



25 October 2019

[100-19]

Approval report – Application A1163

Food irradiation definition of herbs and spices

FSANZ has assessed an application made by Sapro Australia to amend section 1.5.3—4 of the Australia New Zealand Food Standards Code (the Code). Sapro requested clarification of the meaning of the terms herbs and spices with respect to food irradiation, in order to ensure uniform interpretation and enforcement.

On 6 June 2019, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received 8 submissions.

FSANZ approved the draft variation on 21 October 2019. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 25 October 2019.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

Table of contents

EXECUTIVE SUMMARY	2
1 INTRODUCTION	3
1.1 THE APPLICANT	3
1.2 THE APPLICATION	3
1.3 THE CURRENT STANDARDS	3
1.4 INTERNATIONAL STANDARDS	4
1.4.1 <i>Codex Alimentarius</i>	4
1.4.2 <i>European Union</i>	5
1.4.3 <i>Canada</i>	5
1.4.4 <i>United States</i>	5
1.5 REASONS FOR ACCEPTING APPLICATION	5
1.6 PROCEDURE FOR ASSESSMENT.....	5
1.7 DECISION	5
2 SUMMARY OF THE FINDINGS.....	5
2.1 SUMMARY OF ISSUES RAISED IN SUBMISSIONS	5
2.2 RISK ASSESSMENT	11
2.3 RISK MANAGEMENT	12
2.3.1 <i>Regulatory problem</i>	12
2.3.2 <i>Regulatory solution</i>	13
2.3.3 <i>Labelling of irradiated food</i>	13
2.4 RISK COMMUNICATION	14
2.4.1 <i>Consultation</i>	14
2.5 FSANZ ACT ASSESSMENT REQUIREMENTS	14
2.5.1 <i>Section 29</i>	14
2.5.2 <i>Subsection 18(1)</i>	16
3 REFERENCES	17
ATTACHMENT A – APPROVED DRAFT VARIATION TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE</i>	18
ATTACHMENT B – EXPLANATORY STATEMENT	20

Supporting document

The [following document](#)¹ which provides more detailed information on section 1.4 of this Application is available on the FSANZ website:

SD1 International approaches to irradiation of herbs and spices and definitions in Codex texts

¹ <http://www.foodstandards.gov.au/code/applications/Pages/A1163.aspx>

Executive summary

Sapro Australia submitted an application to change the Australia New Zealand Food Standards Code (the Code). Sapro requested clarification of the meaning of the terms herbs and spices in Standard 1.5.3, in order to ensure uniform interpretation and enforcement. The applicant proposed that the current description of herbs and spices in Standard 1.5.3 be replaced either by the commonly understood meaning of herbs and spices or by including generic definitions of herbs and spices.

Herbs and spices may only be irradiated in accordance with section 1.5.3—4 of the Code. Subsection 1.5.3—4(3) of the Code defines what constitutes a herb or a spice for the purposes of section 1.5.3—4.

Section 1.5.3 was inserted into the Code in 2001 following FSANZ's assessment of Application A413 Irradiation of Herbs and Spices (ANZFA 2001). That assessment included a risk assessment that had regard to the best available scientific evidence and concluded there were no public health and safety issues following irradiation of herbs and spices. That conclusion on the safety of irradiated foods has been confirmed by assessments undertaken for subsequent applications to irradiate other foods (e.g. specific fruits and vegetables).

The purpose of the requested amendment was to confirm the intended scope of the 2001 permission. There were no new issues for FSANZ to consider in relation to the public health and safety of irradiated herbs and spices.

FSANZ's assessment was that the requested variation will have no effect on the current Code requirement to declare the use of ionising radiation on food labels.

After assessing A1163, FSANZ prepared a draft variation to the Code to amend subsection 1.5.3—4(3). The amendment provides that herbs and spices includes (but is not limited to) a herb or a spice described in Schedule 22 of the Code. The effect is that any plant derived material within the commonly accepted and ordinary meaning of 'herb' or 'spice', regardless of its form (dried or fresh) may be irradiated in accordance with section 1.5.3—4 of the Code.

A total of eight submissions were received following FSANZ's call for submissions. Five submitters completely supported the draft variation. One submitter supported the draft variation on a limited basis. Two submitters did not support the draft variation. The FSANZ Board has approved the draft variation as proposed following assessment without change after the consideration of submissions.

1 Introduction

1.1 The Applicant

This application was made by Sapro Australia, an importer and distributor of food.

1.2 The Application

The application sought to amend the Australia New Zealand Food Standards Code (the Code), to clarify the meaning of the terms 'herbs' and 'spices' in Standard 1.5.3, in order to ensure uniform interpretation and enforcement. The relevant provisions of the Code are described below.

The applicant requested that the Code be clarified to provide greater certainty regarding the permission to irradiate herbs and spices. The applicant's stated position was that the use of the phrase '*herbs and spices means the herbs and spices described in Schedule 22*' in subsection 1.5.3—4(3) refers to any herb or spice that could be described in Schedule 22 either in the description of the commodity or in the commodities list (i.e. any plant derived material that may be classified as a herb or a spice).

The applicant stated that, as a result of the descriptions and lists of commodities in Schedule 22, the permission to irradiate specific herbs and spices was open to a number of possible interpretations, including as a reference only to the descriptions of herbs and of spices, or only to the commodities listed after each description.

The applicant proposed that the current definition of herbs and spices in Standard 1.5.3 be replaced either by a commonly understood meaning of herbs and spices, or by including generic definitions of 'herbs' and 'spices' in Standard 1.5.3, to align with the Codex Alimentarius (Codex).

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

1.3 The current standards

Australian and New Zealand food laws require food for sale to comply with the following Code requirements.

Permission to irradiate

Paragraphs 1.1.1—10(5)(d) and (6)(h) of Standard 1.1.1 require that, unless expressly permitted, a food for sale must not be irradiated, or have as an ingredient or component a food that has been irradiated.

Section 1.5.3—4 permits herbs and spices to be irradiated for certain purposes and subject to certain conditions. Subsection 1.5.3—4(3) states that, for the purposes of this permission, '*herbs and spices means the herbs and spices described in Schedule 22*'.

The permission for the irradiation of herbs and spices has been part of the Code since 2001. It was inserted as a result of Application A413 Irradiation of Herbs and Spices (ANZFA 2001). In September 2001, under the Final Assessment Report for A413, the definitions for herbs and spices were finalised and subsequently contained in Amendment No. 56 to the Code, stating at that time '*herbs and spices as described in Schedule 4 to Standard 1.4.2*'.

Schedule 4 was the precursor to Schedule 22 in the current Code.

Schedule 22 of the Code currently lists foods and classes of food (see section S22—2). That list includes a separate class each for herbs and for spices. The entry in Schedule 22 for herbs and for spices includes a general description of what constitutes a herb or a spice, as well as a list of food commodities for each class.

Schedule 22 of the Code lists foods and classes of food primarily for the purposes of Standard 1.4.2, which regulates maximum residue limits (MRLs) and extraneous residue limits for agricultural or veterinary chemicals that are permitted in foods for sale in Australia. The MRLs for particular foods are listed in Schedule 20 and the permitted extraneous residue limits for particular foods are listed in Schedule 21.

Similar to subsection 1.5.3—4(3), section 1.4.2—3(4) provides that, for MRLs, a reference to a particular food in Standard 1.4.2, Schedule 20 or 21 is to the food as described in Schedule 22. As explained in section 1.4.1 of this report, the food commodity descriptors in Schedule 22 were initially based on the Codex Committee on Pesticide Residues (CCPR) guidelines that were in place and commodities as traded at the time (but with flexibility, for example, to accommodate Australian specific foods and/or capture a range of plant cultivars under one commodity name), and have not been updated.

Labelling requirements

Paragraph 1.1.1—10(8) requires that food for sale must comply with all relevant labelling requirements in the Code for that food.

For this purpose, section 1.5.3—9 sets out the labelling requirements for foods for sale that have been irradiated, or for foods for sale that have an ingredient or component that has been irradiated.

The Code generally requires food labels to include a statement of ingredients. Standard 1.2.4 sets out the requirements for statement of ingredients. Section 1.2.4—4 requires a statement of ingredients to identify each ingredient by a commonly known name, a name describing the ingredient's true nature, or a generic name that is specified in Schedule 10 and in accordance with any conditions specified in that Schedule. Schedule 10 includes the generic names 'herbs' and 'spices'.

1.4 International standards

Irradiation of herbs and spices is permitted in a number of countries. Other countries such as the European Union, Canada and the United States do not have specific and confined lists of herbs and spices permitted to be irradiated in their regulations, and Codex texts contain various definitions depending on the purpose of the Codex committee. A summary of these requirements is provided below while more detail is provided in Supporting Document 1.

1.4.1 Codex Alimentarius

Three Codex committees have standards, guidelines or Codes of Practice applicable to the definitions of herbs and spices. These are CCPR, the Codex Committee on Food Hygiene, and the Codex Committee on Spices and Culinary Herbs. There is no single Codex definition for herbs and spices that is consistent across all Codex texts, as the purpose of each Codex committee differs.

The descriptions and commodity lists in Schedule 22 were based on the CCPR guidelines in

place and the foods listed in the Schedule to Standard 1.4.2 (e.g. commodities grown and/or traded in Australia) at the time the Schedule was originally developed.

The General Standard for Irradiated Foods sets out the general requirements for food irradiation (CCFH 1983), but does not set requirements for individual foods.

1.4.2 European Union

Irradiation of herbs and spices is regulated under Directive 1999/3/EC (EC 1999). Dried aromatic herbs, spices and vegetable seasonings are permitted to be irradiated. Herbs and spices are not defined.

1.4.3 Canada

The Food and Drug Regulations Division 26 Food Irradiation (CFDR 2019) permits irradiation of whole and ground spices and dehydrated seasoning preparations. Spices and seasonings are not defined in the Canada Food and Drug Regulations.

1.4.4 United States

The United States Food and Drug Administration Code of Federal Regulations (USFDA 2018) permits the use of ionizing radiation for the treatment of food, including culinary herbs, seeds and spices. Spices are defined in separate guidance. While a number of herbs are described, there is no general definition of herbs.

1.5 Reasons for accepting Application

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the FSANZ Act; and
- it related to a matter that warranted the variation of a food regulatory measure

1.6 Procedure for assessment

The Application was assessed under the General Procedure.

1.7 Decision

The draft variation as proposed following assessment was approved without change after the consideration of submissions. The approved draft variation is at Attachment A. The variation takes effect on the date of gazettal.

The related explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ called for submissions on the proposed draft variation between 6 June 2019 and 18 July 2019.

A total of eight submissions were received; three from jurisdictions, three from food businesses in Australia that import and sell South African foods, one from Food Irradiation Watch & Friends of the Earth Brisbane (FIWFEB), and one from the New Zealand Food and Grocery Council (NZFGC).

The three Australian food businesses and two jurisdictions fully supported the proposed draft variation. The FIWFEB supported the application but suggested a change to the drafting. The NZFGC supported an amendment being sought but not the method of drafting. One jurisdiction considered that the proposed variation did not provide further regulatory clarity.

The issues raised in three submissions have been addressed in Table 1 below².

Table 1: Summary of issues

Issue	Raised by	FSANZ response
Drafting approach		
<p>The FIWFEB supported the proposed amendments, with the following comment:</p> <p>The definition should be amended to clarify that it is an inclusive definition; that is, by including in the definition an express statement that it is an inclusive definition and that it encompasses a herb or a spice listed or described in Schedule 22.</p>	<p>FIWFEB</p>	<p>Noted.</p> <p>FIWFEB's suggested amendment is not required. The definition itself states that it is an inclusive definition. The accompanying Explanatory Statement also makes this very clear.</p> <p>It is clear from the definition itself and the accompanying Explanatory Statement that the amendment's effect is that a reference to 'herb' or 'spice' in section 1.5.3—4 of the Code is a reference to any plant derived material within the commonly accepted and ordinary meaning of 'herb' or 'spice' (as the case may be) and includes (but is not limited to) a herb or a spice listed or described in Schedule 22.</p>

² The five fully supportive submissions that did not include any issues for consideration in regard to the application (from two government agencies and three food businesses) are not included in Table 1.

Issue	Raised by	FSANZ response
<p>NZFGC strongly supports amendment of the definition, but does not support how the amendment is drafted as it refers to Schedule 22.</p> <p>NZFGC oppose the Code referring to Schedule 22 for purposes other than residue limits for agricultural or veterinary chemicals in Australia.</p> <ul style="list-style-type: none"> • The purpose of Schedule 22, as set out in Standard 1.4.2—2, is “to set out the maximum residue limits and extraneous residue limits for agricultural or veterinary chemicals that are permitted in foods for sale”. • Schedule 22 was never intended to be a multipurpose schedule. • Definitions in the Code should be tailored for specific purposes. A separate generic definition should be tailored for section 1.5.3—4 that does not refer to Schedule 22. • This would leave Schedule 22 to meet its stated purpose (determining categories of foods and levels of maximum residue levels from the application or agricultural and veterinary chemicals) 	<p>NZFGC</p>	<p>Noted.</p> <p>FSANZ does not share NZFGC’s view.</p> <p>The fact that a law or a Standard exists for one purpose does not mean that that law or Standard, or a list in one part of it, cannot be referenced and used for and by another law or Standard. This is accepted and normal drafting and legislative practice.</p> <p>Schedule 22 and its precursor has been referenced by the Irradiation Standard since 2001. The purpose statement in section 1.4.2—2 cannot of itself change that fact or the legal effect of section 1.5.3—4 and the definition in subsection 1.5.3—4(3).</p> <p>In any event, Schedule 22 itself makes clear that a purpose of Schedule 22 is to describe foods and classes of foods for the purposes of subsection 1.5.3—4(3). See Note 1.</p> <p>No evidence has been presented that the proposed single reference in section 1.5.3—4 to one small part of Schedule 22 will in fact create a practical problem for industry or for enforcement. See in this regard, FSANZ’s responses below.</p>

Issue	Raised by	FSANZ response
<p>Schedule 22 is almost exclusively applied for the purposes of Standard 1.4.2, which is an Australia-only standard. The reference in section 1.5.3—4 to Schedule 22 therefore creates ambiguity for New Zealand industry and enforcement about what parts of the Code applies in New Zealand. The section and the reference have 'long been an irritation in terms of use for this reason.'</p>	<p>NZFGC</p>	<p>Noted.</p> <p>FSANZ does not share NZFGC's view.</p> <p>No evidence has been presented that the single reference in section 1.5.3—4 to one part of Schedule 22 will create ambiguity about what parts of the Code apply in New Zealand.</p> <p>It is axiomatic that a single reference in section 1.5.3—4 to one part of Schedule 22 does not and cannot apply Standard 1.4.2 to New Zealand.</p> <p>The <i>Food Act 2014</i> (NZ) determines what parts of the Code apply in New Zealand. Standard 1.5.3 applies in New Zealand to the extent that its provisions – including the definition provided by subsection 1.5.3—4(3) - are incorporated in or adopted under that Act. The fact that the definition adopts a description of and a list of herbs and spices in Schedule 22 means that that description and list apply for the purpose of that definition in New Zealand together with the rest of Standard 1.5.3 and as part of Standard 1.5.3.</p> <p>Schedule 22 itself makes very clear that a purpose of Schedule 22 is to describe foods and classes of foods for the purposes of Standard 1.5.3 and subsection 1.5.3—4(3) in particular. See Note 1.</p> <p>See also FSANZ's responses above to other issues.</p> <p>FSANZ notes that the New Zealand Ministry of Primary Industries, which is responsible for food law in New Zealand, supported the draft variation in its current form.</p>

OFFICIAL

Issue	Raised by	FSANZ response
<p>The reference in section 1.5.3—4 to Schedule 22 is anomalous and inconsistent internationally in that the European Union, Canada and the United States do not try to define herbs and spices in regulation for the purposes of irradiation.</p>	<p>NZFGC</p>	<p>Noted.</p> <p>FSANZ does not share NZFGC's view.</p> <p>The approaches taken by the European Union (EU), Canada and the United States are explained in section 1.4 above. As stated there: 'herbs' and 'spices' are not defined for the purposes of the EU legislation; 'spices' and 'seasonings' are not defined in Canadian legislation; and, while the United States has defined 'spices in separate guidance, there is no general definition of 'herbs'.</p> <p>In each case, the lack of a definition means that these terms will be given their commonly accepted and understood meanings.</p> <p>The draft variation does the same. It will provide that a reference to 'herb' or 'spice' in section 1.5.3—4 of the Code is a reference to any plant derived material within the commonly accepted and ordinary meaning of 'herb' or 'spice' (as the case may be) and includes (but is not limited to) a herb or a spice described or listed in Schedule 22. Those listed or described in Schedule 22 all fall within what is commonly accepted and understood to be a 'herb' or a 'spice'.</p>

Issue	Raised by	FSANZ response
<p>The draft variation will not provide any greater regulatory certainty for enforcement purposes.</p> <p>The proposed definition is an open-ended definition; that is a list of some plants and plant products that are considered to be herbs and spices with the proviso that other plant material may also be herbs and spices.</p> <p>This means that enforcement agencies will still need to make a decision about whether the material is a herb or spice without specific information to aid the decision.</p> <p>This means that there will be no improvement of clarity in the decision process.</p> <p>For these reasons, no definition should be provided in the Code and the dictionary definitions for herbs and spices should be relied on instead.</p> <p>Alternatively, if required, a dictionary definition of 'a herb' and 'a spice' or a modified dictionary definition could be included in the Code.</p>	<p>South Australia Health</p>	<p>Noted.</p> <p>FSANZ does not share SA Health view.</p> <p>Having no definition in the Code will mean that enforcement officers must make decisions without any specific information to aid their decision other than an open ended (dictionary) definition.</p> <p>The effect of the proposed amendment will be that the terms 'herb' and 'spice' in section 1.5.3—4 have their ordinary and accepted meaning and include a herb or a spice listed or described in Schedule 22. That list and that description provide a clear statement and guidance for enforcement officers as to what is a herb and a spice for the purposes of section 1.5.3—4.</p> <p>If the plant material in question is not in the list or covered by the description, the officers will then have to assess whether the plant material in question meets the ordinary and accepted meaning of what is a 'herb' or a 'spice'. In doing so, they can have regard to dictionary definitions. In that situation, the decision making process for enforcement agencies will be the same as if there was no definition for 'herb' and 'spice' in the Code at all.</p> <p>See also FSANZ responses to other submitters above.</p> <p>No other jurisdiction expressed such view or concern. The Victorian Departments of Health and Human Services and Jobs, Precincts and Regions stated in their submission that the amendment would provide greater clarity. FSANZ also notes Australian industry submissions stating that the proposed amendment will provide certainty.</p>
<p>Food classes in Schedule 22 were never intended as a set of definitions of foods that apply across the Code. The definitions in Schedule for other foods may not align with the definitions in other parts of the Food Standards Code.</p>	<p>South Australia Health</p>	<p>Noted.</p> <p>See FSANZ responses above.</p>

Issue	Raised by	FSANZ response
It is important that the definition for herbs and spices should not include plant materials listed in Schedule 23 Prohibited plants and fungi.	South Australia Health	<p>Noted.</p> <p>The reference in subsection 1.5.3—4(3) to herbs and spices has not permitted and will not permit food for sale to consist of, or have as an ingredient or a component, a prohibited or restricted plant or fungus.</p> <p>The definition of herbs and spices in subsection 1.5.3—4(3) of the Code only relates to the irradiation of herbs and spices in accordance with section 1.5.3—4 of the Code.</p> <p>In the Code, a permission to irradiate a food is not a permission for a food to contain prohibited plants and fungi.</p> <p>A food for sale may only consist of, or have as an ingredient or a component, a prohibited or restricted plant or fungus if permitted by Standard 1.4.4.</p>
Would like to see both labelling regulations and enforcement improved.	FIWFEB	<p>Noted.</p> <p>This is out of scope for this application.</p>
Current regulations do not prescribe labelling statements nor do they require individual labelling of bulk irradiated products, such as fruit.	FIWFEB	<p>Noted.</p> <p>This is out of scope for this application.</p>
Concerns with food irradiation in general, including comments on other irradiation permissions in the Code, and the related safety assessments.	FIWFEB	<p>Noted.</p> <p>These are out of scope for this application.</p>

2.2 Risk assessment

FSANZ's assessment was that amending the Code to provide clarity and confirm the meaning of herbs and spices for the purposes of the permission provided by section 1.5.3—4 would not pose potential adverse health effects.

The safety of irradiated herbs and spices was considered in 2001 under A413 (ANZFA 2001). The Final Assessment Report for A413 concluded that there is no evidence that irradiated plant material in the diet leads to toxicological concerns.

In addition, and since approval of A413, FSANZ has assessed the technological need, safety and nutrient profile of various irradiated tropical fruits; persimmons; tomatoes and capsicums; apple, apricot, cherry, nectarine, peach, plum, honeydew, rock melon, scallopin, strawberry, table grape and zucchini (courgette); and raspberries and blueberries. These assessments were conducted under Applications A443, A1038, A1069, A1092 and A1115 (FSANZ 2002, FSANZ 2011, FSANZ 2013, FSANZ 2014 and FSANZ 2016, respectively). FSANZ concluded that there was an established need to irradiate these foods and that there were no

public health and safety issues associated with their consumption when irradiated up to a maximum dose of 1 kGy.

In conclusion, as the toxicological and microbiological safety of and technological justification for the irradiation of herbs and spices was previously assessed in the context of A413, and as no recent application or other available information has highlighted any public health and safety concerns from irradiated foods, a risk assessment for this application was not undertaken by FSANZ.

FSANZ's assessment did, however, consider other issues relevant to Application A1163, as outlined in the following risk management section and in section 2.5.

2.3 Risk management

2.3.1 Regulatory problem

As explained in section 1.3, subsection 1.5.3—4(3) of the Code states that, for the purposes of irradiation permission, 'herbs and spices means the herbs and spices described in Schedule 22'. Schedule 22 of the Code lists foods and classes of food. That list includes a separate class each for herbs and for spices. The entry in Schedule 22 for herbs and spices includes a general description of what constitutes a herb or a spice as well as a list of food commodities for each class.

The applicant stated these general descriptions and accompanying commodity lists are ambiguous leading to difficulties for importers of processed foods containing irradiated herbs and spices. In some cases, irradiated herbs and spices are being stopped at the Australian import border due to the interpretation of subsection 1.5.3—4(3) of the Code by enforcement officials. In such cases, the reference in subsection 1.5.3—4(3) to a herb and spice 'described in Schedule 22' has been interpreted to mean a herb or spice that is included in *both* the general description and in the list of food commodities. On this interpretation, for example, if a herb or a spice is not expressly mentioned in the list of food commodities for herbs or spices in Schedule 22, it may be considered not to be a herb or spice described in Schedule 22 and therefore not permitted by section 1.5.3—4 to be irradiated. Depending on this variable interpretation, imported foods may be unnecessarily detained and must either be destroyed or re-exported at significant cost.

In addition, the applicant in A1163 proposed four different interpretations of subsection 1.5.3—4(3), each having different implications for food manufacturers and importers. These interpretations and implications are summarised in Table 1 on page 3 of the application. The four interpretations range from the most restrictive (the herb or spice must meet both the definition and be named expressly in the commodity list) to the least restrictive interpretation (the herb or spice can meet either the description or be named in the commodity list).

The least restrictive option is the closest option to the outcome intended in 2001 following the assessment of A413. The intent was that a herb or spice that does not meet the commodity description, but in other respects is considered a herb or a spice (it may be listed in the commodities list, but not necessarily) can be irradiated. That is, the permission was intended to apply to products that met the commonly understood meaning of what is a herb or a spice. Examples are bay leaves and kaffir lime leaves (these are listed, but may be considered as herbs from woody plants not herbaceous plants), and cinnamon bark (bark is not listed in the description of spices). Furthermore, there may be other herbs and spices that are similar to those that are listed, but are not explicitly captured in the relevant description in Schedule 22.

2.3.2 Regulatory solution

The options available to FSANZ, after assessment, were to reject the application or to prepare a draft variation to amend the Code.

The applicant suggested that the current definition of herbs and spices in Standard 1.5.3 be replaced either by the ordinary and commonly understood meaning of 'herbs and spices' or by inclusion of generic definitions of herbs and spices.

FSANZ's assessment was that the definition of herbs and spices in Standard 1.5.3 be amended to provide greater certainty. FSANZ's assessment was that amendment of the Code is the only option available that can provide the required certainty, and that there are no non-regulatory options that can appropriately address the regulatory problem. In making its assessment, FSANZ had regard to the criteria prescribed in the FSANZ Act (see section 2.5).

FSANZ's draft variation is described below in section 2.3.2.1.

2.3.2.1 Standard 1.5.3 amendment

Section 1.5.3—4 of the Code contains the current definition of 'herbs and spices' for food irradiation, as explained in section 1.3.

The draft variation amends subsection 1.5.3—4(3) to provide that, for the purposes of section 1.5.3—4, 'herbs and spices' includes (but is not limited to) a herb or a spice described in Schedule 22. This is an inclusive definition. That is, the terms 'herb' and 'spice' are to be given their ordinary and commonly understood meaning. Plant material which falls within that meaning may be irradiated in accordance with section 1.5.3—4. For the purposes of the irradiation permission, a herb may also fall within either the general description in Schedule 22 of what is a herb or be listed as a commodity in the commodity list provided for herbs in that Schedule (and similarly for a spice).

In effect, section 1.5.3—4 remains unchanged but has been re-written to make clear that the commodity lists in Schedule 22 are not exhaustive.

In its assessment, FSANZ had regard to the various definitions for herbs and spices contained in Codex texts, and, as noted in section 1.4.1, the descriptions and commodity lists in Schedule 22 were based on the CCPR guidelines in place at the time the Schedule was originally developed. Also noted in section 1.4.1, there is no single Codex definition for herbs and spices that is consistent across all Codex texts.

Our drafting approach is consistent with the intent of the permission granted and provided for in the Code as a result of the original variation in 2001, that is, approval to irradiate any herb and spice in accordance with a recognised technological need.

2.3.3 Labelling of irradiated food

The applicant did not request a variation to the labelling requirements for irradiated herbs and spices. Existing labelling requirements for irradiated herbs and spices will continue to apply.

Section 1.5.3—9 of the Code requires where a food has been irradiated, or contains an ingredient or component that has been irradiated, there must be a statement to the effect that the food, ingredient or component has been treated with ionising radiation. This statement must be made available in accordance with Standard 1.2.1, for example:

- where the food must bear a label—in the label of the food (subsections 1.2.1—6(1) and 1.2.1—8(1); and section 1.2.1—15); or
- where the food does not have to bear a label—stated in labelling accompanying or being displayed with the food (see sections 1.2.1—9) or provided in documentation (1.2.1—16); or
- where the food is not for retail sale nor for sale to a caterer—provided to the purchaser either on request by the purchaser or as required by the relevant enforcement authority (section 1.2.1—21); or
- where the food contains an ingredient or component that has been irradiated—on the statement of ingredients related to the food (see section 1.2.4—2 of the Code).

Standard 1.2.4 of the Code requires ingredients to be listed by their common or descriptive names, or by a generic name if one is listed in Schedule 10. Schedule 10 lists 'herbs' and 'spices' as separate generic names that can be used on food labels.

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process.

FSANZ developed and applied a basic communication strategy to this application. All calls for submissions are notified via the FSANZ Notification Circular, media release, FSANZ's social media tools and Food Standards News.

The process by which FSANZ considers standard development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application. Every submission was considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

2.5 FSANZ Act assessment requirements

2.5.1 Section 29

When assessing this application and the subsequent development of a food regulatory measure, FSANZ had regard to the following matters in section 29 of the FSANZ Act.

2.5.1.1 Cost benefit analysis

The OBPR exempted FSANZ from the need to undertake a formal Regulation Impact Statement in relation to the regulatory change proposed in response to this application (OBPR reference number: 25085). This was due to OPBR being satisfied that this appears likely to have only a minor regulatory impact.

FSANZ, however, had regard to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. Section 29(2)(a) of the FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure.

The purpose of this analysis was to determine if the community, government and industry as a whole is likely to benefit, on balance, from a move from the status quo. This analysis considered the option to clarify the meaning of the terms 'herbs' and 'spices' specified in Standard 1.5.3 of the Code to ensure uniform interpretation and enforcement. FSANZ is of the view that no other realistic food regulatory measures exist. A consideration of costs and benefits was included in the call for submissions (CFS) report based on the information and data held at that time. No further information has been received during the consultation process to date that influenced the findings from the analysis of costs and benefits in the CFS.

The analysis of the costs and benefits in this section were not intended to be an exhaustive, quantitative economic analysis of the proposed measures. In fact, most of the effects that FSANZ had regard to cannot easily be assigned a dollar value. Rather, the analysis sought to highlight the likely positives and negatives of moving away from the status quo to the option described above.

Costs and benefits of amending the Code to clarify the definition of herbs and spices

Consumers - There may be some increase in the range of food products containing irradiated herbs and spices available to consumers, particularly from imported sources.

Whilst irradiated herbs and spices have been assessed as being safe, mandatory labelling of food containing any irradiated ingredients will allow consumers wishing to avoid such foods to do so.

Industry and business in general - Food businesses, particularly importers, are likely to benefit from more certain and consistent access to a greater range of food products containing irradiated herbs and spices. That is particularly where irradiation is more effective and/or efficient at controlling bacterial contamination of foods than other techniques.

Government - Government enforcement agencies are likely to benefit from:

- greater certainty regarding the definitions of herbs and spices in Standard 1.5.3 (potentially reducing administration and enforcement costs);
- consistency with international regulations.

International Trade - The proposed change would ensure greater regulatory consistency with trading partners.

Conclusions from cost benefit considerations

FSANZ's analysis was that the direct and indirect benefits that would arise from a food regulatory measure, developed or varied as a result of the application, outweigh the costs to the community, government or industry that would arise from the development or variation of the food regulatory measure.

2.5.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the application.

2.5.1.3 Any relevant New Zealand standards

The standards in question apply in both Australia and New Zealand. There are no relevant New Zealand only standards.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2. Subsection 18(1)

FSANZ has also had regard to the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.5.2.1 Protection of public health and safety

FSANZ considers that there are no public health and safety risks related to the proposed amendment.

2.5.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

The mandatory requirements under Standard 1.5.3 to label irradiated foods will provide information to enable consumers to make informed purchase decisions.

2.5.2.3 The prevention of misleading or deceptive conduct

There are no issues identified with this application relevant to this objective.

2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

See section 2.2 of this report. As explained, FSANZ has previously assessed and characterised the risk from consumption of irradiated foods, and for herbs and spices this was conducted under A413. Those assessments were based on and had regard to the best available scientific evidence. FSANZ is not aware of any new scientific evidence to suggest that these previous risk assessments require revision.

- **the promotion of consistency between domestic and international food standards**

Regulatory certainty that there is approval to irradiate any herb or spice will promote consistency with other countries that permit the irradiation of herbs and spices.

- **the desirability of an efficient and internationally competitive food industry**

Ensuring regulatory clarity relating to food irradiation permissions for herbs and spices helps enable an efficient and internationally competitive food industry.

- **the promotion of fair trading in food**

As explained above, in terms of fair trading and consumer protection, the mandatory requirements under Standard 1.5.3 of the Code to label irradiated foods will provide information to enable consumers to make informed purchase decisions.

- **any written policy guidelines formulated by the Forum on Food Regulation**

The Policy Guideline on the Labelling of Food Produced using New Technologies³ includes specific order policy principles. Labelling of irradiated foods is already a requirement in the Code. FSANZ has determined that clarifying the Code in respect of the definitions of herbs and spices is consistent with the Ministerial Policy Guideline and the specific order principles.

3 References

ANZFA (2001) Application A413 [Irradiation of Herbs and Spices](#). Australia New Zealand Food Authority, Canberra.

CFDR 2019 [Government of Canada Food and Drug Regulations C.R.C.,c 870](#) Division 26 Food Irradiation. Accessed 9 April 2019.

CCFH (1983) Codex Standard for Irradiated Food. [Codex STAN 106-1983-REV.1-2003](#). Accessed 9 April 2019.

EC (1999) [Commission Implementing Directive \(EC\) 1999/3/EC](#) of 22 February 1999 on the establishment of a Community list of foods and food ingredients treated with ionising radiation. Accessed 9 April 2019.

FSANZ (2002) Application A443 [Irradiation of Tropical Fruits](#). Food Standards Australia New Zealand, Canberra.

FSANZ (2011) Application A1038 [Irradiation of Persimmons](#). Food Standards Australia New Zealand, Canberra.

FSANZ (2013) Application A1069 [Irradiation of Tomatoes and Capsicums](#). Food Standards Australia New Zealand, Canberra.

FSANZ (2014) Application A1092 [Irradiation of Specific Fruits and Vegetables](#). Food Standards Australia New Zealand, Canberra.

FSANZ (2016) Application A1115 [Irradiation of Blueberries and Raspberries](#). Food Standards Australia New Zealand, Canberra.

USFDA 2018 [United States Code of Federal Regulations Title 21](#) Part 179 Irradiation in the Production, Processing and Handling of Food. Accessed 9 April 2019.

Attachments

- A. Approved draft variation to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement

³ [Policy Guideline on the labelling of food produced using new technologies](#)

Attachment A – Approved draft variation to the *Australia New Zealand Food Standards Code*



Food Standards (Application A1163 – Food Irradiation definition of herbs and spices) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by the Delegate]

[Insert Delegate's details]

Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1163 – Food Irradiation definition of herbs and spices) Variation*.

2 Variation to a standard in the *Australia New Zealand Food Standards Code*

The Schedule varies a Standard in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

Schedule

[1] Standard 1.5.3 is varied by omitting subsection 1.5.3—4(3) and substituting

(3) In this section:

herbs and spices includes (but is not limited to) a herb or a spice described in Schedule 22.

Attachment B – Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

The Authority accepted Application A1163 which sought to amend the definition of ‘herbs and spices’ in subsection 1.5.3—4(3) of the Code. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislation Act 2003*.

2. Purpose

The Authority has approved a draft variation to amend subsection 1.5.3—4(3) of the Code to clarify the meaning of the terms ‘herbs’ and ‘spices’ for the purposes of food irradiation and to ensure consistent interpretation and enforcement.

3. Documents incorporated by reference

The variation to a food regulatory measures does not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority’s consideration of Application A1163 included one round of public consultation following an assessment; and the preparation of a draft variation and associated assessment summary. Submissions were called for on 6 June 2019 for a six-week consultation period.

A Regulation Impact Statement (RIS) was not required because the proposed variation to Standard 1.5.3 is likely to have a minor impact on business and individuals and is deemed to be deregulatory in nature (see OBPR reference number: 25085).

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

Item [1] amends Standard 1.5.3 by omitting subsection 1.5.3—4(3) and substituting a new subsection 1.5.3—4(3). The new subsection will provide that, in section 1.5.3—4, the term ‘herbs and spices’ includes (but is not limited to) a herb or a spice described in Schedule 22.

This is an inclusive definition. Its effect will be that the terms ‘herb’ and ‘spice’ in section 1.5.3—4 include (but are not limited to): plant material that meets the general description of a ‘herb’ or ‘spice’ in Schedule 22; and/or plant material that is listed in the list of commodities provided in Schedule 22 for ‘herbs and spices’. The definition’s phrase ‘includes (but is not limited to)’ makes clear that a ‘herb’ and ‘spice’ for the purposes of section 1.5.3—4 also includes any plant derived material that is not covered by the latter description or list but which falls within the commonly accepted and ordinary meaning of ‘herb’ or ‘spice’.