

23 August 2000
03/01

**Development of joint
Australia New Zealand Food Standards**
**As part of the process of the Review of the
*Food Standards Code***

**REVIEW OF STANDARD A17 – IRRADIATION OF
FOOD, AND STANDARD A19 – NOVEL FOODS**

Proposal/Full Assessment Report

Proposal P223

August 2000

The Authority should receive written submissions
no later than **5 September 2000**

Submissions should be sent to:

The Project Manager - Proposal P223
Australia New Zealand Food Authority
at one of the following addresses:

PO Box 7186
Canberra Mail Centre ACT 2610
Australia

or

PO Box 10559
The Terrace
Wellington 6036
New Zealand

Submissions will be placed on the Authority's public register (unless a claim of commercial confidentiality is made and accepted by the Authority) and will therefore be open to public scrutiny.

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PROPOSAL / FULL ASSESSMENT REPORT

1 PREFACE

In July 1996 an Agreement between Australia and New Zealand came into force which established the Australia New Zealand Food Authority (the Authority) - a system for developing joint food standards and an Australia New Zealand Food Standards Code.

The aim of the Agreement is to extend the Australian food standard system to include New Zealand so that food standards developed by the Authority and approved by the Australia New Zealand Food Standards Council can be adopted throughout Australia and in New Zealand. The current review of the Australian *Food Standards Code* is an important element in developing joint standards. The provisions of the Agreement provide common policy objectives for developing food standards and a common approach to a transparent, timely, consultative and accountable standards setting process—both key features of the review process. The Authority is seeking to ensure full New Zealand participation in the standards setting process and the review of food standards.

Public comment was sought on the recommendations made in the paper. This paper takes these comments received in respect of each issue into consideration and makes further recommendations and proposes draft variations to the *Food Standards Code* for revised requirements for public comment.

2 BACKGROUND

2.1 Australia New Zealand Food Authority

The Australia New Zealand Food Authority is a joint statutory body responsible for making recommendations on food standards which, when approved by the Australia New Zealand Food Standards Council, are adopted by reference and without amendment into the food laws of the Australian States and Territories. In New Zealand, for the time being, such standards apply as part of a system of dual standards, where the Australian *Food Standards Code* (AFSC) is recognised as an alternative to the New Zealand *Food Regulations 1984* (NZFR). At a future date, standards in the NZFR will be repealed and the standards developed under the joint system will apply in both countries.

The Authority's other functions include;

- developing codes of practice for industry on any matter that may be included in a food standard;
- coordinating the surveillance of food in Australia;
- liaising with the Ministry of Health in New Zealand on arrangements for imported foods;
- conducting research and surveys in relation to food standards matters;
- developing food safety education initiatives in cooperation with the States and Territories; and
- assisting in the coordination of food recalls in Australia.

The Ministry of Health manages recalls in New Zealand. In Australia, the Authority develops assessment policies in relation to imported food.

2.2 Review of Food Standards

In July 1996 an Agreement between Australia and New Zealand came into force which established the Australia New Zealand Food Authority (ANZFA) - a system for developing joint standards and an Australia New Zealand *Food Standards Code* (joint FSC).

The aim of the Agreement is to extend the Australian food standard system to include New Zealand so that food standards developed by the Australia New Zealand Food Authority and approved by Ministerial Council can be adopted throughout Australia and in New Zealand. The provisions of the Agreement provide common policy objectives for developing food standards and a common approach to a transparent, timely, consultative and accountable standards setting process - both key features of the review process. The Authority is seeking to ensure full New Zealand participation in the standards setting process and the review of food standards.

In developing or reviewing food standards, the Authority must have regard to the objectives outlined in section 10 of the *Australia New Zealand Food Authority Act 1991*.

Consistent with these statutory objectives and the policies of the Authority, the review will, where possible;

- reduce the level of prescriptiveness of standards to facilitate innovation by allowing wider permission on the use of ingredients and additives, but with consideration of the possible increased need for consumer information;
- develop standards which are easier to understand and make amendment(s) more straightforward;
- replace standards which regulate individual foods with standards that apply across all foods or a range of foods;
- consider the possibility of industry codes of practice as an alternative to regulation; and
- facilitate harmonisation of food standards between Australia and New Zealand.

The review will also be carried out in accordance with the competition policy principles which have been adopted by the Council of Australian Governments (COAG) and the draft Code of Good Regulatory Practice (New Zealand). These principles require the review of all business regulation to remove unnecessary obstacles to competition, and an assessment of the social, environmental, and economic impacts as well as the impacts on health of proposed regulation on all affected sectors of the community.

2.3 Food Standards Setting in Australia and New Zealand

The Governments of Australia and New Zealand entered an Agreement in December 1995 establishing a system for the development of joint food standards. The Australia New

Zealand Food Authority is now developing a joint *Australia New Zealand Food Standards Code* which will provide compositional and labelling standards for food in both Australia and New Zealand.

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

- **Food imported into New Zealand other than from Australia** must comply with either the *Australian Food Standards Code*, as gazetted in New Zealand, or the *New Zealand Food Regulations 1984*, but not a combination of both. However, in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the *New Zealand Food Regulations 1984*.
- **Food imported into New Zealand from Australia** must comply with either the *Australian Food Standards Code* or the *New Zealand Food Regulations 1984*, but not a combination of both. However, in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the *New Zealand (Maximum Residue Limits of Agricultural Compounds) Mandatory Food Standard 1999*.
- **Food imported into New Zealand from Australia** must comply with either the *Australian Food Standards Code* or the *New Zealand Food Regulations 1984*, but not a combination of both.
- **Food imported into Australia from New Zealand** must comply with the *Australian Food Standards Code*. However, under the provisions of the Trans-Tasman Mutual Recognition Arrangement, food may be imported into Australia from New Zealand if it complies with the *New Zealand Food Regulations 1984* or *Dietary Supplements Regulations 1985*.
- **Food manufactured in Australia and sold in Australia** must comply solely with the *Australian Food Standards Code*, except for exemptions granted in Standard T1.

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

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

2.4 Regulatory Impact Analysis

The Authority is required, in the course of development of regulations suitable for adoption in Australia and New Zealand, to consider the impact of various options (including non-regulatory options) on all sectors of the community, including consumers, the food industry and governments in both countries. The regulatory impact assessment will identify and evaluate, though not be limited to, the costs and benefits of the regulation, and its health, economic and social impacts.

To assist in this process, comment on potential impacts or issues pertaining to these regulatory options are sought from all interested parties in order to complete the development of the regulatory impact statement. Public submissions should clearly identify relevant

impact(s) or issues and provide support documentation where possible.

The Regulatory Impact Assessments relevant to this Proposal are included in the Inquiry Reports in relation to Standard A17 (Proposal P94 – Irradiation of Food) and Standard A19 (Proposal P168- Novel Foods).

2.5 World Trade Organization (WTO) Notification

Both Australia and New Zealand are members of the World Trade Organization and signatories to the agreements on the Application of Sanitary and Phytosanitary Measures (SPS agreement) and on Technical Barriers to Trade (TBT agreement). Within Australia, a memorandum of understanding binding all States and Territories to the agreements has been put in place by the COAG.

In addition, the agreement between the Government of Australia and the Government of New Zealand on joint food standards explicitly requires the Authority to ensure that food standards are consistent with the WTO obligations of both countries.

The WTO agreements are predicated on a set of underlying principles that standards and other regulatory measures should be;

- based on sound scientific principles;
- developed using consistent risk assessment practices;
- transparent;
- no more trade-restrictive than necessary to achieve a legitimate objective;
- recognise the equivalence of similar measures in other countries; and
- not used as arbitrary barriers to trade.

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

SPS Notifications

These are primarily health related, and refer to any measure applied;

- to protect animal or plant life from risks arising from the entry, establishment or spread of pests, diseases or disease carrying organisms;
- to protect human or animal life or health from risks arising from additives, contaminants, toxins or disease-carrying organisms in foods, beverages or foodstuffs;
- to protect human life or health from risks arising from diseases carried by animals,

- plants or products thereof, or from the entry, establishment or spread of pests; and
- to prevent or limit other damage from the entry, establishment or spread of pests.

TBT Notifications

These are primarily not related to health, but are related to matters such as trade, food composition and labelling.

WTO Notification

It is considered that the matters raised in this Full Assessment Report **do not** require a notification to the WTO due to the transitional nature of the regulations.

2.6 Invitation for Public Submissions

Simplified procedures

The Authority considers that, given the previous extensive consultation in relation to Standard A17 and Standard A19, the omission of one round of public comment as would otherwise be required by section 22 of the *Australia New Zealand Food Authority Act 1991* (the Act), would not significantly affect the interests of anyone. The Authority has therefore decided pursuant to section 36 of the Act to omit to invite comment in relation to the Proposal as would otherwise have been required by section 22 of the Act. Comment is however being sought in relation to the issues raised in this combined Proposal/Full Assessment Report.

Section 63 of the Act provides that, subject to the *Administrative Appeals Tribunal Act 1975*, an application for a review of the Authority's decision may be made to the Administrative Appeals Tribunal by a person whose interests are significantly affected by the decision to omit to invite public submissions in relation to the proposal.

The Authority has completed a full assessment of the proposal, developed a draft joint Australia New Zealand food standard and will now conduct an inquiry to consider the draft standard and its regulatory impact.

Written submissions containing technical or other relevant information which will assist the Authority in undertaking a full assessment on matters relevant to the application, including consideration of its regulatory impact, 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 confidential information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it in confidence. The *Australia New Zealand Food Authority Act 1991* requires the

Authority to treat in confidence trade secrets relating to food and any other information relating to food, the commercial value of which would be or could reasonably be expected to be, destroyed or diminished by disclosure.

All correspondence and submissions on this matter should be addressed to the **Project Manager - Proposal P223** at one of the following addresses:

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Submissions should be received by the Authority by **5 September 2000**.

Copies of the Inquiry Reports for Proposal P94 – Irradiation of Food and Proposal P168 – Novel Foods are available from the Information Officer at either of the above addresses.

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 <sl@anzfa.gov.au>. Submissions should not be sent by Email as the Authority cannot guarantee receipt. Requests for more general information on the Authority can be directed to the Information Officer at the above address or by Email <info@anzfa.gov.au>.

PROPOSAL P223 - REVIEW OF STANDARD A17 – IRRADIATION OF FOOD, and STANDARD A19 – NOVEL FOODS

The purpose of this proposal is to adopt draft Standard 1.5.1 (Novel Foods) and draft Standard 1.5.3 (Food Irradiation), for inclusion in the proposed joint *Australia New Zealand Food Standards Code* (the joint Code), which are equivalent in content to Standard A19 (Novel Foods) and A17 (Food Irradiation) respectively. The only significant matter raised by this proposal is that the effect of incorporation of these standards in the joint Code, will be that these standards will be mandatory in New Zealand from May 2002, which is the expected date of repeal of the Food Regulations 1984. It is not intended to vary the legal effect of existing Standard A17 and A19. It is proposed, for the purposes of the Review of the *Food Standards Code* that the existing provisions be translated into the joint Code, with minor drafting, editorial and formatting adjustments as required to accommodate the existing standard into the proposed joint Code.

DISCUSSION

Standard A17 came into legal effect in the *Food Standards Code* on 2 September 1999, and to date, no food is permitted to be irradiated pursuant to this Standard. Standard A19 came into legal effect on 16 December 1999, with the prohibition contained in clause 2 to take effect on 16 June 2001. In order to include the provisions of these Standards A17 and A19 in the Joint Code, it is necessary to prepare a Proposal, as the previous Proposals prepared with respect to these matters dealt only with the inclusion of these Standards in the *Food Standards Code*, and not the Joint Code.

In New Zealand, the *Food Standards Code* is an alternate standard to the *Food Regulations 1984*, and is therefore not mandatory. This means that Standard A17 and Standard A19 are not currently mandatory standards in New Zealand. The effect of the inclusion in the Joint Code would be to make these standards mandatory from the date of repeal of the Food Regulations.

It is the intention of the Authority to maintain the legal intent of the existing Standards A17 and A19 in draft Standards 1.5.3 and 1.5.1 of the joint Code. This proposal is not intended to vary the legal intent of the Standard A17 or A19. Both of these standards have been the subject of significant public consultation during their development and subsequent promulgation.

This proposal therefore is raised simply as a vehicle for transporting these standards, which are currently in place in the current Australian *Food Standards Code*, into the proposed Joint *Australia New Zealand Food Standards Code*. It is proposed, for the purposes of the Review of the *Food Standards Code* that the existing provisions be translated into the joint Code, with minor drafting, editorial and formatting adjustments as required to accommodate the existing standard into the proposed joint Code.

OPTIONS

Novel Foods

There are two options in relation to Standard A19 of the *Food Standards Code* –

1. To include draft Standard 1.5.1 (equivalent in substance to Standard A19 of *Food Standards Code*) in the Joint Australia New Zealand Food Standards Code.
2. To not include draft Standard 1.5.1 (equivalent in substance to Standard A19 of *Food Standards Code*) in the Joint Australia New Zealand Food Standards Code.

Discussion

Standard A19 came into legal effect on 16 December 1999, with the prohibition contained in clause 2 to take effect on 16 June 2001. Given that Standard A19 came into effect so recently, the Authority considers it appropriate and necessary to include the substance of this Standard in the Joint Code in the form of draft Standard 1.5.1.

Preferred Option

Option 1 is the preferred option.

Food Irradiation

There are two options in relation to Standard A17 of the *Food Standards Code* –

1. To include draft Standard 1.5.3 (equivalent in substance to Standard A17 of *Food Standards Code*) in the Joint Australia New Zealand Food Standards Code.
2. To include draft Standard 1.5.3 (equivalent in substance to Standard A17 of *Food Standards Code*) in the Joint Australia New Zealand Food Standards Code.

Discussion

Standard A17 came into legal effect in the *Food Standards Code* on 2 September 1999, and to date, no food is approved to be irradiated pursuant to this Standard. Given that Standard A17 came into effect so recently, the Authority considers it appropriate and necessary to include the substance of this Standard in the Joint Code in the form of draft Standard 1.5.3.

Preferred Option.

Option 1 is the preferred option.

WORLD TRADE ORGANIZATION (WTO) NOTIFICATION

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

In certain circumstances Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comment. Notification is required in the case of any new or changed standards which may have a

significant trade effect and which depart from the relevant international standard (or where no international standard exists).

This matter does not need to be advised to the WTO as a TBT or a SPS Notification as the Standard A17 and Standard A19 were previously notified to the WTO as can be seen from the Inquiry Reports relevant to those Proposals.

Copies of the Inquiry Reports for Proposal P94 – Irradiation of Food and Proposal P168 – Novel Foods are available from the Information Officer at one of the following addresses.

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Attachments:

1. Current Standard A17
2. Proposed draft Standard 1.5.3
3. Current Standard A19
4. Proposed draft Standard 1.5.1

STANDARD A17**IRRADIATION OF FOOD**

Purpose

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

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

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

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

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

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

Table of Provisions

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

Clauses

1. Definitions

In this Standard -

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

re-irradiate does not include the irradiation of food -

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

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

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

2. General prohibition on irradiation of food

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

3. Permitted sources of radiation

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

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

4. Foods permitted to be irradiated

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

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

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

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

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

Table to clause 4

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

Editorial note:

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

5. Record keeping

(1) Records must be kept at a facility where food is irradiated in relation to -

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

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

6. Labelling

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

Examples:

‘TREATED WITH IONISING RADIATION’

‘TREATED WITH IONISING ELECTRONS’

‘IRRADIATED (name of food)’

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

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

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

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

Editorial Note:

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

Standard 1.5.3

Food Irradiation

Purpose

The purpose of this Standard is to prohibit the irradiation of food, or ingredients or components of food, unless a specific permission is given. Permission will only be given to irradiate a food where it is processed in compliance with the recommendations accepted by the Commonwealth Government in 1989 from the report of the House of Representatives Standing Committee on Environment Recreation and the Arts on the Use of Ionising Radiation. The specific permission may impose conditions relating to matters such as dose, packaging materials, approved premises or facilities.

Even where this Standard permits irradiation, food should only be processed by irradiation where such processing fulfills a technological need or is necessary for a purpose associated with food hygiene. Food should not be processed by irradiation as a substituted procedure for good manufacturing practices. Technological need would include the extension of shelf life, the destruction of certain bacteriological contamination and pest deinfestation.

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

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

The operation of irradiation facilities and control of the irradiation process should be undertaken in accordance with any relevant State and Territory law governing radiation control. They should also be undertaken in accordance with an appropriate Code of Practice such as the 1991 Codex Alimentarius General Standard for Irradiated Foods and its associated Code of Practice for the Operation of Irradiation Facilities Used for the Treatment of Foods.

Table of Provisions

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

Clauses

1 Definitions

In this Standard -

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

re-irradiate does not include the irradiation of food -

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

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

2 General prohibition on irradiation of food

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

3 Permitted sources of radiation

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

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

4 Foods permitted to be irradiated

(1) Subject to subclause 4(2), a food listed in column 1 of the Table to this clause may be irradiated, provided that -

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

(2) A food listed in column 1 of the Table to this clause must only be processed by irradiation where such processing fulfills a technological need or is necessary for a purpose associated with food hygiene, and must not be processed by irradiation as a substituted procedure for good manufacturing practice.

Table to clause 4

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

Editorial note:

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

5 Record keeping

(1) Records must be kept at a facility where food is irradiated in relation to -

- (a) the nature and quantity of the food treated;
- (b) lot identification;
- (c) the minimum durable life of the food treated;
- (d) the process used and compliance therewith;
- (e) the minimum and maximum dose absorbed by the food;
- (f) an indication whether or not the product has been irradiated previously and if so, details of such treatment;
- (g) date of irradiation.

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

6 Labelling

(1) The label on or attached to a package containing a food that has been processed by ionising radiation must include, in type of 3 mm, a statement that the food has been treated with ionising radiation.

Examples:

‘TREATED WITH IONISING RADIATION’

‘TREATED WITH IONISING ELECTONS’

‘IRRADIATED (name of food)’

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

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

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

- (a) a statement that the food has been irradiated; 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.

STANDARD A19

NOVEL FOODS

(NOTE: CLAUSE 2 TAKES EFFECT ON 16 JUNE 2001)

Purpose

This Standard regulates the sale of novel food and novel food ingredients. The Standard prohibits the sale of these foods unless they are listed in the Table to clause 2, and comply with any special conditions in that Table. The specific permission may impose conditions relating to matters such as the need for preparation or cooking instructions, warning statements or other advice, or the need to meet specific requirements of composition or purity.

The purpose of this Standard is to ensure that non-traditional foods which have features or characteristics which raise safety concerns will undergo a risk-based safety assessment before they are offered for retail sale in Australia and/or New Zealand.

The Authority will assess the safety for human consumption of each novel food prior to its inclusion in the Table. The safety assessment will be performed in accordance with the Authority's safety assessment guidelines.

Editorial Note:

Foods produced using gene technology are regulated in Standard A18. Standard A18 will subsequently be located in Standard 1.5.2 of the new Australia New Zealand Food Standards Code (ANZFSC). Foods which have been irradiated are proposed to be regulated in Standard 1.5.3 of the new ANZFSC.

Table of Provisions

1	Definitions
2	Sale of novel foods

Definitions

1. In this Standard -

'non-traditional food' means a food which does not have a history of significant human consumption by the broad community in Australia or New Zealand.

'novel food' means a non-traditional food for which there is insufficient knowledge in the broad community to enable safe use in the form or context in which it is presented, taking into account -

- (a) the composition or structure of the product;
- (b) levels of undesirable substances in the product;
- (c) known potential for adverse effects in humans;
- (d) traditional preparation and cooking methods; or
- (e) patterns and levels of consumption of the product.

Editorial Note

Novel food includes novel foods used as ingredients in another food.

2. Sale of novel foods

A novel food must not be sold, by way of retail sale, as food or for use as a food ingredient unless it is listed in column 1 of the Table to this clause and complies with the conditions of use, if any, specified in column 2.

Table to clause 2

Column 1	Column 2
Novel Food	Conditions of Use

Standard 1.5.1

Novel Foods

(Note: Clause 2 Takes Effect on
16 June 2001)

Purpose

This Standard regulates the sale of novel food and novel food ingredients. This Standard prohibits the sale of these foods unless they are listed in the Table to clause 2, and comply with any special conditions of use in that Table. The specific permission may impose conditions relating to matters such as the need for preparation or cooking instructions, warning statements or other advice, or the need to meet specific requirements of composition or purity.

The purpose of this Standard is to ensure that non-traditional foods which have features or characteristics which raise safety concerns will undergo a risk-based safety assessment before they are offered for retail for direct consumption in Australia and/or New Zealand

The Authority will assess the safety for human consumption of each novel food prior to its inclusion in the Table. The safety assessment will be performed in accordance with the Authority's safety assessment guidelines.

Foods produced using gene technology and foods which have been irradiated are regulated in Standards 1.5.2 and 1.5.3 respectively.

Table of Provisions

- 1 Definitions
- 2 Sale of novel foods

Clauses

1 Definitions

In this Standard-

non-traditional food means a food which does not have a history of significant human consumption by the broad community in Australia or New Zealand.

novel food means a non-traditional food for which there is insufficient knowledge in the broad community to enable safe use in the form or context in which it is presented, taking into account -

- (a) the composition or structure of the product; or
- (b) levels of undesirable substances in the product; or
- (c) known potential for adverse effects in humans; or
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Editorial Note
Novel food includes novel foods used as ingredients in another food.

2 Sale of novel foods

A novel food must not be sold by way of retail sale as food or for use as a food ingredient unless it is listed in column 1 of the Table to this clause and complies with the conditions of use, if any, specified in column 2.

Table to clause 2

Column 1	Column 2
Novel Food	Conditions of Use