



## **Issues Paper and Call for Public Submissions**

### **Application A413**

#### **Irradiation of Food:**

### **Request to Include Herbs and Spices, Nuts, Oil Seeds and Teas in Standard A-17 – Irradiation of Food in the Australian Food Standards Code**

**Note:**

This Issues Paper is the 'Preliminary Assessment' referred to in Section 13 of the *Australian New Zealand Authority Act (1991)*.

Public comments are now sought to enable a comprehensive assessment by the Authority. Details about Food Standards Setting in Australia and New Zealand are contained in Appendix 6.

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## **EXECUTIVE SUMMARY**

Steritech Pty Ltd has sought approval from the Australia New Zealand Food Authority (ANZFA) for a variation from ANZFA Standard A-17 Irradiation of Food to allow for the irradiation of nuts, oilseeds, herbs and spices and teas for reasons related to disinfection, disinfestation, sprout inhibition and weed control.

Standard A-17 prohibits the irradiation of food unless specific permission is given on a case-by-case basis, and the irradiation meets a technological need or is necessary for food safety reasons. Case-by-case consideration of applications for the irradiation of foods is subject to the normal statutory processes followed by ANZFA and, following the assessment by ANZFA, approval of a recommendation to the Australian and New Zealand Ministers of Health acting together as the Australia New Zealand Food Standards Council (ANZFSC).

A copy of the application is available for viewing on the ANZFA Public Register. In this case, the applicant has also provided the application electronically and agreed that it be placed on the ANZFA website at [www.anzfa.gov.au](http://www.anzfa.gov.au).

This Issues Paper is a preliminary document in the consideration of this application. It has been prepared by ANZFA, in association with representatives from interested agencies in Australia and New Zealand. It presents an overview of the application and some associated issues, to identify issues of potential interest to stakeholders in Australia and New Zealand and as a base from which to give full consideration to this application. The issues identified thus far include food safety, nutrition, labelling, the efficacy of the treatment, dosimetry, detection methods, facilities, regulatory and international issues, and the potential regulatory impact of the requested approval.

The paper includes information about the requirements of Standard A17–Irradiation of Food and the requirements applicants must meet if permission to irradiate these foods is to be granted. It also includes information on food irradiation and the use of food irradiation in other countries, and information on ANZFA and the role of the Authority and its responsibilities in assessing this application.

ANZFA recognises that the issues and questions raised in the paper may not be comprehensive. Accordingly, in releasing this preliminary assessment for public comment, ANZFA invites the submission of views and information on any matter covered in the paper or otherwise related to this application.

ANZFA's role, in collaboration with others, is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. In carrying out this function, ANZFA seeks to ensure that its regulatory measures are based on sound scientific evidence. ANZFA will review all submissions and associated material on this basis, and give full consideration to the evidence and technical data accompanying each submission.

**The deadline for submissions in this initial round of consultations is 6 December 2000.**

There will be a further round of consultation in the first quarter of 2001, based on ANZFA's consideration of the issues raised in the initial round of consultations.

## **APPLICATION A413 - IRRADIATION OF HERBS, SPICES, NUTS, OILSEEDS AND TEAS**

### **1. INTRODUCTION**

#### **1.1 Invitation for Public Submissions**

The Australia New Zealand Food Authority (ANZFA) received an application on 3 May 2000 to amend the Australian *Food Standards Code* on the above matter. The Authority has accepted the application. This Issues Paper provides further detail and seeks public input and comment on the application.

A Steering Group of representatives from government (health and agriculture portfolios), industry and consumers from Australia and New Zealand and an expert in the irradiation field will be assisting ANZFA in examining this particular application and the public responses received. There will be two opportunities for the public to comment on this application, of which this Issues Paper is the first.

The second opportunity to comment will occur in February/March of 2001.

At that time a draft report will be circulated for public comment. The draft report will assess the scientific evidence, the public comment on the application and proposed courses of action in response to the application.

The Authority now invites public submissions on any issue raised in this Issues Paper, or any other relevant issue, for the purposes of assessing the application. Ideally, technical information presented should be in sufficient detail to allow independent scientific assessment.

After the second public consultation process, the ANZFA Board will finalise recommendations to the Australia New Zealand Food Standards Council (consisting of Health Ministers from Australia and New Zealand), which will make the final decision as to whether or not to adopt the recommended approach

The processes of the Authority are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of the Authority and made available for public inspection. If you wish any confidential information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it in confidence. The *Australia New Zealand Food Authority Act 1991* requires the Authority to treat in confidence trade secrets relating to food and any other information relating to food, the commercial value of which would be or could reasonably be expected to be, destroyed or diminished by disclosure.

All correspondence and submissions on this matter should be addressed to the **Project Manager - Application A413** at one of the following addresses:

Australia New Zealand Food Authority  
PO Box 7186  
Canberra Mail Centre ACT 2610  
AUSTRALIA  
Tel (02) 6271 2222  
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Australia New Zealand Food Authority  
PO Box 10559  
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Tel (04) 473 9942  
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The Authority should receive submissions by no later than 6 December 2000.  
Submissions may be sent by Email to [slo@anzfa.gov.au](mailto:slo@anzfa.gov.au). However, the Authority cannot guarantee accurate transmission and it is suggested that you also forward a hard copy by mail.

General queries on this matter and other Authority business can be directed to the Standards Liaison Officer at the above address or by Email on [slo@anzfa.gov.au](mailto:slo@anzfa.gov.au). Requests for more general information on the Authority can be directed to the Information Officer at the above address or by Email on [info@anzfa.gov.au](mailto:info@anzfa.gov.au).

## 2. OVERVIEW OF THE APPLICATION

ANZFA received an application (May 2000) to irradiate herbs, spices, nuts, oil seeds and teas. A full copy of the application can be obtained from the ANZFA website at [www.anzfa.gov.au](http://www.anzfa.gov.au)

The application was received from Steritech, an established Australian contract irradiation firm. The firm currently irradiates medical products, personal care goods, packaging materials, animal feeds, cosmetic ingredients and decorative household products that are potential carriers of quarantine pests or disease organisms.

The irradiation source to be used for the foods and food ingredients covered by this application will be Cobalt 60. However, should a permission be granted for this application the Australian Standard A17 – Irradiation of Food would allow two other sources of irradiation, x-rays and electrons from machine sources, also to be used.

The foods included in the application and the nominated dose levels and conditions are summarised at Appendix 1.

The application seeks permission to irradiate these foods to achieve specific food safety and technical requirements, namely:

- microbial decontamination;
- pest disinfestation; and
- prevention of sprouting and/or germination of food or weed seeds inadvertently present in food.

The applicant has claimed that this will enhance public health and safety by improving the quality of foods as part of Good Manufacturing Practice (GMP) and food hygiene procedures.

The applicant has proposed that irradiation of herbs, spices, nuts, oil seeds and teas offers the following benefits:

- **Benefits to industry**-the irradiation of the specific foods and ingredients will markedly improve safety of these products if incorporated into a Hazard Analysis and Critical Control Point (HACCP) system for food processors and exporters.
- **Reduction in use of chemical fumigants**-irradiation will decrease the need for use of several fumigants including ethylene oxide (ETO), propylene oxide, phosphine and methyl bromide.
- **Benefits to consumers**-consumers may benefit from foods and ingredients that are microbiologically cleaner and/or free from pests.

### **3. BACKGROUND INFORMATION**

#### **3.1 Standard A17 – Irradiation of Food**

The Australia New Zealand Food Standards Council approved Standard A17 – Food Irradiation for inclusion in the Australian Food Standards Code in the latter half of 1999. A copy of the Standard and details its application in Australia and New Zealand are at Appendix 2.

The Standard prohibits the irradiation or re-irradiation of food, ingredients or components of food unless express permission is given. Such permission, if given, will impose strict conditions in relation to dose, packaging materials and approved premises and facilities.

The Standard clearly specifies that food irradiation must NOT be a substitute for good manufacturing practices and it requires the labelling of food that has been irradiated.

The Standard outlines the purposes for which approval could be given i.e. to fulfill a technological need or for a food safety purpose. It also covers the operation and control of facilities, Codes of Practice, permitted sources of irradiation and the keeping of records.

#### **3.2 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 its 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 vegetable; and to prevent the sprouting of weeds and other seeds for quarantine purposes.

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 in this case 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 food that has deteriorated or is of inferior quality. Nor can it prevent contamination from improper handling after irradiation.

### **3.3 International Practice**

Internationally, there is a wide and increasing amount of legislation allowing the irradiation of certain foods or certain doses for all foods. Details of the standards and permissions for the use of herbs and spices by the Codex Alimentarius Commission, the European Union, Canada and the United States are at Appendix 4.

The International Consultative Group on Food Irradiation, in its October 1996 publication, listed 32 countries that allow the irradiation of herbs and spices or condiments.

More than forty countries currently approve the use of irradiation for food safety and other technological reasons, including to improve shelf life and to reduce sprouting of products, such as potatoes. Evidence indicates a trend to expand the use of irradiation of foods. The United States has approved the irradiation of red meat, poultry, fresh fruit, vegetables, herbs and spices, mostly to eliminate threats posed by human pathogenic organisms that may contaminate these commodities.

There are a number of factors influencing the expanding use of irradiation of food, including:

- consumer acceptance of the technology;
- a demand by consumers to reduce chemical residues in food;
- food security, especially in some developing countries and countries that experience large losses of food from spoilage organisms and pathogens; and
- increasing concerns about food borne illness and its impacts.

Figures provided by the International Atomic Energy Agency indicate that, in 1997, more than 200 000 tonnes of food was irradiated. This figure has increased to about 500 000 tonnes per annum in recent times. The volume of herbs and spices irradiated for food safety purposes rose from 5 000 tonnes in 1987 to 40 000 tonnes in 1995, with more than 80 000 tonnes irradiated in 1997. In the United States, about 30 000 tonnes of herbs and spices were irradiated in 1997.

## **4. PRELIMINARY ISSUES AND QUESTIONS**

This section of the Issues Paper is concerned with identifying some of the issues of importance to stakeholders in relation to the application and seeks further information and views from stakeholders about these or any other issues. ANZFA is also seeking data and comment on the potential regulatory impact should permission to irradiate herbs, spices nuts, oil seeds and teas be granted.



## 4.1 Safety of Irradiated Foods

There is a substantial amount of scientific literature, developed over the last forty years, to support the safety of food irradiation. The technology has been used in Australia and New Zealand for many years to sterilise medical products, bandages, dressings and cosmetic ingredients and for a range of quarantine purposes such as to prevent seeds sprouting and to kill pests in non-food products.

Scientific opinion currently suggests that food irradiated at levels to achieve the intended technological functions and in accordance with Good Manufacturing Practice is both safe and nutritionally adequate (WHO 1994, 1999).

Further details and references are at Appendix 5.

## 4.2 Nutritional Adequacy of Irradiated Foods

All food processes, such as heating, canning and freezing, cause nutrient loss, often to a greater extent than irradiation. While irradiation can cause changes in the nutritional content of foods, generally these changes are small. The macronutrients, carbohydrates, proteins and fats, undergo little change during irradiation even at doses over 10 kGy<sup>1</sup>. Similarly, minerals and most vitamins do not suffer significant losses. The view that irradiated foods are generally nutritionally equivalent or superior to non-irradiated foods subjected to normal processing is supported by many studies [WHO, 1994] [WHO, 1999].

There are four vitamins however that are recognised as being highly sensitive to irradiation: vitamin B1 (thiamin), vitamin C (ascorbic acid), vitamin A (retinol) and vitamin E ( $\alpha$  - tocopherol). In ascertaining the nutritional significance of vitamin losses induced by irradiation in this application, it is necessary to determine the contribution of herbs, spices, nuts, oil seeds and teas to total dietary intake of these nutrients.

Initial results from ANZFA's dietary modelling system, DIAMOND, reveal that herbs, spices and teas contribute only minimal amounts of irradiation sensitive nutrients to total nutrient intake and consequentially irradiation of these select foods would have minimal impact on overall dietary intake.

In comparison, nuts and oilseeds do contribute significant amounts of vitamin E to the diet.

However, the temperature at which food is irradiated, exposure to air, and storage conditions may all affect nutrient content. In many instances, low-temperature irradiation in the absence of oxygen helps to reduce any losses of vitamins in foods, and storage of irradiated foods in sealed packages at low temperatures also helps prevent further loss.

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<sup>1</sup> The Gray is the quantity of radiation energy absorbed by the food as it passes through the radiation field during processing. One gray equals one joule of energy absorbed per kilogram of food being irradiated. 1000 Gray = 1 kGy

*Further data and stakeholder comments are sought on this issue.*

### **4.3 Labelling**

Standard A17 (refer to Appendix 2 for details) requires all irradiated food to be labelled irrespective of how minor the ingredients.

Industry has raised concerns about the practical application of this requirement where there are very minor proportions of irradiated ingredients, e.g. herbs and spices, in the final product

However this labelling requirement is one that consumers strongly favour.

To vary this requirement in the Standard, a specific application would need to be made to amend the Standard.

*Comments are sought on this issue.*

### **4.4 Efficacy of Treatment**

The applicant has claimed that irradiation, at the doses commercially used for herbs and spices, is a more effective method to sanitise spices than ethylene oxide (ETO) treatments currently used. The applicant further claims that irradiation is often the only treatment effective in meeting standards set by processors operating under Hazard Analysis and Critical Control Points (HACCP) or International Standards Organization (ISO) Standards.

ANZFA will further explore this claim.

*Further data and comment is invited on the issue of efficacy of irradiation versus other treatments for the foods in question.*

### **4.5 Doses of Irradiation**

Standard A17 requires that the ionising radiation dose applied, for the purpose of irradiating food, should be the minimum that is reasonably consistent with the technological and public health purposes to be achieved. It also states that it should also be in accordance with good radiation processing practice.

The applicant has requested a range of minimum and maximum absorbed doses for particular products and technical purposes. However, the applicant has requested that maximum doses be published in the Standard but not lower doses, with the exception of use as a quarantine treatment.

In support of this request the applicant advised that the actual minimum will vary from product to product based on the product application and the technical need for processing. In the medical devices field, suppliers must validate their product and take responsibility for the stipulation of a minimum dose.

In radiation processing, the absorbed dose determines the desired effect. Dosimetry is the method of measuring the dose of energy absorbed by a product. An irradiation process is characterised by a minimum effective dose and a maximum dose that does not result in significant, or negative changes to a product. Dosimetry techniques and products are designed, tested, standardised and approved by physicists. These methods have been standardised world-wide (e.g. by the American Society for Testing Materials).

Before commercial irradiation of a product is performed, dose mapping must be conducted. This procedure involves (i) the determination of the density of the product; (ii) the positioning of many dosimeters in specified planes and positions; (iii) the use of routine and reference dosimeters calibrated to national standards; (iv) irradiation at the correct dose; and (v) reading of dosimeters. The results of dose mapping would form part of a record for a product to be irradiated, or part of a standard operating procedure.

*Further data and comment is sought on this matter.*

#### **4.6 Detection Methods**

There has been significant progress in detection methodology for irradiated food since the publication of the Australian House of Representatives report (HOR, 1989; FAO/IAEA, 1991;WHO, 1994) on food irradiation.

Several different detection methods for irradiated foodstuffs are currently being tested on various products and new methods are steadily emerging. These fall into three general categories – physical, chemical and biological. Because of the diversity of foodstuffs found in the diets around the world, no single irradiation detection method can be used universally.

*ANZFA seeks comment on the current method(s) that are the most suitable and practical for the detection of irradiated food, including the level of detection.*

#### **4.7 Irradiation Facilities**

During the development of Standard A17- Irradiated of Food, consumers expressed concern about the safety of irradiation facilities and the irradiation process. They wanted to know that such facilities are adequately regulated and would not pose safety concerns.

These facilities already exist in Australia and New Zealand and must be approved and licensed, a provision that includes personnel requirements for radiation safety and training requirements for operators and managers. The operation of irradiation facilities and control of the irradiation process is undertaken in accordance with the relevant State, Territory and New Zealand law governing radiation control.

Appropriate procedures for irradiation vary for different foods and facilities. Process control is critical to ensure that irradiated food is both safe and wholesome. In the event that the irradiation of specific food is permitted, Standard A17 suggests that applicants can be required to identify codes of Good Manufacturing Practice (GMP),

suitable to their facilities and the foods to be irradiated, to assure the safety of the product or to nominate relevant Codes of Practice.

In addition, Standard A17 – Irradiation of Food states that the operation of irradiation facilities and the control of the irradiation process should be undertaken in accordance with an appropriate Code of Practice such as the 1983 Codex Alimentarius General Standard for Irradiated Foods and its associated Code of Practice for the Operation of Irradiation Facilities Used for the Treatment of Foods, or an equivalent Code which delivers the same measure of safety (FAO, 1991c).

The applicant has suggested that they will irradiate products in accordance with published Standards and Codes of Good Irradiation Practice. The applicant will also use Hazard Analysis and Critical Control Point (HACCP) processing to plan and conduct the irradiation of foods covered by this application. The applicant also notifies the following Standards and Codes as pertinent to this application:

- Standard Guide for the Irradiation of Dried Spices, Herbs and Vegetable Seasonings to Control Pathogens and Other Microorganisms (ASTM Standard F 1885-98);
- Code of Good Irradiation Practice for Insect Disinfestation of Dried Fruits and Tree Nuts (1995);
- Code of Good Irradiation Practice for Sprout Inhibition of Bulbs and Tuber Crops (1991); and
- Code of Good Irradiation Practice for the Control of Pathogens and Other Microflora in Spices, Herbs and other Vegetable Seasonings (1991).

*Further data and comment are sought on this issue.*

#### **4.8 Regulatory issues**

Countries that approve the use of ionising radiation for food safety, phytosanitary and other purposes do so under various regulations covering, among other things, the treatment facility, the process and the applied doses. Regulations may also cover such matters as packaging and labelling. The Australian Standard A17 also addresses such matters. The purposes for such regulations are to:

- allay concerns of consumers who remain apprehensive about the use of ionising radiation of food;
- meet consumer requirements for irradiated food labelling to provide informed choice;
- meet the requirements of importing countries and other customers;
- ensure that treatments are applied in a safe manner; and
- ensure that applied treatments are within prescribed limits and are appropriate for the purpose for which the food is irradiated.

Because of technological difficulties in demonstrating that foods have been irradiated, most regulatory authorities require certification of the process, accompanied by documentation and a requirement to keep appropriate records. These records include full product identification and other information, such as dose (minimum and/or maximum depending on the regulations) and date of irradiation. Regulations may require the irradiation operator to provide certificates of irradiation with the product

documentation, such as shipping documents. Food inspection authorities have access to irradiation records at the irradiation facility, together with shipping and food production documents at food processing facilities.

#### **4.9 International obligations**

Australia and New Zealand are members of the World Trade Organization (WTO) and are bound as parties to WTO agreements. In Australia, an agreement developed by the Council of Australian Governments (COAG) requires States and Territories to be bound as parties to those WTO agreements to which the Commonwealth is a signatory. Under the agreement between the Governments of Australia and New Zealand on Joint Food Standards, ANZFA is required to ensure that food standards are consistent with the obligations of both countries as members of the WTO.

In certain circumstances Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comment. Notification is required in the case of any new or changed standards which may have a significant trade effect and which depart from the relevant international standard (or where no international standard exists).

As members of the WTO, Australia and New Zealand will be obliged to consider the use of irradiation where it facilitates trade by killing food borne pathogens and quarantine pests. The agreement removes the rights of member countries to arbitrarily restrict access to domestic markets on health and safety grounds and calls on members to harmonise sanitary and phytosanitary measures on a global basis by adopting international standards, guidelines and recommendations, where these exist. Scientific evidence must be provided if members wish to maintain SPS measures that are more restrictive than relevant international standards and measures should not discriminate between members.

In cases where irradiation removes quarantine pests and pathogens and there is no scientific evidence that the treatment poses a threat in terms of food safety, a member should not refuse the entry of commodities under existing WTO rules. Nor should a member discriminate in favour of one measure over another to achieve the same sanitary or phytosanitary goal. To do so invites lengthy and costly challenges before the WTO and the possibility of retaliation by our trading partners.

*Are there any comments you wish to make in relation to these obligations and changes to Standard A17 of the Australian Food Standards Code, should a permission be granted for this application?*

#### **4.10 Potential Regulatory Impacts**

The Authority will consider the regulatory impact of this application on all sectors of the community including consumers, the food industry and governments in both countries. The Regulatory Impact Statement (RIS) will identify and evaluate, though not be limited to, the costs and benefits of the regulation, and its health, economic and social impacts. In the course of assessing the regulatory impact, the Authority is guided by the *Australian Guide to Regulation* (Commonwealth of Australia 1997) and the *New Zealand Code of Good Regulatory Practice*.

As of 1 July 1998 all policy proposals which result in government bills or statutory regulations in New Zealand must also be accompanied by a RIS unless an exemption applies. This requirement replaces the previous compliance cost statement.

*To assist in this process, comment on potential impacts or issues pertaining to the regulatory or non-regulatory options are sought from all interested parties. Public submissions should clearly identify relevant impact(s) or issues and provide supporting documentation where possible.*

The remaining part of this Issues Paper raises some regulatory impact issues and questions. These questions are guided by specific requirements for the preparation of Regulatory Impact Statements.

*You are invited to address these or any other issues relevant to this application.*

### ***Identification of affected parties***

- Consumers of foods and food ingredients.
- Industry- food manufacturers, processors and growers, importers and irradiation facilities.
- 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.

### ***What are the problems this application seeks to address?***

The application seeks to address microbial contamination, pest infestation, and sprouting and/or germination of food or weed seeds inadvertently present in herbs, spices, nuts, oil seeds and teas.

The application seeks permission for irradiation of the food categories detailed above to enhance public health by improving food safety and to improve the quality of foods as part of GMP and food hygiene procedures.

It has been recognised that herbs and spices in particular may be contaminated with pathogenic bacteria and irradiation could be used to decrease this contamination.

*-How significant are these problems?*

*-What leads to these contaminations and infestations?*

*-Further data and comments are sought on this issue.*

### ***What are the present alternatives to irradiation?***

There are several alternative treatments for the decontamination or disinfestation of herbs, spices, nuts, oilseeds and teas. Irradiation may offer some advantages over the alternative treatments used to disinfest or disinfect these foods.

The chemical decontamination treatments used are ethylene oxide gas (ETO), propylene oxide (PO) and the physical decontamination treatment is steam. Chemical disinfestation treatments include methyl bromide (MeBr) and phosphine; whereas, the physical disinfestation treatments are heat, cold and modified or controlled atmospheres.

Each of these treatments has advantages and disadvantages. However, not every treatment is compatible with every commodity.

*Data and comment is sought on the alternative treatments available and any benefits or otherwise irradiation may offer as a treatment option.*

***What are the regulatory (or non regulatory) options?***

In this particular case, a regulatory Standard exists under which approval may be given under certain circumstances. The options are:

1. To approve irradiation of these products under prescribed conditions where there is a technological or food safety need; or
2. To rely on existing approved methods to decontaminate, disinfest and stop sprouting, seed and weed germination

Some additional regulatory impact questions are posed below:

***What are the potential costs or benefits of this application to you as a stakeholder? Do the benefits outweigh the costs?***

*-What are the costs or benefits for consumers in relation to public health and safety, consumer information and labelling, costs, savings, food quality etc?*

*-What are the costs or benefits for business- compliance, reporting, costs, savings, alternative technologies, improved food safety and quality, trade etc?*

*-What are the costs or benefits for government – administration, enforcement, public health and safety etc?*

Can you provide any evidence with your response to support your statements about the costs and benefits? If so, please attach.

***How will the potential conditions imposed on this application (e.g. products, dose, labelling requirements etc) affect current policy or existing regulations and/or enforcement issues?***

***Are there implications for overseas regulators?***

***Are there effects on trade, import/export levels?***

While this Issues Paper has attempted to identify issues and questions relating to the application, these may not be a comprehensive range of issues and you are free to comment on any other matter relating to the application.

## APPENDIX I

### Application A413 – Foods, Doses and Conditions

Food	Minimum and Maximum Dose (kGy)	Conditions
<p><u>Nuts</u> – includes the category described in Standard A-14, Schedule 3 and also peanuts (ground nuts)</p>	<ul style="list-style-type: none"> <li>• Minimum dose of 0.2 kGy<sup>2</sup> to control sprouting</li> <li>• Minimum dose of 0.3 kGy for disinfestation</li> <li>• Minimum dose for decontamination 2 kGy</li> <li>• Minimum dose for control of weeds 3 kGy</li> <li>• Maximum dose 10 kGy.</li> </ul>	<p>Food to be handled before and after irradiation according to good manufacturing practice (GMP)</p>
<p><u>Oilseeds</u> – a category described in Standard A-14, Schedule 3</p>	<ul style="list-style-type: none"> <li>• Minimum dose of 0.2 kGy to control sprouting</li> <li>• Minimum dose of 0.3 kGy for disinfestation</li> <li>• Minimum dose for decontamination 2 kGy</li> <li>• Minimum dose for control of weeds 3 kGy</li> <li>• Maximum dose 10 kGy.</li> </ul>	<p>Food to be handled before and after irradiation according to good manufacturing practice (GMP)</p>
<p><u>Herbs and Spices</u> – a category described in Standard A-14, Schedule 3 and including: fresh, dry or dehydrated herbs, spices and vegetable seasonings used for flavour, aroma, texture or colour or for their other properties. Other than being 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). 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 spice blends.</p>	<ul style="list-style-type: none"> <li>• Minimum dose of 0.2 kGy to control sprouting</li> <li>• Minimum dose of 0.3 kGy for disinfestation</li> <li>• Minimum dose for decontamination 2 kGy</li> <li>• Minimum dose for control of weeds 3 kGy</li> <li>• Maximum dose 30 kGy.</li> </ul>	<p>Food to be handled before and after irradiation according to good manufacturing practice (GMP)</p> <p style="text-align: right;"><i>(continues – next page)</i></p>

<sup>2</sup> The Gray is the quantity of radiation energy absorbed by the food as it passes through the radiation field during processing. One gray equals one joule of energy absorbed per kilogram of food being irradiated. 1000 Gray=1 kGy.



<b>Food</b>	<b>Minimum and Maximum Dose (kGy)</b>	<b>Conditions</b>
<p>Tea a category defined in Standard A-14, 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.</p>	<ul style="list-style-type: none"> <li>• Minimum dose of 0.3 kGy for disinfestation</li> <li>• Minimum dose for decontamination 2 kGy</li> <li>• Minimum dose for control of weeds 3 kGy</li> <li>• Maximum dose 30 kGy.</li> </ul>	<p>Food to be handled before and after irradiation according to good manufacturing practice.</p>

## Standard A17 and its Application in Australia and New Zealand

The development of the Standard followed an extensive and detailed process of public consultation and commissioning of reports and inquiries from a period beginning in the mid 1980s and culminating in the decision by Health Ministers in 1999 on a final Standard. A summary of the milestones in the development of the Standard is at Appendix 3.

### *Australia*

The standard applies very strict controls on the irradiation of food and requires applications to be made to ANZFA for permission to irradiate food. Permission to irradiate specific foods will be considered on a case-by-case basis by ANZFA and must have final approval by the Australia New Zealand Foods Standard Council.

### *New Zealand*

In New Zealand irradiated food can be sold either under the Australian Food Standards Code (AFSC) or the New Zealand Food Regulations 1984. If sold under the AFSC the same conditions apply as described for Australia above.

Regulation 264 (1) of the New Zealand Food Regulations 1984 states:

"Subject to subclause (2) of this regulation, no person shall sell any food that has been treated by ionising radiation unless the treatment is for the time being approved for that purpose by the Minister.

(2) No ministerial approval is required where the dose of radiation does not exceed 0.5 kGy".

It is New Zealand Government policy that irradiated food is allowed to be sold in New Zealand, so long as it has been assessed as safe by ANZFA and approved by the Australian New Zealand Food Standards Council (ANZFSC).

### *Proposed Joint Australia New Zealand Food Standards Code*

Under the proposed new Joint Australia New Zealand Food Standards Code, to be considered by ANZFSC later this year there is a proposal to insert a standard identical to the Standard A17 – Irradiated Foods as per the current Australian Food Standards Code.

## **STANDARD A17**

### ***IRRADIATION OF FOOD***

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#### **Purpose**

This 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.

Even where this Standard permits irradiation, food should only be processed by irradiation where such processing fulfils a technological need or is necessary for a purpose associated with food safety. Food should not be processed by irradiation as a substituted procedure for good manufacturing practices.

The absorbed radiation dose applied for the purpose of irradiating food should be the minimum that is reasonably commensurate with the technological and public health purposes to be achieved. It should also be in accordance with good radiation processing practice.

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

The operation of irradiation facilities and control of the irradiation process should be undertaken in accordance with any relevant State, and Territory, and New Zealand law governing radiation control. They should also be undertaken in accordance with an appropriate Code of Practice such as the 1983 Codex Alimentarius General Standard for Irradiated Foods and its associated Code of Practice for the Operation of Irradiation Facilities Used for the Treatment of Foods.

This Standard also sets out permitted sources of radiation, requires the keeping of certain records in relation to the irradiation of food, and requires the labelling of food, which has been irradiated.

#### **Table of Provisions**

1. Definitions
2. General prohibition on irradiation of food
3. Permitted sources of radiation
4. Foods permitted to be irradiated
5. Record keeping
6. Labelling

#### **Clauses**

## 1. Definitions

In this Standard –

**irradiation** means the processing of food by subjecting it to the action of ionising radiation, but does not include ionising radiation imparted to food by measuring or inspection instruments, and ‘irradiate’ and ‘irradiated’ have corresponding meanings.

**re-irradiate** does not include the irradiation of food -

- (a) prepared from materials that have been irradiated at low dose levels (not exceeding in any case 1 kGy) and are irradiated again; or
- (b) which contains less than 50 g/kg of irradiated ingredients; or
- (c) where the required full dose of ionising radiation is applied to the food in divided doses for a specific technological reason;

provided that the cumulative maximum radiation dose absorbed by the food does not exceed that specified in the Table to clause 4.

**technological need**, in relation to the irradiation of food, refers to the minimum dose of ionising irradiation required to ensure the safety or quality of the food, provided the process is performed in accordance with good manufacturing practice, and includes the extension of shelf life, the destruction of certain bacteriological contamination or pest disinfestation.

## 2. General prohibition on irradiation of food

- (1) Food must not be irradiated unless there is a specific permission in this Standard to irradiate the food.
- (2) A permission to irradiate a food is not a permission to re-irradiate the food unless re-irradiation is expressly permitted by this Standard.

## 3. Permitted sources of radiation

Where this Standard permits a food to be irradiated, the ionising radiation must be either -

- (a) gamma rays from the radionuclide cobalt 60; or
- (b) X-rays generated by or from machine sources operated at an energy level not exceeding 5 megaelectronvolts; or
- (c) electrons generated by or from machine sources operated at an energy level not exceeding 10 megaelectronvolts.

#### 4. Foods permitted to be irradiated

(1) Subject to subclause (2), a food listed in column 1 of the Table to this clause may be irradiated, provided that-

- (a) the absorbed dose of radiation is not below the minimum dose value or above the maximum dose value specified in column 2 of the Table to this clause; and
- (b) the conditions specified in column 3 of the Table to this clause, if any, are met.

A food listed in column 1 of the Table to this clause may only be processed by irradiation where such processing –

- (a) fulfills a technological need; or
- (b) is necessary for a purpose associated with food hygiene;

and such processing is not a substitute procedure for good manufacturing practice.

**Table to clause 4**

Column 1	Column 2	Column 3
Food	Minimum and Maximum Dose (kGy)	Conditions
no entries		

**Editorial note:**

The conditions imposed in column 3 will be those necessary to ensure that the purpose of the standard is achieved. They might relate to matters such as packaging materials used throughout processing and subsequent handling, requirements relating to facilities and premises, and particular operating procedures.

#### 5. Record keeping

- (1) Records must be kept at a facility where food is irradiated in relation to -
- (a) the nature and quantity of the food treated;
  - (b) lot identification;
  - (c) the minimum durable life of the food treated;
  - (d) the process used;
  - (e) compliance with the process used;
  - (f) the minimum and maximum dose absorbed by the food;
  - (g) an indication whether or not the product has been irradiated previously and if so, details of such treatment;
  - (h) date of irradiation.

(2) The records required to be kept by subclause (1) must be kept for a period of time that exceeds the minimum durable life of the irradiated food by 1 year.

## 6. Labelling

(1) The label on or attached to a package containing a food that has been processed by ionising radiation must include a statement that the food has been treated with ionising radiation.

Examples:

‘TREATED WITH IONISING RADIATION’

‘TREATED WITH IONISING ELECTRONS’

‘IRRADIATED (name of food)’

(2) If a food contains an irradiated food as an ingredient or component, the label on or attached to a package containing the food must include a statement that the ingredient or component has been treated with ionising radiation, either as part of the declaration of that ingredient or component in an ingredient list or elsewhere on the label.

(3) Where an irradiated food, or a food containing an irradiated food as an ingredient or component, is displayed for retail sale otherwise than in a package, there must be displayed on or in connection with the display of the food a label containing a statement that the food has been treated with ionising radiation, or that it contains an ingredient or component that has been treated with ionising radiation, as the case may be.

(4) Where an irradiated food is sold other than for retail sale, the food must be labelled with -

- (a) a statement that the food has been irradiated;
- (b) the minimum and maximum dose of the irradiation;
- (c) the identity of the facility where the food was irradiated;  
and
- (d) the date or dates of irradiation.

**Editorial Note:**

Clause (2C) of Standard A1 permits this information to be provided in accompanying documentation rather than necessarily being on the label.

## APPENDIX 3

### SUMMARY OF MILESTONES IN THE DEVELOPMENT OF STANDARD A17 – IRRADIATION OF FOODS

Some of the milestones in the development of Standard A17-Irradiated Foods are summarized below:

- A draft Australian National Health and Medical Research Council standard (1986).
- Australian Consumers' Association Inquiry – commissioned by the Minister for Health (1987).
- The *Use of Ionising Radiation* report prepared by the Australian House of Representatives Standing Committee on Environment, Recreation and the Arts in 1989. It recognised the need for a uniform national standard to regulate the sale of irradiated food in Australia
- The Committee foreshadowed the possibility of food irradiation being approved in specific circumstances and recommended criteria to be included in the standard to control the process in this event.
- ANZFA first prepared a proposal (P89B) to develop a standard for irradiated food in October 1992. After an extensive public consultation period, the Authority completed the full assessment of the proposal and prepared a draft standard in August 1995. The draft standard was released for public comment in Australia in November-December 1995.
- WHO Review of the Safety and Nutritional Adequacy of Irradiated Foods – commissioned by the Department of Health (1994)?
- ANZFA finalized its inquiry on the draft standard and for that purpose sought public comment in New Zealand (26 January to 26 March 1999) in order to ensure New Zealand views were taken into account.
- The Australia New Zealand Food Standards Council approved the Standard for food irradiation on 3 August 1999.

## APPENDIX 4

### International Practice – Irradiation of Herbs & Spices

#### *The Codex Alimentarius Commission*

The 1983 Codex General Standard for Irradiated foods sets a maximum overall dose of 10 kGy.

No specific foods are mentioned, although the standards states:

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

(The Codex Alimentarius is a collection of internationally adopted food standards).

#### *European Union*

The European Directive on food irradiation have been recently published as Directives 1999/2/EC and Directive 1999/3/EC of the European Parliament. It features a positive list which includes ‘dried aromatic herbs, spices and vegetable seasonings’ that may be irradiated up to an overall average absorbed dose of 10 kGy. Outside of this group of foods, member states maintain existing authorisations and prohibitions.

#### *Canada*

In Canada, the irradiation of spices, herbs and dry vegetable seasonings is approved to a maximum dose of 10kGy. Herbs and spices are irradiated in commercially significant quantities in Canada.

#### *USA*

Herbs, spices and vegetable seasonings are allowed to be irradiated to a maximum dose of 30 kGy. About 90 million lbs of herbs, spices and vegetable seasonings are irradiated in the USA each year.

The USA Food and Drug Administration approved irradiation of meat products for controlling disease-causing micro-organisms on 3 December 1997. The approval applies to fresh and frozen red meats such as beef, lamb and pork.



## APPENDIX 5

### International Reviews and Scientific References

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

The WHO (1994) 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 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 abuses of other processing methods, such as canning, freezing and pasteurisation.'*

More recently a Joint Food and Agriculture Organization (FAO)/International Atomic Energy Agency (IAEA) /World Health Organization (WHO) expert committee examined the wholesomeness, safety and nutritional adequacy of irradiated food (WHO 1999) at doses above 10 kGy. Some current applications of irradiated food above 10kGy include the development of high quality shelf-stable convenience foods for general use and for specific target groups such as immunosuppressed individuals and those under medical care. Such shelf –stable foods have also been used by astronauts, military personnel and outdoor enthusiasts in some countries.

The WHO (1999) report concluded that:

*'Food irradiated to any dose appropriate to achieve the technological objective is both safe to consume and nutritionally adequate. This conclusion is based on extensive scientific evidence that this preservation process can be used effectively to eliminate spores of proteolytic strains of Clostridium botulinum and all spoilage micro organisms, that it does not compromise the nutritional value of foods and that it does not result in any toxicological hazard.'*

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

#### *Microbiological safety and food spoilage issues*

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).

The WHO (1999) report noted the presence of pathogenic micro organisms such as *Salmonella* species, *Escherichia coli* 0157:H7, *Listeria monocytogenes* or *Yersinia enterocolitica*, is a growing concern to public health authorities all over the world. Irradiation is used as one of the methods to reduce or eliminate those risks.

The report also noted that at high doses irradiation is permitted to sterilize food for immuno-compromised patients in hospitals in a number of countries e.g. the Netherlands and UK.

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**Further Reading**

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## APPENDIX 6

### FOOD STANDARDS SETTING IN AUSTRALIA AND NEW ZEALAND

The Governments of Australia and New Zealand entered into an Agreement in December 1995 establishing a system for the development of joint food standards. The Australia New Zealand Food Authority is now developing a joint *Australia New Zealand Food Standards Code* which will provide compositional and labelling standards for food in both Australia and New Zealand.

Until the joint *Australia New Zealand Food Standards Code* is finalised the following arrangements for the two countries apply:

- **Food imported into New Zealand other than from Australia** must comply with either the Australian *Food Standards Code*, as gazetted in New Zealand, or the New Zealand *Food Regulations 1984*, but not a combination of both. However, in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the New Zealand *Food Regulations 1984*.
- **Food imported into Australia other than from New Zealand** must comply solely with the Australian *Food Standards Code*.
- **Food imported into New Zealand from Australia** must comply with either the Australian *Food Standards Code*, as gazetted in New Zealand, or the New Zealand *Food Regulations 1984*, but not a combination of both.
- **Food imported into Australia from New Zealand** must comply with the Australian *Food Standards Code*. 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 for most products comply solely with the Australian *Food Standards Code*.

In addition to the above, 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* and *Food 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 Australian *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*.

ANZFA has the following objectives (in descending order of priority) in developing food regulatory measures:

- the protection of public health and safety; and
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

ANZFA must have regard to the following factors when developing food regulatory measures:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry; and
- the promotion of fair trading in food.