# Application to Food Standards Australia New Zealand to vary the Food Standards Code Standard 1.5.3 Irradiation of Food to remove the reference to Schedule 22 in relation to the definition of Herbs and Spices.

DATE: 14 May 2018

## Executive Summary

This application is submitted on behalf of Sapro Australia. The application seeks a variation to Standard 1.5.3 section 1.5.3-4 to clarify the meaning of the terms “herbs” and “spices” in order to ensure uniform interpretation and enforcement. The original definition, referencing Standard 1.4.2, Schedule 4 (now replaced by Schedule 22) was introduced as a result of Application A413.

Standard 1.5.3 section 1.5.3-4 currently defines “herbs and spices” as follows: “*herbs and spices means the herbs and spices described in Schedule 22*”. The applicable section of Schedule 22, Herbs and Spices, contains both descriptions of herbs and of spices and lists of commodities. Differential interpretation by enforcement agencies produces inconsistent enforcement outcomes which do not align with the intent of the original amendment, may cause financial harm to food businesses supplying or using irradiated herbs and spices and do not align with Codex Alimentarius standards or those of trading partners.

The applicant proposes that the current definition of herbs and spices in Standard 1.5.3 be replaced either by a fall back to the commonly understood meaning of herbs and spices, or by inclusion of generic definitions of “herbs” and “spices”, in Standard 1.5.3, to align with the Codex Alimentarius.

Currently, the reference to Schedule 22 may be variously interpreted as a reference to the descriptions of herbs and of spices and/or only to the commodities listed in the schedule. The commodity lists are included for the purpose of establishing maximum residue limits (MRLs) for pesticides and, as such, do not include all common herbs and spices, which may be used in food and are not relevant to decisions about the technical justification for food irradiation. There are 4 possible interpretations of the definition “herbs and spices means the herbs and spices described in Schedule 22” for the purposes of 1.5.3-4:

1. All herbs and spices that meet the definitions in the first part of the Schedule 22 entry are “herbs and spices”, or

2. Only herbs and spices named in the commodity lists in Schedule 22 are “herbs and spices”, or

3. All herbs and spices that either meet the definition , OR are named in the commodity lists in Schedule 22 are “herbs and spices”.

4. Only herbs and spices that meet the definition , AND are named in the commodity lists in Schedule 22 are “herbs and spices”, or

Options 2 and 4 are the most restrictive interpretations, do not permit irradiation of herbs and spices such as *Allspice, Cassia Bark, Celery, Chilli-dehydrated, Garlic-Dehydrated, Green Bell Pepper Onion-Dehydrated, Oregano, Paprika-dehydrated, Cayenne Pepper*, and may be interpreted as applying only to the raw, dried agricultural commodities.

Options 1 and 3 are the interpretations most consistent with the Application A 413 Full Assessment conclusions , Codex and international standards and regulations, and the technological justification for irradiation as a sanitary treatment. Option 3 is the most inclusive as it recognises cinnamon, which is a listed spice commodity but, as a bark, does not meet the definition of spices in Schedule 22.

Benefits accrue to consumers, food importers and manufacturers and governments for a consistent interpretation of 1.5.3-4. There are no apparent costs for any parties.

The toxicological and microbiological safety of and technological justification for the irradiation of herbs and spices has previously been assessed by ANZFA, in the context of Application A413. The current application accepts these assessments as relevant applicable and does not seek a review of them.

- *The analysis of the toxicological effects of irradiation on herbs, spices, herbal infusions and selected nuts indicates that the treatment does not produce adverse health effects beyond those arising from conventional treatments.*
- *Irradiation of herbs, spices, herbal infusions and nuts presents no microbiological safety concerns and will not result in the increased induction of particular mutant bacterial species with increased pathogenicity or virulence.*
- *In conclusion, the available research suggests that irradiating herbs and spices is an efficacious technique for the control of microbial decontamination and offers an alternative to more traditional techniques.*

The requested variation will have no effect on the current requirement to declare the use of ionising radiation on food labels.

The proposed variation most closely aligns with Codex Alimentarius Standards and with the standard and regulation of trading partners, which either rely on generic definitions of herbs and spices or on their accepted common meaning.

The application does not contain confidential commercial information.

This applicant is limited to clarification of the technical definition of “herbs and spices”, under Standard 1.5.3 but does not seek of require an assessment of the safety, technological justification or efficiency of the irradiation process. The General Procedure would be the most appropriate assessment procedure for this application.

# Contents

## A Applicant Details

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| (a) | applicant name | Sapro Australia<br><br>Unit C, 5 Skyline Place<br>Frenchs Forest<br>NSW 2086] |
| (b) | name of contact person | |
| (c) | address (street and postal) | |
| (d) | telephone number | |
| (e) | email address | |
| (f) | nature of applicant's business | Sapro Australia are importers and distributors of African foods. |
| (g) | details of other individuals, companies or organisations associated with the application. | The application has been prepared and is managed on behalf of Sapro Australia by<br><br>Sapro Australia are supported in this application by the following Australian businesses:<br>Springbok Foods PTY LTD QLD 4210<br>Cape To Cairo WA 6017<br>The South African Shop Vic 3106 |

## B Purpose of the application

The purpose of this application is to clarify the meaning of the term "herbs and spices" in Standard 1.5.3 Division 2 section 1.5.3—4 - Irradiation of herbs and spices, by removing the reference to Schedule 22 and replacing it with either its common meaning or clear definitions for herbs and spices, in order to ensure consistent interpretation. The standard currently defines "herbs and spices", for the purpose of section 1.5.3—4 as follows "herbs and spices means the herbs and spices described in Schedule 22". The applicable section of Schedule 22, Herbs and Spices, contains both descriptions of herbs and of spices and lists of commodities identified for the purpose of establishing maximum residue limits (MRLs) for pesticides. Differential interpretation of the current definition, by the various enforcement agencies and their officers, produces enforcement outcomes which are not consistent with the intent of the origin amendment, as described in the Application A413 Final Assessment Report, and may cause financial harm to food businesses supplying or using irradiated herbs and spices. In addition, the more restrictive interpretations are not consistent with Codex Alimentarius standard nor those of trading partners.

The applicant proposes that the current definition of herbs and spices "*herbs and spices means the herbs and spices described in Schedule 22*" in Standard 1.5.3 be removed and be replaced either by a fall back to Common Law definitions of herbs and spices, such as in the Macquarie Dictionary, or by

including generic definitions of “herbs” and “spices”, in Standard 1.5.3, to align with the Codex Alimentarius definitions, such as:

***Herbs*** *consist of flowers, leaves, stems and roots from a variety of herbaceous plants used in relatively small amounts to flavour other foods.*

***Spices*** *consist of aromatic seeds, roots, bark, fruits and berries from a variety of plants used in relatively small amount to flavour other foods.*

## C Justification for the application

### Need for the application

The current permission for the irradiation of herbs and spices in Standard 1.5.3 - Irradiation of food resulted from Application A413 in 2001. This application, as amended in consultation with ANZFA during the assessment stage, requested permission for irradiation of herbs and spices apply to products deemed to comply with the definitions given in Standard 1.4.2, Schedule 4 of the *Food Standards Code:*

*Herbs: including leaves, flowers, stems and roots from a variety of herbaceous plants, used in relatively small amounts as condiments to flavour foods or beverages. They are used either in fresh or naturally dried form.*
*Herbs include angelica, balm leaves, basil, bay leaves, burnet (great), burnet (salad), burning bush, catmint, celery leaves, chives, curry leaves, dill, fennel, hops, horehound, hyssop, kaffir lime leaves, lavender, lemon balm, lemon grass, lemon verbena, lovage, marigold flowers, marjoram, mints, mizuna, nasturtium leaves, parsley, rosemary, rue, sage, sassafras leaves, savoury (summer, winter), sorrel, sweet cicely, tansy, tarragon, thyme, winter cress, wintergreen leaves, woodruff and wormwoods.*
*Spices: consist of the aromatic seeds, roots, berries or other fruits from a variety of plants, which are used in relatively small quantities to flavour foods.*
*Spices include: angelica seed, anise seed, calamus root, caper buds, caraway seed, cardamom seed, cassia buds, celery seed, cinnamon bark, cloves, coriander seed, cumin seed, dill seed, elecampane root, fennel seed, fenugreek seed, galangal (rhizomes), ginger (root), grains of paradise, juniper berry, licorice root, lovage seed, mace, nasturtium pods, nutmeg, pepper (black, white), pepper (long), pimento (fruit), tonka bean, turmeric (root), vanilla beans.*

Conversely, the amended application also sought approval for irradiation of herbal infusions and proposed a definition, *Herbal infusions : fresh, dried or fermented leaves, flowers and other parts of plants used to make beverages, excluding tea*, that was expressly included in the final amendment to the Code.

The current reliance on the definition of herbs and spices in Schedule 22 enables various interpretations by enforcement officer and agencies and creates confusion for businesses wishing to include irradiated herbs and spices in their food. This is a particular problem for importers of processed foods containing irradiated herbs and spices which meet the definitions in Schedule 22 but are not named in the commodity lists. In these cases, depending on the interpretation applied by the inspecting officer, the foods may be detained and must either be destroyed or re-exported at significant cost, despite there being a recognised technological justification for the use of irradiation.

In relation to Herbs and Spicers, Schedule 22 states:

### *Herbs and spices*

#### *Herbs*

*Herbs consist of leaves, flowers, stems and roots from a variety of herbaceous plants, used in relatively small amounts as condiments to flavour foods or beverages. They are used either in fresh or naturally dried form. Herbs are fully exposed to pesticides applied during the growing season. There may be registered post-harvest treatments for dried herbs.*

*Commodities: Angelica; Balm leaves (Melissa officinalis); Basil; Bay leaves; Burnet, great (Banguisorba officinalis); Burnet, salad; Burning bush (Dictamnus albus); Catmint; Celery leaves; Chives; Curry leaves; Dill (Anethum graveolens); Fennel; Hops; Horehound; Hyssop; Kaffir lime leaves; Lavender; Lemon balm; Lemon grass; Lemon verbena; Lovage; Marigold flowers (Calendula officinalis); Marjoram; Mints; Nasturtium leaves (Tropaeolum majus L.); Parsley; Rosemary; Rue (Ruta graveolens); Sage; Sassafras leaves; Savoury, summer, winter; Sorrel; Sweet cicely; Tansy; Tarragon; Thyme; Winter cress; Wintergreen leaves (Gaultheria procumbens L.); Woodruff (Asperula odorata); Wormwoods (Artemisia spp.).*

*Portion of the commodity to which the MRL and ERL apply (and which is analysed): whole commodity.*

#### *Spices*

*Spices consist of the aromatic seeds, roots, berries or other fruits from a variety of plants, which are used in relatively small quantities to flavour foods. Spices are exposed in varying degrees to pesticides applied during the growing season. There may be registered post-harvest treatments for dried spices.*

*Commodities: Angelica seed; Anise seed; Calamus root; Caper buds; Caraway seed; Cardamom seed; Cassia buds; Celery seed; Cinnamon bark; Cloves; Coriander, seed; Cumin seed; Dill seed; Elecampane root; Fennel seed; Fenugreek seed; Galangal, rhizomes; Ginger, root; Grains of paradise; Juniper berry; Licorice root; Lovage seed; Mace; Nasturtium pods; Nutmeg; Pepper, black, white; Pepper, long; Pimento, fruit; Tonka bean; Turmeric, root; Vanilla, beans.*

*Portion of the commodity to which the MRL and ERL apply (and which is analysed): whole commodity.*

The inclusion of both descriptions and commodity lists for herbs and spices in Schedule 22 currently leads to various interpretations of 1.5.3—4 by compliance officers and regulatory agencies. There are at least  at least 4 different known interpretations, with different implications for food manufacturers & importers (Table 1).

**Table 1 – Possible interpretations of herbs *spices described in Schedule 22* and the outcomes.**

| | Interpretations | Outcomes |
|---|---|---|
| 1. | Herbs that meet the description in the first part<br>i.e. *Herbs consist of leaves, flowers, stems and roots from a variety of herbaceous plants, used in relatively small amounts as condiments to flavour foods or beverages. They are used either in fresh or naturally dried* | Potentially allows a broad range of herbs spices to be irradiated, including other herbs & spices to those expressly listed in Schedule 22. This interpretation aligns most closely with the definition of spices used in Codex Alimentarius<br>[***Herbs*** *consist of leaves, stems and roots from a variety of herbaceous plants used in relatively small amounts to flavour other foods.* |

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| *form.*<br>AND<br>Spices that meet the description in the first part<br>i.e. *Spices consist of the aromatic seeds, roots, berries or other fruits from a variety of plants, which are used in relatively small quantities to flavour foods,* | *Spices consist of aromatic seeds, roots, fruits and berries from a variety of plants used in relatively small amount to flavour other foods. They are consumed primarily in the dried form as components of other foods]*<br>and with the standards and regulations of major trading partners. |
| 2. Only those herbs and spices named in the second part of the Schedule 22 entry:<br>i.e.<br>*Commodities:* Angelica; Balm leaves (*Melissa officinalis*); Basil; Bay leaves; Burnet, great (*Banguisorba officinalis*); Burnet, salad; Burning bush (*Dictamnus albus*); Catmint; Celery leaves; Chives; Curry leaves; Dill (*Anethum graveolens*); Fennel; Hops; Horehound; Hyssop; Kaffir lime leaves; Lavender; Lemon balm; Lemon grass; Lemon verbena; Lovage; Marigold flowers (*Calendula officinalis*); Marjoram; Mints; Nasturtium leaves (*Tropaeolum majus* L.); Parsley; Rosemary; Rue (*Ruta graveolens*); Sage; Sassafras leaves; Savoury, summer, winter; Sorrel; Sweet cicely; Tansy; Tarragon; Thyme; Winter cress; Wintergreen leaves (*Gaultheria procumbens* L.); Woodruff (*Asperula odorata*); Wormwoods (*Artemisia* spp.).<br><br>*Commodities: Angelica seed; Anise seed; Calamus root; Caper buds; Caraway seed; Cardamom seed; Cassia buds; Celery seed; Cinnamon bark; Cloves; Coriander, seed; Cumin seed; Dill seed; Elecampane root; Fennel seed; Fenugreek seed; Galangal, rhizomes; Ginger, root; Grains of paradise; Juniper berry; Licorice root; Lovage seed; Mace; Nasturtium pods; Nutmeg; Pepper, black, white; Pepper, long; Pimento, fruit; Tonka bean; Turmeric, root; Vanilla, beans.* | Interpretation limits permission for irradiation only to a select group of herbs spices that have been considered by the APVMA in the context of setting MRLs for residues of pesticides permitted to be used in or imported into Australia. There is no technological justification to limit irradiation as a treatment for these listed spices.<br><br>This interpretation does not align with Codex Alimentarius standards nor with the food regulation of major trading partners. In particular, it excludes commonly irradiated herbs and spices, including: *Ajowan, Allspice, Canola, Cassia Bark, Celery, Chilli, Chilli-dehydrated, Garlic-Dehydrated, Green Bell Pepper, Methee, Mustard Seed, Onion-Dehydrated, Origano, Paprika-dehydrated, Cayenne Pepper, Red Bell Pepper.*<br><br>This interpretation may also imply that the permission applies only to the raw, dried agricultural commodity but not to herbs/spices prepared for used by manufacturers within the food supply chain. |
| 3. Either those herbs and spices that | This interpretation gives the broadest permissions, |

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| meet the descriptions in the first part in Schedule 22 or are listed in the list of commodities in the second part, | in that it allows both herbs and spices that meet the definition as per interpretation 1 but also any herb or spice commodities named in the second part, such as cinnamon, which as a bark does not meet the definition. |
| 4. Only those herbs & spices which meet both the description in the first part and are named in the second part of the Schedule 22 entries: | This interpretation is the most restrictive interpretation since it also excludes any herb or spice commodities that do not meet the applicable definition,<br>for example, the definition in the first part of spices is limited to *aromatic seeds, roots, berries or other fruits from a variety of plants* but at least one of the listed commodities, cinnamon, is a bark, which falls outside the definition.<br><br>This interpretation does not align with Codex Alimentarius standards nor with the food regulation of major trading partners. In particular, it excludes commonly irradiated herbs and spices, including: *Ajowan, Allspice, Canola, Cassia Bark, Celery, Chilli, Chilli-dehydrated, Cinnamon, Garlic-Dehydrated, Green Bell Pepper, Methee, Mustard Seed, Onion-Dehydrated, Origano, Paprika-dehydrated, Cayenne Pepper, Red Bell Pepper.*<br><br>This interpretation may also imply that the permission applies only to the raw, dried agricultural products but not to herbs/spices prepared for use by manufacturers within the food supply chain. |

The Full Assessment Report for Application A 413 does not contain any discussion suggesting that approval should be limited only to the listed commodities in the MRL commodity schedule (either the current Schedule 22 or the previous Schedule 3 to Standard A14). The technological justification and efficacy report repeatedly refers to "herbs and spices" and concludes "*the available research suggests that irradiating herbs and spices is an efficacious technique for the control of microbial decontamination and offers an alternative to more traditional techniques*". There is no suggestion that this conclusion is limited to particular herbs or spices. Furthermore, the toxicology report includes studies on spices, such as paprika, that are not listed in the MRL commodity schedule, and un named "mixed spices", and concludes "*The analysis of the toxicological effects of irradiation on herbs, spices, herbal infusions and selected nuts indicates that the treatment does not produce adverse health effects beyond those arising from conventional treatments*".

It is also apparent that the herb and spice commodities named in the MRL commodity schedule (either Schedule 22 or the previous Schedule 3 to Standard A14) refer to herbs and spices that were relevant to assessments undertaken by the APVMA in respect of establishing maximum residue levels (MRLs) for pesticides. This is evident from the definitions of herbs and spices in Schedule 22 which state, respectively:

- *Herbs are fully exposed to pesticides applied during the growing season. There may be registered post-harvest treatments for dried herbs*; and

- *Spices are exposed in varying degrees to pesticides applied during the growing season. There may be registered post-harvest treatments for dried spices*.

Consequently, these commodity lists are not relevant to the establishment of technological justification for the use of ionising radiation.

Reference to the herbs and spices commodity lists in Schedule 22, for the purposes of enforcement of Standard 1.5.3-4 is also inconsistent with the labelling requirements for irradiated herbs and spices. Standard 1.5.3 requires irradiated foods or ingredients to be identified by a statement to the effect that the ingredient or component has been treated with ionising radiation. However, Standard 1.2.4 and Schedule 10 permit the use of the class names "herbs" and "spices". Consequently, irradiated herbs and spices may be declared on a food label as "herbs (irradiated)" or "spices (irradiated)", with no reference to the specific herbs and spices to which this declaration applies. Doubtless, if the intention have been for the [Schedule 22] commodity lists to be applied to the meaning of herbs and spices in 1.5.3-4, as per Table 2 interpretations 2 and 4, the associated amendments to the Code would also have imposed a requirement to name those herbs and spices on the label alongside the declaration of the use of ionising radiation, to facilitate compliance enforcement.

Consequently, the applicant asserts that the use the phrase "*herbs and spices means the herbs and spices described in Schedule 22*" in Standard 1.5.3 section 1.5.3—4 ("*herbs and spices as described in Schedule 3 to Standard A14*"in the original 2001 amendment in Standard 1.5.3) was intended by the drafters to refer any herb or spice that could be described either in the description in the first part or in the commodities list in the commodity schedule, i.e. any plant derived material that may be classified as a herb or a spice. This interpretation would also be consistent with the approach taken in the original amendment in relation to herbal infusions which are defined solely by a function/outcome based description

## C.1 Regulatory impact information

### *C.1.1 Costs and benefits of the application*

#### (a) the cost and benefits to the consumer

Consumers will benefit for access to a wider range of foods, containing herbs and spices that have been safely processed with ionising radiation. Maintaining the *status quo* has the potential to put consumers at risk from the use of spices from alternative sources that have not undergone effective sanitary processing.

All irradiated foods (and ingredients in foods) will continue to be identified as prescribed in the Code. Consumers will be made aware of the use of ionising radiation to treat herbs and spices and able to make informed choices.

There are no anticipated costs to consumers from the proposed variation to Standard 1.5.3.

#### (b) the costs and benefits to industry and business in general, noting any specific effects on small businesses e.g. savings in production costs

Food manufacturers, importers, distributors and retailers will potentially benefit for greater certainly regarding the regulatory compliance of foods they are selling. Businesses will not be exposed to the financial loss of having goods seized due to inconsistent interpretations in relation to herbs and spices.

Certainty regarding alignment with international and other national standards and regulations for irradiation of herbs and spices will also benefit food businesses.

There are not anticipated to be any costs for food manufacturers from the proposed variation to Standard 1.5.3.

### (c) the costs and benefits to government.

Government enforcement agencies are likely to benefit from greater certainty regarding the definitions of herbs and spices in Standard 1.5.3. Governments are also likely to benefit from the removal of uncertainty surround the definitions and their consistency with Codex Alimentarius standards and those of trading partners.

There are not anticipated to be any costs for governments from the proposed variation.

#### *C.1.2 Impact on international trade*

The proposed variation to Standard 1.5.3 will promote international trade by unequivocally aligning the definition of herbs and spices permitted to be irradiated in Standard 1.5.3, with those of Codex Alimentarius and major trading partners, thereby removing doubt for food importers and exporters.

## D Information to support the application

The toxicological and microbiological safety of and technological justification for the irradiation of herbs and spices has previously been assessed by ANZFA, in the context of Application A413. The applicant is not aware of new data that would support revisiting these assessments. The current application accepts the A413 assessments as relevant and applicable, and does not seek a review of them. The information provided below reflects the conclusions of the A413 Full Assessment Report (Attachment 1).

### D1. Safety of Irradiated Herbs and Spices

#### *D.1.1 Toxicological safety of irradiated Herbs and Spices*

In relation to the safety of irradiated herbs and spices, the A413 Final Assessment report concluded: *The numerous toxicological studies on plant materials indicate there is no evidence that irradiated plant material in the diet leads to toxicological concerns. Therefore, by applying the concept of chemi-clearance, there is no evidence to suggest a toxicological concern following irradiation of spices, herbs and herbal infusions.*

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

It is of note, for the current application, that the toxicological data evaluated by ANZFA in the context of A413 included studies on spices that were not named in the Standard 1.4.2, Schedule 4 (now replaced by Schedule 22).

#### *D.1.2 Microbial safety of irradiated Herbs and Spices*

In relation to the safety of irradiated herbs and spices, the A413 Final Assessment report concluded: *Irradiation of herbs, spices, herbal infusions and nuts presents no microbiological safety concerns and will not result in the increased induction of particular mutant bacterial species with increased pathogenicity or virulence.*

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

## D.2 Technological justification and efficacy of Irradiation of Herbs and Spices

### *D.2.1 Microbiological decontamination of Herbs and Spices*

In relation to the technological and efficacy of irradiated herbs and spices, the A413 Final Assessment report concluded:

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

*Irradiation (at a variety of dose levels) has been shown to significantly reduce levels of microorganisms present on herbs and spices. In addition, irradiation has been shown to be more effective than ethylene oxide at reducing microbial populations on herbs and spices. Radiation doses required for microbial decontamination of spices have shown no major effect on the volatile oils that determine flavour quality.*

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

*Recommendation*

*It is recommended that the application*[1], as amended by the applicant, be approved. The recommendation based on the analysis of relevant scientific evidence that demonstrates that the treatment of these foods with irradiation is safe. Overall, public health and safety benefits may be achieved through the use of this technology as an alternative to existing technologies. It is recommended that approval be made on the following conditions:*

1. *Approval be granted for the foods and food safety and technological purposes requested in the amended application.*
2. *A minimum dose of 2.0kGy and a maximum of 30kGy are approved for the decontamination of herbs and spices.*
3. *A minimum dose of 2.0kGy and a maximum dose of 10kGy are approved for the decontamination of herbal infusions.*
4. *Approval be granted for disinfestations (defined as the control of quarantine insects, weeds and plant pathogens), control of weeds (non quarantine) and control of sprouting for herbs and spices, with no minimum dose specified, as the minimum effective dose for these purposes should be based on the appropriate level of protection determined by quarantine authorities. A maximum dose of 6kGy for these purposes should be approved.*

[1] Application A413 - Request to include herbs, spices, herbal infusions, peanuts, cashew nuts, almonds and pistachio nuts in Standards A17 and 1.5.3 - irradiation of foods in the Food Standards Code

5. *Approval be granted for disinfestation and control of sprouting for peanuts, almonds, cashews and pistachio nuts, with no minimum dose specified as the minimum effective doses for these purposes will be determined by quarantine authorities. A maximum dose of 1kGy for these purposes should be approved.*
6. *Approval be granted in all cases based on the condition that the food is to be handled before and after irradiation according to good manufacturing practice (GMP).*

# E Foods containing Irradiated Herbs and Spices

## E1 Nutritional impact of varying the definition of Herbs and Spices for which irradiation is permitted.

The permission to irradiate spices potentially impacts on:

1. Herbs and Spices sold as such, and
2. Processed foods containing irradiated herbs and spices.

Herbs and Spices are generally added to foods a low levels for flavouring purposes. As such they do not make any significant contribution to the nutritional value of the foods to which they are added. The requested variation is intended normalise the interpretation of Standard 1.5.3 in relation to those herbs and spices which may be irradiated but will have no nutritional impact.

Examples of foods containing irradiated herbs and spices, from the range of foods imported and distributed by Sapro Australia, include:

*Marina Braai Salts-Full range*
*Robertsons Spices-Full range*
*Wellington Chutneys-Full range*
*Pakco Pickles- Full range*
*Pakco Sauces- full range*
*Mrs Balls Chutneys-Full range*
*Knorr Aromat Peri Peri seasoning*
*Hinds Seasoning*
*Cerebos seasoning*
*Knorr soup Chakalaka*
*Ina Paarman Marinade Peri Peri*
*Freddy Hirsch range of spices*
*Cartwrights Curry spices*
*Simba Mexican Chilli Chips*

## E2 Labelling of irradiated Herbs and Spices

The requested variation is intended to normalise the interpretation of Standard 1.5.3 in relation to those herbs and spices which may be irradiated but will have no effect on the current requirement to identify irradiated herbs and spices on food labels.

## F Assessment procedure

This applicant is limited to clarification of the technical definition of “herbs and spices”, as applied under Standard 1.5.3 but does not seek of require an assessment of the safety, technological justification or efficiency of the irradiation process, beyond that completed previously under Application A413. The applicant suggests that the General Procedure would be the most appropriate assessment procedure for this application.

## G Confidential commercial information (CCI)

The application does not contain confidential commercial information.

## H Other confidential information

The application does not contain and non-CCI information.

## I Exclusive capturable commercial benefit (ECCB)

The application will not confer an exclusive capturable commercial benefit to the applicant. All food manufacturers manufacturing herbs and spices or food containing herbs and spices will potentially benefit for the requested variations.

## J International and other national standards

### *J.1 International Standards*

Irradiation of food is permitted in the Codex Alimentarius General Standard For Irradiated Foods CODEX STAN 106-1983, REV.1-2003

The standard does not prescribed foods which may or may not be irradiated but established general requirements for food irradiation:

***4.1 General Requirement***

*The irradiation of food is justified only when it fulfils a technological requirement and/or is beneficial for the protection of consumer health. It should not be used as a substitute for good hygienic and good manufacturing practices or good agricultural practices.*

***4.2 Food Quality and Packaging Requirements***

*The doses applied shall be commensurate with the technological and public health purposes to be achieved and shall be in accordance with good radiation processing practice. Foods to be irradiated and their packaging materials shall be of suitable quality, acceptable hygienic condition and appropriate for this purpose and shall be handled, before and after irradiation, according to good manufacturing practices taking into account the particular requirements of the technology of the process.*

Codex Standard CAC/GL 41-1993 Portion of Commodities to which Maximum Residues Limits Apply and which is Analyzed includes definitions of Herbs and Spices:

***Herbs*** *consist of leaves, stems and roots from a variety of herbaceous plants used in relatively small amounts to flavour other foods.*

***Spices*** *consist of aromatic seeds, roots, fruits and berries from a variety of plants used in relatively small amount to flavour other foods.*

The Codex Code Of Hygienic Practice for Spices and Dried Aromatic Herbs CAC/RCP 42 – 1995 Revision 2014 , defines Spices and Dried Aromatic Herbs as follows:

***Spices and Dried Aromatic Herbs*** *– dried components or mixtures of dried plants used in foods for flavouring, colouring, and imparting aroma. This term equally applies to whole, broken, ground and blended forms.*

### *J.2 Other national standards or regulations*

**USA**

Food irradiation is regulated under the food additive regulations as a food additive ]rather than as a food process].

21CFR179[2] permits the use of ionizing radiation for the treatment of food.

Sec. 179.26 Ionizing radiation for the treatment of food.

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| 5. For microbial disinfection of the following dry or dehydrated aromatic vegetable substances when used as ingredients in small amounts solely for flavoring or aroma: culinary herbs, seeds, spices, vegetable seasonings that are used to impart flavor but that are not either represented as, or appear to be, a vegetable that is eaten for its own sake, and blends of these aromatic vegetable substances. Turmeric and paprika may also be irradiated when they are to be used as color additives. The blends may contain sodium chloride and minor amounts of dry food ingredients ordinarily used in such blends | Not to exceed 30 kGy (3 Mrad). |

No class definitions for herbs or spices have been established by the FDA. FDA policy adopts the following definition for spices. The is no corresponding policy statement for herbs.
*SPICES - General Definition - Aromatic vegetable substances, in the whole, broken, or ground form, whose significant function in food is seasoning rather than nutrition. They are true to name and from them no portion of any volatile oil or other flavoring principle has been removed*.

**EU**
Irradiation of herbs and spices is regulated under DIRECTIVE 1999/3/EC

**Foodstuffs authorised for irradiation treatment and maximum radiation doses**

| **Category of foodstuff** | **Maximum overall average absorbed radiation dose (kGy)** |
|---|---|
| Dried aromatic herbs, spices and vegetable seasonings | 10 |

[2] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=179&showfr=1&subpartnode=21:3.0.1.1.10.2

"Herbs" and "spices" are not defined or cross-refenced in the EU directive.

**Canada**

The Food and Drug Regulations DIVISION 26 Food Irradiation[3] permits irradiation of whole and ground spices, and dehydrated seasoning preparations  Maximum Total absorbed dose 10.0 kGy

"Spices" and "seasonings" are not defined in the Canadian Food and Drug Regulations.

[3] http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._870/page-87.html?txthl=irradiation#s-B.26.005

Statutory Declaration – Australia

STATUTORY DECLARATION

*Statutory Declarations Act 1959* [1]

I

make the following declaration under the *Statutory Declarations Act 1959*:

1. the information provided in this application fully sets out the matters required
2. the information provided in this application is true to the best of my knowledge and belief
3. no information has been withheld that might prejudice this application, to the best of my knowledge and belief

I understand that a person who intentionally makes a false statement in a statutory declaration is guilty of an offence under section 11 of the *Statutory Declarations Act 1959*, and I believe that the statements in this declaration are true in every particular.

Declared at: Unit C, 5 Skyline Place, Frenchs Forest on this day, 10/05/2018

Before me,

10/05/2018

[1] http://www.comlaw.gov.au/Series/C1959A00052

## Checklists.

| General requirements (3.1.1) | | |
|---|---|---|
| **Check** | **Page No.** | **Mandatory requirements** |
| ☑ | | A Form of application<br>☑ *Application in English*<br>☑ *Executive Summary (separated from main application electronically)*<br>☑ *Relevant sections of Part 3 clearly identified*<br>☑ *Pages sequentially numbered*<br>☑ *Electronic copy (searchable)*<br>☑ *All references provided* |
| ☑ | | B Applicant details |
| ☑ | | C Purpose of the application |
| ☑ | | D Justification for the application<br>☑ *Regulatory impact information*<br>☑ *Impact on international trade* |
| ☑ | | E Information to support the application<br>☑ *Data requirements* |
| ☑ | | F Assessment procedure<br>☑*General*<br>☐*Major*<br>☐*Minor*<br>☐*High level health claim variation* |
| ☑ | | G Confidential commercial information<br>*n/a CCI material separated from other application material*<br>☐*Formal request including reasons*<br>☐*Non-confidential summary provided* |
| ☑ | | H Other confidential information<br>*n/a Confidential material separated from other application material*<br>☐*Formal request including reasons* |
| ☑ | | I Exclusive Capturable Commercial Benefit<br>*n/a Justification provided* |

| | |
|---|---|
| ☑ | J International and other national standards<br>☑ *International standards*<br>☑ *Other national standards* |
| ☑ | K Statutory Declaration |
| ☑ | L Checklist/s provided with application<br>☑ *3.1.1 Checklist*<br>☑ *All page number references from application included*<br>☑*Any other relevant checklists for Chapters 3.2–3.7* |

| **Irradiated foods (3.5.3)** | | |
|---|---|---|
| **Check** | **Page No.** | **Mandatory requirements** |
| ☑ | | A.1 Nature of the food or food ingredient to be irradiated |
| ☑ | | A.2 Technological need |
| ☑ | | A.3 Food products likely to contain irradiated food |
| ☑ | | B Safety information |
| ☑ | | C Nutritional impact |

## Attachments

### Attachment 1 - Final assessment report (inquiry . Section 17) and Regulatory impact statement Application A413 - Request to include herbs, spices, herbal Infusions, peanuts, cashew nuts, almonds And pistachio nuts in standards a17 and 1.5.3 . Irradiation of foods in the *Food Standards Code.*