higher intakes of nuts in comparison to the whole population and, therefore, there may be potential concerns in regard to changes to the vitamin E contribution from the nuts.

DIAMOND was used to determine the estimated total dietary intakes for vitamin E. The latest Australian NNS did not contain information on the vitamin E concentrations of foods. Therefore, the 1997 New Zealand NNS data were used in the assessment of vitamin E intakes (New Zealand Ministry of Health, 2000). In the absence of relevant Australian data, ANZFA assumes that the dietary patterns of Australia and New Zealand would be similar and, therefore, the New Zealand food consumption data and vitamin E concentration data could be used to reflect dietary patterns and food composition in both Australia and New Zealand.

Vitamin E concentrations for the foods were taken from the New Zealand NNS databases. Therefore, the results give an indication of potential intakes of vitamin E pre-irradiation.

Definition of Vegetarian

The DIAMOND program does not include data from the 1997 New Zealand NNS that related to respondents identifying themselves as vegetarians. Self reported vegetarianism might result in different definitions of vegetarian, for example, some vegetarians eat fish or white meat. For the purpose of the dietary modelling, vegetarians were classified into 2 types:

1. lacto-ovo vegetarians - those that did not consume animal flesh but ate dairy products and eggs on the day of the survey, and;
2. vegans - those that ate no animal flesh or animal products on the day of the survey.

The DIAMOND models were set up so that respondents included in the subset of the population were those who had not consumed from the food groups specified. The lacto-ovo vegetarian models excluded consumers from the food groups beef, veal, lamb, mutton, pork, poultry, other meats, sausages, processed meats, fish and seafood, and dishes where these foods are the major component. The vegan models excluded consumers from the food groups beef, veal, lamb, mutton, pork, poultry, other meats, sausages, processed meats, fish and seafood, eggs, butter, milk, cheese, ice cream, cream, yoghurt and dishes where these foods are the major component.

There may be some food groups that were not excluded, that still contained a trace of meat, dairy, egg or animal product, for example cakes, gelatine-containing foods. Despite this, the major animal food groups were excluded and, therefore, it is considered that the models give a good indication of potential vitamin E intakes for the two types of vegetarians.

Some of the survey respondents that may not describe themselves as vegetarians, may have been included in the vegetarian models if they did not consume meat or animal products on the day of the dietary survey. As these people were included in the models, the models can be described as a proxy for the vegetarian diet.

Estimated intakes of vitamin E

The estimated intakes of vitamin E from the total diet for the whole population and vegetarian groups are displayed in Table 8. The vitamin E intakes were calculated for each individual in the survey based on the foods they ate on the day of the dietary survey, and the natural vitamin E concentrations in the foods, that is, non-irradiated concentrations. The results for each individual were then ranked and data for the population and sub-population, mean and high percentiles, were derived.

Table 8: Estimated intake of vitamin E from the total diet for the whole population and vegetarians from the 1997 New Zealand National Nutrition Survey

Population group	Number consumers (% of total respondents)	Estimated intake mean mg per day (% of RDI)*#	Estimated intake 95th percentile mg per day (% of RDI)*#
All population (15+ years)	4 636 (100)	9.8 (119)	20.1 (236)
Lacto-ovo vegetarians	696 (15)	8.7 (107)	18.2 (222)
Vegan vegetarians	35 (1)	7.1 (84)	24.8 (248)

*RDI: 12-18yrs males 11mg, 12-15yrs females 9mg, 16-18yrs females 8mg, 19+yrs males 10mg, 19+yrs females 7mg
Data are unadjusted for intra-individual variations and thus the 95th percentile data are overestimated

The results indicate that the whole populations' vitamin E intake (mean: 9.8 mg/day and high: 20.1 mg/day) were above the population specific Recommended Dietary Intake (RDI) (NHMRC 1986). This is also the case for the lacto-ovo vegetarian model, although overall intakes (mean: 8.7 mg/day and high: 18.2 mg/day) were slightly lower than for the whole population. The results for the vegan model indicate that vitamin E intakes for mean consumers were below the RDI (7.1 mg/day). This demonstrates that this group of mean consumers may not meet requirements for the vitamin from the natural levels of vitamin E in foods. However, since RDIs are theoretically set at two standard deviations above mean requirements, the actual percent of the population meeting individual vitamin E requirements could not be predicted. Estimated intakes of vitamin E for high consuming vegans meet the RDI.

The main food contributors to total intakes of vitamin E for the whole population, based on mean intakes were butter and margarine (14%), vegetables except potatoes and kumara (12%) and fruits (7%). For the lacto-ovo vegetarians the major contributors were butter and margarine (15%), bread-based dishes (9%) and vegetables except potatoes and kumara (9%). For the vegan population the major percent contributors were vegetables except potatoes and kumara (22%) margarine (14%), bread-based dishes (10%) and pies and pastries (9%).

The percent contributions of vitamin E from the foods addressed in this application are indicated in Table 9. Tea was the major contributor amongst these foods, mainly due to the volume of tea consumed. The tea category includes green and black tea, as well as herbal infusions. Only herbal infusions are covered by this application, therefore, the percent contribution in the total diet would be lower for this selected food than for teas collectively. The DIAMOND software package was unable to separate this data from the New Zealand NNS. The foods addressed in this application are not the major contributors of dietary vitamin E..

Table 9: Percent contribution of vitamin E from selected foods from the 1997 New Zealand National Nutrition Survey

Population group	Food	Percent contribution
All population (15+ years)	Herbs and spices	0.0
	Peanuts, including peanut butter	0.8
	Other nuts	0.4
	Tea, including herbal infusions	4.3
Lacto-ovo vegetarians	Herbs and spices	0.0
	Peanuts, including peanut butter	1.0
	Other nuts	0.9
	Tea, including herbal infusions	3.9
Vegan vegetarians	Herbs and spices	0.0
	Peanuts, including peanut butter	1.8
	Other nuts	0.0
	Tea, including herbal infusions	0.7

The nuts covered by this application include peanuts, cashew nuts, almonds, and pistachio nuts.

Conclusions

Irradiation potentially causes both macro and micro nutrient changes in foods, depending on the irradiation dose, the food's composition and environmental conditions.

The irradiation of herbs, spices, herbal infusions, peanuts, cashew nuts, almonds and pistachio nuts does not cause significant changes in the protein, carbohydrate and saturated fatty acid content of foods.

However, the changes and/or degradation of unsaturated fatty acids that can occur with irradiation generally have significant effects on the long-term stability and quality of foods with significant levels of these nutrients.

Current scientific research indicates that minerals and trace elements are not affected by irradiation. Consequently, the irradiation of the foods under this application, that is, herbs, spices, herbal infusions, peanuts, cashew nuts, almonds and pistachio nuts, is unlikely to significantly affect the presence of these minerals in the general food supply.

The dietary modelling results further indicate that the foods covered by this application are insignificant sources of the radiation sensitive vitamins: vitamin A, vitamin C, vitamin E, thiamin and folate, and unsaturated fatty acids when considered in the context of the total diet.

The available research on the irradiation effects of herbs, spices, herbal infusions, peanuts, cashew nuts, almonds and pistachio nuts and the associated dietary modelling, indicate that there will not be a significant effect on the nutritional content of the current Australia and New Zealand diets due to the irradiation of the foods covered by this application.

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Attachment 3

A413 – Submissions from 1st Round of Public Consultation

Government, Professional Associations, Industry Associations and other groups 35 submissions		
1	**National Council of Women in Australia**	5/12/00
2	**Australian Conservation Foundation**	6/12/00
3	**Consumers' Institute, Wellington, NZ**	5/12/00
4	**Green Party, Wellington, NZ**	4/12/00
5	**Australian Food and Grocery Council**	8/12/00
6	**Unilever Foods, NSW**	6/12/00
7	**New Zealand Pork Industry**	12/10/00
8	**New Zealand Dietetic Association (Inc)**	7/12/00
9	**SAFEfood New South Wales**	6/12/00
10	**Australian Nut Industry Council**	5/12/00
11	**Ministry of Consumer Affairs, Wellington, NZ**	4/12/00
12	**Ministry of Health, Wellington, NZ**	6/12/00
13	**NSW Agriculture**	5/12/00
14	**NSW Environment Protection Authority**	22/11/00
15	**EnuFF, Qld**	1/12/00
16	**Dietitians Association of Australia**	6/11/00
17	**Tetley Australia Pty Ltd**	4/12/00
18	**Christie Tea Pty Ltd**	5/12/00
19	**Madura Tea, NSW**	4/12/00
20	**Agriculture Fisheries & Forestry – Australia, (Biosecurity Australia)**	4/12/00
21	**Canberra Consumers Incorporated**	6/12/00
22	**Consumers' Association of South Australia Inc.**	9/12/00
23	**Friends of the Earth (New Zealand)**	6/12/00
24	**Office of Regulation Review, ACT**	7/12/00
25	**National Herbalists Association of Australia**	5/12/00
26	**Buller Conservation Group, Westport, New Zealand**	undated
27	**Organic Consumers Association, USA**	5/12/00
28	**Queensland Health**	15/12/00
29	**Food Technology Association of Victoria Inc**	20/12/00
30	**Food Safety Victoria**	11/1/01
31	**Food & Beverage Importers Association, Victoria**	16/01/01
32	**Mudgee District Environment Group Inc**	16/01/01
33	**National Nutritional Food Association, NZ**	27/2/01
34	**Narangba Community Progress Association Inc.**	31/3/01
35	**Women's International League for Peace and Freedom**	20/4/01
Campaign submissions – 225		
Individual submissions – 43		

303 SUBMISSIONS RECEIVED IN TOTAL (1st Round of Public Consultation)

A413 – Submissions from 2nd Round of Public Consultation

List of Submitters

Government, professional associations, industry & other groups (36 submissions)		
1	Senator Andrew Bartlett – Australian Democrats	25/7/01
2	Councillor Chris Whiting, Division 6, Caboolture, Qld	9/8/01
3	Ministry of Consumer Affairs, Manatu Kaihokohoko	2/8/01
4	Pine Rivers Shire Council, Qld	14/8/01
5	Organic Growers Association WA (Inc)	22/7/01
6	Myosyn Industries Pty Ltd, Qld	26/7/01
7	Australian Nut Industry Council Inc.	Undated
8	Pistachio Growers Association Incorporated, SA	14/8/01
9	Almondco Australia Limited	14/8/01
10	National Council of Women of Australia	11/8/01
11	National Meat Association of Australia	14/8/01
12	Food Technology Association of Victoria Inc.	13/8/01
13	Australian Pioneer Pistachio Company Pty Ltd	13/8/01
14	Restaurant & Catering Australia	8/8/01
15	Clifton Farming Company Pty Ltd, QLD	10/8/01
16	Organic Consumers Association, Los Angeles, CA USA	25/7/01
17	Peanut Company of Australia Limited	15/8/01
18	The Koala Tea Company	14/8/01
19	Tancon Pty Ltd, QLD	14/8/01
20	Riverland Almonds, SA	15/8/01
21	G. Crumpton & Sons, QLD	Undated
22	GB-Commtrade Pty Limited, NSW	15/8/01
23	Select Harvests, VIC	14/8/01
24	Chiquita Brands Melbourne Pty Ltd	14/8/01

25	**National Herbalists Association of Australia**	**17/8/01**
26	**Michael Waring Trading Pty Ltd, VIC**	**Undated**
27	**Friends of the Earth Australia**	**16/8/01**
28	**Friends of the Earth (New Zealand /Aotearoa)**	**15/8/01**
29	**People Against Food Irradiation (Sydney)**	**15/8/01**
30	**Australian Conservation Foundation**	**14/8/01**
31	**Federated Association of Australian Housewives (Tasmania)**	**12/8/01**
32	**Everyone for a Nuclear Free Future (EnuFF)**	**13/8/01**
33	**Commonwealth Department of Health and Aged Care**	**20/8/01**
34	**Australian Food and Grocery Council**	**15/8/01**
35	**Department of Agriculture, Fisheries & Forestry – Australia**	**20/8/01**
36	**Unilever Australasia**	**21/8/01**
Campaign Submissions - 616		
Individual Submissions - 70		

722 SUBMISSIONS RECEIVED IN TOTAL (2ND Round of Public Consultation)

Attachment 4

Issues Raised in Public Comments

This attachment provides a list of the issues or questions raised by the public in response to the Issues Paper that was published in relation to this application. The issues or questions raised are in bold under broad headings, with responses or further information provided underneath each issue. Many of the issues are covered in Attachment 2, the Scientific Assessment Report. However, for ease of reading, the majority of the responses in this attachment include the relevant information, rather than constantly referring to the Scientific Assessment Report.

SAFETY

2-dodecyclcyclobutanone (2-DCB)

A recent study suggested that a unique radiolytic product 2-DCB caused mutation to cells from the large bowel of rats when they were incubated *in vitro* with 2-DCB.

This study was reviewed in the 1999 WHO report on High Dose Irradiation of Foods. This study suggested that a unique radiolytic product, 2-dodecyclcyclobutanone (2-DCB), formed from food containing fat had possible mutagenic activity (Delincee and Pool-Zobel, 1998). The study indicated that 2-DCB in the concentration range 0.3-1.25 mg/ml produces cytotoxicity and an associated weak effect in DNA. However, the concentrations used were far greater (about three order of magnitude) than the 17μg/g reportedly present in the extracted lipid of chicken meat irradiated to 59kGy.

A note added in the WHO report states:

'In a subsequent *in vivo* study, as yet unpublished, the researchers claim to have found a small positive effect when six rats were administered an extremely high level of the synthetically prepared 2-DCB. Limitations of the experiment, particularly the exclusive reliance on the unvalidated comet assay technique, call into question the significance of this finding. WHO (1999)

In view of the preponderance of evidence, including two negative Ames tests of 2-DCB, demonstrating that irradiated foods pose no health risk to consumers and in the absence of reliable data to the contrary, the WHO as well as the Food and Agriculture Organization of the United Nations and the International Atomic Energy Agency, which together have cosponsored numerous expert meetings on the subject, continue to concur with the conclusion of the Joint FAO/IAEA/WHO Study Group on High Dose Irradiation of Food. Their conclusion was that foods irradiated throughout the technologically appropriate dose range are safe and nutritionally adequate and support the proposed changes in the Codex Standard for Irradiated Food and its accompanying Code of Practice.

No approval to irradiate foods above 10kGy should be granted. The reason why the applicant is requesting a maximum dose of 30kGy for herbs and spices is that the Dose Uniformity ratio (DU ratio of maximum to minimum dose) is 3:1, which is much higher than many overseas countries.

Based on the scientific evidence, the use of 30kGy to decontaminate herbs and spices is safe. The major concern of stakeholders is in relation to the possible use of this technology to replace good manufacturing practice. Any condition to approve the application would require the use of good manufacturing practice before and after irradiation.

It should be noted that herbs and spices are not sterile products – they are naturally occurring and may be contaminated by the soil, air, water and pests and animals of their surrounding environment, including during production, harvesting, processing and transportation.

While the international Codex standard for food irradiation is currently set at a maximum of 10kGy, Codex is currently considering raising this limit based on the studies of the World Health Organisation on high dose irradiation to ensure food safety outcomes.

A number of countries currently permit the irradiation of herbs and spices for microbial control up to a maximum dose of 30kGy including the United States, Argentina and Croatia. Most other countries approve up to 10kGy, consistent with the current Codex standard.

The applicant has two irradiation plants designed to sterilise large packs of medical products. Such plants often have a DU ratio around 3. Such plants are concerned with the minimum dose of 25kGy and not the maximum dose, as the product is nearly always very stable at very high doses.

Advice to ANZFA is that, at irradiation plants designed specifically for food, a lower DU ratio allows better control of the minimum and maximum doses imparted to food as food is sensitive, from a quality perspective, to the maximum dose. Overseas plants, for example, one in France for de-boned chicken, are treating meat in packs about 7cm thick, and may have a DU ratio much lower than 3. Food facilities treating pallet loads, however, would find it difficult to get much below a DU ratio of 2.5. The 1999 WHO report states that most commercial facilities operate in a way that produces a DU ratio of 2 to 3.

The reason for proposing 30kGy to treat herbs and spices is only partly the DU ratio. Herbs and spices can be so heavily contaminated with micro-organisms and that a dose of between 3kGy to 30kGy is required to ensure food safety. Previously, there have been concerns that the maximum dose of 10kGy may not be as efficacious in reducing microbial numbers.

ANZFA should review all the previous submissions to the then NFA on food irradiation and re-examine the various expert reports, in particular, the 1977 and 1981 JECFI reports. Furthermore, the WHO and JECFI reports are not official WHO policy.

ANZFA re-examined the 1977 and 1981 JECFI reports at the request of one of the submitters.

However, during the development of Standard A17, particularly during the Full Assessment process, ANZFA examined all the previous technical reports. In addition, in 1991 the Australian Department of Community Services and Health commissioned the WHO to review the safety and nutritional adequacy of irradiated food. A final report was published in October 1994. Part of this review was on the data in the 1977 and 1981 JECFI reports.

Various experts were employed to review the worldwide databases and literature on the safety aspects of food irradiation. Those experts would have used the previous reports as a starting point and would certainly be aware of any conclusions and recommendations in these reports, particularly with reference to the 10kGy limit.

ANZFA accepts that the 1994 WHO report and the more recent report on high dose irradiation (WHO, 1999) do not constitute an official WHO policy on irradiation. However, the WHO has active interest in irradiation and actively encourages the proper use of food irradiation against food-borne diseases and food losses (WHO, 1994).

There is considerable literature drawn, on by the 1981 JECFI Committee, to show the production of toxic substances above 10kGy. This literature is not referenced in the 1999 WHO report.

Point 5 of the future research section of the 1977 JECFI report suggested that further work be undertaken on chemical, nutritional and toxicological studies on radiolytic products of lipids, with reference to peroxidase and epoxide formation and *cis-trans* isomerization. However, the report does not suggest that toxic substances are produced above 10kGy.

The 1999 WHO report section 2.2 reviews the history of the safety studies performed on irradiated foods. Particular reference is made to the 1981 JECFI report, p.7-8.

The conclusions from this report were stated as follows:

- none of the toxicological studies carried out on a large number of individual foods had produced evidence of adverse effects as a result of irradiation;
- radiation chemistry studies had shown that the radiolytic products of major food components were identical, regardless of the food they were derived. Knowledge of the nature and concentration of these radiolytic products indicated that there was no evidence of a toxicological hazard; and
- supporting evidence was provided by the absence of any adverse effects resulting from the feeding of irradiated diets to laboratory animals, the use of irradiated feeds in livestock production and the practice of maintaining immunologically incompetent patients on irradiated diets.

At that stage, the Committee concluded that irradiation of any commodity up to an overall average dose of 10kGy presented no toxicological hazard; hence, testing of foods so treated was no longer required.

The 10kGy limit adopted by Codex in 1983 following the recommendations of the 1981 JECFI report and at that time was the level, at or below, which safety had been established. Additionally, at that time the anticipated applications, for example, inhibition of sprouting, insect disinfestation, extension of shelf life and control of microbes in meat, poultry, fish for irradiation of food require doses of less than 10kGy.

Since that time, the safety of high dose irradiated foods (above 10kGy) has been evaluated in many feeding studies with a variety of diets in animals and humans (WHO 1999). The 1999 Study Group on High Dose Irradiation of Foods does not mention a specific high dose up to which food is safe. It specifically talks about irradiated foods being wholesome throughout the technologically useful dose range.

It indicates that high dose irradiated food will be unsaleable through loss of quality prior to any onset of concerns about toxicity. Codex is now considering removal of the 10kGy limit from its General Standard, as a result of the 1999 WHO report's conclusions.

Presently, there are current approvals of food irradiation involving doses above 10kGy that include foods for general use and in immunosuppressed patients.

There are no long-term studies on consuming irradiated foods.

Food irradiation is a thoroughly investigated food processing technology and a large number of toxicological studies have been undertaken. These include many long-term studies that specifically address any evidence of long-term effects in animals. The data derived from animal studies are especially relevant to humans because of the composite nature of the food material used and the manner in which the diets were administered.

Animal and human feeding studies have not been conducted on every possible food. However, studies on a wide range of foods have established that foods of similar class and composition react similarly following irradiation. This concept is termed chemi-clearance (WHO 1994, 1999).

Although it has not been feasible to run long-term tests in humans for irradiated foods, or any other new food technology, the long-term animal studies are supported by the more limited human data. These data include studies of up to 90-day duration in humans with thirty five different varieties of irradiated foods and studies to indicate any mutagenic or cancerous effects in animals. Humans in many countries have consumed irradiated foods, in particular, herbs and spices, for some time now without any known adverse health effects. In addition, some hospital patients have consumed considerable quantities of irradiated food and the health of these patients has been well monitored for clinical reasons.

Over thirty years of research have shown that virtually all the radiolytic products, that is, chemical compounds that originate from a food following irradiation, that have previously been found in irradiated foods are either naturally present in food or produced in thermally processed foods (WHO 1994, 1999). All reliable scientific evidence, based on animal feeding tests and consumption by humans, has indicated that these products pose no risk to humans.

While a FAO/WHO expert panel endorsed irradiation, other prominent scientists have expressed reservations about unidentifiable chemicals forming in irradiated food.

This issue was addressed during the process of establishing Standard A17 and in the Safety Evaluation report.

In summary, the overwhelming majority of scientific opinion concurs with the view that food irradiated at levels necessary to achieve a technological need or food hygiene purpose, in accordance with specific criteria inherent in good manufacturing practice, is safe.

Repeated concerns have been raised about the formation of trans fatty acids, fatty acid peroxides and epoxides as possible carcinogens.

The USFDA (1986) considered that that the yields of peroxides and epoxides were sufficiently low to raise no concerns about safety. Additionally, numerous studies at higher doses of irradiation were reviewed by the WHO Study Group in 1999. There has been no evidence of carcinogenesis in the various animal studies at the higher doses.

A number of studies have been carried out to detect unique mutagenic and potentially carcinogenic compounds in irradiated foods and it is generally considered that the above concerns are not unique to irradiated foods but also apply following the application of other foods processing techniques, for example, heating of fatty foods. Peroxides and epoxides are also formed in non-irradiated foods and are thermally and chemically unstable, decomposing to various aldehydes, ketones, alcohols and hydrocarbons which constitute end products of both unprocessed and conventionally processed foods (USFDA 1986).

Furthermore, these concerns relate to irradiation above a dose of 10kGy in nuts. The applicant has applied for a maximum dose of 10kGy for nuts and has withdrawn the request to irradiate any oilseeds.

Bacteria are able to grow without the warning signs of spoilage being apparent.

Any treatment of food that does not completely sterilise the food such as pasteurisation and irradiation may result in some surviving bacteria growing in the absence of spoilage bacteria. Irradiation should only be used in conjunction with good manufacturing practice to prevent proliferation of pathogenic and toxigenic micro-organisms. The same requirements exist for other food preservation techniques.

What guarantees are there that the packaging used will be safe?

Food to be processed by irradiation, and the packages and packing materials used or intended for use in connection with food so processed, must be of suitable quality and in an acceptable hygienic condition, appropriate for the purpose of such processing. These should also be handled before and after irradiation, according to good manufacturing practice, taking into account, in each case, the particular requirements of the technology of the process.

Various types of packaging materials have been approved overseas for use when food is irradiated. Their suitability for irradiation has been studied in Canada, the United Kingdom and the USA.

It is the responsibility of Australian and New Zealand food manufacturers and retailers to ensure that their products are safe and that they comply with all relevant legislation.

Are irradiated peanuts, grains and oilseeds more susceptible to mould attack than non-irradiated products?

No. Contamination of foods by moulds after decontamination, by any method, can only occur due to poor storage and handling techniques. No increased risk of contamination of foods following irradiation has been established. Because irradiation can be carried out on pre-packaged foods, the foods are protected from contaminants and moisture, reducing the possibility of post-irradiation contamination or the growth of micro-organisms.

Can irradiation cause any surviving mould spores to produce increased levels of aflatoxins?

The experimental evidence on aflatoxin-producing mould species indicates that under all practical situations any surviving mould spores only produce the same level of aflatoxins as spores which have not undergone irradiation. This is confirmed by the FDA, which states:

'It has no evidence that would lead it to conclude that food irradiated and stored under normal handling practices would show increased aflatoxin production' (FDA 1988).

Other safety issues

Other issues which were raised and which are addressed in the scientific assessment report (pages 35-40) were:

- impacts of unique radiolytic products on human health; and
- a further discussion on studies performed on animals and humans that demonstrate the safety of irradiated foods at specific doses.

TECHNOLOGICAL NEED

Is there a technological need for irradiation?

Standard A17 in Vol. 1 of the *Food Standards Code*, Regulation 264 of the New Zealand Food Regulations and Standard 1.5.3 of Vol. 2 of the *Food Standards Code* state that where irradiation is permitted, food should only be processed by irradiation where such processing fulfils a technological need or is necessary for a purpose associated with food safety.

The need for improved ingredient sanitation is growing due to a move towards higher standards of processing control such as Codex Hazard Analysis and Critical Control Point standards or International Standards Organisations standards; exporters ensuring their products meet or exceed the quality standards of the importing countries and preventing contamination of food processed or prepared in Australia and New Zealand.

Is there a technological need for the irradiation of herbs and spices?

The pathogens identified as commonly present in herbs and spices, and therefore likely to pose a public health and safety issue for consumers, are *Salmonella*, *Escherichia coli*, *Bacillus cereus*, and *Clostridium perfringens*. *Salmonella* is found infrequently, but in a wide variety of spices (ICMSF 1986), and has been responsible for outbreaks of human salmonellosis (CSIRO 1996). In New Zealand and Australia the principle spices of concern are peppercorns. These have been found to have the highest level of contamination (Pafumi 1986) and are the spices most commonly subjected to ethylene oxide fumigation.

Evidence of pathogenic micro-organisms associated with herbs and spices, and of food borne illnesses associated with the consumption of these foods, illustrates a technological need for the irradiation of herbs and spices.

Low levels of irradiation turn endosperm brown and black.

A large number of items are included under the definition of herbs and spices. Among these are roots such as garlic and onion, and rhizomes such as ginger. Low levels of irradiation turn the endosperm of these foods brown and black. Therefore irradiation may not be suitable, or necessary, for these foods, but may still be suitable for their ground and dried products.

Is there a technological need for the irradiation of nuts?

Nuts are not known as common hosts of the usual microbial contaminants. However, moulds such as *Aspergillus flavus* are commonly present, and some strains may produce aflatoxins when allowed to grow to high levels.

Peanuts have occasionally been identified as a source of *Salmonella* although such outbreaks are difficult to trace unless a food manufactured from a batch of nuts is identified. Several outbreaks have been traced to peanut butter (AIFST 1997). However, it is not always apparent whether the source of the problem is the nuts themselves, the processing plant, or a combination of both.

The US Food and Drug Administration has identified nuts and nut products, which do not undergo a bactericidal step, as a *Salmonella* hazard. As a result, nuts are included in the FDA sampling plan for *Salmonella*.

There is evidence of a technological need for the disinfestation of nuts, particularly for quarantine purposes.

Pests and disease associated with nuts are numerous. For example, there are at least a dozen arthropod pests of peanuts known to infest the seed pod during fruit fill and or post-harvest. There are at least four species that are of quarantine concern to Australia.

Currently for quarantine purposes, nuts are treated for one of two reasons. Firstly, where live insects are found during inspection and, secondly if they are hosts of Khaphra beetle, a mandatory treatment applies. In the case of live insect detection that are not Khaphra beetle (most cases), methyl bromide fumigation at varying rates, phosphine and freezing are allowed treatments. For Khaphra beetle, only high dosages of methyl bromide are allowed. Irradiation efficacy data indicate that a dose of 0.5kGy to 2.0kGy, dependent upon species, would be sufficient to either kill or sterilise these pests.

Is there a technological need for the irradiation of teas and herbal infusions?

Tea is defined as ‘the product made from leaves and buds of one or more varieties of *Camellia sinensis*’. There are no bacterial or microbial problems associated with true tea (green or black) as the firing and drying process by which teas are prepared, together with Good Manufacturing Practice, would normally destroy micro-organisms and result in a product that exhibits low levels of microbial contamination. There is no technological need for the irradiation of true tea. Furthermore, the applicant has formally withdrawn the request for permission to irradiate tea from *Camellia sinensis.*

Microbial contamination of herbal infusion raw materials such as juniper, peppermint, sage, St John's wort, horse chestnut, liquorice root, chamomile flowers, mint leaves, linden flowers, dog-rose hips and sage leaves has been reported (Kedzia 1997; Katusin-Razem et al 1988). Micro-organisms present on these herbs include aerobic bacteria, yeasts and moulds, *Enterobacteriaceae*, enterococci, *Bacillus* and *Clostridium* spores (Kedzia 1997).

There is some evidence that the micro-organisms present in plant materials are able to survive the procedures used to prepare infusions (Baxter and Holzapfel 1982). This was confirmed by Katusin-Razem et al (1985 and 1988) who reported that thermoresistant and spore-forming bacteria present on some tea herbs, mint leaves and dog-rose hip, were able to survive hot water infusion. This potential for survival represents a public health problem especially given that infusions may be prepared using warm or even cold water.

In recent years, *Salmonella* has increasingly been isolated from plant material intended for infusions. An outbreak of salmonellosis due to consumption of rooibos tea occurred in South Africa (Niemand 1985).

There is evidence of a technological need for the irradiation of herbs and plants used to prepare herbal infusions.

Shouldn't contamination be reduced at the source, not controlled later by irradiation?

Removing contamination at the source is preferable and steps should be taken to reduce contamination at all stages of the production process. However, preventing contamination is not always possible. Despite all efforts at good agricultural practice, certain raw foodstuffs may still become contaminated with pathogenic organisms. Irradiation may provide a decontamination procedure that does not damage the intrinsic characteristics, for example aroma and flavour associated with the food.

EFFICACY OF FOOD IRRADIATION

Is there any scientific evidence illustrating the efficacy of irradiation when applied to herbs and spices, nuts and herbal infusions?

The efficacy of irradiation when applied to herbs and spices is well documented (Kiss and Farkas 1988; Vajdi and Pereira 1973; Farkas and Andrassy 1988). Based on scientific evidence relating to the irradiation of herbs and spices, WHO (1999) have concluded that irradiation, in terms of biological hazard control, is analogous to current processing technologies.

Irradiation is more commonly applied to nuts as a disinfestation method than a decontamination method. As such, there is limited evidence available on the efficacy of irradiation when applied to nuts. Chiou et al (1990) found irradiation at 5kGy effective at eliminating surface moulds on peanuts. No information on the efficacy of irradiation at reducing pathogens on nuts is readily available in the literature.

The efficacy of irradiation when applied to tea herbs has been demonstrated. Kedzia (1997) reported that irradiation at doses from 1kGy to 10kGy was effective in decreasing microbial contamination levels on herbal raw materials such as juniper, peppermint, sage, St John's wort, horse chestnut and liquorice root.

Is irradiation more effective than ethylene oxide at decontaminating herbs and spices?

Yes. There is evidence that irradiation is more effective than ethylene oxide at reducing microbial populations on herbs and spices (Farkas and Andrassy, 1988; Vajdi and Pereira, 1973; Kiss et al, 1978, 1988; Szabad and Kiss, 1979, 1988). The physical nature of spices is very protective to micro-organisms and can interfere with the effectiveness of ethylene oxide treatment. As a result, ethylene oxide treatment is commonly required to be repeated before the microbial contamination reaches levels suitable for food processing requirements.

There is also evidence that irradiated spices tend to become even cleaner on storage as injured bacteria continue to die off (Farkas et al, 1962, 1988).

Clostridium botulinum **is very resistant to irradiation. Does this present a public health hazard?**

Although the spores of *Clostridium botulinum* are very resistant to irradiation, this bacterium, and similar spore formers in plant materials, does not present a public health or spoilage issue. *Clostridium* is therefore unlikely to be the main concern of food processors seeking to irradiate foods. The main pathogens in plant materials to be controlled by irradiation are the enteric pathogens such as *Salmonella.* These are easily inactivated by irradiation.

Is irradiation the only treatment effective in meeting microbiological limits set by processors operating under HACCP or ISO-based plans, or can currently used decontamination methods also achieve these standards?

Limits for microbiological contamination of spices can be set very low for processors operating under HACCP or ISO standards. Although currently used decontamination methods can meet these standards, irradiation may enable these standards to be met more efficiently. For example, ethylene oxide treatment of herbs and spices may need to be repeated in order to achieve acceptable microbial levels. This can cause delays.

What advantages do alternative decontamination methods used for herbs and spices, nuts and herbal infusions have over irradiation?

Alternative decontamination methods have associated advantages and disadvantages. The applicant is proposing an additional and alternative technology. To protect public health and safety, it is wise to have a range of safe technologies available for use when needed. The application should be considered against the objectives of the food standards and the choice of alternative methods of treatment can then be left to the food manufacturers.

MICROBIOLOGICAL

Is there a public health benefit associated with using irradiated food ingredients in the production of processed foods?

Pathogens contaminating foods can be hazardous when these foods are used as ingredients in processed foods. The risk of food-borne illness is greatest when contaminated herbs and spices are added to foods that do not undergo a further treatment step, such as cooking.

Because irradiation results in foods with improved microbiological quality, the use of irradiated ingredients in processed foods would provide an increased level of safety.

Can irradiation lead to the development of mutant forms of micro-organisms that are more resistant to radiation, have increased pathogenicity, or increased virulence?

In a laboratory environment, bacteria can be trained over time to become more resistant to factors such as antibiotics or irradiation. This selection process involves exposing a population of bacteria to a dose that is lethal to a large fraction of the population, but not to all the bacteria present. By selecting the survivors for further growth, then re-irradiating them and repeating the process many times with gradually increasing dose levels, the bacteria can develop increased resistance. In contrast, irradiation of food exposes micro-organisms to a single lethal dose of irradiation.

WHO (1994) has stated that although both irradiation and conventional processing techniques have the potential to increase the rate of mutation in micro-organisms, there is no evidence of increased pathogenicity or virulence of pathogenic organisms as a result of these techniques. The FDA is in agreement with these findings (United States General Accounting Office 2000).

How will irradiation affect micro-organisms that are radiation resistant?

WHO (1999) established that micro-organisms that survive irradiation are likely to be more sensitive than untreated cells to environmental conditions such as temperature, pH, and nutrients. Therefore, micro-organisms that survive irradiation will be destroyed at a lower cooking temperature than those that have not been irradiated (United States General Accounting Office 2000). In many cases, the foods being irradiated will be heated before being consumed, thereby destroying surviving micro-organisms.

Can irradiation destroy the toxins produced by bacteria and mould?

No. Irradiation cannot inactivate toxins. Therefore, manufacturers must ensure that toxins, and the micro-organisms responsible for producing them, are absent prior to irradiation. This same requirement already exists for other food preservation processes.

Irradiation is however effective in destroying the moulds that can produce aflatoxins during storage of plant material.

Does the fact that irradiation can destroy the micro-organisms that produce toxins, but not the toxins themselves, create a false sense of security?

The elimination of micro-organisms responsible for the production of aflatoxins does not create a false sense of security. All decontamination methods (even cooking) destroy the micro-organisms that produce toxins, but not the toxins themselves.

Plant products susceptible to aflatoxin formation, for example peanuts, are currently tested for levels of aflatoxins, not for the moulds that produce them. Products exceeding the permitted aflatoxin level would not be considered suitable for irradiation. Food producers and processors need to follow good agricultural practice and good manufacturing practice.

Will the application of HACCP further back in the food chain reduce the extent of contamination and products needing treatment?

Possibly. However this may not be an alternative for imported material. Pathogen reduction in plant material, even in countries able to implement some degree of control over food production systems, is very difficult given the extent of environmental contamination and the lack of decontamination procedures that do not damage the essential qualities of the commodity.

Are organically produced foods safer and fresher?

In many cases, organic production would not differ significantly from the conditions under which herbs and spices are currently grown and harvested. There is no logical reason for organically grown herbs and spices to have fewer microbial pathogens than conventionally harvested material. Foodborne illness has been associated with the consumption of both organically produced and non-organically produced foods.

Could irradiated food harbour harmful pathogens, for example viruses and prions causing BSE, that could recover and grow in the absence of other competing micro-organisms?

Viruses, such as hepatitis, and prions do not multiply in food. Irradiation has been shown to be effective against the organisms of concern for the foods listed in the application.

In addition, the foods listed in the application are usually too dry to support the growth of micro-organisms. Therefore, there is no opportunity for the recovery and growth of either pathogens or spoilage bacteria. Growth of surviving pathogenic bacteria would only be possible if the irradiated product was added to a food which supported microbial growth and which was subjected to temperature and/or time abuse.

Regrowth of surviving pathogenic bacteria would need to be considered if the foods proposed for irradiation in this application were able to support the growth of bacteria.

Won't irradiation also eliminate the spoilage bacteria that warn us when a food is going off?

Destruction of the spoilage bacteria means that foods will not go 'off' unless they are re-contaminated after irradiation.

In high protein and high moisture foods, the growth of spoilage bacteria indicates that the quality of the food is declining. Irradiation is not the only decontamination technique that eliminates spoilage bacteria. Heat pasteurisation, chemical treatments and certain packaging methods also do this in order to prolong the shelf life of perishable foods.

The foods listed in this application are not perishable, as they have been preserved through drying, packaging and storage. They have low moisture content and will not support the growth of spoilage organisms. Irradiation is applied to these foods to destroy pathogenic micro-organisms, not as a preservation process. The elimination of the micro-organisms that indicate food spoilage is, therefore, not relevant for the foods listed in this application.

NUTRITION

Will the consumption of foods devoid of micro-organisms affect the natural balance that exists in the gastrointestinal tract?

In addition to irradiation, processes such as cooking and canning render foods microbe free. Therefore, many of the foods we already eat are devoid of micro-organisms. In fact, a traditional diet of mainly cooked foods would be virtually devoid of live bacteria.

The foods proposed for irradiation are currently decontaminated by alternative methods that also render them devoid of micro-organisms.

There is no evidence to suggest that consumption of foods that are devoid of micro-organisms has any effect on the gut microflora of humans.

Won't irradiation of tea destroy its taste and antibacterial qualities?

The applicant has withdrawn that part of the application relating to green and black teas. The perception of taste to the individual is highly subjective across the populations of Australia and New Zealand. Furthermore, the specific taste of a particular herbal infusion is dependent on the base ingredient's characteristics and the method used in preparation.

Consumers do not usually drink tea primarily for any perceived antibacterial activity. If they did want this effect, they would still be able to select untreated teas.

Won't the irradiation of nuts reduce folate intake?

The primary sources of folate acid, and associated derivatives in the human diet are vegetables; wheat-based and yeast-based products (refer to nutrition report for additional information). Herbs, spices, herbal infusions, peanuts, cashew nuts, almonds and pistachio nuts are insignificant contributors of dietary folate in the context of the total diet due to low consumption levels, as indicated in the dietary modelling.

ANZFA reviewed the addition of folate to foods based on one of the Codex principles, in that vitamins and mineral can be added to foods where there is reasonable evidence for public health justification. As a direct consequence voluntary folate fortification is permitted to several foods (as indicated in *Food Standards Code*) which are regularly consumed by the specific population sub-group. These foods include those which are natural sources of folate, and include wheat-based products and yeast-based products. These foods, in conjunction with unfortified foods (especially vegetables), form the primary dietary sources of folate in the human diet.

How can the dietary intakes of the Australia and New Zealand populations be most appropriately estimated?

ANZFA has conducted dietary modelling, using a specific software package, DIAMOND, to determine any potential dietary effects on the New Zealand and Australian populations.

As indicated in the Nutrition Report, DIAMOND is based on the 1995 Australian National Nutrition Survey (NNS) and the 1997 New Zealand NNS. The 1995 Australian NNS surveyed 13 858 people aged two years and above, using a 24-hour food recall methodology. The 1997 New Zealand NNS surveyed 4 636 respondents, aged fifteen years and above, using a 24-hour food recall methodology.

DIAMOND estimates intakes based on aggregates of individual dietary records and physical measurements from the national surveys. DIAMOND provides more information about the distribution of the individual food and nutrient consumption than is possible using point estimates of population consumption, apparent consumption or food production data.

OTHER ISSUES

Ionising radiation causes heat increases that can be substantial.

A dose of 10kGy causes the temperature of water to raise 2.4^0C if the heating is adiabatic. Adiabatic means if all the heat energy is converted to a temperature rise and there is no loss of temperature to the outside environment. However, lower doses cause proportionately less temperature rise. In practice, the temperature rise is much less because adiabatic heating is not feasible.

The actual temperature rise depends on the thickness, density, moisture, ambient temperature and even structure of the food. It is therefore accepted that to state that irradiation causes no rise in temperature is not strictly accurate, but it can be concluded that there is no significant rise in the temperature of the food.

There is no single international method of detection available for irradiated foods.

It is correct that there is no internationally recognised single method of detection for irradiated foods; rather there are various methods. No method of detection will allow the actual dose that was applied to be measured as the changes that irradiation induces in foods is minimal.

Recently, the Codex Alimentarius Commission listed five methods of detection for irradiated foods, which allow for detection of food containing fat, bone, cellulose, for example nuts, and food from which silicate minerals can be isolated, herbs and spices. In the paper for the Codex Alimentarius Commission, it was suggested that the methods provided a very high percentage of correctly identifiable samples, that these methods were currently used in some countries and were thoroughly validated.

Products need a use by date.

Under the Standard 1.5.3 *Irradiation of Food* records are required to be kept at the facility where food is irradiated, including records of the minimum durable life of the food treated. At the retail level, Standard 1.2.5 *Date Marking of Packaged Food* requires food with a minimum durable shelf life of less than two years to be date marked.

Are withholding periods needed for irradiated foods?

No withholding period is needed for irradiated foods.

Will the additions of additives be necessary to control some of the undesirable effects of irradiation such as with irradiated meat?

ANZFA is not aware of any such need for the proposed food commodities.

How will irradiation improve the safety of the foods listed in the application?

The microbiological hazards associated with the consumption of foods listed in the application have been identified. Irradiation, at a variety of dose levels, has been shown to significantly reduce levels of micro-organisms present on herbs and spices (Kedzia 1997; Kiss and Farkas 1988; Farkas and Andrassy 1988), and on herbs used to prepare infusions (Kedzia 1997). Irradiation can be used to decrease mould contamination of nuts to prevent production of aflatoxins during storage. Irradiation has also been shown to be effective at reducing the amount of mould present on nuts (Chiou et al 1990).

Irradiation improves food safety by offering the opportunity to begin with a product that is virtually devoid of pathogens, so that if food handling errors do occur during preparation and cooking, the risk of food-borne illness is minimised (ICGFI 1999).

Do irradiated foods need to be protected against cross contamination after irradiation?

Yes. Food irradiation does not replace proper food handling or prevent contact with food-borne bacteria after irradiation. Irradiated foods can be re-contaminated if they come into contact with unclean surfaces or raw foods, or if they are improperly stored, handled or prepared. This is true for all foods preserved by all preservation procedures. There are no additional needs for irradiated foods.

Should imported products be banned if their safety cannot be guaranteed?

In Australia, all imported food products are required to conform to the *Food Standards Code* and in New Zealand all imported food must meet the requirements of the *New Zealand Food Act*. In both cases, the first consideration is that imported food must be safe for consumption. Raw unprocessed food, no matter which country it is sourced from, may be contaminated with harmful organisms that occur in the environment. Irradiation under good manufacturing practice may enhance the overall safety of the imported food products.

Will the proposed Food Safety Standards and the use of good manufacturing practice resolve the issues raised by the application?

The use of irradiation to decontaminate ingredients could allow food processors to implement GMP and food safety programs more effectively, as these systems require the reduction of microbial hazards in ingredients and foods.

Will food irradiation have an impact on food-borne disease? How will this be monitored?

It is difficult to determine whether food irradiation will have an impact on food borne disease and indeed it should be monitored. However, it is difficult to identify if any reduction in illnesses such as *Salmonella*s achieved through the use of irradiation. A significant part of the food supply would need to be irradiated in order to detect trends in the incidence of food-borne illness.

Can irradiation be used to clean up dirty food?

Irradiation, like alternative decontamination methods, does not replace good manufacturing processes. Food intended for processing by irradiation should be of a suitable quality and in an acceptable hygienic condition. Foods should also be handled before and after processing according to good manufacturing practice.

However, because products such as herbs and spices are grown in an agricultural environment it is possible that, during growing, harvesting, processing and storage, contamination may occur with micro-organisms and insects from the soil or other parts of the environment.

Concerns with the use of irradiation to clean up foods may relate to foods that are already spoiling being subjected to irradiation to halt the spoilage progressing. The foods listed in the application are not subject to gross spoilage. Therefore there is no possibility of irradiation being used to mask spoilage of these foods.

For the foods listed in the application, irradiator operators will have access to information on usual microbial contamination ranges. The International Consultative Group on Food Irradiation (ICGFI) has developed provisional guidelines for untreated herbs, spices and vegetable seasonings. Where foods contain levels outside of the usual levels of contamination, and no reasonable explanation for this is provided, foods will not be accepted for irradiation by the applicant.

Most causes of food-borne illness are due to bad food handling practices and inadequate hygiene. How would irradiation affect these practices?

Irradiation cannot prevent poor food handling practices. However, it should be noted that the impact of these poor practices would be lessened if the ingredients used in food preparation do not have high pathogen loads. This can be achieved through the use of irradiation.

MONITORING AND ENFORCEMENT

How can these products be detected to enable the requirements under the Standard to be enforced?

In Australia, food producers will be required to comply with the *Food Standards Code* that is enforced by the States and Territories. There are significant penalties for individuals and companies in the Food Acts for breaches of requirements of the *Food Standards Code*. In New Zealand, food producers are required to comply with the Food Act that also contains significant penalties for breaches.

Imported products to Australia and New Zealand will also be required to comply with the requirements of the relevant Standard.

In early 2001, the Codex Alimentarius Commission's Committee on Methods of Analysis and Sampling endorsed five methods for the detection of different irradiated foods (CAC, 2001). The methods provide a very high percentage of correctly identifiable samples, which in some cases are 100 percent. The methods are currently used in practice in some countries with significant success and are thoroughly validated. These methods will detect the foods related to this application.

The techniques and capability to use these methods exist in Australia and New Zealand but not, at this stage, specifically for testing foods. The necessary set up and quality control systems would need to be established to specifically test for irradiated foods.

In addition, guidelines for a certification system and a model certificate have been developed for the use of import and export authorities for foods irradiated for phytosanitary and other purposes.

What assurance is there that auditing or other appropriate monitoring of irradiation facilities will be undertaken to ensure compliance with the Standard for the Irradiation of Food and other relevant codes or standards?

In Australia, State and Territory regulatory authorities regulate irradiation facilities and compliance with the *Food Standards Code*. The Australian Quarantine and Inspection Service will ensure that imported foods meet requirements of the Australian *Food Standards Code* through the Imported Food Inspection System.

In New Zealand, the National Radiation Laboratory undertakes monitoring of irradiation facilities. The Ministry of Health and Public Health Units oversight the inspection of any imported food for compliance with New Zealand food regulations.

Under current food laws, any food business including the applicant or other food manufacturer, would not be required to be audited until the Food Safety Program Standard became mandatory for that class of food business in the relevant State. In the interim, enforcement officers would continue to inspect food businesses to ensure compliance with the regulatory requirements of the *Food Standards Code*.

What mechanisms would be in place to track irradiated food once it has left an irradiation plant in case of any irregularities coming to light at an irradiation facility?

For any approval under the relevant Standard in Australia or New Zealand, records must be kept at the facility where the food is irradiated that identify the nature and lot identification of the food. The food manufacturer, wholesaler or importer under the *Food Safety Standards* must have in place a written food recall plan to enable it to recall foods if the need arises.

DOSAGES

Minimum irradiation doses for phytosanitary (plant quarantine) treatments should not be specified in the Standard. The specification of minimum effective doses for individual phytosanitary treatments should be left to the relevant quarantine authorities for negotiation and agreement on a bilateral basis.

In Australia, within the portfolio of Agriculture, Fisheries and Forestry, Biosecurity Australia has responsibility for negotiating quarantine arrangements for the import and export of plant and animal products. Biosecurity Australia works closely with the Australian Quarantine and Inspection Service (AQIS) who have responsibility for ensuring that quarantine arrangements for imports and exports have been appropriately implemented in order to protect Australia's biosecurity and to meet the import requirements of Australia's trading partners.

In New Zealand, responsibility for negotiating requirements for imported plant products is shared by the Ministry of Health, for processed foods, and the Biosecurity Authority for unprocessed products. At the border, the New Zealand quarantine service ensures that quarantine arrangements for imports are actioned in order to deliver on New Zealand's biosecurity requirements and to protect New Zealand from unwanted pests and diseases.

In both Australia and New Zealand, in the context of food, measures are applied in order to prevent the introduction and establishment of quarantine pests or diseases. All measures, including any proposed treatments such as irradiation, that are targeted against critical quarantine pests, are set through a process of bilateral negotiation and agreement between the relevant quarantine authorities, a similar process applies at the Australian interstate level between State and Territory plant quarantine authorities.

Such negotiations occur on a commodity and geographic area specific basis, taking account of the particular pests and diseases present in the importing and exporting areas and whether or not they are likely to be present in the commodity in question. Because of the vast number of pests and diseases and the fact that each has a different geographic distribution, quarantine import requirements are developed on a case by case basis.

Quarantine authorities generally require a very high degree of efficacy for treatments against critical quarantine pests. Often lengthy, large-scale laboratory or field trials are required to show that the individual quarantine treatments are effective against the pest or disease on the commodity in question. From an Australian perspective, the level of efficacy required by importing countries for individual quarantine treatments must contribute to the appropriate level of protection (ALOP) of the importing country. The ALOP may vary from country to country.

ANZFA has considered these issues and consulted with Biosecurity Australia and the Biosecurity Authority in New Zealand to find a suitable means to ensure continued quarantine protections in Australia and New Zealand without creating administrative mechanisms that are burdensome.

It is proposed that minimum effective dosages for the purposes of disinfestations and control of weeds and sprouting should not be included in the standard and that the relevant quarantine authorities determine the minimum effective dose for these purposes.

What is the availability of dosimeters? These are not generally available for low doses.

Standard and reference dosimeters are available that provide excellent dosimetry throughout the dose range used in food irradiation. Such dosimeters would be used in any pre-treatment dose-mapping exercise to set the irradiation conditions. However, there has been little need in non-food facilities for the simple routine dosimeters used in daily checks to operate at the very low doses that would be required in some phytosanitary applications. Greater dependence upon documentation and setting the physical conditions would be necessary at low doses. Biosecurity Australia, the New Zealand Biosecurity Authority, AQIS and other quarantine regulatory authorities would need to consider whether there is adequate assurance that the minimum treatment has been provided. This matter has no food safety relevance.

Flavour changes occur in some nuts at 0.4kGy.

The modification of the unsaturated fatty acids in foods through processing treatments, for example, drying, heating and irradiation, typically alters the perceived flavour or taste of that food. Ultimately, the perception of a food's flavour is dependent on an individual's preferences and would be highly variable across the populations of Australia and New Zealand.

Minimum doses need to be specified to ensure it is sufficient for the purpose.

The American Society of Testing Materials (ASTM) has published the *Standard Guide for the Irradiation of Dried Spices, Herbs and Vegetable Seasonings to Control Pathogens and Other Micro-organisms* (1988) advising that the irradiation of these foods takes place between 3kGy to 30kGy. Individual product minimum doses will vary according to the level of contamination as will the minimum dose ranges between products.

The applicant maintains that setting a lower minimum dose will encourage manufacturers and growers to produce commodities with low contamination levels. Lower contamination levels will mean a lower dose will be required, resulting in lower irradiation costs. The higher the radiation dose required the higher would be the cost to the food business.

Significant penalties exist for breaching the Food Standards Code (which if amended as recommended will require that the minimum dose to achieve the technological purpose be used). Significant penalties exist for misleading or deceptive conduct under the Commonwealth *Trade Practices Act,* the New Zealand *Fair Trading Act* and State and Territory Fair Trading Acts. For example it may be a breach of the trade practices legislation, where it was claimed that a product was irradiated to eliminate micro-organisms when in fact this was not the case, or where a lesser dose was used.

The relevant standard requires that records on the minimum and maximum doses absorbed by the food be kept for a period of time that exceeds the minimum durable life of the product by one year.

The proposed international certification system for irradiated foods also requires details of the minimum and maximum absorbed doses to be recorded and verified using proper dosimetric measurement practices in accordance with internationally accepted standards such as those published by ASTM (E1204, E1261, E1431, E1539) or similar standards organisations.

LABELLING

Request for a change to the labelling requirement to include a one percent threshold where there are minor ingredients in foods.

This issue would require an application to change the current relevant Standard. It is very clear that consumers wish to have irradiated foods labelled.

Request for an exemption to the labelling requirement where there are minor ingredients in food.

This issue would require an application to change the current relevant Standard. It is very clear that consumers wish to have irradiated foods labelled.

Request that the radura symbol be able to be used as an alternative to the proposed labelling requirement using words as detailed in the *Standard for the Irradiation of Food*.

The relevant standard requires that food must be labelled with a statement that the food has been treated with ionising radiation. The standard provides three examples of such statements. The ANZFA document, *Irradiated Food - Information to Applicants,* states that the use of the international radura symbol is optional and should be in close proximity to the name of the food. However, the use of the symbol should be in addition to a statement that the food has been treated with ionising radiation.

An indication of the benefit of food irradiation would also be permitted to be placed on the label provided that was not false, misleading or deceptive.

The 3mm labelling requirement in the Food Standards Code is inadequate. Point of sale food is not covered, for example restaurants, and labelling 'on or in connection with display' as outlined in the Standard is not adequate.

Point of sale food, such as in restaurants, would not be covered. However the consumer has the right to ask if the food contains irradiated ingredients. This approach is consistent with the general labelling requirements in the *Food Standards Code*.

The Standard requires that where an irradiated food, or a food containing irradiated components, is displayed for retail sale, other than in a package, then that display must have on it or in connection with the display a label stating that the food, or its ingredients, has been treated with ionising radiation. Any change to this requirement would require an application to change the Standard.

What would the penalties be for not labelling irradiated foods in Australia and New Zealand?

It would be an offence under food law not to label irradiated food. Penalties would be those prescribed under the individual Australian State and Territory food laws, or in the case of New Zealand, the *Food Act 1981*.

INTERNATIONAL PRACTICES

Which other countries allow the irradiation of the products in question and for what purposes and at what doses?

See Attachment 1, page 29, for details.

No other country currently permits the irradiation of tea.

A number of countries including South Africa, Brazil, Croatia, Ghana, Mexico and Yugoslavia permit herbal teas to be irradiated. They are generally irradiated for the purpose of microbial control up to a maximum dose of 10kGy. Further details are provided at Attachment 1, page 29.

COSTS VS BENEFITS

There could be higher consumer prices for irradiated foods due to the transport, labeling and packaging requirements.

Commercial-in-confidence data received by ANZFA indicate that the cost of irradiating these products at a facility would be less than the cost of some of the alternative technologies.

It is likely there would be similar costs for the transporting of foods for the purpose of some of the alternative treatments, for example, ethylene oxide and steam sterilization, as there might be for transporting foods to irradiation facilities.

Food businesses regularly change labels for a variety of reasons including for their own purposes and regulatory reasons. An irradiation labelling requirement is, therefore, not expected to significantly increase costs.

One of the benefits of irradiation as a technology is the ability to irradiate packaged food and thus ensure that there is no further contamination of the food post-irradiation and prior to consumption. However, not all foods in this application would be presented in consumer level packaging as they may be treated in wholesale level packaging and then sent to food processors or spice blenders.

The applicant notes that most of the packaging materials used for the foods included in the application are well suited for irradiation, with the exception of oriented polypropylene. It is also noted that normal glass may discolour. The products related to this application are dry, dehydrated or surface-dry and present the least opportunity for reaction with the packaging material.

Standard 1.4.3 of the *Food Standards Code* provides for permission for articles and materials to be in contact with food in accordance with the conditions set out in the Standard. There is also an extensive body of work in relation to the packaging materials for use with irradiated foods and an ASTM *Standard Guide for Packaging Materials for Foods to be Irradiated* (1995).

There could be higher industry costs for irradiated food due to transport, packaging, paperwork, certification, auditing and labeling costs.

Industry may choose which technology it requires for the technological or food safety purpose it is trying to achieve. If there is a range of technologies available for the product and technological or food safety purpose of similar efficacy, then it would be a commercial decision for the company as to whether it wished to choose irradiation if it involved any increased transport or labelling costs.

There may however be some situations where a choice of an alternative technology is not possible. For example, the current permission in Australia for the use of ethylene oxide, used for the decontamination of herbs and spices, will expire at the end of September 2001. A similar provision in the New Zealand Food Standard 1999 is not time limited but developments relating to the products are being monitored. Ethylene oxide as a chemical fumigant has safety concerns associated with its use and the treatment sometimes needs to be repeated. This causes delays for industry.

Methyl bromide, currently the principle post-harvest insect disinfestation treatment for quarantine and pre-shipment, is known to deplete the ozone layer and is being phased out globally under the Montreal Protocol. Although not under immediate threat, the use of methyl bromide cannot increase and its future use, availability and cost are uncertain.

The possibility of the lack of alternative technologies raises other issues in relation to public health and quarantine measures. These are further explored in the main body of this report.

In relation to packaging, see the previous section.

The relevant standard requires the facility where food is irradiated to keep records in relation to the foods irradiated. Under the Food Safety Standards and the New Zealand Food Standard, wholesalers, manufacturers and importers must have a written food recall system for the recall of unsafe food. Irradiation facilities must already keep adequate records. In Australia, this is as part of the regulatory requirements and the registration requirements with other bodies such as the Australian Quarantine Inspection Service and the Therapeutic Goods Administration.

The costs of certification are primarily borne by the exporting country's government or certifying body.

There could be increased government costs in relation to monitoring, certification and audit costs.

The costs to government of monitoring any approval under the relevant standards for these products would be small and comprise inspection to assess compliance with the *Australian Foods Standard Code* (which would include compliance with the Standards and the Food Safety Standard) and the New Zealand Food Standard 1999. The applicant is currently third party audited, at their cost, as a requirement of their registration with the Australian Quarantine Inspection Service and the Therapeutic Goods Administration.

Under current Australian food laws, any food business including the applicant or other food manufacturer would not be required to be audited until the Food Safety Program Standard became mandatory for that class of food business in the relevant State. In the interim, enforcement officers would continue to inspect food businesses to ensure compliance with the regulatory requirements of the *Food Standards Code*.

An effective framework for the regulation of irradiation facilities exists in both Australia and New Zealand. In Australia this includes the Commonwealth (environment protection, Australian Quarantine and Inspection Service, Therapeutic Goods and Customs) and State and Territory (planning, radiation, occupational health and safety). In New Zealand this is across the portfolios of Health, Environment and Biosecurity.

In both cases, the aim is provide a high level of assurance to Australian and New Zealand communities that the products will be produced using best radiation practice. In relation to food, the relevant irradiation standards aim to ensure that the food is produced in accordance with good manufacturing practice and that a technological or food safety need must be demonstrated before any permission could be considered.

What, if any, are the audit requirements for authority to operate as a radiation facility?

The applicant is currently third party audited, at their own cost, as a requirement of their registration with the Australian Quarantine Inspection Service and the Therapeutic Goods Administration.

IRRADIATION FACILITIES

In this section, liaison has occurred with regulators of irradiation facilities in order to develop responses to the issues raised.

Many consumer submissions raised the issue of whether an environmental impact assessment of proposed facilities in Queensland had been undertaken.

This is a matter for consideration by the relevant regulatory authorities as follows:

1. Environment Australia (under the Commonwealth's Environment Protection and Biodiversity Conservation Act) and;
2. The Queensland Department of Communication, Local Government Planning and Sport (under the Integrated Planning Act).

Queensland Health considers applications for permission to possess a radioactive substance under the Queensland Radiation Safety Act.

Consumers raised concerns about food irradiation adding to nuclear waste.

The relevant standards for the irradiation of food would permit certain sources of ionising radiation: gamma rays from cobalt 60 or machine generated radiation, X-rays not exceeding 5 MeV or electrons not exceeding 10 MeV. The irradiation of food with these radiations does not result in the production of radioactivity within the food and hence does not result in the production of any radioactive substance that may subsequently become a radioactive or nuclear waste.

Gamma irradiation facilities do not use radioactive waste materials. They use cobalt-60 as the irradiation source. This source does not produce radioactive waste material but decays over time to produce non-radioactive nickel. The sources are removed from the irradiator when the radioactivity falls to between six to twelve percent of the initial level. This takes 16 to 21 years for cobalt 60). The sources can be returned to the supplier for reactivation or reuse in another application.

Concerns have been raised about the transport, use and storage of radioactive materials.

The use and storage of radioactive materials is covered by the conditions of license of the relevant regulatory authority. The transport of radioactive materials within Australia is required to be in accordance with the *Code of Practice for the Safe Transport of Radioactive Substances.* This Code adopts in full the International Atomic Energy Agency (IAEA) *Regulations for the Safe Transport of Radioactive Material,* which are used internationally.

Concerns have been raised about the adequacy of the irradiation process, monitoring of facilities and occupational health and safety.

The applicant currently operates facilities that undertake the irradiation of a range of medical products, personal care goods, packaging materials, animal feeds, cosmetic ingredients and decorative household products that are potential carriers of quarantine pests and disease organisms. The facilities are licensed and regulated by the relevant Australian State regulatory authorities.

In addition, the Australian Therapeutic Goods Administration has licensed the facilities to sterilise therapeutic goods for human use. The Australian National Registration Authority for Agricultural and Veterinary Chemicals also licenses these same facilities in relation to veterinary chemicals. The Commonwealth Department of Agriculture, Fisheries and Forestry, under the Quarantine Act, has registered the company to perform quarantine treatments.

Any approval to permit the irradiation of food would require the company to be registered under the relevant Australian State or New Zealand requirements as a food business and comply with the relevant requirements of the applicable food regulatory regime.

In Australia, the requirements for the design, administration, operation and safety of irradiation facilities that use X-rays, electrons or gamma radiation for non-medical purposes are established in the *National Health and Medical Research Council Code of Practice for the Design and Safe Operation of Non-Medical Irradiation Facilities* (Radiation Health Services No. 24, AGPS, Canberra). This Code is applicable to Australian facilities that irradiate foods.

The issue of potential environmental disasters with radioactive materials has been raised.

The cobalt-60 used in irradiators is in the form of sealed sources that are required by the Code to undergo safety tests for potential loss of integrity and tests for contamination.

Concerns have also been expressed about the potential for contaminated ground water from the use of irradiation facilities.

The Code requires that the design and safety systems for the irradiators utilising sealed radioactive sources are such that the risk of environmental contamination under all foreseeable circumstances is negligible.

Consultation should occur with Commonwealth and State environment and radiation regulators.

ANZFA has consulted with the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) and the Radiation Health Branch of Queensland Health for assistance with a response to the issues relating to the regulation of irradiation facilities.

Irradiation facilities are licensed and regulated by the relevant Commonwealth, State or Territory authorities.

ISSUES RAISED AT SECOND ROUND OF PUBLIC CONSULTATION

What is Chemiclearance?

Chemiclearance is a concept devised by past international Expert Committees (JECFI, 1981; reviewed in WHO, 1994; 1999) on food irradiation, and refers to the clearance and ultimately approval of an irradiated food of a particular class for human consumption, based on the precise chemistry of products that are produced following irradiation of that class (these are referred to as radiolytic products). Therefore, foods that are similar in their chemical makeup to others which have already previously undergone an extensive safety evaluation can be approved for food use without the necessity to undertake a further safety evaluation.

An information sheet (peer reviewed by international experts) explains in more detail this concept. For a more detailed scientific description of chemiclearance refer to the Safety Assessment report.

Why has ANZFA not included various reported studies that have contrary findings?

It is correct that ANZFA did no directly take into account contrary toxicological findings and these studies are not referenced in the reports. However, the various international expert group's employed in the past to review all the available toxicological studies evaluated these contrary findings and the discrepancies or inadequacies in some of the toxicological data.

As a result of some of these unresolved concerns in relation to the safety data, the Australian government in 1990 requested the WHO to prepare a report on the safety and nutritional adequacy of irradiated foods. This final report was completed by the WHO in 1994 and it discussed the contrary studies. In addition, the USFDA (1986) decision on irradiated foods also discusses the contrary studies. The USFDA reviewed over 400 studies of which 250 were 'accepted' or 'accepted with reservation', 150 were rejected and 20 review articles were not categorised (WHO, 1999). A publication by Diehl (1995) also devotes a special section on previous toxicological studies that have raised concerns.

Therefore, ANZFA was aware that there were previous contrary findings, although not specifically cited in the ANZFA safety assessment as previous expert committees had considered all of the available data. ANZFA concurs with the conclusions of the WHO (1994) and more recently the WHO's (1999) evaluation of the safety of irradiated foods that it is a safe and alternative technique for decontamination/disinfestation of selected foods.

Diehl JF (1995) Safety of Irradiated Foods, Pub Marcell Dekker, NY.

USFDA (1986) United States Food and Drug Administration. Irradiation in the production, processing, and handling of food; final rule. Federal Register, 51 FR 13375-13399, 18 April 1986.

WHO (1994) The Safety and Nutritional Adequacy of Irradiated Food. Geneva.

WHO (1999) High-dose irradiation: wholesomeness of food irradiated with doses above 10kGy. A Report from a Joint FAO/IAEA/WHO Study Group. *WHO Technical Report Series 890.*

Won't the irradiation of nuts reduce folate intake?

The primary sources of folate acid, and associated derivatives in the human diet are vegetables; wheat-based and yeast-based products (refer to nutrition report for additional information). Herbs, spices, herbal infusions, peanuts, cashew nuts, almonds and pistachio nuts are insignificant contributors of dietary folate in the context of the total diet due to low consumption levels, as indicated in the dietary modelling.

ANZFA reviewed the addition of folate to foods based on one of the Codex principles, in that vitamins and mineral can be added to foods where there is reasonable evidence for public health justification. As a direct consequence voluntary folate fortification is permitted to several foods (as indicated in *Food Standards Code*) which are regularly consumed by the specific population sub-group. These foods include those which are natural sources of folate, and include wheat-based products and yeast-based products. These foods, in conjunction with unfortified foods (especially vegetables), form the primary dietary sources of folate in the human diet.

How can the dietary intakes of the Australia and New Zealand populations be most appropriately estimated?

ANZFA has conducted dietary modelling, using a specific software package, DIAMOND, to determine any potential dietary effects on the New Zealand and Australian populations.

As indicated in the Nutrition Report, DIAMOND determines dietary intake using information from the 1995 Australian National Nutrition Survey (NNS) and the 1997 New Zealand NNS. The 1995 Australian NNS surveyed 13 858 people aged two years and above, using a 24-hour food recall methodology. The 1997 New Zealand NNS surveyed 4 636 respondents, aged fifteen years and above, using a 24-hour food recall methodology.

DIAMOND estimates intakes based on aggregates of individual dietary records and physical measurements from the national surveys. DIAMOND provides more information about the distribution of the individual food and nutrient consumption than is possible using point estimates of population consumption, apparent consumption or food production data.

In reviewing the contribution of nuts to the diet, was any consideration given to the various relationships between dietary intake of nuts and public health outcomes?

Various studies, for example epidemiological and clinical trials, have been noted in reviewing the dietary contribution of nuts to the health of Australian and New Zealand populations. Food –health relationships in themselves are multi-factorial, and consideration needs to be given to the application and interpretation of research in this area.

As previously mentioned, the DIAMOND dietary modelling indicates that the contribution of nuts to the intakes of the nutrients in question, in respect of the Australian and New Zealand diets, are insignificant due to relatively low consumption levels.

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ASTM E1261 *Guide for the Selection and Calibration of Dosimetry Systems for Radiation Processing*

ASTM E1431 *Practice for Dosimetry in Electron and Bremsstrahlung Irradiation Facilities for Food Processing*

ASTM E1539 *Guide for the Use of Radiation Sensitive Indicators*

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CAC, 2001 Report of the Twenty-Third Session of the Codex Committee on Methods of Analysis and Sampling:
EN 1784: Detection of Irradiated food containing fat, gas chromatographic analysis of hydrocarbons
EN 1785: Detection of Irradiated food containing fat, gas chromatographic/mass spectrometric analysis of 2-alkylcyclobutanones
EN 1786: Detection of Irradiated food containing bone, method by ESR spectroscopy
EN 1787: Detection of Irradiated food containing cellulose, method by ESR spectroscopy
EN 1788: Detection of Irradiated food from which silicate minerals can be isolated, method by thermoluminescence.

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Attachment 5

World Trade Organization implications

The World Trade Organization (WTO) obligations on signatory nations essentially require national standards to be notified to the WTO where such standards are inconsistent with international standards. ANZFA's Standard for the Irradiation of Food is considered to be consistent with the international 1983 Codex Alimentarius Commission General Standard for Irradiated Foods. However, the ANZFA Standard requires a pre-market assessment for foods on a case by case basis. In terms of labelling, the relevant Australian and New Zealand standards for the irradiation of food are consistent with the requirements for irradiated foods in the relevant Codex standard on the Labelling of Prepackaged Foods.

An approval under this Standard would add another treatment option to existing trade and as such would be a trade facilitating measure. Nonetheless, for reasons of transparency, it is proposed that Australia and New Zealand notify other WTO members under both the SPS and TBT agreements.

Attachment 6

DRAFT VARIATION TO THE *FOOD STANDARDS CODE*

To commence: on gazettal

[1] ***Standard A17*** *of Volume 1 of the Food Standards Code is varied by omitting the Table to clause 4, substituting -*

Table to clause 4

Column 1 **Food**	**Column 2** **Minimum and Maximum Dose** **(kGy)**	**Column 3** **Conditions**
Peanuts, cashew nuts, almonds and pistachios	Minimum: Subject to the condition specified in Column 3 - none Maximum: 1 kGy	Food may only be irradiated for the purposes of controlling sprouting and pest disinfestation, excluding control of weeds. The minimum dose to achieve the above technological purposes. Food must be handled before and after irradiation according to good manufacturing practice (GMP).
Herbs and spices as described in Schedule 3 to Standard A14 Herbal infusions – fresh, dried or fermented leaves, flowers and other parts of plants used to make beverages, excluding tea	Minimum: Subject to the condition specified in Column 3 - none Maximum: 6 kGy	Food may only be irradiated for the purposes of controlling sprouting, pest disinfestation, and control of weeds. The minimum dose to achieve the above technological purposes. Food must be handled before and after irradiation according to good manufacturing practice (GMP).

Herbs and spices as described in Schedule 3 to Standard A14	Minimum: 2 kGy Maximum: 30 kGy	Food may only be irradiated for the purposes of decontamination. Food must be handled before and after irradiation according to good manufacturing practice (GMP).
Herbal infusions – fresh, dried or fermented leaves, flowers and other parts of plants used to make beverages, excluding tea	Minimum: 2 kGy Maximum: 10 kGy	Food may only be irradiated for the purposes of decontamination. Food must be handled before and after irradiation according to good manufacturing practice (GMP).

[2] ***Standard 1.5.3*** *of Volume 2 of the Food Standards Code is varied by omitting the Table to clause 4, substituting –*

Table to clause 4

Column 1 **Food**	**Column 2** **Minimum and Maximum Dose (kGy)**	**Column 3** **Conditions**
Peanuts, cashew nuts, almonds and pistachios	Minimum: Subject to the condition specified in Column 3 - none Maximum: 1 kGy	Food may only be irradiated for the purposes of controlling sprouting and pest disinfestation, excluding control of weeds. The minimum dose to achieve the above technological purposes. Food must be handled before and after irradiation according to good manufacturing practice (GMP).

Herbs and spices as described in Schedule 4 to Standard 1.4.2 Herbal infusions – fresh, dried or fermented leaves, flowers and other parts of plants used to make beverages, excluding tea	Minimum: Subject to the condition specified in Column 3 - none Maximum: 6 kGy	Food may only be irradiated for the purposes of controlling sprouting, pest disinfestation, and control of weeds. The minimum dose to achieve the above technological purposes. Food must be handled before and after irradiation according to good manufacturing practice (GMP).
Herbs and spices as described in Schedule 4 to Standard 1.4.2	Minimum: 2 kGy Maximum: 30 kGy	Food may only be irradiated for the purposes of decontamination. Food must be handled before and after irradiation according to good manufacturing practice (GMP).
Herbal infusions – fresh, dried or fermented leaves, flowers and other parts of plants used to make beverages, excluding tea	Minimum: 2 kGy Maximum: 10 kGy	Food may only be irradiated for the purposes of decontamination. Food must be handled before and after irradiation according to good manufacturing practice (GMP).