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26 June 2002

DRAFT ASSESSMENT REPORT
(FULL ASSESSMENT – S. 15)

APPLICATION A443

IRRADIATION OF TROPICAL FRUITS BREADFRUIT, CARAMBOLA, CUSTARD APPLE, LITCHI, LONGAN, MANGO, MANGOSTEEN, PAPAYA AND RAMBUTAN.

DEADLINE FOR PUBLIC SUBMISSIONS to the Authority in relation to this matter:
7 AUGUST 2002
(See "Invitation for Public Submissions" for details)

THE AUSTRALIA NEW ZEALAND FOOD AUTHORITY

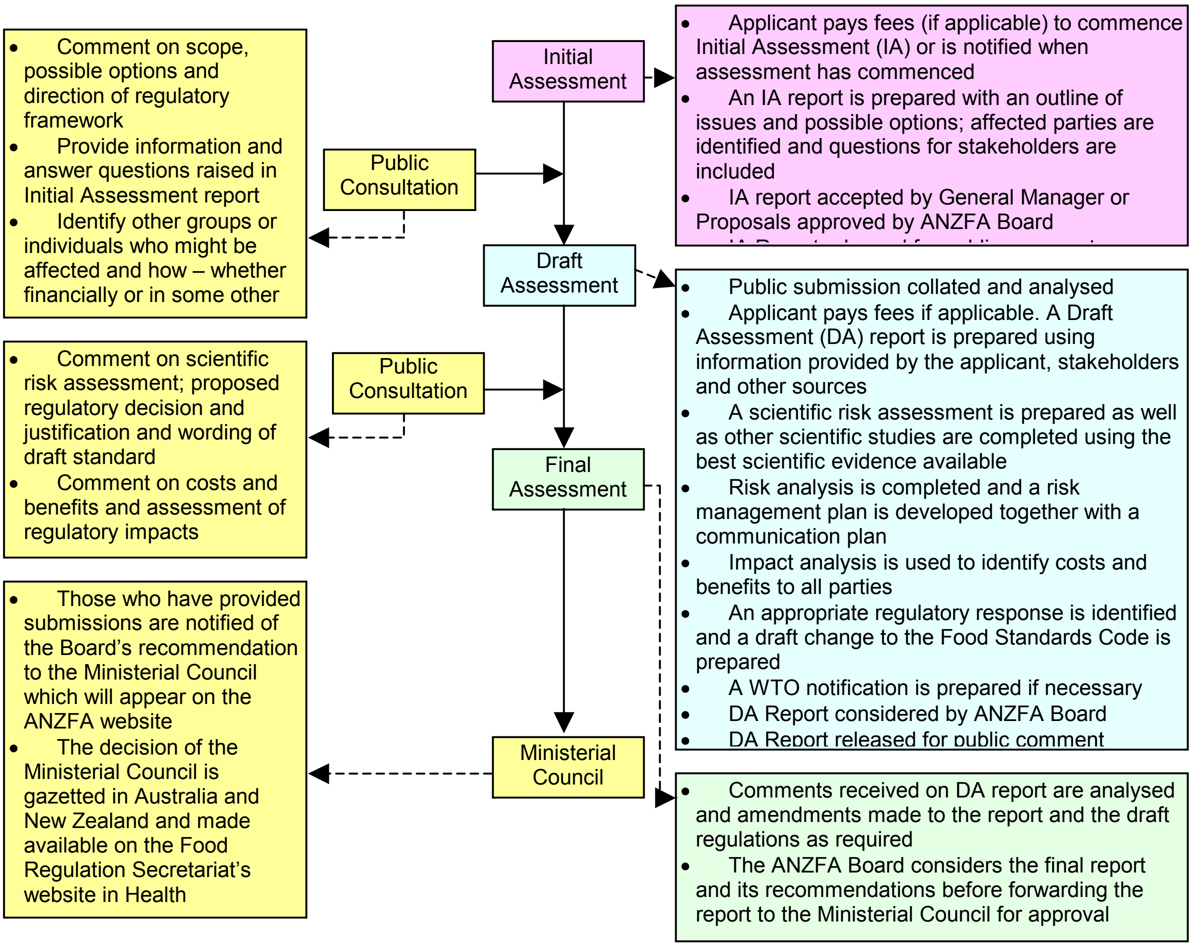
The Australia New Zealand Food Authority's (ANZFA) is a partnership between the Commonwealth Government, Australian State and Territory governments and the New Zealand Government. ANZFA is a bi-national, statutory body whose role, in association with others, is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply.

ANZFA seeks to achieve this goal by developing, varying and reviewing standards for food available for sale in Australia and New Zealand and through a range of other functions including national food surveillance and recall systems, conducting research, assessing policies about imported food and developing codes of practice with industry.

In developing and reviewing food standards for both Australia and New Zealand, ANZFA makes recommendations to change the food standards to the Australia New Zealand Food Standards Council, a Ministerial Council made up of Commonwealth, State and Territory and New Zealand Health Ministers. If the Council approves the recommendations made by ANZFA, the food standards are automatically adopted as regulations into the food laws of the Australian States and Territories and New Zealand.

STEPS IN DEVELOPING AND REVIEWING FOOD STANDARDS

The process for amending the *Australia New Zealand Food Standards Code* is prescribed in the *Australia New Zealand Food Authority Act 1991* (ANZFA Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



INVITATION FOR PUBLIC SUBMISSIONS

The Authority has made a Draft Assessment on Application A443 (referred to as the 'Full Assessment' in section 15 of the *Australia New Zealand Food Authority Act 1991*, which includes: a Draft Assessment; and draft variation to Volume 1 and 2 of the *Food Standards Code.* The Authority will hold a Final assessment (referred to as 'Inquiry' in section 17 of the *Australia New Zealand Food Authority Act 1991*).

The Authority invites public comment on the: Draft Assessment, the draft variation to Volume 1 and 2 of the *Food Standards Code;* and the Regulatory Impact Assessment for the purpose of preparing a Final assessment (referred to as the 'Inquiry' under section 17 of the Act).

Written submissions containing technical or other relevant information that will assist the Authority in preparing the Final assessment for this application are invited from interested individuals and organisations. Technical information presented should be in sufficient detail to allow independent scientific assessment.

Submissions providing more general comment and opinion are also invited. The Authority's policy on the management of submissions is available from the Standards Liaison Officer upon request.

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 inspection. If you wish any information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it as commercial-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.

Submissions must be made in writing and should clearly be marked with the "Submission" and quote the correct project number and name. Submissions may be sent to 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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Submissions should be received by the Authority by: 7 AUGUST 2002.
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. Requests for more general information on the Authority can be directed to the Information Officer at the above addresses.

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EXECUTIVE SUMMARY

The Australia New Zealand Food Authority (ANZFA) received an application on 28 May 2001 from Surebeam Australia Pty Ltd to amend Standard 1.5.3-Food Irradiation to permit the treatment of specified tropical fruits (breadfruit, carambola, custard apple, litchi, longan, mango, mangosteen, papaya and rambutan) with machine sourced electron beams or x-rays as a phytosanitary measure[1] within the dose range of 150 Gy (minimum) to 1 kGy (maximum). The Applicant stated that approval of irradiation for the above tropical fruits would provide an alternative treatment to existing techniques (such as chemical treatments) and facilitate access to New Zealand markets for Australian tropical fruit growers.

Regulatory Problem

The sale of irradiated foods in Australia and New Zealand (under Standards A17/1.5.3 - Irradiation of Food) is prohibited unless the food is listed in the Table to clause 4 of the Standards. There is currently no permission to irradiate tropical fruits in Standards A17/1.5.3.

Objective

To determine whether the food regulations can be changed to permit the sale of irradiated tropical fruits. Such an amendment needs to be consistent with the section 10 objectives of the ANZFA Act.

Background

This is the second application to ANZFA to amend the *Food Standards Code* to permit the irradiation of food. ANZFA previously considered an application to irradiate herbs, spices, herbal infusions, peanuts, cashew nuts, almonds and pistachio nuts for food safety and quarantine purposes. Permission was granted by the Australian New Zealand Food Standards Council (ANZFSC) to treat herbs, spices and herbal infusions only.

Seven countries, including the USA and UK, approve the use of irradiation as a phytosanitary treatment for all fruits. In addition, another 8 countries approve the use of irradiation as a phytosanitary treatment for some of the tropical fruits, which are the subject of this application.

Issues considered during assessment of the application

A range of issues were considered during the assessment of the application; namely, the safety, nutritional impact, technological need and the need for labelling of irradiated tropical fruits. Other issues such as the provision of information for consumers about irradiated food, the quality of irradiated food, the benefits to industry, and import and export issues were also addressed.

[1] A Phytosanitary measure includes treatment that is applied in order to prevent the introduction and establishment of pests from one area to another. They are often applied as a quarantine measure. A phytosanitary measure may also be applied in respect of specific diseases.

It was considered that there is a valid technological need to use either electron beams or x-rays to treat the specified tropical fruits for the purpose of pest disinfestation for either the fruit fly or other critical pests that may be of quarantine significance.

The available studies on fruits indicate that there are no safety concerns and there are no new compounds formed following irradiation of tropical fruits that are likely to cause public health and safety concerns. The overall conclusion is that irradiation of tropical fruits up to a maximum of 1 kGy employing Good Manufacturing/Irradiation Practices is safe for Australian and New Zealand consumers.

The nutritional analysis and dietary intake assessment performed established that irradiation would have minimal impact on the nutrient status of the tropical fruits. The tropical fruits proposed to be irradiated are minor contributors to the total dietary intakes of β-carotene, folate vitamin C and Vitamin B1 when considered in the context of the overall diet.

In accordance with Standards A17/1.5.3, irradiated tropical fruits will be required to be labelled to give consumers an informed choices in purchase of these fruits. Some reductions in textural quality of the fruit can occur with increasing doses of irradiation.

There are benefits for both industry and consumers in the approval of irradiation of tropical fruits, although it is recognised that there still needs to be further public education and information programs on the safety and benefits of irradiating food.

Options

ANZFA identified two options, namely:

1. Not to permit the irradiation of tropical fruits; or

2. Permit the irradiation of tropical where there is a technological need and the process does not compromise the safety and nutritional adequacy of the fruits. Prescribed conditions would include adherence to Good Agricultural Practice, Good Radiation Practices and a minimum dose of 150 Gy and a maximum dose of 1kGy

Impact analysis

The impact analysis shows that **option 2** satisfies the objectives based on the outcome of the scientific risk assessment and the Regulatory Impact Statement (RIS) taking into account all matters raised following the public consultation period. These matters included an assurance of the safety and wholesomeness of irradiated tropical fruits, the provision of adequate labelling so as to give consumers informed choices for purchases of irradiated tropical fruits, the provision of benefits to industry and Governments, in terms of enhanced market opportunities and trade (under Australia and New Zealand's requirements under the World Trade Organization), respectively, and in addition, the benefits to consumers in regard to possible greater seasonal availability of fruits.

Any permission in the *Food Standards Code* would permit irradiated foods to be lawfully sold on the Australian and New Zealand markets. It should be noted, however, that for imported foods, the relevant authorities must assess and approve irradiation as an acceptable phytosanitary measure for quarantine purposes on a case-by-case basis.

Consultation

There are many parties affected by the application and ANZFA has consulted widely on the advantages and disadvantages to specific stakeholders should permission be granted to irradiate the specific tropical fruits and evaluated the costs and benefits to consumers, the Government and industry.

Statement of Reasons

ANZFA recommends the approval of Application A443 for the following reasons:

- there is no evidence of any public health and safety concern associated with consumption of irradiated tropical fruits and there are no significant nutritional losses of vitamins and minerals in the context of total dietary intakes at a dose of up to 1kGy;

- a specific technological need (pest disinfestation) has been shown to exist and a minimum dose of 150Gy and a maximum dose of 1kGy is considered to be an appropriate dose range to control the range of pests of likely concern. This has been confirmed by quarantine officials in Australia and New Zealand;

- mandatory labelling statements are required to ensure that consumers are informed that the food has been irradiated.

- the proposed changes to Volume 1 and 2 of the *Food Standards Code* are consistent with the section 10 objectives of the *Australia New Zealand Food Authority Act 1991*.

- the Regulatory Impact Statement indicates that, for the preferred option, namely, to approve the use of irradiation on tropical fruits, the benefits of the proposed amendment outweigh the costs.

It is recommended that approval be subject to the following conditions:

- Approval is granted for the tropical fruits requested in the application.

- Approval be granted for control of fruits fly pests and other quarantine pests with a minimum dose of 150 Gy and maximum dose of 1 kGy.

- 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 amendments to Standards A17/1.5.3 is at Attachment 1 of the Draft Assessment Report.

1. Introduction

An Application was received on 28 May 2002 from Surebeam Australia Pty Ltd to amend Standard 1.5.3-Food Irradiation to permit the treatment of specified tropical fruits with machine sourced electron beams or x-rays as a phytosanitary measure. A phytosanitary measure specifically refers to 'pest disinfestation' under the definition of a technological need (below) in Standards A17/1.5.3 - Irradiation of Food.

The aim is to have available an effective technique that will reduce or alleviate pest infestation in selected tropical fruits. The Applicant argued, in part, that such permissions would facilitate trade and market access (particularly New Zealand).

ANZFA, in assessing this Application, has considered the matter in the context of Standards A17/1.5.3 and its statutory objectives.

ANZFA notes that the *Food Standards Code* applies to food that is produced and sold on the Australian and New Zealand markets, but not to food that is for export. It does, however, have implications for the movement of food between the two countries, though it does not obviate the need for other requirements, such as quarantine requirements, to be met.

2. Regulatory Problem

Standards A17/1.5.3 prohibit the sale of irradiated foods in Australia and New Zealand unless the food is listed in the Table to clause 4 in the Standard. Irradiated foods are required to undergo a pre-market assessment before they can be sold in Australia or New Zealand. The key requirements of the standards are that the irradiated foods should be safe, nutritionally adequate and that there should be a technological need[2] for the irradiation process. The purpose of this Application is for ANZFA to consider whether there is justification in providing an exemption for the tropical fruits under the requirements of Standards A17/1.5.3 and the ANZFA Act (below).

3. Objectives

To determine whether the food regulations can be changed to permit the sale of irradiated tropical fruits. Such an amendment needs to be consistent with the section 10 objectives of the ANZFA Act.

The objectives in the *Australia New Zealand Food Authority Act 1991* (section 10 objectives of ANZFA) are:

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

[2] Technological need, in relation to irradiation of food, refers to the minimum dose of ionising irradiation required to ensure the safety or quality of 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 (Standard 1.5.3, Clause 1, Definitions).

In developing and varying such measures, ANZFA must also have regard to:

- 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.

The specific objectives for this application are:

- to determine that irradiating the tropical fruits is safe for consumers and that there is no diminished nutritional value following irradiation, ie, the food is wholesome;

- to determine that a technological need exists to irradiate tropical fruits and that the technique is efficacious in meeting that technological need (in this case pest disinfestation);

- to determine the conditions under which irradiation is permitted (e.g., minimum and maximum doses)

- to determine whether any additional labelling requirements are needed for irradiated tropical fruits in order that consumers may make an informed choice; and,

- to ensure that ANZFA considers alignment with any other international standards under its World Trade Organization (WTO) obligations.

4. Background

Standard A17 - Irradiation of Food in Volume 1 of the *Food Standards Code* came into effect on 2 September 1999. It was replicated in Volume 2 of the *Food Standards Code* as Standard 1.5.3.

The key provisions of Standards A17/1.5.3 are:

- prohibition on the irradiation of food, or ingredients or components of food, unless a specific permission is given. This consideration is on a case-by-case basis;

- irradiation of food is only permitted where it fulfils a technological need or is necessary for a purpose associated with food hygiene;

- irradiation of food is not a substitute procedure for good manufacturing practices; and

- specification of the permitted sources of ionising radiation, listing of minimum and maximum doses, requirements for the keeping of certain records in relation to the irradiation of food, and requirements for the labelling of food which has been irradiated.

4.1 Background to the intent of the current application

An application has been received from Surebeam Australia Pty Ltd to amend Standard 1.5.3-Food Irradiation to permit the treatment of specified tropical fruits with machine sourced e beams or x-rays as a phytosanitary measure.

The intent of the Application under Standards A17/1.5.3 is to have available an effective measure in order that disinfestation of pests of quarantine significance can be achieved on specific tropical fruits.

The Applicant has stated in the application that a range of treatments are currently available for use on tropical fruits:

- *Post harvest chemicals*-such as dimethoate, fenthion and methyl bromide. However, these treatments either do not meet New Zealand Quarantine requirements or are under review for public health and safety reasons (eg occupational health or environmental concerns);

- *Heat Treatments*-hot air or hot water at specified temperature and time is currently approved for mango and papaya for some Australian interstate trade. However, heat treatments do not meet requirements New Zealand Quarantine requirements and product losses and costs are high under Australian conditions;

- *Cold treatment*-is not an economical measure because of product damage and high costs under Australian conditions;

- *Maturity standards* - i.e. relatively less mature or unripe fruit less attractive or 'non host' to critical quarantine pests is an option for papaya. However, the fruit is less mature and ripe, flavour is not well developed and the treatment does not meet New Zealand Quarantine requirements; and

- *Unbroken skin*-for fruits such as litchi, longan, rambutan and mangosteen. However, this does not meet New Zealand Quarantine requirements

During the periods 26 June to 23 August 2001 and from 21 December 2001 to 11 February 2002 further information was sought from the Applicant on:

- An appropriate minimum dose to achieve the technological purpose of pest disinfestations and the efficacy of the irradiation treatment for this technological purpose at a maximum dose of 1 kGy;

- Toxicological studies on irradiated foods (specifically fruits) and dietary exposure and nutritional data; and

- The range of countries that currently irradiate tropical fruits for the purpose of pest disinfestations.

The Applicant advised ANZFA on 7 February 2002 that they wished to amend the application to delete the reference to "As specified by a relevant plant quarantine authority as a phytosanitary measure' in the original application and throughout the text of the application; and, consequently insert a minimum dose of 150 Gy.

The revised Application is as follows:

Column 1	Column 2	Column 3
Food	**Minimum and Maximum Dose (kGy)**	**Conditions**
Fruits Breadfruit Carambola Custard Apple Longan Litchi Mango Mangosteen Papaya Rambutan.	Minimum dose: 150 Gy Maximum dose: 1 kGy	Fruit to be treated should be of good overall quality and reflect the results of Good Agricultural Practice (GAP) Recommended handling and storage procedures should be used prior to and after treatment

4.2 Approval to irradiate tropical fruits in other countries

4.2.1 Codex

The 1983 Codex standard for irradiated foods sets a maximum overall dose of 10 kGy.

No specific foods are mentioned, although the standard states:

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

This Standard is currently undergoing a review with a view to removing the maximum level of 10 kGy. This was last considered at the 34th meeting of the Codex Committee on Food Additives and Contaminants (CCFAC), March 2002. The decision was deferred for further consideration at the next meeting of CCFAC in 2003.

4.2.2 Other Countries

Seven countries, including the USA and UK, approve the use of irradiation as a phytosanitary treatment for all fruits. In addition, another 8 countries approve the use of irradiation as a phytosanitary treatment for some of the tropical fruits proposed to be irradiated in this application (**Attachment 6**).

The United States Department of Agriculture (USDA) currently approves the use of irradiation on the following tropical fruits from Hawaii to the US mainland at a maximum dose of 0.25 kGy[3] for control of pests (Melon fly, Mediterranean fruit fly, Oriental fruit fly, Malaysian fruit fly) in:

Abui
Custard Apple
Carambola
Longan
Litchi
Papaya rambutan
Sapodilla

Approvals are anticipated from the USDA to permit the treatment of breadfruit, jackfruit, mango and mangosteen. In May 2000, the USDA proposed a rule on irradiation that will establish a treatment of between 0.15-.250 kGy for 11 species of fruit fly and a treatment of 0.1 kGy for mango seed weevil regardless of host.

A Supplement to that rule was issued by the USDA on 15 March 2002 proposing additional requirements; namely, the use of radiation indicators and additional inspection and monitoring of irradiation facilities. A final ruling is now anticipated in June 2002.

In the USA, the Food and Drug Administration (USFDA) do not prohibit irradiation as a treatment and have similar rules to Australia and New Zealand in that irradiated food must be labelled and that irradiation is not a substitute for Good Manufacturing Practice (GMP) and good hygienic practices.

4.3 Previous irradiation Application (A413)

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. The Application sought to achieve certain technological and food safety requirements including (as described in the application) microbial decontamination, pest disinfestations and the prevention of sprouting and germination of weed seeds inadvertently present in the foods.

The Applicant sought approval for the use of the technology on the specified products for both quarantine and non-quarantine (including food safety) treatments.

The Application was finalised by ANZFA in July 2001 and a recommendation was made to the Ministerial Council in September 2001. The Council approved (19 September 2001) the use of irradiation on herbs, spices and herbal infusions for both quarantine and non-quarantine purposes.

[3] The US Food and Drug Administration maximum dose for tropical fruits is 1 kGy based on food safety considerations.

5. Issues Relevant to this Application

5.1 Scientific Assessment

The overall conclusions of the scientific assessment are as follows:

- there is an established technological need to irradiate tropical fruits for the purposes of pest disinfestation;

- international scientific opinion is that irradiated food is safe when the irradiation is performed at dose levels necessary to achieve the intended technological function and, in accordance with good radiation/manufacturing practice;

- there are chemical changes in tropical fruits following irradiation (albeit limited) resulting in the formation of radiolytic products. However, these products are not always unique to irradiation and are also present following more traditional processing of food, namely, heat;

- as a form of food processing, irradiation will have some impacts on the nutrient status of tropical fruits; however, there are few indications that these impacts are any greater than other forms of food processing, especially for irradiation doses less than 10 kGy;

- the research indicates that carbohydrates, proteins, fatty acids, minerals and trace elements in tropical fruits undergo very minimal alteration during irradiation; although selected vitamins are affected following irradiation of tropical fruits. However, any potential reductions in specific vitamins are unlikely to have significant impact on dietary intakes of these vitamins by the Australian or New Zealand populations;

- overall, there are no toxicological concerns resulting from the formation of new radiolytic products following irradiation of tropical fruits. By virtue of the concept of chemiclearance and the past safety studies performed on fruits (including tropical fruits) irradiated food is considered equivalent to non-irradiated food or fruits that have been treated with more conventional treatment protocols (eg heating for quarantine purposes) with respect to safety, nutritional properties and wholesomeness.

5.2 Safety of irradiated foods

Public submissions to the Initial Assessment raised the following issues:

- long-term health effects of a diet containing a variety of irradiated foods are not known;

- only one 15-week study in humans has been performed;

- the USFDA never performed or obtained the battery of tests required for approval of irradiation;

- USFDA's approval in 1986 of irradiation of fruits and vegetables was not based on animal studies, but rather on an estimate of the number and amount of unique radiolytic chemicals likely to be created at 1 kGy;

- the cumulative effects of consumption of multiple foods that have been approved for irradiation are not considered by ANZFA; and

- packaging and whether it is suitable for irradiation.

5.3 Evaluation

Although ANZFA recognises that many consumers have fears about consumption of irradiated foods, which were repeatedly expressed in public submissions, food irradiation is a thoroughly investigated food processing technology, with a large number of toxicological studies having 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 and is described below.

The long-term animal feeding studies on irradiated food are supported by more limited toleration studies in humans. These include studies of up to 90-day duration with thirty-five different varieties of irradiated foods. Irradiated foods have been consumed in many countries, in particular, herbs and spices and fruits, for some time now without any known adverse health effects. In addition, some hospital patients have consumed irradiated food and the health of these patients has been monitored for clinical reasons.

Over thirty years of research have shown that virtually all the radiolytic products (i.e. 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. All reliable scientific evidence, based on animal feeding tests and consumption by humans, has indicated that these products pose no risk to humans (**Attachment 2**).

5.4 Radiolytic products

Chemiclearance is a concept devised by past international Expert Committees[4] (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.

For a more detailed scientific description of chemiclearance refer to the Science Report (**Attachment 2**). An ANZFA information sheet (peer reviewed by international experts) explains in more detail this concept (**Attachment 7**).

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[4] References cited can be found in the Science Report (Attachment 2)

5.5 Packaging

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. 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.

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.

The USDA have mandated in their proposed rule change 'Irradiation Phytosanitary Treatment of Imported Fruits and Vegetables' 7 CFR 305 & 319 that 'the cartons may be constructed of any material that prevents the entry of fruit flies and prevents oviposition by fruit flies into the articles in the carton'. The US FDA has a regulation '179.45 - Packaging materials for use during the irradiation of pre-packaged foods'. Current commercial practice in the US, including both Hawaii and Florida, is the use of standard commercial produce industry packaging materials including corrugated Kraft paper boxes.

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. In the editorial note, Standard 1.4.3 refers to Australian Standards AS2070-1999, which details standards for plastic materials for food contact use. AS2070 refers to the USA Code of Federal Regulations and the EU Directives on plastics suitable for use on irradiated foods.

There is also an extensive body of work in relation to the packaging materials for use with irradiated foods and an American Society of Testing Methods (ASTM) Standard Guide for Packaging Materials for Foods to be Irradiated (1995): 'Standard Guide for Packaging Materials for Food to be Irradiated' - ASTM 1640.

Advice received by ANZFA indicated that the tropical fruits listed in this application are not in 'intimate' contact with the packaging, most of the fruits have an inedible skin and an irregular shape with very little of the surface of the product in contact with the packaging. Therefore, the product contact area with the irradiation beam is the skin (apart from carambola skin) and discarded prior to consumption.

At a low maximum dose of 1 kGy it would not be expected that packaging material in contact with the tropical fruits would undergo significant alteration of its functional properties or yield materials which could transfer to the food as a result of irradiation at phytosanitary doses (International Consultative Group on Food Irradiation (ICGFI) Document 7 - 'Code of Good Irradiation Practice for Insect Disinfestation of Fresh Fruits').

Therefore, provided that manufacturers adhere to Good Manufacturing Practice (GMP) there are currently appropriate provisions under Standard 1.4.3-Articles and materials in Contact with Food and other international legislation (ICGFI and ASTM 1640) to ensure the safety and quality of packaging used for irradiated tropical fruits.

5.6 Nutritional Impacts

Public submissions were concerned that irradiation may diminish the nutritional value and wholesomeness of the tropical fruits.

5.6.1 Evaluation

The nutritional analysis suggested that irradiation potentially causes both macro and micronutrient changes in foods, depending on the irradiation dose, the food's composition and environmental conditions. Therefore, as a form of food processing, irradiation will have some impact on the nutritional composition of foods. However, the available data indicate that carbohydrates, proteins, fatty acids, minerals and trace elements in tropical fruits undergo minimal alteration during irradiation, particularly at the low maximum dose of 1 kGy proposed to be used on tropical fruits.

The nutritional assessment (**Attachments 2 and 3**) indicates that the selected tropical fruits proposed for irradiation are minor contributors to the total dietary intakes of β-carotene, folate, vitamin C and vitamin B_1 when considered within the context of total dietary intake.

Therefore potential reductions, of β-carotene, folate, vitamin C and vitamin B_1 due to irradiation is unlikely to have a significant impact on dietary intakes of these vitamins by the Australian or New Zealand populations, even when considered on a regional basis.

5.6.2 Conclusions on the safety and nutritional adequacy of irradiated tropical fruits

The safety of food irradiation has been evaluated in animals and humans. The available studies on fruits indicates that there are no toxicological concerns and there are no compounds formed following irradiation that are likely to cause public health and safety concerns.

Previous expert committees under the auspices of the World Health Organization reviewed numerous safety studies. The overall conclusion is that irradiation of tropical fruits up to a maximum of 1 kGy employing Good Manufacturing/Irradiation Practices is safe for Australian and New Zealand consumers.

The nutritional analysis indicates that carbohydrates, proteins, fatty acids, minerals and trace elements in tropical fruits undergo very minimal alteration during irradiation. Any likely reductions in specific nutrients following irradiation of the selected tropical fruits are not likely to impact on the nutritional status of Australian and New Zealand consumers.

*Refer to **Attachments 2 and 3** for more detail.*

5.7 Technological Need and efficacy of the Irradiation Process

Public submissions raised the following issues:

- Is there a specific technological need to irradiate tropical fruits?

- Previously, there was research regarding the breeding of insect resistant tropical fruits. ANZFA should follow this up with CSIRO.

- Why if the papaya fruit fly in Queensland has been totally eradicated is there a technological need in this application to irradiate papayas?

5.7.1 Evaluation

Approval for the use of irradiation as an alternative treatment for the purpose of pest disinfestation in the *Food Standards Code* does not automatically mean that approval will be granted for this purpose under the quarantine provisions of Australia and/or New Zealand as regards international trade; rather, it is a two-step approval process.

Firstly, the use of food irradiation on the proposed tropical fruits must be approved by the Ministerial Council following a recommendation by ANZFA based on food safety, nutritional adequacy, a recognised technological need and other considerations under the ANZFA Act 1991. This is necessary to allow lawful sale of irradiated food on the market in Australia and New Zealand. Secondly, the relevant Australian and New Zealand quarantine agencies must then assess the appropriateness of the irradiation treatment for the specific pests of quarantine concern and determine an appropriate dose (within the minimum and maximum range specified in the draft standard) for the individual tropical fruits/pest on a case-by-case basis.

5.7.2 Consultation with relevant quarantine agencies

ANZFA received advice from the Applicant indicating that Biosecurity Australia (BA), the Ministry of Agriculture and Forestry, New Zealand (MAFNZ) and the Australian Interstate Plant Health Regulation Working Group (IPHRWG) were considering the issue of efficacy of treatment for the specified pest/tropical fruit commodities identified in the application. In particular, that the maximum dose of 1 kGy will be an appropriate and efficacious dose for the technological need of treatment of quarantine pests. These responses were taken into account. In addition, the relevant quarantine authorities were consulted directly when assessing the merits of the application.

ANZFA recognises that the relevant quarantine agencies need to develop specific import health standards for the import and movement of the specified tropical fruits.

5.7.3 Technological need

Advice received by ANZFA from quarantine authorities is that irradiation of tropical fruits for the purpose of pest disinfestation would provide an alternative to currently used disinfestation methods. The proposed minimum dose of 150 Gy and maximum dose of 1 kGy will provide a dose range in order for quarantine agencies to consider irradiation as a treatment for pest disinfestation of the selected tropical fruits. Therefore, determination of the efficacy of irradiation as a pest disinfestation measure is the responsibility of BA and MAFNZ.

It is BA's preferred option to have no listing of a minimum dose in the *Food Standards Code* and that this dose should be determined by relevant quarantine agencies. However, there is a specific legal requirement in Standards A17/1.5.3 that a minimum and maximum dose be listed to cover the specific technological purpose to irradiate food.

Under the separate regulatory requirements of the Australian and New Zealand Quarantine legislation, if a lower minimum dose was needed for disinfestation of a particular pest, then these Acts would enable those requirements to be achieved before a particular fruit could be imported into Australia or New Zealand. However, ANZFA would need to be advised by these bodies that a lower minimum quarantine dose was required. ANZFA would then be required to amend the *Food Standards Code* to reflect the revised minimum dose to make the food lawful for sale in the Australian and New Zealand markets.

5.7.4 Insect resistant fruit and the Papaya fruit fly

ANZFA approached the Queensland Department of Primary Industry (QDPI) and the Commonwealth Scientific Industrial and Research Organisation (CSIRO) on the issue of insect resistant tropical fruits and whether a technological need now exists to irradiate papayas if papaya fruit fly had been eradicated.

Advice from QDPI and CSIRO with respect to insect resistant tropical fruits was that that there is no active research program being pursued on breeding insect resistant tropical fruits. BA also advised ANZFA that it is most improbable that a level of resistance to fruit flies could be bred into host fruit that would be considered sufficient for quarantine purposes. Such "breeding for resistance" cannot be considered equivalent to the quarantine security provided by current disinfestation treatments.

With respect to technological need to irradiate papayas, the QDPI declared on 30 April 1999 that the Papaya fruit fly, an introduced species, had been eradicated.

However, the overall intent of this application is to use irradiation for the disinfestations of many different fruit fly pests and other critical quarantine pests. Other species of fruit fly exist, and thus there is still a technological need to treat these other species and in addition other pests (such as mango seed weevil and macadamia nut borer in litchi) with an appropriate quarantine treatment such as irradiation.

Other individual and more specific questions raised in public submissions on the technological need for irradiation of the specified tropical fruits have been addressed in the Question and Answer section (**Attachment 5**).

5.7.5 Conclusion on technological need

Disinfestation of the specified tropical fruits by irradiation is a valid treatment for quarantine purposes and meets the requirements of a technological need (pest disinfestation) under Standards A17/1.5.3. Insect pests of quarantine significance to importing countries represent a major barrier in gaining access to some markets. E-beam and X-ray irradiation techniques are considered efficacious treatments for tropical fruits. These techniques have the capacity to attain an equivalent level of efficacy when compared to current alternatives (chemicals, heat, cold treatments and manipulating maturity standards).

5.8 Labelling

Public submissions raised the following issues:

- ANZFA does not specify the labelling required for irradiated uncooked fruits and vegetables?

- Concerns that fruits will not be adequately labelled for consumers.

- Use of the term ‘electronic pasteurisation’ rather than irradiation is misleading to consumers.

5.8.1 Evaluation

Standards A17/1.5.3 - Irradiation of Food, require that a package of food for retail sale or for catering purposes that has been irradiated must be labelled with a statement that the food has been treated with ionising radiation. The Standard provides three examples of such statements. These are ‘Treated with ionising radiation’, ‘Treated with ionising electrons’ and ‘Irradiated (name of food)’. 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. The standard also contains requirements for labelling in relation to irradiated ingredients, and in relation to food not otherwise required to bear a label.

Standards A17/1.5.3 contain specific requirements for the labelling of those irradiated foods used as ingredients in composite or mixed foods, such as packaged pizza or pasta sauce. In this case, the declaration of the presence of irradiated ingredients may be in association with the name of the ingredient in the ingredient list, or a declaration elsewhere on the label.

Standards A17/1.5.3 require that irradiated food that is exempt in Standard 1.2.2 - Application of Labelling and Other Information Requirements from bearing a label and which is displayed for sale must have a written statement that the food, or an ingredient of a food or a component of the food has been treated with ionizing radiation. This would mean that irradiated food sold unpackaged and displayed for sale, including ready to eat foods, would need to be accompanied by a written statement advising consumers of the treatment of food with ionizing radiation.

A package of food sold other than at retail must also include:

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

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.

ANZFA agrees that the term ‘electronic pasteurisation’ may be misleading and should not be used to indicate that a food or an ingredient of a food had been irradiated. Clause 6(1) of Standards A17/1.5.3 require that the food be labelled with a statement that the food has been treated with ionising radiation. The term ‘irradiated’ is permitted.

5.9 Irradiation Facilities

Public submissions raised the following issues:

- The location of the proposed Surebeam facility was not detailed for public information. Requested ANZFA to publish this location on its website.

- What regulatory agencies license irradiation facilities and what measures are in place to protect the occupational health and safety of irradiation workers and the general public?

5.9.1 Evaluation

These matters are not addressed by the *Food Standards Code*, but are the subject of regulatory and planning decisions of the relevant State/Territory authorities.

Irradiation facilities are licensed and regulated by the following authorities in Australia and New Zealand:

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)		

The other issues raised (eg occupational health and safety for irradiation workers, and licensing of irradiation facilities) are matters for consideration by the relevant regulatory authorities such as:

- Environment Australia (under the Commonwealth's Environment Protection and Biodiversity Conservation Act) and;

- the Queensland Department of Communication, Local Government Planning and Sport (under the Integrated Planning Act).

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

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.

5.10 Import/Export issues

Public submissions raised the following issues:

- A maximum dose of 1 kGy may be used in some countries to irradiate tropical fruits where, in some cases, only a minimum dose was necessary.

- Australia and New Zealand may be required to accept highly irradiated fruits from those countries. Furthermore, if the proposed removal of the maximum dose limit of 10 kGy on irradiated foods is agreed by Codex, Australia and New Zealand may have to accept food that has been treated at a dose above the 1 kGy maximum.

5.10.1 Evaluation

In Australia, within the portfolio of Agriculture, Fisheries and Forestry, BA has responsibility for negotiating quarantine arrangements for the import and export of plant and animal products. BA 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 conducted by MAFNZ who ensure 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.

Importers of irradiated foods would be required to adhere to the strict provisions of Standards A17/1.5.3. This would mean adherence to a minimum dose of 150 Gy and the maximum limit of 1 kGy. Significant penalties exist for breaching the *Food Standards Code* (which if amended as recommended will require that the minimum dose be used to achieve the technological purpose).

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.

If a dose higher than 1 kGy were considered necessary in some circumstances, then food treated with higher doses could not be legally sold in Australia or New Zealand unless a formal amendment to the *Food Standards Code* was made.

5.11 Potential Markets for Irradiated Tropical Fruits

Public submissions raised the following issue:

- Irradiating tropical fruit has the potential to increase market opportunities for the Australian tropical fruit industry.

5.11.1 Evaluation

The *Food Standards Code* does not apply to foods exported from Australia or New Zealand. The permissions apply only to foods sold in the Australian and New Zealand markets. Permissions to irradiated tropical fruits may have implications for trade between Australia and New Zealand, though quarantine requirements would need to be met.

5.12 Quality of Irradiated Fruits

Public submissions raised the following issue:

- Doesn't irradiating tropical fruits influence the ultimate quality of the final product?

5.12.1 Evaluation

At certain doses, particularly, doses closer to the maximum of 1 kGy the quality of the fruit can be affected and ANZFA concurs that not all tropical fruits may be equivalent in quality to each other following irradiation. This is also true for other treatments that are used to meet quarantine regulations (eg, cold and heat treatments may influence the quality of tropical fruits).

ANZFA does not mandate the particular technologies that can be used to maintain quality of food as the final quality of food. In particular, the use of irradiation for treatment of tropical fruit is a commercial and marketing decision for growers of tropical fruits and operators of irradiation facilities. This will ultimately determine consumer acceptance of irradiation-treated produce by consumers. Further information on this issue is provided in **Attachment 5**.

5.13 Unintended consequences of approval

Public submissions raised the following issues, based on the Applicant's arguments:

- Is there enough demand in New Zealand for irradiated mangoes from Australia?

- If there is limited demand in New Zealand, the irradiation company may try to make money by irradiating fruits for the domestic market to increase shelf life. This will lead to a market imbalance for small producers of non-irradiated fruits.

- Surebeam is using this application to 'soften up' the Australian public for future irradiation of beef.

5.13.1 Evaluation

These issues relate to the Applicant's statements of purpose for the application. ANZFA notes that an amendment to Standards A17/1.5.3 would make it legal for such fruit, treated with irradiation to be sold in Australia and New Zealand.

Letters of support were received from a range of organizations and fruit growers, who argued that this change would provide an expanded market for Australian growers.

The identified technological purpose is for pest disinfestation. ANZFA acknowledges that there may be a concurrent benefit in terms of an increase in shelf life. However, previous research has suggested that only a very short shelf-life extension resulted from irradiation at 0.1 to 0.3 kGy used to suppress spoilage organisms[5]. ANZFA also recognises that some consumers do not necessarily want increased shelf life of products but consider irradiated foods with extended shelf life to not be as fresh as non-irradiated fruits. In either case, mandatory labelling will distinguish irradiated products in the marketplace.

The Applicant has informed ANZFA that the immediate intent, if approval is granted to irradiate tropical fruits, is access to the market for tropical fruits in New Zealand, provided quarantine requirements can be met.

Any further applications to irradiate other foods, for example, beef will be evaluated on merit against the requirements of Standards A17/1.5.3, and the objectives of the ANZFA Act for setting food standards.

5.14 Case-by-Case approach to Irradiated Foods

Public submissions raised the following issue:

- The case-by-case approach suggested by ANZFA and Ministers is misleading as any irradiation facility can irradiate food (including using Cobalt 60).

5.14.1 Evaluation

The case-by-case approach applies to requiring various applications for individual foods to be irradiated. Standards A17/1.5.3 identify the various sources of irradiation that may be used on those foods. It is correct that if this Application is approved then tropical fruits could be irradiated by e-beam/x-ray or gamma rays from a Cobalt 60 source.

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[5] (Sommer NF and Mitchell F (1986) Gamma Irradiation-a quarantine treatment for fresh fruit and vegetables, Hort Science, 21, 356-360).

5.15 Information for consumers about food irradiation

Public submissions raised the following issue:

- ANZFA has been inadequate in informing consumers about food irradiation.

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.

Recently the Health Ministers of Australia and New Zealand directed officials in the Department of Health and Aging to develop an education strategy on irradiation of food. This is currently being developed.

5.16 Consumer and Industry Perceptions of Food Irradiation

- There has been no market research to determine the negative impact on Australian farmers, nor any public information programme.

5.16.1 Evaluation

The International Consultative Group on Food Irradiation (ICGFI) prepared a publication on food irradiation, titled:

- Consumer Attitudes and Market Response to Irradiated Food (ICGFI, 1999).

The publication suggested that worldwide consumer awareness of food irradiation is increasing. The paper reviewed consumer attitudes and marketing of irradiated foods in the period 1984-1997 and concluded the following:

- people in several countries have purchased irradiated food;
- in some markets, the availability of a high quality produce item out of season was an important benefit;
- greater microbiological safety was a benefit in other markets; and
- consumers will buy irradiated foods.

The Applicant provided ANZFA with a copy of a document titled: "Perceptions of food irradiation in New Zealand and Australia" by Roger Harker et al, HortResearch (2001). In this report consumer opinions were explored before and after the viewing of a video on irradiated foods using a focus group approach in which a moderator directed the flow of the discussion and in a series of questionnaires. Industry opinion was solicited in a series of interviews with Australian and New Zealand companies. The Executive Summary is at **Attachment 9.**

Conclusions from the report were as follows:

Consumers

- Australian and New Zealand consumers have some concerns about irradiated foods, although the level of concern is lower than other food safety issues (eg chemicals in food).

- The willingness to purchase irradiated foods is much lower than in the USA (20-25% for strawberries, 50-55% for sterilised foods for immuno-compromised patients); although, there was a greater willingness to purchase non-food items (eg medical or household goods).

- Consumers raised similar fears over irradiated foods as found in other countries; namely, exposure to radiation, reduction in nutrition and wholesomeness of foods, damage to the environment, occupational health for workers and the use of irradiation as a substitute for safe food production. Some consumers did not want increased shelf life of food.

- New Zealand consumers were concerned with retention of the "clean, green image" of NZ food exports.

- Consumers seemed supportive of irradiated foods once the need for treatment has been established. For example, consumers were very supportive of using irradiation to sterilise foods for immuno-compromised patients compared to use on general commodity foods such as meat and strawberries.

Industry

- Some Australasian food exporters anticipate that many clients will require products to be irradiated to fulfil phytosanitary and/or food safety regulations, but fear a consumer "backlash" against the technology by anti-irradiation activists within their own country will stall future developments.

- In any marketing strategy that industry employs it will be necessary to alert consumers to the high levels of microbiological risk associated with some food products which although food irradiation may enhance food safety it may be a "double edged sword" in that it will emphasise the current microbiological risks in the food supply.

The final paragraph of the conclusions summarises the current situation in Australia and New Zealand:

> *Consumer awareness of irradiated food needs to be enhanced, and there probably needs to be a more public debate in order to develop a consensus. In this study it was clear that in the absence of a basic understanding of the issues, consumer support for irradiation fluctuates wildly depending on the bias of individuals. This lack of knowledge may expose Australasian industries to the risk that public opinion may be easily swayed towards rejecting irradiation of foods on the basis of irrational arguments. Providing consumers with even the simplistic information that was presented in the video resulted in consumers reaching a consensus that irradiation was only of minor concern. They reached this conclusion even though they expressed negative concerns about the bias of the video.*

It seems that New Zealanders and Australians may expect to hear both the pro-irradiation and ant-irradiation points of view before they are willing to make their own decision.

In addition, ANZFA has commissioned Donovan Research (Marketing and Communications Research Consultants) to undertake qualitative consumer research on food safety issues one of which was irradiated foods. The results of this research are now available on ANZFA's website (www.anzfa.gov.au) and are summarised below:

Irradiated Foods

There was even less awareness and more misunderstanding about irradiated foods. The word 'irradiation' is almost synonymous with 'radiation' [also connoting 'nuclear'] and is consequently suspected to be unsafe or bad for you.

Much would need to be done by ANZFA to educate people about exactly what irradiation means, how irradiated foods compare safety-wise and nutritionally to similar products preserved in other ways, and what the potential benefits are before it would be acceptable to consumers at large.

5.18 Public education programs

Given the strong sentiments expressed by consumers, it is evident that a significant information gap exists in relation to irradiation. However, there is an imperative for other agencies and bodies to also play a role in providing relevant information to consumers in relation to this technology and its benefits. ANZFA can play a role in terms of providing factual information in relation to the application, the process for assessing it, issues in relation to the application including fact sheets and an occasional paper on the assessment process to facilitate transparency of the process.

However, other bodies have roles to play and should be strongly encouraged to do so. For example, industry can have a role to play, facilitated by the labelling requirement in the Standard, to specify in positive ways the purpose of the irradiation process, for example, 'disinfestation to control critical quarantine pests'. Quarantine agencies can also have a role to play in providing information on the biosecurity aspects of the technology and the benefits to both the economy as a whole and industry in general.

Health Ministers of Australia and New Zealand directed officials in the Department of Health and Aging to develop an education strategy on irradiation of food. The Development and Implementation Subcommittee of the Food Regulation Standing Committee are currently undertaking this task.

5.19 Other Issues

A range of other broader issues was raised in submissions, which have been individually addressed in the Questions and Answer section (Attachment 5).

6. Regulatory Options

Options available are:

Option 1. Not to permit irradiation of tropical fruits and to rely on existing methods for phytosanitary purposes, although the Applicant has stated that the present methods are not accepted by MAFNZ.

Option 2. Amend the Table to Clause 4 in Standard 1.5.3 to permit irradiation of selected tropical fruits, where there is a technological need and the process does not compromise the safety and nutritional adequacy of the fruits. Prescribed conditions would include adherence to Good Agricultural Practice, Good Radiation Practices and a minimum dose of 150 Gy and a maximum dose of 1 kGy.

7. Impact Analysis

Approval to irradiate tropical fruits has the potential to impact on many sectors, namely, consumers, industry and governments.

Parties affected if permission to irradiate tropical fruits is granted are:

1. Those sectors of the food industry wishing to use irradiation as a phytosanitary treatment for tropical fruits and operators of irradiation facilities and exporters.

2. Consumers who may wish to purchase irradiated fruits in order to avoid chemical residues in fruit or conversely, consumers who wish to avoid purchase of irradiated foods.

3. Government agencies enforcing the food regulations.

The Applicant has presented an argument that the use of irradiation is a technologically justified and efficacious treatment and will provide access to new markets for Australian growers. Therefore, there is presently a market failure that this application is seeking to remedy.

The Applicant states that this alternative treatment will increase competition in the marketplace, improve seasonal availability, increase price competition; reduce the use of chemicals on tropical fruits; and may improve flavour of fruits available to consumers via the harvesting of more mature fruits (compared to heat treatments or maturity standards where fruit must be harvested less mature).

Government regulatory agencies involved in approval for food irradiation, namely, ANZFA, AQIS, BA and MAFNZ will need to ensure that irradiation at the levels proposed, in relation to the selected tropical fruits, results in food that is safe and nutritionally adequate, that there is a specific technological need and that the permitted dose is efficacious in meeting quarantine requirements. Enforcement agencies will be required to enforce labelling requirements for foods that have been treated with irradiation.

These cost and benefits to the affected parties are further expanded below under the two proposed options.

Option 1-Not to permit irradiation of Tropical Fruits

Benefits

Consumers

- Submissions stated that there would be a benefit to consumers who prefer not to consume irradiated foods, due to belief that such foods are potentially unsafe and/or nutritionally inadequate. However, mandatory labelling would allow such foods to be avoided by those wishing to do so.

Industry

- No benefits to industry were identified. *Status Quo*.

Governments

- There are no perceived benefits in not permitting an additional pest disinfestation measure unless the scientific assessment had concluded that there is no technological need or that the food is unsafe or nutritionally compromised following irradiation.

- There may be a benefit in not approving the application, as Governments would avoid controversy, as there is significant opposition to establishment of irradiation plants and the view that production of unsafe products following irradiation and any loss of nutrition in tropical fruits following irradiation may ultimately reflect negatively on the government.

Costs

Consumers

- No costs to consumers were identified.

Industry

- There may be loss of trade opportunities and access to markets where current disinfestation methods are not accepted.

Submissions also stated the following:

- Australian Industry will not develop global competitiveness and market opportunities may be lost;

- The Australian and New Zealand industry development may be reduced; and

- Further costs in Research and Development in an attempt to identify alternative treatments may be incurred by industry as existing chemical or other treatments are phased out.

Governments

- No costs were identified.

Option 2: To permit the Irradiation of Tropical Fruits

Benefits

Consumers

- There may be an expansion of availability of tropical fruits in some markets/regions.

- In comparison with methyl bromide, heat or cold treatments there may be a greater shelf life (although not all consumers will see this as a benefit).

- May result in better quality fruit for the consumer depending on the dose of irradiation imparted, as the fruit can be harvested at a more mature stage than would otherwise be possible if using alternative techniques.

- Approval of irradiated tropical fruits may increase competition in the marketplace, improve selection and seasonal availability and increase price competition; and may improve flavour of fruits due to later picking.

- Mandatory labelling will ensure that consumers who wish to avoid irradiated fruits can do so by clear labelling.

Industry

- Increased trade opportunities and increased markets available to tropical fruit growers.

Governments

- The application of irradiation to a range of tropical fruits concurrently may increase the efficiency of biosecurity negotiations between relevant quarantine agencies.

- Economic development in rural and regional Australia will be enhanced.

- Will provide an additional pest disinfestation treatment at a time when existing methods are not accepted or are being phased out (eg some chemical treatments). This may facilitation trade.

Costs

Consumers

- No apparent costs to consumers have been identified other than a possible transient increase in price of irradiated tropical fruits passed onto consumers as a result of the cost of establishment of a new irradiation facility in Queensland. Competitive forces should keep this to a minimum, particularly with mandatory labelling.

Industry

- Cost of labelling irradiated foods.

Governments

- The relevant quarantine agencies must agree on a minimum dose that would meet quarantine requirements for international trade. For domestic movement of fruit, there would need to be agreement among jurisdictions about the efficacy of such treatments for disinfestation. This may require an extensive risk analysis, with associated resource allocation. Additional costs may ensue to these authorities if efficacy data is not available or additional research is required.

- The extensive risk analysis necessary to protect both the Australian and New Zealand borders from quarantine pests in order that an Appropriate Level of Protection is ensured may take many years.

Option 1 would not allow the use of irradiation on tropical fruits. It imposes costs on consumers by loss of choice where the safety and wholesomeness had been established. It may deny Australian Tropical fruits grower's access to new markets and may hinder regional development.

Option 2 allows the use of irradiation, which has been determined to be safe for pest disinfestation (namely, fruit fly, in tropical fruits). The dose range listed (150 Gy to 1 kGy) has been verified by the appropriate quarantine regulatory agencies as being adequate to fulfil the technological need of pest disinfestation. However, it must be noted that ANZFA is not the appropriate regulatory body to determine whether or not the treatment is adequate to fulfil specific quarantine requirements. ANZFA has relied on advice from the relevant quarantine agencies, BA and MAFNZ. Option 2 does not subject consumers, the community or Governments to other costs other than those already highlighted.

Overall, **Option 2** is preferred because, by virtue of the scientific risk assessment, it most clearly achieves the objectives of: providing assurance of the safety of consuming irradiated fruits, providing labelling information to consumers that serve to give them informed choice, and provides a fair trading aspect to allow tropical fruits manufacturers new markets and meets Australia's requirements under the WTO by virtue of liasing with other international regulations on irradiated fruits. It also meets the requirements of Standards A17/1.5.3 of having a technological need and appropriate dosage levels.

8. Consultation

8.1 Public consultation

ANZFA conducted an initial assessment (Preliminary Assessment under section 13 of ANZFA Act 1991) on A443-Irradiation of Tropical Fruits. Public comment was called for on the application from 19 September 2001 to 31 October 2001.

A total of 61 submissions were received and are summarised in **Attachment 4**; 16 submissions supported the application, 41 did not support (included 25 signatures on two separate but individually submitted form letters), 4 did not specifically state whether they were in agreement or not.

The issues raised were addressed above and in **Attachment 5**.

8.2 Advisory Group Consultation

ANZFA consulted with an Advisory Group established for a previous application (A413- Irradiation of herbs, spices, selected nuts and herbal teas), which was representative of a broad range of stakeholders with an interest in the present application.

The Advisory Group comprises of the following representation:

- Health Departments (WA, QLD, VIC, NSW, Commonwealth and New Zealand)
- Agriculture and quarantine agencies in Australia and New Zealand (Agriculture, Forestry and Fisheries Australia, AQIS and NZMAF)
- Australian Consumers Association
- New Zealand Consumers' Institute
- Australian Food and Grocery Council
- New Zealand Grocery Marketers Association Inc
- Radiation expert
- ANZFA

This Group assisted ANZFA in relation to development of the Draft Assessment Report and consideration of submissions from the public consultation rounds.

All stakeholders that made a submission in relation to the application were included on a mailing list and received further ANZFA documents in relation to the application. Other interested parties as they came to the attention of ANZFA were also added to the mailing list for public consultation. This practice will continue in order to generate a range of opinions and information on this application that ANZFA can evaluate.

8.3 Notification to the World Trade Organization (WTO)

Australia and New Zealand are members of the WTO and are signatories to the agreements on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and on Technical Barriers to Trade (TBT Agreement). In some 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 comments.

Amending the *Food Standards Code* to allow the use of irradiation of tropical fruits may significantly affect trade, i.e., increase market opportunities for Australian growers and increase market opportunities for overseas growers. Therefore, notification will be made to the WTO as a TBT in accordance with the WTO Technical Barrier to Trade (TBT) agreements.

9. Conclusions

The conclusions from the draft assessment are as follows:

- There is no evidence of any public health and safety concern associated with consumption of irradiated tropical fruits and there are no significant nutritional losses of vitamins and minerals in the context of total dietary intakes at a dose of up to 1 kGy;

- A specific technological need (pest disinfestation) has been shown to exist and a minimum dose of 150 Gy and a maximum dose of 1 kGy is considered to be an appropriate dose range to control the range of pests of likely concern. This has been confirmed by quarantine officials in Australia and New Zealand;

- Mandatory labelling statements are required to ensure that consumers are informed that the food has been irradiated.

- The proposed changes to Volume 2 of the *Food Standards Code* are consistent with the section 10 objectives of the *Australia New Zealand Food Authority Act* 1991.

- The Regulatory Impact Statement indicates that, for the preferred option, namely, to approve the use of irradiation on tropical fruits, the benefits of the proposed amendment outweigh the costs.

10. Recommendation

It is recommended that the application and subsequently that irradiation of tropical fruits (Breadfruit, Carambola, Custard Apple, Litchi, Longan, Mango, Mangosteen, Papaya and Rambutan be approved. The recommendations are based on the analysis of relevant scientific evidence that demonstrates that the treatment of these foods with irradiation is safe and nutritionally adequate. Overall, benefits may be achieved through the use of this technology as an alternative to existing technologies, which currently do not meet MAFNZ requirements.

It is recommended that approval be subject to the following conditions:

- Approval is granted for the tropical fruits requested in the application.

- Approval be granted for control of fruits fly pests and other quarantine pests with a minimum dose of 150 Gy and maximum dose of 1 kGy.

- 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 to Volume 1 and 2 of the *Food Standards Code* is shown in **Attachment 1**.

11. Attachments

1. Draft variation to Volume 1 and 2 of the *Food Standards Code*
2. Science report
3. Dietary Modelling report
4. Summary of public submissions
5. General issues raised in public submissions
6. List of other countries that irradiate fruits
7. Chemiclearance Fact Sheet
8. Technical Facts Sheet
9. Consumer and Industry Perception of Irradiated Foods (Executive Summary)

ATTACHMENT 1

DRAFT VARIATIONS TO VOLUME 1 and 2 OF ***THE*** **FOOD STANDARDS CODE**

To commence: On gazettal

[1] ***Standard A17*** *of Volume 1 of the Food Standards Code is varied by inserting in* Column 1, Column 2 and Column 3 *respectively of the* Table to clause 4*, after the last occurring entry -*

Tropical fruit – Breadfruit, Carambola, Custard Apple, Longan, Litchi, Mango, Mangosteen, Papaya and Rambutan.	Minimum: 150 Gy Maximum: 1 kGy	Food may only be irradiated for the purposes of controlling pest disinfestation. The minimum dose to achieve the above technological purposes. 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 inserting in* Column 1, Column 2 and Column 3 *respectively of the* Table to clause 4*, after the last occurring entry –*

Tropical fruit – Breadfruit, Carambola, Custard Apple, Longan, Litchi, Mango Mangosteen, Papaya and Rambutan.	Minimum: 150 Gy Maximum: 1 kGy	Food may only be irradiated for the purposes of pest disinfestation. The minimum dose to achieve the above technological purposes. Food must be handled before and after irradiation according to good manufacturing practice (GMP).

ATTACHMENT 2

SCIENCE REPORT

The Technical, Safety and Nutritional Aspects of Irradiation of Tropical Fruits

SUMMARY

Technological Need to Irradiate Tropical Fruits

Disinfestation of the specified tropical fruits by irradiation treatment is a valid technological need for the purposes of Standards A17/1.5.3. Insect pests of quarantine significance to importing countries represent a major barrier to overcome in gaining access to some markets. E-beam and X-ray irradiation techniques are an efficacious pest disinfestation method for tropical fruits, with a capacity to attain an equivalent level of efficacy when compared to current alternatives (chemicals, heat, cold treatments and manipulating maturity standards).

Safety of Irradiated Food

The safety of food irradiation has been evaluated in animals and humans. The available studies on fruits indicates that there are no toxicological concerns and no compounds are formed following irradiation that are likely to cause public health and safety concerns.

Previous expert committees under the auspices of the World Health Organization reviewed numerous safety studies. The overall conclusion is that irradiation of tropical fruits up to a maximum of 1 kGy employing Good Manufacturing/Irradiation Practices is safe for Australian and New Zealand consumers.

Nutritional quality of irradiated tropical fruits

The Nutritional analysis suggested that irradiation potentially causes both macro and micronutrients changes in foods, depending on the irradiation dose, the food's composition and environmental conditions. Therefore, as a form of food processing, irradiation will have some impacts on the nutrient status of foods; however, there are few indications that these impacts are any greater than other forms of food processing, especially for irradiation doses less than 10 kGy. In summary, the previous research indicates that carbohydrates, proteins, fatty acids, minerals and trace elements in tropical fruits undergo very minimal alteration during irradiation, although selected vitamins are affected following irradiation of tropical fruits.

1. Introduction

1.1 Technological need

The intent of technological need in Standard A1/1.5.3 is that irradiation can be used where a recognised technological need exists. With respect to this application, the Applicant has sought permission to use irradiation to control pest disinfestation of tropical fruits.

Pest infestation of food commodities, in particular, tropical fruits is a worldwide quarantine problem. Irradiation is currently used in other countries (other than Australia and New Zealand) to reduce critical pests of quarantine concern, namely, fruit fly. Irradiation essentially offers plant quarantine authorities with a further disinfestation measure to current methods employed, some of which are not acceptable in some markets, or are being phased out.

1.2 Current disinfestation techniques

Determination on the efficacy of pest disinfestation is the responsibility of the relevant quarantine authorities, namely, Biosecurity Australia (BA), the Ministry of Agriculture and Forestry New Zealand (MAFNZ) and the Australian Interstate Plant Health Regulation Working Group (IPHRWG). Quarantine authorities require a very high degree of efficacy for a phytosanitary measure against critical quarantine pests.

Quarantine disinfestations of commodities can be accomplished by a variety of means, such as pesticide applications, chemical fumigants, extreme temperatures, low-oxygen atmospheres and ionising radiation (Hallman, 2001). The Interstate Certification Assurance (ICA) is a national scheme set up to govern the movement of tropical fruit in Australia. Plant health certification adopted by the ICA is accepted by all Australian States and Territories; current disinfestation treatments approved for use on the specified tropical fruit include: the use of post harvest chemicals, heat treatment, maturity standards, cold treatment and unbroken skin (ICA, 2001).

Chemical treatments are based on the use of dimethoate, fenthion and methyl bromide. The use of post-harvest chemicals is under review worldwide due to concerns about potential health effects associated with chemical residues. Methyl bromide is recognised as an ozone depleting agent and Australia has agreed to reduce the use of methyl bromide, with total phase out for non-quarantine uses by 2005. Post harvest chemical dips and sprays (fenthion, dimethoate) are under review for environment, and workplace health and safety reasons.

Heat treatment (hot air or hot water at specified temperature for specified period of time) is currently approved for mango and papaya for interstate trade. Heat treatments are not widely adopted by tropical fruit growers, as product losses tend to be unacceptably high. Research undertaken in Australia has shown, whilst, heat treatment is efficacious for most fruit fly species at 47°C, it is not effective for all species at specified time/temperature periods. Beyond this temperature range tropical fruit can become irreparably damaged (ICA, 2001).

Manipulating maturity standards by harvesting unripe fruit less attractive as a fruit fly host can be effective, but determination of treatment efficacy is an arduous process. The quality issue is a major disadvantage with immature fruit an unattractive product due to firmness, lack of colour, and reduced flavour.

Cold treatment is not a viable measure for tropical fruit with product damage and high costs under Australian conditions making it economically unsustainable. Unbroken skin is not a reliable indicator of fruit fly infestation and may not meet stringent quarantine requirements of importing countries.

The range of disinfestation treatments currently approved for use on the specified tropical fruits for interstate trade in Australia do not meet MAFNZ quarantine requirements and consequently, no trade is possible from Australia to New Zealand in tropical fruits.

1.3 Benefits of irradiation as an alternative technology for disinfestation of tropical fruits

For quarantine pest disinfestation of commercial commodities in international trade, irradiation is one risk management option that may be selected to mitigate relevant quarantine risks identified through the import risk analysis (IRA) process. Standards A17/1.5.3, clause 4 of the *Food Standards Code* states that foods may only be processed by irradiation where this is in accordance with Good Manufacturing Practice (GMP) and such processing (a) fulfils a technological need; or (b) is necessary for a purpose associated with food hygiene.

The purpose of using irradiation is disinfestation of fruit fly. Tropical fruits are a known host for fruit fly larvae during their life cycle. Plant Biosecurity Australia previously regarded the maximum dose requested of 1 kGy as one that exceeds the level required to enable Probit 9 security (99.9968% mortality) of fruit fly (Heather and Corcoran, 1990). However, Australian quarantine requirements with respect to efficacy of various treatments vary depending on the specific situation and availability of other measures for quarantine requirements. The development of an International Standard for Phytosanitary Measures (ISPM) to cover the use of irradiation as a phytosanitary treatment will ultimately provide additional guidance for Australian, New Zealand and State/Territory quarantine authorities.

Determination of an appropriate radiation dose is likely to focus on a minimum level that enables quarantine measures to be fulfilled, whilst limiting the damage to the tropical fruit. The Applicant claims that a delay of ripening and senescence in tropical fruit is an ancillary benefit stemming from the use of irradiation.

Irradiation for the purpose of disinfestation, in particular fruit fly, does not require deep penetration radiation but rather a dose that has the power to reach the eggs which reside on the surface or the mesocarp of the fruit, which is the habitat of fruit fly larvae. Irradiation doses of up to 1 kGy on tropical fruits are used as a phytosanitary measure, with considerations regarding the level of the doses likely to focus more on the minimum dose required to prevent unacceptable changes in the quality of fruit without compromising treatment efficacy.

For example a dose range of 74-101 Gy on the ‘Kensington’ variety of mango is sufficient to provide probit 9 security of fruit fly. Other pest targets such as the mango seed weevil are more resistant to irradiation and doses of 300 Gy are needed to prevent adult emergence. No damage to the ‘Kensington’ mango occurs at the fruit fly treatment range; however, the dose required to disinfest the mango seed weevil is near the threshold for damage to the ‘Kensington’ variety of mango (Heather and Corcoran, 1990).

Determining the appropriate level of radiation dose for disinfestation is dependent upon variables such as the target pest and the penetrability of the exocarp of the fruit. MAFNZ and BA to date have not carried out an in-depth analysis on the technical data supporting irradiation as a phytosanitary treatment.

2. Nature of the Irradiation Process

Food irradiation is a processing technology that exposes food to a source of ionising energy. Safe food irradiation techniques require exposure to a source of ionising radiation of known energy under specific time and environmental conditions to produce a desired result.

Standards A17/1.5.3 permit the following sources of ionising radiation; Cobalt 60 sourced gamma rays, machine operated X-rays, and high-speed electrons generated by an electron beam.

Cobalt 60 is obtained as highly refined Cobalt-59 pellets that are converted into a radioactive gamma source in a nuclear reactor via neutron activation. The pellets are placed in a stainless steel capsule in the form of a "pencil" to minimise self-absorption and heat build-up. With this configuration, about 95% of the emitted energy is available for use. Because gamma radiation does not elicit neutrons, meltdown and chain reactions cannot occur, and irradiated foods and their packaging are not made radioactive. The gamma energy penetrates the food and its packaging but most of the energy passes through the food leaving no residue, although a small amount of energy is retained as heat (WHO, 1994).

The advantages of Cobalt-60 as an irradiation source are: its high penetration and good dose uniformity, and this allows effective treatment of products of variable size, shape and density. Disadvantages include; a half-life of 5.3 years, so that 12% of the source must be replaced annually to maintain the original strength; and a rather slow processing rate compared with electron beam irradiation. Radiation facilities using Cobalt-60 also require the construction and operation of source storage (a water pool or dry storage), source handling (generally using electrical power and gravity), and massive shielding to protect workers and the environment (WHO, 1994).

In contrast to the gamma-emitting isotope sources, the radiation from electron beam (e-beam) and X-ray machines is produced electronically. E-beam is a stream of high-energy electrons propelled out of an electron gun. A significant advantage of e-beam accelerators is that they adapt to different radiation process requirements. This includes different beam energies and using dual radiation fields (particles or X-rays). E-beam accelerators also have an advantage in that the source does not need to be replenished, meaning there is no recycling or storage of wastes as is the case with Cobalt-60 isotopes. Safety advantages of e-beam are offered by having an on/off accelerator source option, and this factor facilitates easy adaptation to processing and portability (Lagunas-Solar, 1995).

X-rays are an outgrowth of e-beam technology having a greater penetration than electrons and are generated by impacting high-energy electrons on to a suitable target. To produce X-rays a beam of electrons is directed at a thin plate of gold or other metal, producing a stream of X-rays coming out the other side (USDHS, 1999).

A number of studies have compared the effects of electron beam, gamma rays and X-rays; but comparison between these technologies is inconclusive due to differences in the doses applied. Electrons (10 MeV) have a limited penetration depth of about 5 cm in food, while X-rays have significantly higher penetration depths (60 - 400 cm) depending upon the energy used. X-rays consequently require heavy shielding for safety, however, like e-beams the machine can be switched on and off, and no radioactive substances are involved (USDHS, 1999).

3. General Aspects on the Safety of Food Irradiation

3.1 Overview of previous safety studies performed on irradiated foods

The safety of irradiated food has been examined through 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 both short and long-term studies. Various expert committees have assessed the results of these studies in order to examine whether there are any toxicological concerns following consumption of irradiated foods. These studies have provided no evidence that irradiated foods in the diet leads to toxicological concerns (**Appendix 1**).

The following sources of radiation were used in these toxicological studies:

- Gamma rays from either Caesium 137 or Cobalt 60; and
- E beam from electrons.

As gamma rays or e-beams/x-rays are ionising radiation when they interact with a medium electrons are produced which scatter in many directions. These scattered electrons cause ionisations and excitation of the medium (eg food) and this leads to radiation-induced chemical changes in the irradiated medium. However, these radiolytic changes are largely the same, regardless of whether gamma rays, e-beams or x-rays are used as the source of irradiation (Diehl, 1995). Consequently, there is both qualitative and quantitative equivalence between gamma rays and electrons with respect to physical, chemical and microbiological effects. A summary of some of the further basic technical facts of the irradiation process is at **Attachment 8.**

The early studies on the safety of irradiated food led to the adoption of a 10 kGy limit by the Codex Alimentarius Commission (Codex) in 1983, following the recommendations of a 1980 Joint Expert Committee on Food Irradiation Report (JECFI, 1980). 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 10 kGy. The Committee concluded that irradiation of any commodity up to an overall average dose of 10 kGy 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 10 kGy) has been evaluated in many feeding studies with a variety of diets in animals and humans as detailed in the 1999 WHO Report.

3.2 World Health Organization and other reports on the safety of irradiated foods.

In addition to reports on the safety of irradiated foods from the World Health Organization (WHO, 1994 and 1999), irradiated foods have been previously evaluated for safety by national and international expert panels (SCF 1986, 1998; NFA Denmark 1986; JECFI 1964, 1969, 1976, 1980). The available 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 WHO, Codex, 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 specifically 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 toxicological data concluded 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 multigenerational 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.

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 10 kGy limit from its General Standard as a result of the conclusions in this report.

4. Toxicological Issues

Toxicological issues in relation to irradiated foods is centred around the possible production of new chemical products arising following irradiation treatment, which to date have not been found from more traditional processing of food, e.g., heating of foods.

There have been an extensive number of specific toxicological studies on irradiated foods as discussed in section 3 above; however, by virtue of previous safety studies performed on particular food groups (eg fruits) that data can in fact be used to support the safety of similar food products (eg tropical fruits). This concept is explained in section 4.2 below.

4.1 Production of radiolytic products

When food is irradiated, a large number of new compounds (radiolytic products[6]) 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 to chemicals found in either unprocessed foods or in thermally processed foods. A few could be unique to the irradiation process (refer to section 4.2 below).

The three major macronutrients, carbohydrates, proteins and lipids, give rise to different types of radiolytic products following irradiation. However, research has found that the majority of 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.

4.2 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 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 the Joint Expert Committee on Food Irradiation (JECFI, 1964). The Committee 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 (Elias 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.

[6] 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 similarity 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 the similarity in the chemistry. Studies on volatile and non-volatile products derived from fatty acids, fatty acid esters and oils also show a consistency 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).

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 (JECFI, 1980). 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[7] (Thayer, 1995 and 1997).

4.3 The practical application of chemiclearance

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 as discussed above (**4.2**). Therefore, the results of studies on a particular class of food can be extrapolated to others (WHO, 1994 and 1999).

Chemiclearance can be used in two ways:

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.

[7] The D_{10} value is the dose required to reduce the microbial population by 90%.

From a safety point of view, foods of animal origin such as beef, pork, chicken and fish are quite similar in macronutrient composition so safety data on any of the irradiated foods can be viewed as being relevant to the whole class of foods and constituting a single database. Similarly, data on irradiated plant products such as vegetables and grains, herbs and spices, fruits and other plant products can be used for the whole class (WHO 1994).

With respect to lipids, the mechanisms by which radiolytic products are formed involve reactions common to both saturated and unsaturated fatty acids as well as reactions specific to unsaturated fatty acids. Accordingly, fish is included in the same class as the other muscle foods, due to the similarities in proteins and since the differences in unsaturation lead to predictable differences in radiolytic products (Diehl, 1995; Elias and Cohen, 1983).

Therefore, on the basis of the chemistry of proteins, lipids and starches, it has been concluded that radiolytic products produced even at doses above 10 kGy (WHO 1999) are similar to those already detected at doses below 10 kGy (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.

4.4 Studies on 2-alkylcyclobutanones (2-ACBs)

2-ACBs have been recently identified as possible unique radiolytic products following the irradiation of food.

Several 2-ACBs are used as markers to detect irradiated foods (Stevenson *et al*, 1990) and since 1996 a European Standard to detect fat-containing irradiated food has been promulgated (EN: 1785: 1996). More recently 2-ACBs have been found to be markers for detection of irradiated tropical fruits, in particular, mango and papaya (Stewart *et al* 2000). 2-tetradecylcyclobutanone (2-TCB) was identified as the main marker for irradiated mangoes and could be detected in samples following storage for 14 days at 10°C at doses of 0.1 kGy. 2- dodecylcyclobutanone (2-DCB) was identified as the principal irradiation marker in papayas, although 2-DCB decreased significantly over time, so that by day 21 of storage at 10°C it could only be detected at a dose of 2 kGy. 2-Tetradecenylcyclobutanone (2-TDCB) was also detected in irradiated mango and papaya, although its use as a marker was dose limited to 0.5 kGy or greater (Stewart *et al*, 2000).

Therefore, this study suggests that mangoes and papayas contain all three of the 2-ACBs, although it has yet to be determined whether other fruits in the tropical fruits class also contain 2-ACBs as the relative percentage of fatty acids and type (eg palmitic versus oleic) in these fruits varies (Table 1 and 2) which determines the presence of the specific 2-ACBs (Stewart *et al*, 2000). Overall, the percentage of these fats that can produce 2-ACBs in tropical fruits is low (Table 1).

Table 1: Fat content of tropical fruits g/100 g edible portion

Fruit#	Saturated Fat	Polyunsaturated Fat	Monounsaturated Fat
Carambola*	0	0	0
Custard Apple*	0.2	0.1	0.2
Mango*	0	0	0
Rambutan*	0	0	0
Litchi**	0.1	0.1	0.1
Breadfruit**	0.05	0.03	0.07
Papaya**	0.04	0.04	0.03

Legend:
* Australia New Zealand Food Authority 1999. AUSNUT - Australian Food and Nutrient Database. Australia New Zealand Food Authority. Canberra.
** US Department of Agriculture, Agriculture Research Service (2001). USDA Nutrient Database for Standard Reference.
\# No data could be identified for Mangosteens and Longans

Table 2: Fatty Acid Composition of Tropical Fruit g/100g edible portion

Fruit#	Lauric 12:0	Myristic 14:0	Palmitic 16:0	Stearic 18:0	Palmitoleic 16:1	Oleic 18:1	Linoleic 18:2	Linolenic 18:3
Carambola*	0	0	0.012	0.008	0	0.031	0.164	0.028
Mango*	0.001	0.007	0.052	0.003	0.048	0.054	0.014	0.037
Litchi**	0	0.002	0.07	0.024	0.001	0.119	0.067	0.065
Breadfruit**	0	0	0.031	0.017	0.002	0.032	0.048	0.018
Papaya**	0.001	0.007	0.032	0.002	0.02	0.018	0.006	0.025
Mean	0.0004	0.0032	0.0952	0.045	0.0142	0.238	0.0598	0.0476

Legend:
* Australia New Zealand Food Authority 1999. AUSNUT - Australian Food and Nutrient Database. Australia New Zealand Food Authority. Canberra.
** US Department of Agriculture, Agriculture Research Service (2001). USDA Nutrient Database for Standard Reference.
\# No data could be identified for Custard Apple, Rambutan, Mangosteens and Longans

A recent study suggested that 2-DCB caused DNA strand breaks in cells from the large bowel of rats and humans when they were incubated *in vitro* with 2-DCB (Delincee and Pool-Zobel 1998). The study indicated that 2-DCB in the concentration range 0.3-1.25 mg/ml produced cytotoxicity and an associated weak effect in DNA. However, the significance of the result is still not clear since only one genotoxicity test (the Comet Assay), which has not been validated for regulatory purposes, had been used.

In relation to the significance of this study following irradiation of tropical fruits the following can be concluded:

- the observed DNA strand breaks may well be the result of cytotoxicity and the use of relatively pure compounds which would not simulate the concentrations of 2-DCB following irradiation of whole foods;

- *in vitro* studies in isolation cannot be linked to potential hazards without other evidence, eg, *in vivo* studies;

- the concentrations of ACBs following irradiation are extremely low; and

- the low percentages of fats in tropical fruits make it unlikely that 2-ACBs are of any toxicological significance and consequently pose any risk to human health.

In a subsequent follow up *in vivo* study rats received 2-DCB at doses of 1.12 or 14.9 mg/kg bw and then cells from the colon were isolated and a Comet assay performed (Delincee H et al, 1999). The following was concluded:

[... *At higher concentrations of 2-DCB (14.9 mg per kg body weight) a small but significant DNA-damage in the experimental group was observed. Further studies are necessary in order to evaluate the relevance of these findings for risk estimation with regard to the consumption of irradiated food*.] (Translated by Ehlermann D., personal communication).

4.5 The concept of equivalence as it applies to irradiation

Although there have been extensive feeding studies conducted on irradiated foods, the concept of irradiated foods being 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 (WHO 1999). Data indicate that irradiated foods do not contain either measurable levels of radioactivity or toxicologically significant levels of radiolytic products.

4.6 Conclusions of the Toxicological Issues

- When food is irradiated, several new compounds (radiolytic products) are formed but their total concentration is very low.

- Virtually all the radiolytic products (except possibly for 2-ACBs) that have previously been found in irradiated foods are either naturally present in food or produced in thermally processed foods.

- The available data does not suggest that 2-ACBs are of toxicological concern to consumers following consumption of irradiated tropical fruits.

- Based on the concept of chemiclearance, the previous studies on fruit (including tropical fruits) indicate there is no evidence that irradiated fruit in the diet leads to safety concerns.

- The past safety studies performed on irradiated fruits indicates that the treatment does not raise any safety concerns beyond those raised by conventional treatment of fruits.

5. Nutritional Issues

5.1. Nutritional implications for irradiated food

Macro and micronutrients of food are sensitive to food processing methods including irradiation. The effect of irradiation on the nutritional quality and flavour characteristics of food depends on the level of irradiation treatment, the food's composition and structure, and environmental conditions (Diehl, 1981). Research indicates that any irradiation effects on micronutrients increases in a dose-dependent relationship, and nutrient losses are comparable to other food processing techniques, for example drying and heating (ACINF 1986; Diehl, 1981; Diehl, 1995; WHO, 1999). Generally, it is concluded that, "irradiation of food up to an overall average dose of 10 kGy introduces no special nutritional … problems" (WHO, 1981).

5.2. Impact of conditions under which irradiation is conducted

The nutrient content of irradiated foods is affected by environmental conditions, exposure to oxidising agents and storage conditions (Diehl, 1995, WHO, 1994). Low -temperature and oxygen free food irradiation assists in minimising any potential nutrient degradation during processing (Diehl, 1995, WHO, 1994).

5.3 Specific nutrients

5.3.1. Macronutrients

The particular effect of irradiation on the nutritional value of proteins, carbohydrates and fats depends 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 research indicates that the effect of irradiation on the nutritional quality of proteins, carbohydrates and fats in tropical fruits is minimal due to the particular composition and characteristics of tropical fruit (Diehl, 1991, Diehl, 1995, WHO, 1999). Irradiated mangos have similar macronutrient profiles during ripening to non-irradiated mangos (Gholap et al 1990, Diehl 1995). Furthermore, there is a very low susceptibility to any oxidation processes that may be directly related with irradiation processing (Diehl, 1995).

5.3.2. Minerals

From the scientific research there is no evidence that irradiation has any effect on the minerals and trace elements in foods (WHO, 1994), and that the bioavailability of these elements is not affected by current irradiation techniques (WHO, 1994, WHO, 1999).

5.3.3. Water-soluble vitamins

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

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

Vitamin B_1 → Vitamin C → Vitamin B_6 → Vitamin B_2 → Folate→ Cobalamin (B_{12})

The primary sources of vitamin B_1, vitamin B_2, vitamin B_6, folate (and associated derivatives) and vitamin C in the human diet are collectively: grains, wheat-based products, yeast-based products, fruits, vegetables, meat and dairy products (WHO, 1999, Diehl, 1995). The tropical fruits that are the subject of this application (i.e. the 'selected tropical fruits') are a very minor dietary source of these vitamins in the context of the total diet, over time, due to low and variable consumption levels (Diehl, 1995, WHO, 1994). Refer to **Attachment 3** for Australian and New Zealand dietary intake assessment information in relation to vitamins B_1, C and folate, as being the respective nutrients most relevant to the selected tropical fruits.

5.3.4. Fat-soluble vitamins and associated pre-cursors

Similar to the water-soluble vitamins, the sensitivity of fat-soluble vitamins to radiation varies according to the specific food, irradiation dose, environmental and storage conditions. In general, the order of sensitivity for fat-soluble vitamins to irradiation is as follows, from most sensitive to least sensitive, (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 diet are collectively: oils, red and orange fruits, red and green vegetables, wholegrains, yeast-based products, meat and dairy products. Although the specified tropical fruits are dietary sources of some of these vitamins and associated pre-cursors, the dietary intake assessment indicates that these foods are very minor contributors, due to low consumption levels within the context of the total diet (Diehl, 1991, Diehl, 1995). Refer to **Attachment 3** for Australian and New Zealand dietary intake assessment information in relation to β-carotene, as being the respective nutrient most relevant to the selected tropical fruits.

5.4 Key nutrient profile of selected tropical fruits

In order to identify the micronutrients that may be at-risk in relation to the dietary intakes of Australian and New Zealand populations (in the context of this application), the nutritional profile of the selected tropical fruits has been considered and key micronutrients identified. Due to a paucity of data on some of these micronutrients for the selected foods not all values have been obtained. Note that papaya is sometimes referred to as pawpaw in Australia and New Zealand, however the two names actually apply to separate species of tropical fruit (*C. papaya* and *A. triloba* respectively). In the interests of consistency with the application, papaya will only apply to *C. papaya* throughout this document.

Table 1. Key micronutrient profile of selected tropical fruits per 100 g edible portion

Fruit	β-carotene µg	Vitamin C mg	Vitamin B_1 mg	Vitamin B2 mg	Preformed Niacin mg	Folate µg
Breadfruit*	N/A	29	.11	.03	.9	14
Carambola #	20	35	.02	.04	.6	2
Custard Apple #	5	43	.05	.08	1.0	5
Litchi*	N/A	72	.01	.07	.6	14
Longan*	N/A	84	.03	.14	.3	N/A
Mango #	2370	28	.02	.04	.9	3
Mangosteen**	N/A	4	.03	.03	.3	N/A
Papaya*	N/A	62	.03	.03	.3	38
Rambutan #	0	78	.02	.06	1.0	2

Legend:
Australia New Zealand Food Authority 1999. AUSNUT - Australian Food and Nutrient Database. Australia New Zealand Food Authority. Canberra.
* US Department of Agriculture, Agriculture Research Service (2001). USDA Nutrient Database for Standard Reference.
** Ministry of Agriculture, Malaysia: http://agrolink.moa.my/comoditi/manggis.html
N/A Not Identified

Extensive research on the impact of irradiation on carotenoid content has produced differing results from no effect on pineapples irradiated at 2.45 kGy through to 2-7% carotenoid losses in wheat irradiated at 1 kGy (WHO, 1994). Of the B vitamins, vitamin B_1 is arguably the most sensitive however, such losses are also largely influenced by access to oxygen during processing and storage (WHO, 1994). Major decreases in vitamin C activity were reported by early studies where relatively high doses of irradiation were used however, 'more typical' examples are cited in WHO (1994) where doses of less than 1 kGy applied to oranges have not shown significant effects. The subsequent storage conditions are potentially more significant in relation to vitamin C activity retention than the process of irradiation. Folate is considered to be considerably less vulnerable, and possibly not affected at all (Muller, 1991, as cited in WHO, 1994) but has been modelled in order to provide a more complete assessment.

On the basis of the above nutrient profiles, and the relative susceptibility of various micronutrients to irradiation, a dietary intake assessment has been used to further consider the contribution of the selected tropical fruits to the overall dietary intakes of β-carotene, vitamin B_1, vitamin C and folate (refer to Dietary Modelling report-**Attachment 3**).

5.5 Conclusions of the nutritional issues

- Irradiation potentially causes both macro and micronutrient changes in foods, depending on the irradiation dose, the food's composition and environmental conditions. The impact of irradiation on nutritional status of the New Zealand and Australian populations however, will be dependent on the level of intake of irradiated foods.

- In respect of macronutrients, the irradiation of the selected tropical fruits does not cause significant changes in the protein, carbohydrate and saturated fatty acid content of foods.

- The available data indicates that minerals and trace elements in food are not affected by irradiation. Therefore, the irradiation of the selected tropical fruits is unlikely to significantly affect the presence of these minerals from these foods.

- There is evidence to indicate that certain vitamins (i.e. vitamin E, vitamin C, thiamine and beta-carotene are decreased to some degree in the irradiation process. This aspect of food irradiation will therefore have the greatest impact on the nutritional content of tropical fruit and subsequently a detailed dietary exposure assessment has been performed (**Attachment 3**).

6. Overall Conclusions

The overall conclusions are as follows:

- There is an established technological need to irradiate tropical fruits for the purposes of pest disinfestation;

- International scientific opinion is that irradiated food is safe when the irradiation is performed at dose levels necessary to achieve the intended technological function and, in accordance with good radiation/manufacturing practice;

- There are chemical changes in tropical fruits following irradiation (albeit limited) resulting in the formation of radiolytic products. However, these products are not always unique to irradiation and are also present following more traditional processing of food, namely, heat;

- As a form of food processing, irradiation will have some impacts on the nutrient status of tropical fruits; however, there are few indications that these impacts are any greater than other forms of food processing, especially for irradiation doses less than 10 kGy;

- The research indicates that carbohydrates, proteins, fatty acids, minerals and trace elements in tropical fruits undergo very minimal alteration during irradiation; although selected vitamins are effected following irradiation of tropical fruits;

- Overall, there are no toxicological concerns resulting from the formation of new radiolytic products following irradiation of tropical fruits. By virtue of the concept of chemiclearance and the past safety studies performed on fruits (including tropical fruits) irradiated food is considered equivalent to non-irradiated food or fruits that have been treated with more conventional treatment protocols (eg heating for quarantine purposes) with respect to safety, nutritional properties and wholesomeness.

APPENDIX 1

Studies on Irradiated Fruits/Tropical Fruits

The following table is a concise summary of the range of studies that have been performed to evaluate the wholesomeness and safety of irradiated fruits in cell lines, animals and humans. A complete list of all studies undertaken on irradiated foods is available in the World Health Organization reports (1994 and 1999).

Genotoxicity studies

Species/Food	Type of Study	Duration	Dose (kGy)	Effects	References
Human lymphocyte cells/Strawberries	*In vitro* test for chromosomal aberrations	3-days	15 kGy	No mutagenicity observed	Schubert et al (1973)
Mouse /Strawberries at 5% in diet	*In vivo* for chromosomal aberrations	5-days	15 kGy	No mutagenicity observed	Schubert et al (1973)
Rat/Mangoes at 15% in diet	*In vivo* Dominant lethal study	112 days	0.8 kGy	No mutagenicity observed	Derse (1978)
Rat/Mangoes	Chromosomal aberration study	Varied	0.08 kGy	No mutagenicity observed	Derse (1979)

Animal Studies

Species/Food	% in the diet	Duration	Dose (kGy)	Effects	References
Rats					
Mangoes	At 15% in the diet	90 days	0.8 kGy	No adverse effects	Raltech Scientific Services (1979)
Strawberries	At 5% in the diet (powder and juice)	90-days	50 kGy	Decreased growth in male rats consuming powder form. No effects on females or on animals consuming strawberry juice.	Verschuuren, Van Esch and Kooy (1966)
Peaches or Strawberries	at 35% in the diet	8-12 weeks	Up to 60 kGy	Decrease in growth in rats consuming peaches. However, this was attributed to high sucrose levels.	Read, Kraybill and Witt (1958)
Mangoes	At 15% in the diet	2 years	0.8 kGy	No adverse effects observed	Raltech Scientific Services (1981)
Strawberries	Not stated in WHO (1994) Report	2 years	3 kGy	No adverse effects observed	Nees (1970)

Rats (contin.)					
Peaches	35% in the diet	2 years	56 kGy	No adverse effects observed	Bone (1963)
Fruit compote	at 35% in the diet	2 years or 4 generations	Up to 56 kGy	Longevity decreased in 4th generation.	Mead and Griffith (1959)
Peaches	at 20% in the diet	2 years or 4 generations	Up to 56 kGy	Decreased weight gain in females of 4th generation.	Read et al (1961)
Peaches	at 35% in the diet	2 years	Up to 56 kGy	No adverse effects	Tinsley, Bone and Bubl (1963)
Oranges	at 35% in the diet	2 years	Up to 56 kGy	No adverse effects	Phillips, Newcomb and Shankin (1961)
Mice					
Fruit compote	at 9% in the diet	1-2 years	Up to 56 kGy	No adverse effects	Radomski et al (1965)
Peaches	at 17% in the diet	2 years	Up to 56 kGy	No adverse effects	Calandra and Kay (1961)
Dogs					
Fruits (Cherries, apricots and prunes)	at 35% in the diet	90 days	4 kGy	No adverse effects	Gabriel and Edmonds (1977)
Fruit compote	at 35% in the diet	2 years	Up to 56 kGy	No adverse effects	Larson et al (1957)
Monkeys					
Peaches and whole oranges	at 35% in the diet	2 years	Up to 55.8 kGy	No adverse effects noted	Blood et al (1963)

Human studies

Food	Duration	Dose (kGy)	Effects	References*
Thirty-five different kinds of irradiated foods-grains, beans, vegetable and fruits, meat, fish, eggs, poultry and flavourings 60% of diet	90 days	1-8 kGy	No adverse effects. No chromosomal abnormalities.	Shao and Feng 1988; Yang (1990).
Fifty four items of various foods	Periods of 15 days, separated by control diet and washout intervals	25-40 kGy	No toxic effects observed nor change in clinical parameter (including at follow up examinations at one-year post exposure)	Bierman (1958)
Canned pork	Two periods of 15 days separated by a 5 day washout interval	30 kGy	No adverse effects noted	Plough et al (1957, 1961)

The tables above summarise some of the available studies in animals and on humans, where a broad range of irradiated foods have been administered in the diet.

These animal and human studies have shown minimal adverse effects on the wholesomeness and subsequent safety of irradiated foods in animal and humans.
The studies on chemistry of irradiated fruits in conjunction with the specific safety studies on mangoes justify extrapolating the conclusions about safety and nutritional adequacy to all members of the fruit class, in particular, tropical fruits.

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ATTACHMENT 3

DIETARY INTAKE ASSESSMENT REPORT

1. Dietary intake assessment

This application considers dosages up to 1 kGy, which as identified by the research outlined in Attachment 2, are unlikely to have significant impact on the nutritional profiles of the tropical fruits proposed to be irradiated. Nonetheless, the potential impact of losses of at-risk nutrients from irradiation of these tropical fruits has been considered within the context of total dietary intakes for the Australian and New Zealand populations. No population sub-groups in respect of age or gender have been identified for whom the selected tropical fruits were a major nutrient source. Therefore, the modelling has been conducted for the population as a whole.

ANZFA's dietary modelling computer program, DIAMOND, was used to estimate the total dietary intakes of β-carotene, folate, vitamin C and vitamin B_1 for Australian and New Zealand populations. Vitamin concentrations of foods in Australia and New Zealand, as contained in DIAMOND reference files, were derived from the databases that supported the most recent National Nutrition Surveys for Australia and New Zealand respectively. These surveys were the 1995 National Nutrition Survey (NNS) in Australia that surveyed 13,858 people aged 2 years and above; and the 1997 New Zealand NNS that surveyed 4,636 people aged 15 years and above. Both surveys utilised a 24-hour food recall methodology.

DIAMOND was also used to estimate the consumption of the selected tropical fruits (including the associated products where these foods are ingredients) in Australia and New Zealand.

1.1 Food consumption data

The consumption of the selected tropical fruits, raw only, and the selected tropical fruits, from raw and other sources (such as ingredients in mixed foods or as juices), were estimated separately using DIAMOND; the results are shown in Table 1. The estimated consumption figures are limited to the tropical fruits reported as consumed in each of the respective surveys. In the Australian 1995 NNS, carambola, custard apple, litchi, mango, papaya and rambutan were reported as consumed. In the New Zealand 1997 NNS, breadfruit, litchi, mango and papaya were reported as consumed. Longans and mangosteens were not reported as consumed and therefore, were unable to be considered.

Table 1. Consumption of selected tropical fruits as reported in Australia and New Zealand National Nutrition Surveys

Country	Tropical Fruit	Raw only		Raw + other sources	
		Number* of consumers (as % of respondents)	Mean consumption (g/day)	Number* of consumers (as % of respondents)	Mean consumption (g/day)
Australia	Carambola	2 (0.01)	50.2	2 (0.01)	50.2
	Custard apple	11 (0.1)	253.6	11 (0.1)	253.6
	Litchi	9 (0.1)	103.3	12 (0.1)	105.5
	Mango	137 (1.0)	192.5	344 (2.5)	178.7

Country	Tropical Fruit	Raw only			Raw + other sources		
		Number* of consumers (as % of respondents)		Mean consumption (g/day)	Number* of consumers (as % of respondents)		Mean consumption (g/day)
	Papaya	72	(0.5)	135.8	72	(0.5)	135.8
	Rambutan	4	(0.03)	24.4	4	(0.03)	24.4
New Zealand	Breadfruit	NC	-	-	3	(0.1)	668.6
	Litchi	NC	-	-	2	(0.04)	61.8
	Mango	7	(0.2)	283.3	11	(0.2)	234.8
	Papaya	5	(0.1)	102.5	6	(0.1)	91.6

* Consumers are those respondents to each NNS that reported consuming one or more of the tropical fruits in Table 1
NC = No consumption reported

Mango and papaya presented as the main fruits consumed from the 'selected tropical fruit' category, as recorded in the surveys. The number of consumers of raw mango represented 1% of all respondents to the Australian 1995 NNS and the number consuming both raw and other sources of mango represented 2.5%. The reported consumption of the selected tropical fruits overall was much smaller for the New Zealand population, with 0.2% of respondents to the New Zealand 1997 NNS reporting consuming mango in any form.

1.2. Estimated intakes of β-carotene, vitamin C, folate and vitamin B_1

The estimated intakes of β-carotene, folate, vitamin C and vitamin B_1 from the total diet for Australia and for New Zealand are shown in Table 2. Table 2 also shows the proportion of the RDI the estimated intakes represent. The vitamin intakes were calculated for each individual respondent in the survey based on the foods they consumed on the day of the nutrition survey, and the concentrations of the vitamins in these foods. The estimated vitamin intakes for each individual were compared to the specific Recommended Dietary Intake (RDI) for his/her age and gender. All individual RDI intakes were then ranked and statistics for the population (mean, and high percentiles) were derived. The estimated vitamin intakes are unadjusted, and do not account for intra-individual variation. A second 24-hour recall was conducted on a subset of both the NNS's respondents in order to allow for correction or adjustment for variation in nutrient intakes over longer periods of time. The use of unadjusted values is likely to have little impact on estimated mean intakes, but is likely to produce higher estimated 95th percentile intakes than if the adjustments were made (Rutishauser, 2000).

Table 2. Estimated intake of vitamin C, vitamin B_1, β-carotene and folate from the diets of Australia and New Zealand

Country	Vitamin		Estimated Intake	
			Mean	95th percentile
Australia				
	Vitamin C	mg/day	122	333
		x RDI^{+}	*3.63*	*9.95*
	Vitamin B1	mg/day	1.6	3.4
		x RDI	*1.82*	*3.64*
	B-carotene	µg/day	3326	10623
		x RDI (RE)*	*0.8*	*2.58*

Country	Vitamin		Estimated Intake	
			Mean	95th percentile
	Folate	µg/day	289	564
		x RDI	*1.08*	*2.46*
New Zealand				
	Vitamin C	mg/day	110	312
		x RDI	*3.27*	*9.09*
	Vitamin B1	mg/day	1.4	2.7
		x RDI	*1.57*	*2.89*
	B-carotene	µg/day	3517	11859
		x RDI (RE)*	*0.78*	*2.64*
	Folate	µg/day	243	460
		x RDI	*0.76*	*1.61*

*RE=retinol equivalents

+ Multiples of RDIs are weighted for age and gender

The RDI listed for β-carotene is derived from the RDI for vitamin A, as there is no separate RDI for β-carotene. β-carotene is converted to retinol at the average rate of 6 µg β-carotene = 1 µg retinol (NHMRC 1991). The RDIs for vitamin A are expressed as Retinol Equivalents (REs). Therefore, for the purposes of dietary modelling, the RDIs for vitamin A were multiplied by six and compared to the estimated intakes of β-carotene. The contribution of retinol to vitamin A is not taken into account.

The mean and 95th percentile level of intakes of vitamin C and vitamin B_1 for Australia and New Zealand for the surveyed populations of both countries each exceeded the RDI. The mean estimated β-carotene intakes for Australia and New Zealand, when expressed as a proportion of the Vitamin A RDI, were calculated at approximately 80% vitamin A RDI; however, β-carotene itself does not have an RDI and it is not expected that β-carotene alone would meet the equivalent RDI (RDI for total vitamin A activity) used in the dietary modelling. The estimated 95th percentile levels of β-carotene intake for both countries expressed as a proportion of the Vitamin A RDI was greater than 100%. The mean estimated dietary intakes of folate for Australian and New Zealand populations were approximately 100% and 80% of the RDI, respectively, with the 95th percentile level for each population exceeding the RDI.

Tables 3 to 6 given below indicate the percentage contribution of the vitamin intake from consumption of the selected tropical fruits to the mean total dietary intake of vitamin C, vitamin B_1, β-carotene and folate respectively. The major contributors to the mean total dietary intake of each vitamin are also shown. Contribution by the tropical fruits subject to this application has been estimated by the summation of 'other fruit' and 'other tropical fruit' categories. This will, therefore, be an overestimate as these categories, particularly the 'other fruit' category, include fruits additional to the selected tropical fruits relevant to this application. The particular fruits included in the 'other fruit' and 'other tropical fruits' categories are listed at Appendix 1 to this Attachment.

Table 3. Percent contribution of high dietary contributors and tropical fruits to mean total vitamin C intake for Australia and for New Zealand

Country	Food	Percent contribution to mean dietary intake
Australia	Single fruit juices	21.8
	Potatoes	11.9
	Brassica vegetables	10.4
	Oranges	5.0
	Other fruit*	2.8
	Bananas	2.4
	Other tropical fruit*	1.0
	Pineapples	0.4
New Zealand	Fruit juices	11.9
	Cordials and fruit drinks	10.0
	Brassica vegetables	8.9
	Oranges	7.8
	Boiled and baked potatoes	6.0
	Other fruit*	4.4
	Banana	2.8
	Other tropical fruit*	1.0
	Pineapple	0.3

* See Appendix 1 for a list of the fruits contained in these categories in the dietary model

The contribution of 'other fruit' and 'other tropical fruit' to the estimated mean dietary intake of vitamin C is 3.8% for Australia and 5.4 % for New Zealand. The actual contribution of the selected tropical fruits will be smaller than the values reported above and, based on dietary modelling, these fruits do not appear to be major contributors to vitamin C intake from the diet.

Table 4. Percent contribution of high dietary contributors and tropical fruits to mean total vitamin B_1 intake for Australia and for New Zealand

Country	Food	Percent contribution to mean dietary intake
Australia	Breads, rolls, white	12.5
	Yeast, vegetable and meat extracts	10.3
	Breakfast cereal, wheat based biscuits and shredded wheat	4.9
	Breads, rolls, wholemeal	4.5
	Bananas	0.7
	Other fruit*	0.2
	Pineapples	0.1
	Other tropical fruit*	< 0.1
New Zealand	Bread and rolls, white	12.2
	Bread and rolls, wholemeal	9.0
	Bread and rolls, mixed grain	3.9
	Yeast and vegetable extracts	3.1
	Banana	0.9
	Other tropical fruit*	0.2
	Other fruit*	0.1
	Pineapple	0.1

* See Appendix 1 for a list of the fruits contained in these categories in the dietary model

The contribution of 'other fruit' and 'other tropical fruit' to the mean estimated dietary intake of vitamin B_1 is <0.5% for both Australian and New Zealand populations. The contribution of the selected tropical fruits to vitamin B1 intakes would therefore be relatively insignificant.

Table 5. Percent contribution of high dietary contributors and tropical fruits to mean total β-carotene intake for Australia and for New Zealand

Country	Food	Percent contribution to mean dietary intake
Australia	Carrot and similar root vegetables	45.9
	Pumpkin	10.2
	Vegetable based soup	3.9
	Tomato	3.1
	Other fruit*	1.7
	Other tropical fruit*	1.6
	Bananas	0.5
	Pineapples	< 0.1
New Zealand	Carrots	36.2
	Pumpkin/squash/butternut	11.6
	Leafy greens	8.3
	Carrots/peas/beans/corn mixes	4.2
	Stone fruit	3.9
	Other tropical fruit*	0.7
	Other fruit*	0.4
	Banana	0.3
	Pineapple	<0.1

* See Appendix 1 for a list of the fruits contained in these categories in the dietary model

The contribution of 'other fruit' and 'other tropical fruit' to the mean estimated dietary intake of β-carotene is 3.3 % for the Australian population and 1.1% for the New Zealand population. The contributions of the selected fruits relevant to this application will be lower than the levels reported above. The dietary modelling also assumes β-carotene has an RDI and does not take into account other sources of vitamin A from the diet. Based on dietary modelling the tropical fruits relevant to this application are not major contributors to dietary β-carotene and vitamin A intake.

Table 6. Percent contribution of high dietary contributors and tropical fruits to mean total folate intake for Australia and for New Zealand

Country	Food	Percent contribution to mean dietary intake
Australia	Potatoes	6.6
	White bread	5.2
	Breakfast cereal, wheat-based biscuits & shredded wheat†	4.4
	Cauliflower and similar brassica vegetables	4.1
	Bananas	1.1
	Other fruit*	0.2
	Other tropical fruit*	< 0.1
	Pineapples	< 0.1
New Zealand	White bread	5.4

Tea	5.2
Yeast and vegetable extracts	4.2
Cauliflower and similar brassica vegetables	4.2
Single cereal, puffed, flakes or extruded cereals†	3.9
Banana	2.8
Other fruit*	1.0
Other tropical fruits*	0.2
Pineapple	< 0.1

* See Appendix 1 for a list of the fruits contained in these categories in the dietary model
† Includes fortified breakfast cereals

In Table 6, 'other fruit' and 'other tropical fruit' contributed less than 0.3% for the Australian population and 1.2% for the New Zealand population to the mean estimated dietary intake of folate. The contributions of the selected tropical fruits relevant to this application will be smaller than the levels reported above, particularly for the 'other fruit' category. The contribution to of the selected tropical fruits to folate intakes will therefore be relatively minor.

If the worst-case scenario were assumed, that is, that the irradiation process completely destroyed all β-carotene, folate, vitamin C and vitamin B_1 in the selected tropical fruits, then the estimated mean intakes of β-carotene, folate, vitamin C and vitamin B_1 from the selected tropical fruits would be 0% rather than the approximate ranges between 0% and 5% as indicated above. Dietary modelling was conducted to estimate the total dietary intakes of each nutrient assuming irradiation had completely destroyed the nutrient content of the selected tropical fruits. The potential reductions in mean dietary nutrient intakes were 5% or less for β-carotene and vitamin C and 1% or less for vitamin B1 and folate for both the Australian and New Zealand populations. In the context of the total diet, and given that many of the alternate sources of these micronutrients are readily available to the Australian and New Zealand populations, it is considered that the nutritional impact would be negligible at the broader population level.

2. Regional considerations

It is recognised that the fruits in question are tropical and as such, may be consumed more frequently and in greater amounts by those population sub-groups residing in tropical areas. This relates in particular to Queensland and the Northern Territory of Australia. Consideration of relevant dietary intakes has been applied on a regional basis in order to consider this aspect further.

The following table (Table 7) identifies the contribution of the 'other tropical fruits' category, as the category representing most of the fruits in question, to intakes of β-carotene, folate, vitamin C and vitamin B_1 on a regional (i.e. state and territory) basis.

Table 7. Percent contribution of "other tropical fruit" to mean total nutrient intake by State and Territory in Australia, and for New Zealand

State	Nutrient			
	Vitamin C	Vitamin B1	β-carotene	Folate
NSW	0.9	0.05	2.3	0.04
Victoria	0.4	0.02	0.8	0.02
Queensland	3.0	0.13	3.8	0.07
South Australia	0.2	0.13	0.5	0.01
Western Australia	0.4	0.02	0.8	0.01
Tasmania	0.3	0.003	0.04	0.001
Northern Territory	1.9	0.09	3.9	0.05
ACT	0.6	0.03	0.9	0.01
New Zealand	1.0	0.2	0.7	0.2

As can be seen in Table 7, the contribution of 'other tropical fruit' to the mean vitamin C and β-carotene intakes for Queensland and Northern territory populations are higher than for the other states and territories in Australia. New Zealand values have also been included in Table 7 for comparative purposes.

Dietary modelling indicates the contributions to total intake from the tropical fruits relevant to this application are still relatively small for Queensland and Northern Territory and the respective RDIs can be readily achieved through other food sources. It is not considered that the impact, even within these jurisdictions, would be sufficiently significant to warrant concern.

3. Limitations of the dietary intake assessment

A limitation of estimating habitual dietary nutrient intake associated with this dietary intake assessment is that only 24-hour dietary survey data were available. These data do not take into consideration the variation in nutrient intake over time by the same individual (intra-individual variation). Also, 24-hour data tend to overestimate habitual food consumption amounts for high consumers, and therefore may result in higher estimated nutrient intakes for this group. Thus, predicted high percentile nutrient intakes are likely to be greater than actual high percentile nutrient intakes over a lifetime.

A further limitation is the inability of the dietary intake assessment to clearly segregate the fruits in question from the other fruit categories. However, the assessment as conducted represents an over-estimate of the contribution of these fruits to total dietary intakes and as such, more accurate values would diminish rather than increase the significance of these fruits in the Australian and New Zealand diets.

4. Conclusions

The dietary intake assessment indicates that the selected tropical fruits proposed to be irradiated are minor contributors to the total dietary intakes of β-carotene, folate, vitamin C and vitamin B_1 when considered within the context of the overall diet.

Therefore it is concluded that any potential reductions-of β-carotene, folate, vitamin C and vitamin B_1 due to irradiation are unlikely to have a significant impact on dietary intakes of these vitamins by the Australian or New Zealand populations, even when considered on a regional basis.

Appendix 1

Table A1 Fruits included in the "Other tropical fruit" and "Other fruit" categories listed in Tables 3, 4, 5, 6 and 7.

Category	Fruits in category[+]	
	Australia	New Zealand
Other tropical fruit	CARAMBOLA	Guava
	CUSTARD APPLE	LITCHI
	Guava	MANGO
	Jackfruit	Passionfruit
	MANGO	PAPAYA (pawpaw)
	PAPAYA (pawpaw)	Watermelon
	Pepino	Rockmelon
	RAMBUTAN	Honeydew melon
	Tamarillo	Grapes
		Tamarillo
		Olives
Other fruit	Date	Feijoa
	Feijoa	Kiwifruit
	Fig	Persimmon
	Grape	Rhubarb
	Honeydew melon	Gooseberry
	Kiwifruit	Jackfruit
	Loquat	Pepino
	LITCHI	Babaco
	Passionfruit	BREADFRUIT
	Persimmon	Avocado
	Rhubarb	
	Rockmelon	
	Watermelon	

[+] Fruits appearing in CAPITAL letters are those that potentially are to be irradiated.

NHMRC (1991) *Recommended Dietary Intakes for use in Australia*. AGPS. Canberra.

Rutishauser I (2000), *Getting it Right: How to use the data from the 1995 National Nutrition Survey.* Commonwealth Department of Health and Aged Care/National Food and Nutrition Monitoring Unit.

ATTACHMENT 4

SUMMARY OF PUBLIC SUBMISSIONS

Submitter	Supports / Does not support	Details
Queensland Department of Primary Industries	**Supports**	The Department supports the application based on the scientific evidence that the treatment is safe and efficacious and that there is a need for this technology to access new markets. This technology is approved and recognised as a treatment procedure for selected tropical fruits from Hawaii to the US mainland. This treatment is of particular importance to Queensland's tropical fruit industries to establish new markets.
Cairns Region Economic Development Corporation	**Supports**	High level of support for the application as it will open up critical export markets for North Queensland: 1. NZ Markets-mango, papaya, lychee and other fruits; 2. US market for lychee, rambutan, longan and other fruits; 3. Potential markets in north Asia; 4. Market opportunities for 10,000t/yr of tropical fruits worth A$50m.
Tableland Economic Development Corporation Inc	**Supports**	Expressed a very high level of support for irradiation of tropical fruits, as the current range of phytosanitary treatments available to farmers in North Queensland is expensive, inadequate or ineffective.
State Development Centre, Cairns	**Supports**	Irradiation appears to offer a sound solution to treating pests. Accessing a suitable technology to treat tropical fruits for export has been identified as a Regional Development Priority and a Regional Export Priority for Far North Queensland.
Queensland Fruit and Vegetable Growers	**Supports**	Irradiation has the potential to assist industry access export and domestic markets because of the ability to disinfest produce infected with fruit fly. QFVG trusts that ANZFA will ensure that the resulting food does not pose a risk to public health and safety or food that is nutritionally inadequate. QFVG emphasises that operators of irradiation facilities must adhere to adequate labelling and that the proponents of irradiation rigorously adhere to an open and transparent process to overcome barriers to acceptance of treated produce.
Rambutan and Tropical Exotic Growers Association	**Supports**	This will create export opportunities and has potential to make a huge difference to the viability of the industry.

Dr N Dasari, Horticulture, Northern Territory	**Supports**	Irradiation has the capacity to treat a range of horticultural and other food products and offers the opportunity to attract a phytosanitary treatment facility to the region thereby building the regions capacity to develop export markets. Also offers opportunities to harvest relatively mature fruit and transport without shelf life disadvantages. Will offer an alternative treatment for some fruits intolerant of vapour heat or hot water dipping and include an ability to treat packed boxes of fruit leading to reduced cross contamination of pests and diseases. Provided the fruit is labelled there are benefits to consumers in terms of seasonal spread, quality, flavour and diversity of product. Costs are restricted to the industry in terms of labelling, treatment costs and market development. Industry must assess the risk of consumer reaction, both negative and positive and make an investment decision accordingly. Stated that the benefits to consumers (to avoid irradiated foods) of Option 1 (Not to permit irradiation of tropical fruits) is incorrect as consumers will be forced to avoid irradiated fruit under this option as irradiation would not be available.
Food Technology Association of Victoria Inc	**Supports**	Suggested that the labelling issue should be thoroughly considered, as there appears to be uncertainty as to how unpackaged, individually displayed fruit would be designated as being irradiated. Suggested that sticky labels could be utilised. Stated that mandatory labelling regarding information to be displayed at point of sale is historically ignored and not policed. An alternative approach to irradiation is that an attempt be made to harmonise the range of phytosanitary treatments that are permitted in Australia but do not meet New Zealand Quarantine requirements.
Advance Cairns Limited	**Supports**	Has the potential to generate a significant increase in production of tropical fruits in the Cairns region, establish a food production plant and increase exports through the Cairns International Airport.
Cairns City Council	**Supports**	This will allow increased production of tropical fruits in the Cairns region and increased export earnings for Australia.
Cairns Port Authority	**Supports**	Has the potential to generate a significant increase in production of tropical fruits in the Cairns region, establish a food production plant and increase exports through the Cairns International Airport.

Australian Horticultural Exporters' Association	**Supports**	
International Consultative Group on Food Irradiation	**Supports**	Based on the principle of chemi-clearance ICGFI would urge ANZFA to approve fruits as a class without being specific to individual items. This would allow other fruits grown in Australia to be treated with irradiation for phytosanitary purposes. Endorses the max dose of 1 kGy; however suggested that a minimum dose of 150 Gy and 300 Gy is sufficient to ensure quarantine protection against fruit fly and other insect species respectively. Irradiation is an efficacious treatment for fresh horticultural commodities. With the exception of methyl bromide fumigation, irradiation costs less than other physical treatments
Australian Mango Industry Association Ltd	**Supports**	This application will be an important step in securing acceptance of irradiation as a phytosanitary treatment in other key markets. Irradiation is an effective and viable phytosanitary disinfestation treatment for Australian exporters.
Department of Agriculture, Fisheries and Forestry Australia	**Supports**	Irradiation will provide governments with an additional quarantine control option and the additional affect of providing a non-quarantine control option to achieve public health and safety, and provide industry with an effective safe technology.
Ministry of Health New Zealand	**Supports**	No particular concerns at this stage.
Danila B Oder-Stop Food Irradiation Co-ordinator	**Does not support**	An extensive submission* was submitted which covered three main aspects: 1. Details of the US approval of food irradiation, including expected problematical developments for the USA and Australia/New Zealand; 2.A description of unintended consequences of approval; and 3. The difficulties with adequate labelling for consumers.
Suzi Tooke	**Does not support**	Concerned over the health effects caused by consumption of food exposed to ionising irradiation. The cumulative health effects of numerous food applications are not considered by ANZFA. The case-by-case approach suggested by ANZFA and Ministers is misleading as any irradiation facility can irradiate food (including using Cobalt 60). This will lead to Surebeam establishing an irradiation plant and could lead to further expansion of existing nuclear irradiation facilities.

		ANZFA has been inadequate in informing consumers about food irradiation. Concerned that fruits will not be adequately labelled for consumers. Also, the labelling should include the negative effects as well. ANZFA and ANZFSC ignored each and every study unfavourable to food irradiation. There has been no market research to determine the negative impact on Australian farmers, nor any public information programme. ANZFA should reject the application on the basis that the technology is unsafe, unhealthy and should not be swayed into accepting food irradiation because of international trading obligations.
Ian and Lexie Gray	**Does not support**	Food Irradiation is something we do not need
Form Letter from Zenith Design (No Name listed) Sonja Perrone Heidi Muller Fred Muiler Bruce Henry Hetty Thomas Brigitte Goerres Bruno Goerres R Wester M Lester Drew Jones Anna Barnes Mathew Smith Helen Maitland Kerry Scanlan MAK Williams Danielle Burette Grant Young	**Does not support**	Concerned over the health effects of the consumption of irradiated foods and that approval will allow food to be treated with ionising radiation from a highly radioactive material, namely, cobalt 60. The majority of concerns raised in this submission were covered in the submissions by Suzi Tooke and Danila B Oder. In addition, this form letter stated that Surebeam (USA) had misled the public over labelling of irradiated food by referring to 'electronic pasteurisation' rather than irradiated foods.
Janet Ablitt	**Does not support**	Irradiation is dangerous, relatively new and untried. Option 1 not to irradiate food is the only option.
Bettina Quatacker	**Does not support**	Food irradiation is unsafe for consumers; The location of the proposed Surebeam facility was not detailed for public information. Requested ANZFA to publish this location on its website. Tropical fruits would be irradiated at Narangba in Queensland. The proposed Steritech nuclear radiation facility (at Narangba) is too close to residential areas, which may increase the risk to public health and safety. There are no plans to monitor radiation levels in the area to protect resident's health.

		Other concerns raised in this submission were covered in the submissions by Suzi Tooke and Danila B Oder.
National Council of Women of Australia	**Does not support**	It is disappointing to find yet another application has been received to irradiated food-an entirely unnecessary process. Questioned NZMAF with respect to why if not all the alternative treatments are acceptable to other countries (including Australia) is it not acceptable to New Zealand? Does not believe that there is justification for the use of irradiation when other methods are available. Labelling of unpackaged foods such as tropical fruits will not be adhered too. Seeks clarification of doses expected to be used. Overall supports Option 1, not to permit irradiation of tropical fruits and rely on existing methods for phytosanitary purposes. Additionally, NZMAF should re-consider its requirements and to ascertain from NZ consumers whether they want irradiated foods.
BJ Turner	**Does not support**	Irradiation does not kill micro-organisms, can mask dirty processing and handling methods, leads to significant loss of vitamins and nutrients and there is a risk to health from eating irradiated foods due to increased carcinogens, new and dangerous unique radiolytic products. Other methods should be investigated other than irradiation. The precautionary principle should apply to food irradiation.
Peter Milton	**Does not support**	Was amazed to find that the Australian Government has permitted the consideration of applications to irradiate food based on the findings of a preliminary WHO (1992) report. ANZFA should not consider that irradiation from x rays or e beams and gamma rays are identical as x rays are far less intense and penetrating and dangerous to food products. Until there is a reliable testing method for irradiated food, irradiation should not be approved. ANZFA does not appear to be giving the submissions relating to the loss of nutrition and the lack of food safety the rigorous attention they deserve.
Brenda Lewis	**Does not support**	Raised safety and nutritional concerns over irradiated foods.

People Against Food Irradiation (Sydney)	**Does not support**	Wish to protest against the lack of time to comment on this application and the undue haste of the Surebeam application following the previous irradiation application (A413). Questions why ANZFA would approve the use of gamma rays to treat fruits when Surebeam is applying for use of e-beam/x-rays? The safety of e-beam/x-ray is seriously questioned in its proposed use on tropical fruit and the workers operating the equipment. Are the Australian tropical fruits producers aware of this application, what effects on food e-beam/x-rays may have and do they want this technology over present methods? Additionally, is there a market for producers and is it financially viable for them? Cited alternative techniques that may be used; namely, carbon dioxide/nitrogen blasting, sonar detection, and biological controls (disease/insect resistant plants). Request that ANZFA approach the CSIRO and Department of Primary Industries to ask for information on fruit developed by these two organizations which have been bred to be insect resistant. Provided references on Mangoes and Papaya's which suggest that irradiation is not a suitable process for these fruits (e.g. mangoes fail to ripen, colour spotting occurs on the skin, pores turn black and mottled browning of the skin occurs).
Public Citizen	**Does not support**	Opposes the application on the basis of the failure to protect public health and safety of consumers (irradiated food is unsafe), Surebeam's failure to uphold standards of honest, trustworthy conduct and to provide adequate and accurate information about its products and the failure to meet a technological need that benefits consumers, industry and government.
Federated Association of Australian Housewives	**Does not support**	E-beam/x-ray sources were not recommended by the House of representatives Standing Committee Enquiry (1989) Report. Irradiated foods are not safe, nutritious and irradiation facilities malfunction and kill people. Stated that enough time was not given to prepare a detailed submission.

Action for Environment (New Zealand)	**Does not support**	Irradiating tropical fruits will not be in the best interests of New Zealand consumers. The irradiation process will affect the appearance of the fruits and will deplete the vitamin content. As the irradiation process does not kill fruit flies but rather sterilises them, there is a real possibility that there may be surviving larvae. This could be disastrous for New Zealand's horticulture industry.
Form letter (2) Nimbin Organic's Judy Canales Hemp Party People of Nimbin Nimbin Hot Bread Kitchen Nimbin Village Meats Happy High Herbs Nimbin Newsagency and General Store	**Does not support**	Insufficient public information has been supplied, and the five-week comment period is insufficient for members of the general public to research, evaluate and respond to the Initial Assessment report. Opposed to the term 'electronic pasteurisation' to replace irradiation. Requires clarification of this term. Questions the standards of an organization that finds it acceptable to administer large doses of irradiation yet finds it unacceptable to use existing treatments such as heat or cold treatments. Raised the issue of previous safety studies, in particular, studies that showed that irradiated food is unsafe, particularly over a long-term period. Other concerns raised in this submission were covered in the submissions by Suzi Tooke and Danila B Oder.
Friends of the Earth (New Zealand)	**Does not support**	1. Inadequate information has been provided by the applicant with respect to energy levels of the e-beams and x-rays and how the fruit would be packaged or presented to the irradiation beams. This suggests that the efficacy of using such beams on thicker unevenly shaped produce such as tropical fruits is doubtful. How will the applicant ensure that all surfaces and the inner flesh of the fruits receive an irradiation dose exceeding the minimum required to sterilise ALL fruit fly larvae. 2. The applicant has only supplied a maximum dose, which at 1 kGy is higher than some tropical fruits can tolerate. 3. The claims that NZMAF will not accept tropical fruits from Australia are false. 4. There has been inadequate notification and consultation with stakeholder groups. 5. There are intrinsic problems in the use of irradiation as a treatment on tropical fruits. Cited the paper by Carpenter and Baker, 1987 which expressed this.

		6. NZ would be solely reliant on a Queensland certificate that claimed that produce had been properly irradiated. This would lower NZ quarantine protection measures and would greatly increase the likelihood of fruit fly outbreaks in NZ, lead to environmental concerns (as it would require widespread aerial spraying of insecticides), Key NZ producer groups should be consulted further. Support option 1 not to irradiate tropical fruits.
Mark Loveridge	**Does not support**	Not happy with ANZFA's approval of food irradiation due to safety concerns, no benefits to consumers, industry and governments, international trade should be scaled down not increased, irradiation will destroy the 'life-force' of food and there is not a final assessment report to review.
Canberra Consumer (CC) 2 submissions (31 October 2001 and 13 November 2001)	**Not specifically stated**	Insufficient information has been provided in the application to be able to make detailed comments. CC attached a copy of a paper by Carpenter and Baker (1987) of the NZ Ministry of Health titled: "The place of irradiation for insect control on fresh produce entering or leaving New Zealand". CC supports this paper and conclusions. No information has been provided on what insects are to be targeted and at what dose. Many tropical fruits are sensitive to irradiation damage below 1 kGy. CC provided a copy of a comparison of maximum tolerable doses and minimum dose required for desirable technical effects on fruits and vegetables. Supplied a reference on Kensington Pride Mangoes (the main variety grown in Australia) that they are damaged by radiation doses of 100 Gy (0.1 kGy). Therefore, published overseas data may not be applicable to fruits grown in Australia. The concept of equivalence does not apply to different varieties of the same fruit. It is necessary for Surebeam to provide data on the necessary radiation dose for the different insects, and the effects of that dose on the Australian varieties of the fruits to be irradiated. CC is opposed to the use of gamma rays, as they are unsuitable for use at low levels. It is essential that the irradiation procedures be HACCP compliant. Since the submission of 31 October 2001, CC has obtained a statement from the Queensland department of Primary Industries Web Site that the papaya fruit has been eradicated in Queensland. This means that there is no technological need to irradiate papayas as a quarantine measure.

Environmental Health Branch, South Australia	**Not specifically stated**	To ensure that this application fulfils a technological need, information from the New Zealand import authority and Biosafety Australia indicating that the proposed treatment will satisfy quarantine requirements should be provided.
Queensland Health	**Not specifically stated**	Why in Attachment 1 of the Initial Assessment report under the heading 'Guava' is some countries missing (Russian Federation, Turkey, United Kingdom and USA). What does ** mean in Attachment 1. It should be noted that most irradiation treatments for phytosanitary purposes do not kill pests but rather prevent their emergence or cause sterility. The suitability of packaging material would need to be considered for use when food is irradiated.
The National Organisations for Fruit and Vegetable Growers (New Zealand)	**Not specifically stated**	Why is the application before ANZFA, and not directly before NZMAF? What are the issues that require it to be dealt with by ANZFA? Are the industries such as ours being consulted (they do not appear to be?

*Further details of this submission.

Safety of Irradiated fruits

- Long-term health effects are not known of a diet containing a variety of irradiated foods;
- Only one 15-week study in humans has been performed;
- The USFDA never performed or obtained the battery of tests required for approval of irradiation;
- USFDA's approval in 1986 of irradiation of fruits and vegetables was not based on animal studies, but rather on an estimate of the number and amount of unique radiolytic chemicals likely to be created at 1 kGy.

Import/Export issues

- A maximum dose of 1 kGy may be used to irradiate tropical fruits and there may be a neglect of the use of a minimum dose. This may cause problems in countries that choose to irradiate fruits in that there may be inadequate oversight of the process of irradiation and how competent those operators (other than those in the USA that are required to meet specific requirements) are. This raises concerns for Australia and New Zealand in that Australia/New Zealand may be required to accept irradiated fruits from countries without the same level of rigor as the USA. Furthermore, if the proposed elimination of the maximum dose limit on irradiated foods is granted by Codex, Australia/New Zealand and the USA will have to accept food that has been treated at a dose above the 1 kGy maximum.

Unintended consequences of approval

- Questions whether there is enough demand in New Zealand for irradiated mangoes from Australia?
- If there is not enough demand, the irradiation company may try to make money by irradiating fruits for the domestic market for shelf life. This will lead to a market imbalance for small producers of non-irradiated fruits.
- Surebeam is using this application to ‘soften up’ the Australian public for future irradiation of beef.

Labelling

- ANZFA does not specify the labelling required for irradiated uncooked fruits and vegetables?

ATTACHMENT 5

GENERAL ISSUES RAISED IN PUBLIC SUBMISSIONS

This attachment provides a list of the issues or questions raised by the public submissions in response to the Initial Assessment report 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. The major issues raised are also covered in the main body of the draft assessment report, and **Attachments 2 and 3**.

GENERAL

Why is the application before ANZFA, and not directly before the Ministry of Agriculture and Forestry, New Zealand (NZMAF)?

The Applicant made a specific application to ANZFA to amend the *Food Standards Code*. ANZFA has a responsibility to progress all applications that are accepted for initial assessment (referred to as Preliminary Assessment under Section 13 of the ANZFA Act) under its statutory timeframes.

However, approval for the use of irradiation as an alternative treatment for quarantine purposes in the *Food Standards Code* does not automatically mean that approval will be granted for this process under the quarantine provisions in either Australia or New Zealand.

Firstly, the use of food irradiation on the proposed tropical fruits must be approved by the Ministerial Council following a recommendation by ANZFA based on food safety, nutritional adequacy, a recognised technological need and other considerations under the ANZFA Act 1991. This is necessary to allow lawful sale of irradiated food on the market in Australia and New Zealand. Secondly, the relevant Australian and New Zealand quarantine agencies must then assess the appropriateness of the irradiation treatment for the specific pests of quarantine concern and determine an appropriate dose (within the minimum and maximum range specified in the draft standard) for the individual tropical fruits/pest on a case-by-case basis.

Insufficient public information has been supplied, and the five-week comment period is insufficient for members of the general public to research, evaluate and respond to the Initial Assessment report.

ANZFA operates under a strict statutory timeframe of 1 year from the commencement of an application until a final recommendation is made to the ANZFA Board. It is acknowledged that this limits the amount of time for public consultation that can be undertaken. However, with this application a Steering Group representing many stakeholders (Consumers, Industry and Government) is advising ANZFA on many of the issues raised from the first comment period. These stakeholders may disseminate information on irradiation provided by ANZFA when they can.

ANZFA disseminated as much information as was available at the time of preparation of the Initial Assessment Report. Since then more information has been provided and researched by ANZFA as detailed in the Draft Assessment Report.

The House of Representatives (HOR) Standing Committee Enquiry Report (1989) did not recommend e-beam/X-ray sources of irradiation.

This relates to recommendation 13 of the HOR Report:

> *The Minister for Community Services and Health discuss with State and Territory Health Ministers the prohibition of the use of electron beam or x-ray machines for use in mobile commercial irradiation facilities until suitable operating techniques have been developed and problems relating to regulation and safety have been resolved.*

Therefore, this relates to mobile facilities not to permanently based facilities. In addition, Health Ministers approved the use of e-beam and x-ray sources of irradiation in 1999 as safe and viable sources of irradiation.

Why is ANZFA approving the use of gamma rays when the application is for the use of irradiation by electron beam machines or x-rays?

Standards A17/1.5.3-Food Irradiation allow the use of gamma rays from the radionuclide cobalt 60 or from x-rays generated by or from machine sources operated at an energy level not exceeding 5 mega-electronvolts; or electrons generated by or from machine sources operated at an energy level not exceeding 10 mega-electronvolts. The Ministerial Council approved these sources of radiation for use on food on 2 September 1999.

Based on the principle of chemi-clearance the International Consultative Group on Food Irradiation (ICGFI) would urge ANZFA to approving fruits as a class without being specific to individual items. This would allow other fruits grown in Australia to be treated with irradiation for phytosanitary purposes.

The overall basis and intent of Standards A17/1.5.3 - Irradiation of Food, is to allow applications to be made to ANZFA on a case-by-case basis. Health Ministers agreed to this, as an appropriate approach in 1999 and any departure from this would require a specific application to change Standards A17/1.5.3.

The case-by-case approach suggested by ANZFA and Ministers is misleading as any irradiation facility can irradiate food (including using Cobalt 60)?

The case-by-case approach applies to requiring applications for individual foods to be irradiated and is not specific for the source of irradiation used on those foods. Any appropriate facility could undertake irradiation of food. However, such food could not be lawfully sold on the Australian or New Zealand markets unless listed in Standards A17/1.5.3 and labelled in accordance with those Standards.

ANZFA has been inadequate in informing consumers about food irradiation?

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.

Health Ministers of Australia and New Zealand directed officials in the Department of Health and Aging to develop an education strategy on irradiation of food. The Development and Implementation Subcommittee of the Food Regulation Standing Committee are currently undertaking this task.

There has been no market research to determine the negative impact on Australian farmers, nor any public information programme.

Irradiation is a new technology for Australian and New Zealand industry and consumers and it is appropriate that governments, industry and consumer organizations play a critical role in dissemination of information on this technology.

The Applicant has provided ANZFA with a copy of a document titled: "Perceptions of food irradiation in New Zealand and Australia" by Roger Harker et al, HortResearch (2001). This report was sent to members of ANZFA's Steering Group and could be used to assist with information to all key stakeholders.

In this report consumer opinions were explored before and after the viewing of a video on irradiated foods using a focus group approach in which a moderator directed the flow of the discussion and in a series of questionnaires. Industry opinion was solicited in a series of interviews with Australian and New Zealand companies. The Executive Summary is at Attachment 11 to the Draft Assessment Report.

A further discussion on this issue is in the main body of the Draft Assessment Report.

SAFETY

ANZFA and ANZFSC ignored each and every study unfavourable to food irradiation.

The Australian Government should not permit consideration of applications to irradiate food based on the findings of a preliminary WHO (1992) Report.

ANZFA noted that 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 the 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. A preliminary report was compiled in 1992.

The WHO completed a final report in 1994. This was further refinement and review of the provisional report, taking into account comments of observers from the National Food Authority of Australia and the International Organization of Consumer Unions. The WHO (1994) report also 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 is aware that there were previous contrary findings that are 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. ANZFA concludes that it is a safe and alternative technique for disinfestation (Application A443) of selected foods.

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).

The long-term animal feeding studies on irradiated food are supported by more limited toleration studies in humans. These include studies of up to 90-day duration with thirty-five different varieties of irradiated foods. Irradiated foods have been consumed in many countries, in particular, herbs and spices and fruits, for some time now without any known adverse health effects. In addition, some hospital patients have consumed irradiated food and the health of these patients has been 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.

The suitability of packaging material would need to be considered for use when food is irradiated and possibly approved for use when food is to be irradiated.

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.

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 American Society of Testing Methods (ASTM) Standard Guide for Packaging Materials for Foods to be Irradiated (1995).

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.

This issue is further addressed more detail in the main body of the Draft Assessment Report.

TECHNOLOGICAL NEED

Is there a technological need for the irradiation of Tropical Fruits?

ANZFA requested advice (via the Applicant) from Biosecurity Australia (BA), the Ministry Agriculture and Forestry New Zealand (MAFNZ) and the Interstate Plant Health Regulation Working Group (IPHRWG) indicating that these quarantine bodies have considered the issue of efficacy of treatment for the specified pest/tropical fruit commodities identified in the application. In particular, that the maximum dose of 1 kGy will be an appropriate and efficacious dose for the technological need of treatment of quarantine pests. These responses were taken into account and in addition the relevant quarantine authorities were consulted when assessing the merits of the application.

It was concluded by the relevant quarantine agencies that irradiation of tropical fruits would provide an alternative to current disinfestation methods and that the proposed maximum dose of 1 kGy will provide sufficient scope as a treatment for country/crop/pest combinations.

A number of submissions raised the following points (below in italics) in relation to this issue. ANZFA sought advice on these issues from BA, MAFNZ and other regulatory agencies involved in quarantine regulation (eg Queensland Department of Primary Industry).

- *The claims that NZMAF will not accept tropical fruits from Australia are false.*

MAFNZ will not accept fruit fly host products from Australia unless they have been treated to ensure freedom from fruit flies and other pests. Quarantine requirements for imports to New Zealand are a matter for determination by MAFNZ. For the fruits specified in the application irradiation treatment is a possible way of achieving such disinfestations. In some situations irradiation may be the only practical and economic treatment available.

The current application does not address quarantine considerations but examines whether irradiation meets a technological need and is acceptable under the terms of the *Food Standards Code.*

- *MAFNZ were questioned with respect to why if not all the alternative treatments are acceptable to other countries (including Australia) why is it not acceptable to New Zealand?*

- *An alternative approach to irradiation is that an attempt be made to harmonise the range of phytosanitary treatments that are permitted in Australia but do not meet New Zealand Quarantine requirements.*

- *There is no justification for the use of irradiation when other methods are available.*

The requirements for amendment of Standards A17/1.5.3 are clear. There must be a technological need, minimum and maximum dose must be specified and the objective in setting food standards must be met. Whilst quarantine requirements may support the technological need, approval in the *Food Standards Code* does not meet quarantine requirements.

- *The International Consultative Group on Food Irradiation (ICGFI) endorses the max dose of 1 kGy; however, suggested that a minimum dose of 150 Gy and 300 Gy is sufficient to ensure quarantine protection against fruit fly and other insect species respectively.*

- *Clarification of the doses to be used was sought as no information has been provided on what insects are to be targeted and at what dose.*

The maximum of 1 kGy provides an upper limit within which specific minimum doses will be determined based on the pest species and level of quarantine security required. Good agricultural and radiation practice will ensure that the minimum effective dose will be delivered in any situation. However, the minimum dose of 150 Gy was specified as being appropriate to cover most species of fruit fly for pest disinfestations purposes subject to a detailed assessment by the relevant quarantine agencies.

- *As the irradiation process does not kill fruit flies but rather sterilises them, there is a real possibility that there may be surviving larvae. This could be disastrous for New Zealand's horticulture industry.*

This is incorrect. All fruit fly treatments prevent emergence of flies, effectively killing the pests. Furthermore, the mortality rates required are very high so the probability of insects surviving to the adult stage is extremely low. In this respect irradiation quarantine treatments are identical to any other treatment technology.

- *It is necessary for Surebeam to provide data on the necessary radiation dose for the different insects, and the effects of that dose on the Australian varieties of the fruits to be irradiated.*

This information will need to be provided to the relevant quarantine agencies as part of the process of negotiating treatment protocols for pest disinfestations.

- *Alternative techniques that may be used; namely, carbon dioxide/nitrogen blasting, sonar detection, and biological controls (disease/insect resistant plants) for quarantine purposes.*

The techniques cited above may not provide the level of quarantine security required for high-risk pests such as fruit flies. Decisions on the efficacy of such alternatives are a matter for quarantine authorities.

- *Request that ANZFA approach the CSIRO and the Department of Primary Industries to ask for information on fruit developed by these two organizations which have been bred to be insect resistant.*

The CSIRO and Department of Primary Industry stated that there was no active research program being pursued on insect resistant tropical fruits.

- *NZ would be solely reliant on a Queensland certificate that claimed that produce had been properly irradiated. This would lower NZ quarantine protection measures and would greatly increase the likelihood of fruit fly outbreaks in NZ, lead to environmental concerns (as it would require widespread aerial spraying of insecticides).*

- *Key NZ producer groups should be consulted further.*

Quarantine certification requirements are a matter for relevant quarantine authorities. MAFNZ has a policy of industry consultation in matters of import quarantine security. ANZFA has also obtained and added further contacts with key NZ Producer groups in order to keep them fully informed of the application. ANZFA undertakes wide public consultation in Australia and New Zealand on all applications to amend the *Food Standards Code.*

- *Since the submission of 31 October 2001, Canberra Consumer has obtained a statement from the Queensland department of Primary Industries Web Site that the papaya fruit fly has been eradicated in Queensland. This means that there is no technological need to irradiate papayas as a quarantine measure.*

The Queensland Department of Primary Industries declared on 30 April 1999 that the papaya fruit fly had been eradicated. Australia has a number of endemic fruit fly species of quarantine significance in addition to the papaya fruit fly. These will require an effective quarantine treatment before approval to import host produce will be approved by NZ and other countries.

The overall intent of the application is to use irradiation to treat fruit fly pests and other critical quarantine pests, not just papaya fruit fly. Other species of fruit fly exist other than papaya fruit fly. Hancock et al (2000) details that there are 278 species of fruit fly in Australia. However, there are other critical quarantine pests such as mango seed weevil and macadamia nut borer (litchi), which restrict access to markets and where irradiation is the only treatment.

Therefore, there is a justified technological need to treat these other species of fruit fly and in addition other pests with an appropriate quarantine treatment such as irradiation.

EFFICACY OF FOOD IRRADIATION

Is there any evidence illustrating the efficacy of irradiation when applied to tropical fruits?

Disinfestation of tropical fruits by irradiation treatment is a valid technological need for the purposes of quarantine. Insect pests endemic to Queensland and of quarantine significance to importing countries represent a major barrier to overcome in gaining access to some markets. E-beam and X-ray irradiation techniques are considered to be equivalent in efficacy to current treatments used.

NUTRITION

Irradiation may diminish the nutritional value and wholesomeness of foods?

Dietary intake assessment indicates that the specified tropical fruits are not significant sources of certain vitamins, including β-carotene, folate, vitamin C and vitamin B_1 within the context of the total dietary intake. Research on the irradiation of the specified tropical fruits in conjunction with the analysis of dietary intake indicate that irradiation will not have a significant nutritional effect on the diet of the Australian and New Zealand populations.

MONITORING AND ENFORCEMENT

How can irradiated 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.

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.

DOSAGES

Clarification of the doses to be used was sought as no information has been provided on what insects are to be targeted and at what dose.

This is solely an issue for BA and MAFNZ to determine based on an appropriate risk assessment. The appropriate quarantine agencies have indicated to ANZFA that a more detailed import risk assessment of the appropriate dose to control pest disinfestation is necessary, even though international research on the efficacy of irradiation as a disinfestation treatment for fruits flies would suggest that the minimum dose of 150 Gy and a maximum of 1 kGy would be an appropriate dose range.

In Australia, within the portfolio of Agriculture, Fisheries and Forestry, BA has responsibility for negotiating quarantine arrangements for the import and export of plant and animal products. BA 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 conducted by MAFNZ who ensure 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.

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

Significant penalties exist for breaching the Food Standards Code (which if amended as recommended will require that the minimum dose of 150 kGy as specified in the standard be used to achieve the technological purpose). 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 quarantine pests 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.

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 is absolutely specific in measurement of the actual dose that was applied to be measured as the changes that irradiation induces in foods is minimal.

However, the International Atomic energy Agency (IAEA) recently published a report detailing the research that had been undertaken on the use of a standardised commercially available label dose indicator which is used to verify the minimum/maximum absorbed dose of irradiated foods (IAEA, 2001).

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.

LABELLING

Labelling issue should be thoroughly considered; as there appears to be uncertainty as to how unpackaged, individually displayed fruit would be designated as being irradiated?

ANZFA does not specify the labelling required for irradiated uncooked fruits and vegetables?

Use of the term 'electronic pasteurisation' rather than irradiation is misleading to consumers?

Standards A17/1.5.3 require that a package of food that has been irradiated must be labelled with a statement that the food has been treated with ionising radiation. The Standard provides three examples of such statements. These are 'Treated with ionising radiation', 'Treated with ionising electrons' and 'Irradiated (name of food)'. It also contains requirements for labelling in relation to irradiated ingredients, and in relation to food not otherwise required to bear a label. 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. Any change to this requirement would require an application to change Standards A17/1.5.3.

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.

ANZFA agrees that the term 'electronic pasteurisation' should not be used to indicate that a food or an ingredient of a food had been irradiated. Irradiated food must be labelled in accordance with the general provisions in food law and fair trading law as they relate to false, misleading or deceptive conduct. A declaration that a food had been subject to 'electronic pasteurisation' would not comply with the requirements of the standard.

Mandatory labelling regarding information to be displayed at point of sale is historically ignored and not policed?

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. As it is a mandated requirement for irradiated food to be labeled, it would be an offence not to do so under Standard 1.5.3. These requirements cover both packaged food and food otherwise exempt from bearing a label where that food is displayed.

IMPORT/EXPORT ISSUES

A maximum dose of 1 kGy may be used to irradiate tropical fruits and there may be a neglect of the use of a minimum dose. This may cause problems in countries that choose to irradiate fruits in that there may be inadequate oversight of the process of irradiation and how competent those operators (other than those in the USA that are required to meet specific requirements) are?

This raises concerns for Australia and New Zealand in that Australia/New Zealand may be required to accept irradiated fruits from countries without the same level of rigor as the USA?

Furthermore, if the proposed elimination of the maximum dose limit on irradiated foods is granted by Codex, Australia/New Zealand and the USA will have to accept food that has been treated at a dose above the 1 kGy maximum?

Importers of irradiated foods would be required to adhere to the strict provisions of Standards A17/1.5.3. This would mean adherence to a minimum dose of 150 Gy and the maximum limit of 1 kGy. Standards A17/1.5.3 require mandatory record keeping to show, among other things, the minimum and maximum doses imparted to food.

Significant penalties exist for breaching the *Food Standards Code* (which if amended as recommended will require that the minimum dose be used to achieve the technological purpose). 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.

If a dose higher than 1 kGy were considered necessary in some circumstances, then food treated with higher doses could not be legally sold in Australia or New Zealand unless a formal amendment to the *Food Standards Code* was made.

COSTS vs BENEFITS

Are the Australian tropical fruits producers aware of this application, what effects on food e-beam/x-rays may have and do they want this technology over present methods?

Is there enough demand in New Zealand for irradiated mangoes from Australia?

Is there a market for producers and is it financially viable for them?

The *Food Standards Code* does not apply to foods exported from Australia or New Zealand. The permissions apply only to foods sold in the Australian and New Zealand markets. Permissions to irradiated tropical fruits may have implications for trade between Australia and New Zealand, though quarantine requirements would need to be met.

Letters of support were received from a range of organizations and fruit growers, which would provide a market for Australian growers.

The Cairns Port Authority, State Development Centre Cairns, Cairns Regional Economic Development Corporation and Advance Cairns has estimated that by initiating the Surebeam facility for irradiation of tropical fruits an export market worth $50 million could be established in North Queens land. Markets identified to date include New Zealand, United States and North Asia. The Australian Mango Industry Association Ltd sees the application as an important step in securing other key markets for the purpose of phytosanitary measures; namely, China, Taiwan, Korea and the USA.

IRRADIATION FACILITIES

Many consumer submissions raised issues with respect to proposed irradiation facilities in Queensland. In particular, the following specific questions were raised:

- *The location of the proposed Surebeam facility was not detailed for public information. Requested ANZFA to publish this location on its website.*
- *Tropical fruits would be irradiated at Narangba in Queensland. The proposed Steritech nuclear radiation facility (at Narangba) is too close to residential areas, which may increase the risk to public health and safety. There are no plans to monitor radiation levels in the area to protect resident's health?*

These matters are not addressed by the *Food Standards Code*, but are the subject of regulatory and planning decisions of the relevant State/Territory authorities.

Irradiation facilities are licensed and regulated by the following authorities in Australia and New Zealand:

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)		

The other issues raised (eg occupational health and safety for irradiation workers, and licensing of irradiation facilities) are matters for consideration by the relevant regulatory authorities such as:

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

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

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.

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

- *The safety of e-beam/x-ray is seriously questioned in its proposed use on tropical fruit with respect to the workers operating the equipment?*

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.

QUALITY OF IRRADIATED TROPICAL FRUITS

Submissions raised a number of points on the quality of irradiated tropical fruits.

At certain doses, particularly, doses closer to the maximum of 1 kGy the quality of the fruit can be affected and ANZFA concurs that not all tropical fruits may be equivalent in quality to each other following irradiation. This is also true for other treatments that are used to meet quarantine regulations (eg, cold and heat treatments may damage tropical fruits).

ANZFA does not mandate what particular technologies can be used to maintain quality of food as the final quality of food, in particular, irradiated tropical fruit is a commercial and marketing decision for growers of tropical fruits and operators of irradiation facilities. This will ultimately determine consumer acceptance of irradiation-treated produce by consumers.

ANZFA sought specific advice from relevant experts to address the following specific questions (in italics) arising from submissions on quality of irradiated tropical fruits.

- *Mangoes and Papaya's-irradiation is not a suitable process for these fruits (e.g. mangoes fail to ripen, colour spotting occurs on the skin, pores turn black and mottled browning of the skin occurs).*

- *Many tropical fruits are sensitive to irradiation damage below 1 kGy. Canberra Consumer provided a copy of a comparison of maximum tolerable doses and minimum dose required for desirable technical effects on fruits and vegetables.*

- *The concept of equivalence does not apply to different varieties of the same fruit.*

Mangoes, papaya and other tropical fruits will tolerate irradiation treatment at the doses required to control fruit flies and other high-risk quarantine pests. Generally, effective irradiation treatments are independent of fruit type. That is, they are based on the pest species and level of quarantine security required.

The Queensland Department of Primary Industries and New South Wales Agriculture conducted irradiation tolerance studies on a wide range of tropical, sub-tropical and temperate fruit using gamma irradiation in the late 1980's and early 1990's. A dose of 600 Gy was the maximum tolerated by 'Kensington Pride' mangoes [Jessup, AJ, CJ Rigney and PA Wills, "Effects of gamma irradiation combined with hot dipping on quality of 'Kensington Pride' mangoes", *J. Food Sci*. 53(5): 1486-1489.]

Results from a Co-ordinated Research Project between the International Atomic Energy Agency (IAEA) and a large number of countries indicate that papaya, carambola, rambutan, litchi and mango are highly tolerant of irradiation. Atemoya and avocado are of low tolerance. ["Irradiation as a quarantine treatment of arthropod pests", Proceedings of a Final Research Co-ordination Meeting, Joint FAO/IAEA Honolulu, Hawaii, 3-7 November, 1997. IAEA-TECDOC-1082.]

- *It is accepted in the radiation industry that high dose gamma sources are unsuitable for use at low levels, especially less than 1 kGy.*

- *Inadequate information has been provided by the applicant with respect to energy levels of the e-beams and x-rays and how the fruit would be packaged or presented to the irradiation beams. This suggests that the efficacy of using such beams on thicker unevenly shaped produce such as tropical fruits is doubtful. How will the applicant ensure that all surfaces and the inner flesh of the fruits receive an irradiation dose exceeding the minimum required to sterilise ALL fruit fly larvae?*

The larger and more dense the product the less penetrative are electron beams, X rays and gamma irradiation. "Dose mapping" where sample products, in their packaging, are tested for uniformity of dose received is essential for any irradiation procedure. This is carried out by placing a number of dosimeters (small indicators of dose received) on, in and around the product. Dose mapping gives details of the ratio of the maximum dose received by the product to the minimum dose received (max:min ratio).

The max:min ratio, when the product is being irradiated for phytosanitary purposes, must be such that the minimum dose received is the target insecticidal dose e.g. 150 Gy for fruit flies. If the max:min ratio is 4 then that means that some portions of the load will receive a dose of 600 Gy which may damage the appearance of some mango varieties.
Product uniformity, uniformity of packaging, mixtures of different-sized products and variability of tightness of packaging within the load will affect the dose received.

Therefore, the technical aspects of applying irradiation treatments are well understood and the regulatory framework will ensure that treatment equipment is performing efficiently. The maximum energy associated with e-beams is defined at 10 MeV. Proper dose mapping and dosimetry will ensure that treatments are applied so as to deliver an effective dose to the centre of the product. This will be a critical aspect of the development and demonstration of an effective treatment protocol.

REFERENCES

ASTM E1204 Practice for Dosimetry in Gamma Irradiation Facilities for Food Processing

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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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.

Hancock DL, Hamacek EL, Lloyd AC and Elson-Harris MM (2000) The Distribution and host plants of fruit flies (diptera: tephritidae) in Australia, QDPI, Brisbane 2000

House of Representatives (1989) Report on the Use of Ionising Radiation prepared by the House of Representatives Standing Committee on Environment, Recreation and the Arts, Canberra.

International Atomic Energy Agency (IAEA) (March 2001). Standardised methods to verify absorbed dose in irradiated food for insect control. *Proceedings of a final Research Co-ordination Meeting organized by the Joint FAO/IAEA Division of Nuclear Technologies in Food and Agriculture, Portugal, 30 March-3 April 1998.*

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WHO, 1994. Safety and Nutritional Adequacy of irradiated Food. Geneva, Switzerland: World Health Organization; 1994.

WHO, 1999. High-dose irradiation: wholesomeness of food irradiated with doses above 10kGy. Report of a Joint FAO/IEAE/WHO study group. WHO Technical Report Series 890.

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.

ATTACHMENT 6

The following approvals have been granted for irradiation of fruits, including tropical varieties. This data was obtained from the International Consultative Group on Food Irradiation data-base of clearances of irradiated foods.

Approval of Irradiation of Fruits (General)

Explanations for Codes : 1. Delay 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. Sterilization, 10. Unstated.

FRUIT

Country	Code	Type of Clearance	Date	Dose Max (kGy)
BRAZIL	1,4,5	UNCONDITIONAL	30.01.01	**
CROATIA	1,3	UNCONDITIONAL	21.06.94	3.00
GHANA	1,2,4	UNCONDITIONAL	15.01.98	1.00
GHANA	5	UNCONDITIONAL	15.01.98	2.50
ISRAEL	2	UNCONDITIONAL	17.02.87	1.00
MEXICO	1,4	UNCONDITIONAL	07.04.95	1.00
MEXICO	5	UNCONDITIONAL	07.04.95	2.50
PAKISTAN	1,2,4	UNCONDITIONAL	07.03.96	1.00
RUSSIAN FEDERATION	5	CONDITIONAL	11.07.64	4.00
TURKEY	1,2,4	UNCONDITIONAL	06.11.99	1.00
TURKEY	5	UNCONDITIONAL	06.11.99	2.50
UKRAINE	5	CONDITIONAL	11.07.64	4.00
UNITED KINGDOM	2	UNCONDITIONAL	01.01.91	2.00
USA	1,2	UNCONDITIONAL	18.04.86	1.00

Approvals for Mangoes

Explanations for Codes : 1. Delay 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. Sterilization, 10. Unstated.

MANGO

Country	Code	Type of Clearance	Date	Dose Max (kGy)
BANGLADESH	1,2	UNCONDITIONAL	29.12.83	1.00
BRAZIL	1,4,5	UNCONDITIONAL	30.01.01	**
CHILE	2	UNCONDITIONAL	29.12.82	1.00
COSTA RICA	2,5	UNCONDITIONAL	07.07.94	1.00
CROATIA	1,3	UNCONDITIONAL	21.06.94	3.00
CUBA	1	CONDITIONAL	01.07.92	0.75

GHANA	1,2,4	UNCONDITIONAL	15.01.98	1.00
GHANA	5	UNCONDITIONAL	15.01.98	2.5
INDIA	1,2	UNCONDITIONAL	06.04.98	0.75
ISRAEL	2	UNCONDITIONAL	17.02.87	1.00
MEXICO	1,4	UNCONDITIONAL	07.04.95	1.00
MEXICO	5	UNCONDITIONAL	07.04.95	2.50
PAKISTAN	1,2,4	UNCONDITIONAL	07.03.96	1.00
RUSSIAN FEDERATION	5	CONDITIONAL	11.07.64	4.00
SOUTH AFRICA	2	CONDITIONAL	25.08.78	4.00
SYRIA	2	UNCONDITIONAL	02.08.86	1.00
THAILAND	1,2	UNCONDITIONAL	04.12.86	1.00
TURKEY	1,2,4	UNCONDITIONAL	06.11.99	1.00
UKRAINE	5	CONDITIONAL	11.07.64	4.00
UNITED KINGDOM	2	UNCONDITIONAL	01.01.91	2.00
USA	1,2	UNCONDITIONAL	18.04.86	1.00

Guava

Explanations for Codes : 1. Delay 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. Sterilization, 10. Unstated.

GUAVA >>Refer to the Explanatory Notes<<

Country	Code	Type of Clearance	Date	Dose Max (kGy)
BRAZIL	1,4,5	UNCONDITIONAL	30.01.01	**
CROATIA	1,3	UNCONDITIONAL	21.06.94	3.00
GHANA	1,2,4	UNCONDITIONAL	15.01.98	1.00
GHANA	5	UNCONDITIONAL	15.01.98	2.5
ISRAEL	2	UNCONDITIONAL	17.02.87	1.00
MEXICO	1,4	UNCONDITIONAL	07.04.95	1.00
MEXICO	5	UNCONDITIONAL	07.04.95	2.5
PAKISTAN	1,2,4	UNCONDITIONAL	07.03.96	1.00
RUSSIAN FEDERATION	5	CONDITIONAL	11.07.64	4.00
TURKEY	1,2,4	UNCONDITIONAL	06.11.99	1.00
UKRAINE	5	CONDITIONAL	11.07.64	4.00
UNITED KINGDOM	2	UNCONDITIONAL	01.01.91	2.00
USA	1,2	UNCONDITIONAL	18.04.86	1.00

Unconditional:
Regulatory approval of an application without any further condition to be fulfilled for the continued application of irradiation treatment of the food or group/class of food.

Conditional:
Regulatory approval of the irradiation treatment of the food or group/class of food subject to certain conditions relating to duration of approval, total quantity of food permitted to be irradiated.

****** The minimum dose must be sufficient to achieve the intended objective; the maximum dose must be less than that which would compromise the functional properties or the organoleptic attribute of the food.

ATTACHMENT 7

INFORMATION SHEET-CHEMICLEARANCE AND RADIOLYTIC PRODUCTS

- The safety evaluation of irradiated foods based on the results of chemical analysis has been termed **chemiclearance** and has been used by International Expert Committees to clear foods that are similar in chemical makeup to others that have had extensive toxicological evaluations previously performed (WHO, 1981).

- Irradiation of food like other food processing techniques breaks larger molecules into smaller ones (fragments). Each of the three major macronutrients in food (carbohydrates, proteins and fats) gives rise to different types of radiolytic products. These radiolytic products have been chemically analysed and consist of common chemicals produced either in the biochemical pathways of the human body or from other treatment processes such as heating. Examples include, carbon dioxide, hydrogen, ammonia, short chain alkanes, alkenes, aldehydes, triglycerides and free fatty acids.

- Previous studies have concluded that no volatile compounds produced in foods by irradiation have been found that were not found naturally occurring in raw foods or in foods processed by other technologies.

- The possible exceptions to this are compounds known as 2-alkylcyclobutanones, in particular, 2-dodecyclobutanone (2-DCB), which, although not yet proven to be a unique radiolytic product is produced following irradiation of fat-containing food. It was suggested in a recent study that 2-DCB caused DNA strand breaks in cells taken from the large bowel of rats when they were incubated *in vitro* with 2-DCB.

- However, this study was inconclusive, because there were limitations in the assay used to detect mutations, and the number of rats used were small (six in number). Further studies have been recently undertaken with 2-DCB and other alkylcyclobutanones. These will be published in the near future.

- Overall, previous studies have also determined that the production of radiolytic products follow predictable pathways and that irradiation of specific classes of food groups (eg meats, fats and starches) produces a similar range of chemical products. However, there are some exceptions with fats that are saturated compared to unsaturated fats; both, producing quite different products following irradiation.

- This has allowed scientists to conclude that data from toxicological studies including chemical analysis, various test-systems as microorganisms and animal feeding studies previously performed on individual irradiated foods can be extrapolated to other untested members of the same class by virtue of the consistency in chemistry and the precise toxicological studies performed on similarly chemically related foods.

WHO (1981) Wholesomeness of irradiated food. Report from a Joint FAO/IAEA/WHO Expert Committee. WHO Technical Report Series 659.

ATTACHMENT 8

TECHNICAL FACTS SHEET

Technical Facts

Ionising radiation-energy at high levels that causes the ejection of electrons from their orbitals, resulting in charged or ionised particles. Types of radiation are found in the Electromagnetic Spectrum, have short wavelengths, high energy –several million electron volts (MeV). These include gamma and x-rays. Accelerated electrons are also used.

Mechanism of Food Irradiation

The high-energy radiation (gamma/e-beam/x-ray) can produce ions or charged particles after being absorbed by matter. Absorption of ionising radiation by food molecules results in the breaking of chemical bonds and the formation of free radicals and charged ions, leading to the formation of radiolytic products. These radicals are usually unstable and very reactive; however, are subsequently converted to stable end-products. There is a linear relationship between radiation dose and amount of products produced (i.e. double dose-double products produced). The presence of water and oxygen can influence the radiolytic process.

Radiation destroys microbes or spoilage organisms by partial or total inactivation of genetic material in living cells, either by direct effects on deoxyribonucleic acid (DNA) or through production of radicals and ions that attack DNA. Radiation has direct or primary effects and indirect or secondary effects.

Primary

- Ionisation-removal of electrons;
- Dissociation-loss of Hydrogen atoms;
- Excitation-molecule raised to higher energy level.

Secondary

As a result of highly reactive free radicals there is a number of secondary reactions-recombination, dimerization or electron capture.

Sources-Gamma rays and x rays are quite similar in their characteristics, but e-beams are different in the way the exposed product absorbs the dose (*Gamma and X-ray have NO mass and can penetrate deeply; whereas, electrons have a small mass resulting in limited penetration*).

Gamma rays-produced by radioactive isotopes such as Cobalt 60 and Caesium 137 have initial energies from 0.66 to 1.33 MeV.

E-Beam/X-ray-electrons that are accelerated with a linear accelerator or a Van de Graaf generator to achieve energy levels of up to 10 MeV. These accelerated electrons are used to irradiate materials such as food. Accelerated electrons can also be converted to x-rays when they are made to collide with metal targets. Compared to gamma sources, there is a greater efficiency in the utilisation of electrons because they are directed at the product rather than emitted in all directions.

Advantages-(1) Can be switched 'on' or 'off'; (2) source does not need to be replenished; (3) readily available; (4) high throughput rate.

Disadvantages- (1) need for regular maintenance; (2) large requirements for power and cooling; (3) e-beam is not as penetrating as gamma sources or x-rays.

Process (Electrons)-Energy from accelerated electrons is absorbed as it enters the surface of the product. Due to their mass, electrons begin to slow down rapidly and the absorbed dose increases under the surface of the product. Therefore, electrons with higher energy (5 versus 10 MeV) can penetrate to a greater depth and the absolute depth of penetration is relative to the density of the product. Dose-depth curves show that when a product is irradiated a range of doses are absorbed and there will always be a minimum and maximum.

Process (Gamma and X-rays)-these sources have some finite differences but their use in food irradiation can be considered the same. Compared to electrons, photon penetration is deeper and the absorbed dose is highest at the surface and diminishes exponentially as they penetrate through the product.

Cobalt 60-is produced by exposing pure natural cobalt-59 pellets to a neutron source in a nuclear reactor to produce radioactive Cobalt 60. The Cobalt-60 pellets are encased in double stainless steel cylinders, called pencils. *Gamma rays* are produced continuously and emitted in all directions.

Advantages- (1) high penetration and good dose uniformity which allows treatment of products of variable size, shape and density; (2) long history satisfactory use; (3) low environmental risk.

Disadvantages-(1) half life 5.3 years; therefore, needs constant replenishing (2) slow food processing rate.

Caesium-137-*Gamma* emitter. Produced as a result of uranium fission and may be reclaimed as a by-product of nuclear fuel processing. This is not available in sufficient quantities to play a role in commercial food irradiation.

Cobalt-60 and Caesium-137 decay to non-radioactive nickel and barium respectively.

References

Murano EA (1995) *Food Irradiation: A Source Book.* Ames, IA: Iowa State University Press.

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.*

ATTACHMENT 9

EXECUTIVE SUMMARY OF CONSUMER REPORT

Perceptions of Food Irradiation in New Zealand and Australia

Sensory and Consumer Team

June 2001

Consumer and industry beliefs, attitudes, and perceptions of irradiated foods have been investigated and previous studies carried out in this area have been reviewed. Consumer opinions were explored before and after the viewing of a video on irradiated foods using a focus group approach in which the moderator directed the flow of the discussion, and in a series of questionnaires. Industry opinion was solicited in the series of interviews with Australian and New Zealand companies.

CONSUMERS

Knowledge and education:

- consumers have little knowledge of irradiated foods, and many are suspicious of the technology and expect it will be dangerous;
- this lack of knowledge may expose Australasian industries to the risk that public opinion may reject irradiation of foods on the basis of irrational arguments;
- public education should be a priority;
- the content and context in which the information is presented are critical;
- consumers are suspicious of educational material that seems to present only one side of the story;
- consumers would trust safety endorsements from consumer organizations, Government health departments, ANZFA and AIFST, and television current affair programmes;
- consumers tend to mistrust organizations not specific to their own country (eg. American Medical Association and the FDA).

Level of concern:

- following the presentation of information to participants in this study, we found that they developed a consensus that irradiation was of only minor concern;
- consumers who initially had major concerns about irradiation became less concerned, while consumers who initially had no concern or were unsure of their concern became more concerned;
- other food safety issues such as use of spray chemicals, spoilage of food, and fumigation were of more concern than irradiation.

Fears:

- the fears that consumers have for irradiated foods include: exposure to radiation, reduction in nutrients and wholesomeness of the food, damage to the environment, and workers' safety;

- consumers are also concerned that irradiation will be used as a substitute for safe food production and they do not want shelf life to be increased.

Willingness to purchase irradiated products:

- this is much lower in Australia and New Zealand than in the USA;
- purchase intent for irradiated products varies between 20 to 25% for strawberries and 50 to 55% for sterilised foods for the immuno-compromised, and is much higher for non-food products such a sterilised medical or household goods with 75% of consumers indicating they will purchase these products.

Views on domestic use of irradiated foods:

- within the domestic market, consumers continue to have faith in the integrity of the food supply chain;
- while food irradiation will enhance food safety in the domestic market, it will be a double-edged sword in that successful marketing may need to alert consumers to the high levels of risk associated with some products.

Views on export of irradiated foods:

- consumers were very sensitive to positive and negative impacts that irradiation might have in the export markets for our commodity products;
- some consumers may respond to pragmatic economic arguments that export industries need access to irradiation facilitates in order to remain competitive in the future.

INDUSTRY

Food Exporters:

- many food exporters anticipate that many of their clients will require products to be irradiated to fulfil phytosanitary and/or food safety regulations, but fear that a backlash against the technology by anti-irradiation activists within their own country will stall future developments.
- they also fear that regulations may stop the building of an irradiation facility and prohibit the irradiation of food;
- many food exporters believe that they will benefit from irradiated foods and may be willing to contribute to public education in order to increase the speed with which irradiation and facilities can be established.

Food Importers:

- importers focus on the perceptions of their own domestic consumers, who they feel will be suspicious of irradiated products;
- they feel that the benefits of irradiation will be in improved public health and improved biosecurity;

- they expect that consumers will benefit in terms of having access to better tasting produce that has not been fumigated and is available out of season, and new products which do not usually have a sufficient shelf life for importation into Australia or New Zealand;
- many importers have indicated that they would not be prepared to import irradiated foods due to the high cost of educating New Zealand and Australian consumers. They expect that once this education process has occurred, competitors will enter the market with their own irradiated products and without having to carry the cost of educating the public;
- importers expect that the government should have the major role in public education.