13 November 2018
[63-18]

Approval report – Application A1129

Monk Fruit Extract[1] as a Food Additive

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Saraya Co., Ltd. to permit the use of monk fruit extract as a food additive to perform the technological purpose of an intense sweetener.

On 20 July 2018, FSANZ sought submissions on draft variations and published an associated report. FSANZ received 16 submissions.

FSANZ approved the draft variations on 31 October 2018 . The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 12 November 2018.

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

[1] The applicant has used another common name for monk fruit extract, this being 'luo han guo extract' throughout the application.

Table of contents

Supporting document

The following document[2] which informed the assessment of this application is available on the FSANZ website:

SD1 Risk and Technical Assessment Report (amended at approval)

[2] http://www.foodstandards.gov.au/code/applications/Pages/A1129-MonkFruitFA.aspx

Executive summary

Saraya Co., Ltd. submitted an application to Food Standards Australia New Zealand (FSANZ) seeking to permit the use of monk fruit (or luo han guo) extract as a food additive to perform the technological purpose of an intense sweetener. Saraya's intention is to export to Australia and New Zealand table-top sweetener products containing monk fruit extract and ready-to-consume food products sweetened with monk fruit extract.

Monk fruit extract is derived from the fruit of *Siraitia grosvenorii*, a perennial vine, native to southern China. Monk fruit extract has a number of advantages over other already approved intense sweeteners. It has a relative lack of bitter taste and can be used as a sugar substitute in baking (as it has high temperature stability and no unpleasant aftertaste).

The applicant provided information about the food groups proposed to contain monk fruit extract, when used as an intense sweetener, and the proposed maximum concentrations of the extract. FSANZ's risk assessment concluded that there were no public health and safety issues associated with the proposed use of monk fruit extract as an intense sweetener. The assessment also concluded that its use as an intense sweetener was technologically justified. In addition, in the absence of any identifiable hazard, FSANZ concluded that an acceptable daily intake (ADI) 'not specified' is appropriate. A dietary exposure assessment was therefore not required.

A number of submissions on FSANZ's assessment report asked for additional food groups to be permitted to contain monk fruit extract. There are no additional public health and safety issues associated with adding monk fruit extract to a larger number of food groups. Other submitters suggested an alternative approach of adding monk fruit extract as a GMP (Good Manufacturing Practice) food additive to the table to section S16—2 in Schedule 16, since it has an ADI of 'not specified'. This alternative approach was supported by FSANZ.

The FSANZ Board has approved different draft variations to FSANZ's initial assessment report, adding monk fruit extract to the table of section S16—2, as a food additive permitted at GMP and not adding specific entries with numerical maximum permitted levels (MPLs) for many food categories in the table to section S15—5. However, for completeness a small number of permissions were also added to the table to section S15—5 for some food categories with the MPL of GMP.

1 Introduction

1.1 The applicant

Saraya Co., Ltd. manufactures and sells health and hygiene products and services. Saraya has been developing, producing and selling monk fruit (or luo han guo) extract-sweetened products since 1995 in Japan and other markets.

1.2 The application

The application was received on 8 March 2016.

The application sought to change the Australia New Zealand Food Standards Code (the Code) to permit monk fruit extract as a food additive, specifically as an intense sweetener. The applicant intends to produce table-top sweetener products containing monk fruit extract, and ready-to-consume food products sweetened with monk fruit extract for export to Australia and New Zealand.

The food groups initially proposed to contain monk fruit extract are outlined in Table 4.1 of the application, together with the proposed maximum permitted levels (MPLs) at which the extract is to be added to these foods. The application sought amendments to Schedule 15 (Substances that may be used as food additives) and Schedule 8 (Food additive names and code numbers (for statement of ingredients)) in the Code.

Monk fruit extract is derived from the fruit of *Siraitia grosvenorii*, a perennial vine native to southern China and a member of the Cucurbitaceae family. The components of the extract that impart the sweetness are collectively known as mogrosides (cucurbitane glycosides), with pure mogroside V the primary component, exhibiting a sweetness of between 250 and 400 times that of sucrose.

Monk fruit extract has advantages over other already approved intense sweeteners. It has a less bitter taste relative to other intense sweeteners and it makes for a versatile sweetener that can also be used as a sugar substitute in baking (as it has high temperature stability and no unpleasant aftertaste).

1.3 The current standard

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

Permitted use

Paragraph 1.1.1—10(6)(a) of the Code provides that food for sale cannot contain, as an ingredient or component, a substance ‘used as a food additive’ unless that substance’s use as a food additive is expressly permitted by the Code.

Section 1.3.1—3 details which substances are permitted to be used as a food additive for the purposes of the Code. The permitted food additives for different food categories are listed in the table to section S15—5 of the Code.

Section 1.1.2—11 also provides that a substance is ‘used as a food additive’ if it is added to a food to perform one or more technological functions listed in Schedule 14 of the Code and is one of the following: a substance identified in the table to section S15—5 as a permitted food additive; a substance identified in section S16—2 as an additive permitted at GMP

(Good Manufacturing Practice); a substance identified in section S16—3 as a colouring permitted at GMP; a substance identified in section S16—4 as a colouring permitted at a maximum level; or a prescribed non-traditional food.

Schedule 14 lists the permitted technological purposes of food additives. The table in section S14—2 of that Schedule provides that use as an intense sweetener is a permitted technological purpose. The table also provides that use to perform the technological purpose of a 'flavouring' is different to and does not include use to perform the technological purpose of an intense sweetener – see the definition of 'flavouring' used in the table.

Schedules 15 and 16 list the specific food additive permissions for different categories of food products.

Section 1.3.1—5 imposes limitations on the use of food additives to perform the technological purpose of an intense sweetener. A substance that may be used as a food additive to perform this technological purpose may be added to food only: (a) as a flavour enhancer; or (b) in an amount necessary to replace, either wholly or partially, the sweetness normally provided by sugars.

Monk fruit extract is not currently permitted to be added to food as a food additive to perform the technological purpose of an intense sweetener.

Monk fruit extract permitted for use as a favouring, not as an intense sweetener

The Code currently permits the use of monk fruit extract as a food additive to perform the technological purpose of flavouring. As explained above, the Code provides that use for this technical purpose does not include or permit use to perform the technological purpose of an intense sweetener.

The following sections of the Code permit monk fruit extract's use as a food additive to perform the technological purpose of flavouring.

Section 1.1.2—11 of the Code permits the use as a food additive of a substance identified in section S16—2 as 'an additive permitted at GMP'. The table to section S15—5 also lists 'additives permitted at GMP' as permitted in various categories of food products.

Section S16—2 provides that 'permitted flavouring substances, excluding quinine and caffeine', are an additive permitted at GMP. Section 1.1.2—2(3) contains a definition of what is a 'permitted flavouring substance'. The definition provides that a permitted flavouring substances includes, among other things, a substance that is listed in the following publications: the Generally Recognised as Safe (GRAS) lists of flavouring substances published by the Flavour and Extract Manufacturers' Association of the United States (FEMA) from 1960 to 2015 (edition 27).

Monk fruit extract is listed as a flavouring in the GRAS lists under FEMA reference no. 4711 – luo han fruit concentrate. FEMA, which listing the latter, considers that the concentrate does not impart sweetness at the levels used as a flavouring.

Labelling

Paragraph 1.1.1—10(8) of the Code provides that food for sale must comply with all relevant labelling requirements imposed by the Code for that food.

Standard 1.2.4 of the Code generally requires food products to be labelled with a statement of ingredients. Section 1.2.4—7 of that Standard requires food additives to be declared in the

statement of ingredients by their class name (where it can be classified into a class of additives), followed by the individual additive name or code number in brackets or otherwise the name of the additive as listed in Schedule 8.

Schedule 7 lists the food additives class names and Schedule 8 lists the names and code numbers of food additives that are to be used for labelling purposes, including in the statement of ingredients.

Schedule 8 does not refer to monk fruit extract as this substance is not currently permitted to be added to food as a food additive.

Identity and purity requirements

Paragraph 1.1.1—15(1)(a) of the Code requires substances used as food additives to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code. The specifications listed in that Schedule include the specifications as described in the United States Pharmacopeial Convention (2016) Food Chemicals Codex (10th edition). These include a specification for monk fruit extract.

1.4 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
- it related to a matter that warranted the variation of a food regulatory measure.

1.5 Procedure for assessment

The application was assessed under the General Procedure.

1.6 Decision

The draft variations as proposed following assessment were approved with amendment after the consideration of submissions. The approved draft variations are at Attachment A. The approved variations take effect on 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.

The draft variations on which submissions were sought are at Attachment C.

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ called for submissions on a proposed draft variation on 20 July 2018. Sixteen submissions were received: from government agencies (three submissions); the food industry, including the applicant (twelve submissions) and health professional organisations (one submission). All but one submission supported the application. In addition, food industry submissions asked for additional food groups to be permitted to contain monk fruit extract either by: adding additional permissions in the table to section S15—5; or that the food additive be approved under section S16—2 as an additive permitted under GMP. A summary of the issues raised by submissions and FSANZ's response is provided in Table 1.

Table 1: Summary of issues raised by submissions

Raised by	Issue	FSANZ response
Saraya Co., Ltd.	Requested additional food groups be permitted to contain monk fruit extract, including their proposed MPLs (to be added into the table to section S15—5). Justification for these requests were provided, which included: • That the ADI was 'not specified' • There are benefits to consumers and industry • It allows for an internationally competitive food industry • Benefits the food regulatory system by not requiring a future new application seeking to broaden permissions.	The applicant's justification for extending the range of food groups to which monk fruit extract can be added, based on safety considerations, is considered valid. The risk assessment completed by FSANZ determined that an ADI 'not specified' was appropriate for monk fruit extract and, as such, a dietary exposure assessment was not required. Therefore, there would be no additional public health and safety issues associated with adding monk fruit extract to a larger number of food groups. Further consideration of this issue, including suggestions received in submissions, has led FSANZ to add monk fruit extract to the section to S16—2 (additives permitted at GMP). This is because the food additive has an ADI of 'not specified' and therefore it is appropriate to be considered as an additive permitted at GMP. There are also other comparable intense sweeteners listed in S16—2. Making this change means FSANZ is also addressing the various submissions made requesting permissions to additional foods and increases in MPLs. There are a broad range of food categories within the table to section S15—5 to which 'additives permitted at GMP' are allowed. There still is a need to add permissions to two other categories requested by the applicant, being 5 (confectionery) and 14.1.4 (formulated beverages) with the qualification note – 'section 1.3.1—5 does not apply', both with the MPL of GMP. This is explained in section 2.3.
Hawkins Watts Group	Supported the application. Requested that additional food groups be permitted to contain monk fruit extract. In support of their submission, the submitter noted the following: • No safety issues – an ADI is not specified • Benefit to consumers and industry.	See FSANZ's response to Saraya's submission above.

Raised by	Issue	FSANZ response
Ingredient Box	Supported the application. Reflects the comments made in the Hawkins Watts Group submission above.	See FSANZ's response to Saraya's submission above.
Australian Beverages Council	Supported the application. Requested that monk fruit extract be permitted for use in beverages through either section S16—2 Additives permitted under GMP (preferable); **OR** by including some additional food groups for permission under section S15—5, in particular, beverages. The submitter noted: • No safety issues – an ADI was not set and there is significant technical justification for use • Supporting public health initiatives – respond to consumer calls for reduced sugar in the food supply • Favourable sensory attributes • History of use in China and Japan, and US GRAS determination was issued in 2010 • Benefits for industry and consumers • Efficient and internationally competitive food industry • Savings to food regulatory system by not requiring a new future application to further extend permissions • Clarity on labelling – the submitter supports use of the term 'extract' as opposed to 'concentrate' as a more accurate description of the food additive, and seeks clarification from FSANZ as to whether these terms will be used interchangeably or not.	See FSANZ's response to Saraya's submission above. For labelling purposes, FSANZ has proposed the names of 'monk fruit extract' or 'luo han guo extract'. Both are included in Schedule 8 as the available names permitted under this schedule.
Frucor Suntory Ltd.	Supported the application. Reflected the comments made by the Australian Beverages Council. Monk fruit extract is already used in overseas markets. There are no safety issues – no ADI has been set.	See FSANZ's response to Saraya's submission above.

Raised by	Issue	FSANZ response
PepsiCo Australia	Supported the application. Requested that the list of permitted categories could be expanded to include a range of beverages such as standard carbonated soft drinks, still drinks such as iced teas, and fruit drinks. The submitter also noted: • No safety issues – an ADI was not set • History of use in China, Japan and the USA • Benefits for industry and consumers.	See FSANZ's response to Saraya's submission above.
Guilin Layn Natural Ingredients Corp	Supported the application. Requested that a number of additional food groups be permitted to contain monk fruit extract being dairy, non-alcoholic beverages, and formulated supplementary sports foods. The following information was provided in support of their application: • Favourable characteristics • International use – monk fruit extract is already used in the US, China and Japan as a general food additive • Benefits for industry and consumers • Tradition/history of use • No safety issues – an ADI was not set • Savings to regulatory system by not requiring an additional future application seeking extension of use of the additive.	See FSANZ's response to Saraya's submission above.
Tate and Lyle	Supported the application. Requested that monk fruit extract be permitted as a general purpose sweetener to be used at Good Manufacturing Practice (GMP) levels. In support of their submission: • An ADI of 'not specified' is appropriate • Consistent with GRAS Notifications submitted to FDA • China and Japan permit the use of monk fruit extract in foods and beverages with no maximum limits (according to GMP) e.g. non-alcoholic beverages, flavoured milk etc.	See FSANZ's response to Saraya's submission above.

Raised by	Issue	FSANZ response
Dietitians Association of Australia	Supported the application, noting that there are no public health and safety issues; generic labelling requirements would apply; and the proposed amendments would enable greater choice by consumers and industry. The submitter recommends that FSANZ review the evidence on the long term safety of artificial sweeteners. The submitter also recommended an ongoing public awareness campaign and education on the effects of sweeteners to ensure that consumers can make informed choices.	Monk fruit extract is derived from the fruit of a perennial vine native to southern China and is a natural low-kilojoule sweetener rather than an artificial sweetener, which is typically produced synthetically. FSANZ notes the terms 'intense sweetener' and 'artificial sweetener' have different meanings. The technological purpose for the food additive is intense sweetener, as described in Schedule 14. Artificial sweetener is not a term used in the Code. FSANZ's assessment has been to assess the food additive as an intense sweetener (see sections 2.1.3 and 2.1.4 in SD1).
New Zealand Beverage Council	Supports the application for similar reasons to other submissions. It appreciates having the choice to label the food additive as either 'monk fruit extract' or 'luo hang guo extract', noting that it prefers the term 'monk fruit extract' compared to 'monk fruit concentrate'. The submitter requests broadening permissions to other beverages. This request is to add monk fruit extract to either: • Section S16—2 (additives permitted under GMP) within Schedule 16, or • The additional beverages being food categories 1.1.2, 1.2.2, 13.3, 13.4 and 14.1 within the table to section S15—5.	See FSANZ's response to Saraya's submission above.
Monk Fruit Corp	Supports the application but like other submissions also requests an expansion of the food categories; in particular it mentions dairy, non-alcoholic beverages and formulated supplementary sports foods. It provides justification for the request to broaden the food categories and a table of proposed food categories with the proposed MPLs, and typical use levels.	See FSANZ's response to Saraya's submission above.

Raised by	Issue	FSANZ response
The a2 Milk Company Limited	Supports the application but requests a broadening of the food categories to which monk fruit extract can be added. The justification for this is the same as that of the application. It requests permissions for four additional food categories, with the proposed MPLs provided. These are for food categories 1.1.2, 1.2.2, 13.3 and 13.4 within the table to section S15—5.	See FSANZ's response to Saraya's submission above.
New Zealand Ministry for Primary Industries	It notes the narrow range of permissions and the numerical MPLs which it suggests can be considered as conservative when compared to other food additives with an ADI of 'not specified'. It questions why numerical MPL are proposed rather than GMP and separately suggests it may be appropriate to place permission in Schedule 16 (at GMP).	See FSANZ's response to Saraya's submission above.
New Zealand Ministry for Primary Industries	It notes that the Joint FAO/WHO Expert Advisory Committee on Food Additives (JECFA) has not performed an assessment of the food additive, since no data was received in 2014 to allow an assessment to be conducted. It seeks FSANZ to discuss this further, and to seek a response from the applicant or supplier of the food additive whether there is an intention to request a future JECFA safety evaluation and specification.	FSANZ's risk assessment based on the best available scientific evidence is that there are no public health and safety issues associated with the proposed use of the food additive as an intense sweetener. A JECFA safety evaluation and specification of a substance is not of itself a prerequisite for a Code variation to permit that substance's use as a food additive. The applicant commissioned an animal toxicity study which it provided to allow FSANZ to complete its safety assessment. This new toxicity study could form part of any data package required by JECFA to undertake a safety evaluation. Current data should also be available for JECFA to also complete a specification for the food additive. Comment was sought from the applicant on whether it, or some other monk fruit supplier, plans to seek a JECFA safety assessment and specification. The applicant advised they are considering whether there is now sufficient toxicology data to seek a JECFA evaluation, and this includes consulting with the relevant food safety authority, which may take some time.

Raised by	Issue	FSANZ response
New Zealand Ministry for Primary Industries	Questioned whether the alternative name *luo han guo extract* is required for labelling purposes. It suggests that an INS number is required in the near future which can be added into the Code for labelling. This INS number would also be used internationally for labelling so ensuring consistency for trade purposes and consistency with labelling of other sweeteners and food additives. It therefore suggests that FSANZ take an active role, preferably working with the applicant, to ensure an INS number is requested as soon as possible through the Codex Committee on Food Additives (CCFA).	FSANZ agrees with MPI's suggestion to request the CCFA to determine an INS number and food additive name so the food additive can be added to the Codex Standard CAC/GL 36-1989 (Class names and the international numbering system for food additives). It will propose to work in conjunction with the applicant for this purpose. Until an INS number is determined and added to the Code it is still important to have appropriate food additive names for labelling purposes. Having the two options as requested by the applicant allows food manufacturers the choice of using the most appropriate name for their product and their markets.
South Australia Health	Noted that there was only one round of public comment. It was concerned that, for approving a new intense sweetener, the assessment of public health and safety should be conducted to the same minimum level as described in the FSANZ Application guidelines [taken to be the Application Handbook]. Specific concerns are listed below.	FSANZ's assessment was consistent with that conducted for any new food additive. The assessment is conducted, as outlined in FSANZ's Application Handbook, for a general procedure to be completed in 9 months with one round of public comment. This was determined at the administrative assessment stage. A general procedure is standard practice for assessments of new food additives unless it is determined that there are likely added complexities that justify a major procedure. Use of the major procedure was not warranted in this case. The administrative assessment conclusion was the assessment was appropriate as a general procedure, level 2 (up to 650 hours) since it 'involves an assessment of the risk to public health and safety of average complexity'.
South Australia Health	The submitter has concerns about whether the applicant has provided any, or relevant, safety studies associated with its proprietary extract (1 or possibly 2 are mentioned in the application).	The developmental and reproductive study described in SD1 was conducted with the applicant's proprietary extract. The doses administered to the parent (P generation) rats used in this study were very high and therefore also provide evidence that the applicant's proprietary extract is in practical terms nontoxic. The studies conducted with PureLo® as the test article are also representative because PureLo® is equivalent.

Raised by	Issue	FSANZ response
South Australia Health	A concern in the change in the paradigm for the safety assessment of food additives that are typically well defined and characterised substance(s) to those that are poorly defined mixtures. The submitter refers to section 3.3.1 B (Information related to the safety of the food additive) of the Application Handbook in support of its concern.	FSANZ has assessed the submitted evidence, as well as information from other sources, concerning the safety of monk fruit extract, and is satisfied that the available data met the Application Handbook requirements and are sufficient to assess the hazard of monk fruit extract. FSANZ considers that the monk fruit extract is well-defined and characterised, having a Food Chemicals Codex specification.
South Australia Health	It is concerned that the lack of international approvals of the food additive for the proposed uses should cause FSANZ to take a more cautious approach to permitting the use of the food additive to ensure public health and safety.	FSANZ's risk assessment based on the best available scientific evidence is that there are no public health and safety issues associated with the proposed use of the food additive as an intense sweetener. FSANZ has assessed the submitted evidence, as well as information from other sources, concerning the safety of monk fruit extract, and is satisfied that the available data meet the Application Handbook requirements and are sufficient to assess the hazard of monk fruit extract. FSANZ notes that monk fruit is a traditional food and folk medicine in China, and monk fruit extract has a long history of safe use in Japan. Monk fruit extract has been available in the USA for a number of years and was recently approved in Canada. No adverse effects on human health or development associated with monk fruit extract consumption have been reported in the populations of any of those countries.

Raised by	Issue	FSANZ response
South Australia Health	Questioned the use of the alternative name '*luo han guo extract*' being added to the Code in addition to the name of '*monk fruit extract*' for purposes of labelling of food containing the food additive. It supports the use of a single name of the food additive for purposes of identity as adding extra synonyms into regulations make them cumbersome, as many food additives will also have synonyms. Interested parties can search for alternative names for food additives using different approaches including the internet. Listing the name in the Code does not make this name a prescribed name for labelling purposes. A food manufacturer can choose the most appropriate name that will be understood by the market without requiring it to be listed in the Code.	The Code is explicit about how food additives need to be declared on labels. These labelling requirements are detailed within section 1.2.4—7 (Declaration of substances used as food additives) within Standard 1.2.4 – Information requirements – statement of ingredients. Section 1.2.4—7 requires that a food additive must be listed in a statement of ingredients by specifying their class name, followed by the individual additive name or code number in brackets or otherwise the name of the additive as listed in Schedule 8 (see section 1.3 above). Therefore, the Code needs to be explicit on which particular names are permitted for a food additive, hence both '*monk fruit extract*' and '*luo han guo extract*' as an alternative are included in Schedule 8.
South Australia Health	Noted that the applicant will need to comply with all the requirements of the relevant specification for monk fruit extract in Schedule 3 (Identity and Purity). The Food Chemicals Codex (10th edition) is a primary reference for specification in the schedule and it contains a specification for monk fruit extract. The applicant needs to ensure its food additive preparations meet all the requirements within this specification, including the levels of arsenic. It notes that two of the applicant's samples exceed the arsenic limits.	FSANZ concurs the applicant will need to ensure its food additive preparations meet the appropriate specification, which in this case at this current time is the Food Chemical Codex. It needs to meet all specification requirements, including those relating to arsenic levels.
South Australia Health	FSANZ has determined the ADI as 'not specified' is appropriate. Then to be consistent with this conclusion the food additive should be permitted for use in all appropriate foods consistent with GMP. Entry to the appropriate section in Schedule 16 [section S16—2] is therefore appropriate rather than adding maximum permitted levels based on usage levels within food categories in the table to section S15—5.	See FSANZ's response to Saraya's submission above.

2.1.1 Summary and conclusions from addressing issues in submissions

A shortened list of FSANZ's responses to issues raised in submissions is provided below.

Many submitters indicated it is appropriate to both permit, and broaden the permissions for, monk fruit extract as a food additive with the technological purpose of intense sweetener. The justifications for these views are:

- The safety assessment has concluded that there are no public health and safety concerns with its use as proposed and so an ADI of 'not specified' was assigned.
- There is a history of safe use of monk fruit extract in the USA, Japan and China, and in Canada as a tabletop sweetener.
- It is an alternative intense sweetener extracted from a natural food, so there are potential marketing benefits.
- It has flavour benefits compared to other intense sweeteners, so has advantages for food manufacturers.
- Like other intense sweeteners it is an alternative sweetener to replace, possibly with other sweeteners, the use of sugar, so also has advantages for consumers who wish to reduce their consumption of sugar.

FSANZ's safety assessment has been completed with the same scientific rigour it applies for all new food additives. That risk assessment, based on the best available scientific evidence, concluded that there are no public health and safety issues associated with the proposed uses of the food additive as an intense sweetener (see section 2.2 below).

The food additive will need to comply with all the requirements of an appropriate reference for specifications listed in Schedule 3. At this time, that is the Food Chemicals Codex.

The applicant is considering the suggestion to request a JECFA safety assessment. It also agrees that it is appropriate to seek the CCFA to confer an INS number, food additive name, function class and technological purpose on the food additive.

FSANZ also considered the approach proposed by Saraya and many other submissions was safe (see section 2.2 below) and would, on balance, provide the most pragmatic and agile option to dealing with the requested changes to the draft variation (as opposed to the submission of another application at later date). This approach was also consistent with the Forum's Food Regulation System priorities for 2017-2021[3], namely, to maintain a strong, robust and agile food regulation system that not only gives confidence to consumers that their food is safe, but that can also manage new and innovative industry approaches.

Based on these considerations, FSANZ determined that it would permit the addition of monk fruit extract to some additional food groups, by adding it to section S16—2. This required a change to the draft food regulatory measure that was released at call for submissions stage. The draft food regulatory measure, including the amendments required after the consideration of submissions, is at Attachment A.

2.2 Risk assessment

FSANZ's risk assessment concluded that there are no public health and safety issues associated with the proposed use of the food additive as an intense sweetener because:

[3] http://foodregulation.gov.au/internet/fr/publishing.nsf/Content/forum-communique-2017-April

- Metabolism studies indicate that mogroside V is largely degraded in the intestinal lumen, with numerous metabolites formed. A number of the metabolites can be measured in plasma, urine, liver and other organs, indicating systemic absorption, but there is also excretion of parent compound and metabolites in the faeces, which suggests that systemic absorption is only partial.

- The available evidence shows that monk fruit extract is not genotoxic, and the acute toxicity in mice could not be established because the toxicity of monk fruit extract is very low. Repeat-dose subchronic studies showed no adverse effects of monk fruit extract at the highest doses tested which were 5 g/kg bodyweight (bw)/day in mice, 7.07 g/kg bw/day in male rats, 7.48 g/kg bw/day in female rats, and 3 g/kg bw/d in dogs.

- No chronic toxicity/carcinogenicity studies are available but because monk fruit extract is not genotoxic and no lesions that might progress to neoplasia by nongenotoxic mechanisms were observed in subchronic studies, such studies are not considered to be necessary.

- A reproductive and developmental screening study of monk fruit extract containing 30% mogroside V (w/w) found no adverse clinical or reproductive effects on male or female rats of the P generation, or on F1 pups up to postnatal day 13, of daily doses of monk fruit extract to the P generation up to 4000 mg/kg bw/day. Treatment did not have any effect on development or on markers of sexual differentiation or thyroid function in the F1 pups.

- Monk fruit is a traditional food and folk medicine in China, and monk fruit extract has a long history of use in Japan. Monk fruit extract has been available in the USA for a number of years and was recently approved in Canada. No adverse effects on human health or development associated with monk fruit extract consumption have been reported in the populations of any of those countries. There is no evidence from human studies that there are any adverse effects of monk fruit consumption at up to 60 mg/kg bw mogroside V.

Based on the reviewed toxicological data, it is concluded that, in the absence of any identifiable hazard, an Acceptable Daily Intake (ADI) ‘not specified’ is appropriate for monk fruit extract. A dietary exposure assessment was therefore not required.

The evidence presented to support the proposed uses provides adequate assurance that monk fruit extract, in the commercial form and proposed levels of use, is technologically justified and has been demonstrated to be effective in achieving its stated purpose. The food additive meets international purity specifications. There is an analytical method for quantifying the food additive in food.

For further details on the risk assessment, refer to the Risk and technical assessment report (SD1).

2.3 Risk management

The hazard assessment provided evidence that there are no safety risks from the use of monk fruit extract as a food additive, specifically an intense sweetener. As food additives require permissions in the Code, the main risk management option available to FSANZ was to approve or reject the request to amend the Code and, if approved, to impose any conditions that may be appropriate. Other risk management issues for this application are related to international standards and labelling, which are discussed below. The regulatory

options analysed in section 2.5.1.1 take account of the safety of the food additive.

Although monk fruit extract is already permitted as a flavouring substance in the Code, approval of this application allows the use of monk fruit extract also as an intense sweetener. Uses can include table-top sweetener products containing monk fruit extract, and a range of ready-to-consume food products sweetened with monk fruit extract.

The applicant provided information about the specific food groups proposed to contain monk fruit extract, and the proposed MPLs at which the extract is to be added to these foods, in their application and subsequent submission, and its use was supported by other submitters.

FSANZ agreed with the suggestion made by some submitters that it is more appropriate to add monk fruit extract to the table to section S16—2 (additives permitted at GMP) since the determined ADI is 'not specified'. This was considered a more appropriate alternative to including additional permissions and different MPLs for the food additive in the table to S15—5, as requested by many submitters.

As noted in section 2 of the preamble to the Codex Alimentarius General Standard for Food Additives (GSFA, CODEX STAN 192-1995), an ADI of 'not specified' does not represent a hazard to health. Establishing a numerical ADI is not deemed necessary. Use of the food additive must meet the requirements of GMP (as defined in section 3.3 of the GSFA, and replicated in the definition in section 1.1.2—2 of the Code). It is therefore appropriate for such food additives to be listed in section S16—2. There are some other intense sweeteners permitted at GMP, by being listed in section S16—2.

For the reasons above, FSANZ permitted monk fruit extract as a food additive at GMP by adding it to the table to section S16—2 (additives permitted at GMP). This allows use of the food additive in a wide variety of food categories listed in the table to section S15—5 that allow additives permitted at GMP. To meet the applicant's request, two additional permissions with MPL of GMP have also been made to the table to section S15—5. The first is to food category 5 (confectionery) since it does not currently permit additives at GMP. The other entry is to food category 14.1.4 (formulated beverages) to be consistent with other intense sweeteners and to apply a qualification comment that the new permission for food category 14.1.4 does not need to comply with the requirements of section 1.3.1—5. This exemption allows monk fruit extract to be used at levels greater than just to replace the sweetness of sugars. This makes it consistent with the permissions for aspartame, neotame and sucralose.

One of the food groups that permit additives at GMP is 'food for special medical purposes' (food category 13.5). There are a number of permitted intense sweeteners for use in this particular group of foods. Approval of monk fruit extract will provide manufacturers an alternative to these approved intense sweeteners.

The applicant proposed that the term 'luo han guo extract' could be used in permissions in the Code. However, FSANZ has determined that 'monk fruit extract' to be the food additive name in the Code for permissions (with 'luo han guo extract' in brackets) (for entries to Schedules 8, 15 and 16). Codex has not assigned an INS code number to monk fruit extract, so the column for INS numbers will be left blank in Schedules 8, 15 and 16.

A specification is not required to be written for the food additive in Schedule 3 (Identity and Purity), since there are already relevant specifications for monk fruit extract in the United States Pharmacopeial Convention (2016) Food Chemicals Codex (10th edition), which is a primary reference for specifications in this schedule.

2.3.1 International standards

There is no international (i.e. Codex) standard for monk fruit extract as a food additive. However, monk fruit extract has already been permitted for use in the United States, Canada, Japan and China, as detailed below:

- United States – the US Food and Drug Administration (US FDA) has made four GRAS determinations (GRN nos. 301, 359, 522 and 556) for the use of monk fruit extract as a food additive, approved under the name *Siraitia grosvenorii* Swingle (Luo Han Guo) fruit extract (US FDA 2010, 2011, 2014, 2015).

- Canada – Health Canada has approved the use of monk fruit extract in table top sweeteners (Health Canada, 2013). A maximum level of use of 0.8% has been set as per the applicant's request, calculated as mogroside V concentration in the final product (Health Canada, 2015).

- Japan – monk fruit extract is included on the List of Existing Food Additives under the name *rakanka extract* (The Japan Food Chemical Research Foundation, 2014). Substances included on this list are permitted for use and distribution in Japan, as exceptions, and without being subjected to the designation system as provided by the *Food Sanitation Act 2010,* because they are widely used in Japan and have a long history of consumption by humans. Monk fruit extract is therefore exempt from the requirements of new food additives and can be used freely in food products without restrictions on use or concentration (MHLW 2015).

- China – monk fruit extract is listed for use as a food additive in the Chinese National Food Safety Standard for Uses of Food Additives (GB 2760-2015), under the name Luohanfruit tincture [*Siraitia grosvenorii* (Swingle) C. Jeffrey]. Its classification is as a 'natural flavouring substance permitted in foods'. This classification does not have any associated restrictions on the scope of application or maximum allowable concentration levels.

2.3.2 Labelling considerations

As explained above, substances used as food additives are required to be declared in the statement of ingredients on the label of most packaged foods (see section 1.3 above).

For labelling purposes, FSANZ has proposed that the class name 'sweetener' be used, with the food additive names of 'monk fruit extract' or 'luo han guo extract' (both included in Schedule 8 as available names). As mentioned above, monk fruit extract does not have an INS code number, and so no INS number for labelling purposes can be provided in Schedule 8. At this time the entry is left blank. If and when an INS number is provided by the CCFA, this can be added into the Code in the future.

2.3.3 Risk management conclusion

The proposed use of monk fruit extract as a food additive, specifically an intense sweetener, in the commercial form and proposed levels of use, is technologically justified. The risk assessment conclusions indicated that there were no public health and safety issues associated with its use. The risk management conclusion is therefore to add the permission for monk fruit extract as a food additive to perform the technological purpose of an intense sweetener. This permission has been added to the table to section S16—2 as an additive permitted at GMP. Additional permissions have been added to food category 5 (confectionery) and 14.1.4 (formulated beverages) at GMP in the table to section S15—5, to meet the applicant's request for these foods and to be consistent with how other intense

sweeteners are listed in the schedule.

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process. The process by which FSANZ considers standard development matters is open, accountable, consultative and transparent. FSANZ calls for submissions on draft variations to obtain the views of interested parties on issues raised by the application and the effects of regulatory options.

FSANZ released the draft variation for public comment between 20 July and 31 August 2018. The call for submissions was notified via the FSANZ Notification Circular, media release, FSANZ's social media tools and Food Standards News. Subscribers and interested parties were also notified.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application. The applicant and organisations that made submissions on this application will be notified at each stage of the assessment.

Documents relating to Application A1129, including submissions received, are available on the FSANZ website[4].

2.5 FSANZ Act assessment requirements

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for the approval of additional food additives (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting additional food additives is a minor, deregulatory change and their use is voluntary. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

FSANZ, however, gave consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. 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 (Section 29 (2)(a)).

The purpose of this consideration 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 (i.e. rejecting the application). This analysis considers permitting the use of monk fruit extract as a food additive, including it in an expanded range of food groups, as outlined in submissions received during the public comment period of 20 July – 31 August 2018. FSANZ is of the view that no other realistic food regulatory measures exist beyond the consideration of approving or not approving the application.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the

[4] http://www.foodstandards.gov.au/code/applications/Pages/A1129-MonkFruitFA.aspx

assessment seeks to highlight the likely positives and negatives of moving away from the status quo by permitting the use of monk fruit extract as a food additive.

Costs and benefits permitting the use of monk fruit extract as a food additive

Consumers may benefit from the additional option of table-top sweetener that has a relative lack of bitter taste, that can be used as a sugar substitute in baking, and that is derived from a plant source. An additional range of food products may become available due to the domestic production of ready-to-eat products sweetened with monk fruit extract by Australian and New Zealand manufacturers as well as access to imported products containing monk fruit extract that are currently manufactured overseas. Permitting use of the extract in a larger range of food groups, as proposed in submissions received, may benefit consumers by providing them with more options of ready-to-eat food products and beverages than what was initially envisaged by the application.

There are no identified costs to consumers.

Industry may benefit from the increased choice of sweeteners; monk fruit extract has a number of benefits over other approved intense sweeteners, such as being a suitable sugar substitute in baking due to its high temperature stability and no unpleasant aftertaste. This may enable manufacturers the opportunity to market new products, including table-top sweeteners and foods sweetened with the extract. Permitting the use of the food additive in a larger range of food groups (as proposed in submissions received) may provide industry with greater opportunities to create and market new products, compared with what was initially envisaged at the time of the original application. Due to the voluntary nature of the permission, industry will only use the food additive where they believe a net benefit exists. The extract is approved as a food additive in several other countries which may be a business opportunity for Australia and New Zealand industries, although there may also be competing imports from these countries into the domestic market.

There are no identified costs to businesses.

Permitting the food additive may result in a small cost to government in terms of adding it to the current range of additives that are monitored for compliance.

Conclusions from cost benefit considerations

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting the use of monk fruit extract as a food additive most likely outweigh the associated costs.

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 as a result of the application.

2.5.1.3 Any relevant New Zealand standards

The Standards described in section 1.3 apply in both Australia and New Zealand and 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 also considered 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 undertook a safety assessment (SD1) and concluded there were no public health and safety issues associated with the use of monk fruit extract as a food additive.

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

The labelling requirements for this food additive are discussed in Section 2.3.2 – Labelling considerations. The existing labelling requirements for food additives will apply for the permitted use of the food additive providing information to enable consumers to make an informed choice.

2.5.2.3 The prevention of misleading or deceptive conduct

There were 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**

FSANZ used the best available scientific evidence to conduct the risk analysis which is provided in SD1 – Risk and technical assessment report. The applicant submitted a dossier of scientific studies as part of their application. Other technical information sourced by FSANZ, including scientific literature, was also used in assessing the application.

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

There is no international (i.e. Codex) standard for monk fruit extract as a food additive. However, monk fruit extract has been permitted for use in a number of countries overseas (see section 2.3.1). In addition, there are specifications for monk fruit extract in the United States Pharmacopeial Convention (2016) Food Chemicals Codex (10th edition) (see Section 2.3).

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

As mentioned above, the use of monk fruit extract as a food additive is already permitted in a number of countries overseas. Therefore, the approval of monk fruit extract would bring Australia and New Zealand into line with other countries where it is already approved for use.

The applicant advises that their primary interest is in the export to Australia and New Zealand of table-top sweeteners containing monk fruit extract, and ready-to-consume food products sweetened with monk fruit extract. Its approval in a larger range of food groups (as proposed in submissions received) would bring Australia and New Zealand more into line with other countries where it is already approved. The domestic food industry will make their own economic decisions, taking into account the costs and benefits of using monk fruit extract as

a new intense sweetener, to determine if it is of benefit to their business.

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

Monk fruit extract as an intense sweetener food additive has been assessed as safe and permitted for use in other countries. It is therefore appropriate that the local Australian and New Zealand food industries also benefit by gaining permission to use this same food additive, which FSANZ has also assessed as having no public health and safety issues.

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

The Ministerial Policy Guideline Addition to Food of Substances other than Vitamins and Minerals[5] includes specific order policy principles for substances added to achieve a solely technological function, such as food additives. These specific order policy principles state that permission should be granted where:

- the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (i.e. the 'stated purpose')
- the addition of the substance to food is safe for human consumption
- the amounts added are consistent with achieving the technological function
- the substance is added in a quantity and a form which is consistent with delivering the stated purpose
- no nutrition, health or related claims are to be made in regard to the substance.

FSANZ determined that permitting the use of monk fruit extract as a food additive is consistent with the specific order policy principles for 'Technological Function'.

3 References

Health Canada (2013), Notice of modification to the list of permitted sweeteners to enable the use of monk fruit extract (luo han guo) as a sweetener in table-top sweeteners. Viewed 3 May 2017. www.hc-sc.gc.ca/fn-an/consult/nom-adm-0019/index-eng.php

The Japan Food Chemical Research Foundation (2014), List of existing food additives. Viewed 3 May 2017.
www.ffcr.or.jp/zaidan/FFCRHOME.nsf/pages/list-exst.add

The United States Pharmacopeia (2016), Food Chemicals Codex 10th Edition, United States Pharmacopeial Convention, Rockville, MD. Viewed 3 May 2017.
http://www.usp.org/food-ingredients/food-chemicals-codex

USDA Foreign Agricultural Service (2015), Chinese standards for food additives - GB2760-2015. Viewed 3 May 2017.
https://www.google.com.au/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEwiU9MScj9PTAhUJa7wKHagRBCkQFggiMAA&url=https%3A%2F%2Fgain.fas.usda.gov%2FRecent%2520GAIN%2520Publications%2FFood%2520and%2520Agricultural%2520Import%2520Regulations%2520and%2520Standards%2520-%2520Narrative_Beijing_China%2520-%2520Peoples%2520Republic%2520of_12-12-2013.pdf&usg=AFQjCNH7GSvDuP5Dijs6KJ_euZ4Bp0X3gA&sig2=7sNe8cQqusn6vPJOhBuvFQ

US Food and Drug Administration (2010), GRAS notices - GRN no. 301. Viewed 3 May 2017.
http://www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=301

[5] http://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Addition-of-Substances-other-than-Vitamins-and-Minerals

US Food and Drug Administration (2011), GRAS notices - GRN no. 359. Viewed 3 May 2017. www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=359

US Food and Drug Administration (2014), GRAS notices - GRN no. 522. Viewed 3 May 2017. www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=522

US Food and Drug Administration (2015), GRAS notices - GRN no. 556. Viewed 3 May 2017. www.accessdata.fda.gov/scripts/fdcc/?set=GRASNotices&id=556

Attachments

A. Approved draft variations to the Australia New Zealand Food Standards Code
B. Explanatory Statement
C. Draft variation to the Australia New Zealand Food Standards Code (call for submissions)

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

FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

Food Standards (Application A1129 – Monk Fruit Extract as a Food Additive) 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 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 A1129 – Monk Fruit Extract as a Food Additive) Variation*.

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

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

3 Commencement

The variation commences on the date of gazettal.

Schedule

[1] Schedule 8 is varied by

[1.1] inserting in the table in section S8–2 entitled 'Food additive names—alphabetical listing', in alphabetical order

monk fruit extract or luo han guo extract	

[1.2] inserting in the table in section S8–2 entitled 'Food additive names—numerical listing', above the entry for 'Sodium hydrosulphite'

monk fruit extract or luo han guo extract	

[2] Schedule 15 is varied by

[2.1] inserting in item 5 of the table to section S15–5, after the heading 'Confectionery'

monk fruit extract (luo han guo extract)	GMP	

[2.2] inserting in item 14.1.4 of the table to section S15–5, after the entry for 'Colourings permitted to a maximum level'

monk fruit extract (luo han guo extract)	GMP	Section 1.3.1—5 does not apply

[3] Schedule 16 is varied by

[3.1] inserting in the table in section S16–2 entitled 'Additives permitted at GMP—alphabetical listing', in alphabetical order

Monk fruit extract (luo han guo extract)

[3.2] inserting in the table in section S16–2 entitled 'Additives permitted at GMP—numerical listing', above the entry for 'Permitted Flavouring substances, excluding quinine and caffeine'

Monk fruit extract (luo han guo extract)

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 A1129 which seeks to permit the use of monk fruit extract as a food additive to perform the technological purpose of an intense sweetener. 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 draft variation of a standard.

Section 94 of the FSANZ Act specifies that 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 sunsetting under the *Legislation Act 2003*.

2. Purpose

The purpose of the variations is to permit the use of monk fruit extract (luo han guo extract) as a food additive to perform the technological purpose of an intense sweetener at GMP, by listing in: the tables to section S16—2, and; for confectionery (food category 5) and formulated beverages (food category 14.1.4) in the table to section S15—5. The permission for 14.1.4 has a condition that the limitation on use of intense sweeteners imposed by section 1.3.1—5 does not apply, enabling that food additive to be used in formulated beverages at levels greater than just to replace the sweetness of sugars.

3. Documents incorporated by reference

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

Existing provisions of the Code incorporate a document by reference that will prescribe identity and purity specifications for the food additive to be permitted by the approved variation. Section 1.1.1—15 of the Code requires substances used as food additives to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code. Section S3—2 of Schedule 3 incorporates by reference the specifications listed in the United States Pharmacopeial Convention (2016) Food Chemicals Codex (10th edition). These include a specification for monk fruit extract.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1129 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 20 July 2018 for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variations are likely to have a minor impact on business and individuals.

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

6.1 Variation to Schedule 8

Item [1] varies Schedule 8.

Item [1.1] varies the table to subsection S8—2 entitled 'Food additive names—alphabetical listing' by inserting into that table, in alphabetical order, a new entry for "monk fruit extract or luo han guo extract".

Item [1.2] varies the table to subsection S8—2 entitled 'Food additive names—numerical listing' by inserting above that table's entry for 'Sodium hydrosulphite' a new entry for "monk fruit extract or luo han guo extract".

The effect of these amendments is that "monk fruit extract" or "luo han guo extract" are the food additive names for monk fruit extract, for labelling purposes. The numerical column for each new entry has been left blank as monk fruit extract has no assigned INS code number.

6.2 Variation to Schedule 15

Item [2] varies Schedule 15.

Item [2.1] inserts in item 5 of the table to section S15—5, after the heading 'Confectionery', a reference to 'monk fruit extract (luo han guo extract)' with a maximum permitted level of 'GMP'.

Item
[2.2] inserts into item 14.1.4 of the table to section S15—5, after the entry for 'Colourings permitted to a maximum level', a reference to 'monk fruit extract (luo han guo extract)' with a maximum permitted level of 'GMP' and with a condition that section 1.3.1—5 does not apply.

The effect of these amendments is to permit the use of monk fruit extract (luo han guo extract) as a food additive in the above mentioned classes of food (food categories), up to a maximum permitted level consistent with Good Manufacturing Practice, with a condition for formulated beverages (14.1.4) that the limitation on the use of intense sweeteners imposed by section 1.3.1—5 does not apply.

6.3 Variation to Schedule 16

Item [3] varies Schedule 16.

Item [3.1] varies the table to section S16—2 entitled 'Additives permitted at GMP—alphabetical listing' by inserting into that table, in alphabetical order, a reference to 'monk fruit extract (luo han guo extract)'.

Item [3.2] varies the table to section S16—2 entitled ‘Additives permitted at GMP—numerical listing’ by inserting above that table’s entry for ‘Permitted flavouring substances, excluding quinine and caffeine’ a reference to ‘monk fruit extract (luo han guo extract)’.

The effect of these amendments is to permit the use of monk fruit extract (luo han guo extract) as an ‘additive permitted at GMP’.

Attachment C – Draft variation to the Australia New Zealand Food Standards Code (call for submissions)

FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

Food Standards (Application A1129 – Monk Fruit Extract as a Food Additive) 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 Standards Management Officer]

Standards Management Officer
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 A1129 – Monk Fruit Extract as a Food Additive) Variation*.

2 Variation to standards in the Australia New Zealand Food Standards Code

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

3 Commencement

The variation commences on the date of gazettal.

Schedule

[1] Schedule 8 is varied by

[1.1] inserting in the table in section S8–2 entitled 'Food additive names—alphabetical listing', in alphabetical order

monk fruit extract or luo han guo extract	–

[1.2] inserting in the table in section S8–2 entitled 'Food additive names—numerical listing', above the entry for 'Sodium hydrosulphite'

–	monk fruit extract or luo han guo extract

[2] Schedule 15 is varied by

[2.1] inserting in item 4.3.4 of the table to section S15–5, after the heading 'Fruit and vegetable spreads including jams, chutneys and related products'

monk fruit extract (luo han guo extract)	1100

[2.2] inserting in item 5 of the table to section S15–5, after the heading 'Confectionery'

monk fruit extract (luo han guo extract)	1000

[2.3] inserting in item 6.3 of the table to section S15–5, after the entry for 'Colourings permitted to a maximum level'

monk fruit extract (luo han guo extract)	1000

[2.4] inserting in item 6.4 of the table to section S15–5, after the entry for 'Colourings permitted to a maximum level'

monk fruit extract (luo han guo extract)	1000

[2.5] inserting in item 7.2 of the table to section S15–5, after the heading 'Biscuits, cakes and pastries'

monk fruit extract (luo han guo extract)	1000

[2.6] inserting in item 11.4 of the table to section S15–5, after the entry for ‘Colourings permitted to a maximum level’

monk fruit extract (luo han guo extract)	8000

[2.7] inserting in item 13.5 of the table to section S15–5, after the entry for ‘Colourings permitted to a maximum level’

monk fruit extract (luo han guo extract)	1000

[2.8] inserting in item 20.2.0.3 of the table to section S15–5, after the heading ‘Dairy and fat based desserts, dips and snacks’

monk fruit extract (luo han guo extract)	1000

[2.9] inserting in item 20.2.0.4 of the table to section S15–5, after the heading ‘Sauces and toppings (including mayonnaises and salad dressings)’

monk fruit extract (luo han guo extract)	5000