

20 July 2018
[54–18]

Call for submissions – Application A1129

Monk Fruit Extract¹ as a Food Additive

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, and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#). All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 31 August 2018

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

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KINGSTON ACT 2604
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¹ The applicant has used another common name for monk fruit extract, this being 'luo han guo extract' throughout the application.

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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

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

Executive summary

Saraya Co., Ltd. has submitted an application seeking to permit the use of monk fruit (or luohan 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 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 exhibits a number of advantages over other already approved intense sweeteners. It has a relative lack of bitter taste; it can be used as a sugar substitute in baking (as it has high temperature stability and no unpleasant aftertaste).

FSANZ's risk assessment concluded that there were no public health and safety issues associated with the proposed use of the food additive as an intense sweetener. The assessment also concluded that its use as an intense sweetener was technologically justified. The applicant has provided information regarding the available analytical method for detection. 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 is therefore not required.

The applicant provided information about the specific food groups proposed to contain monk fruit extract, when used as an intense sweetener, and the proposed maximum concentrations at which the extract is to be added to these foods. FSANZ proposes to amend the table at section S15—5 in Schedule 15 (Substances that may be used as food additives) to permit the use of monk fruit extract as a food additive to perform the technological purpose of an intense sweetener. This permission will be for all of the food groups and at the maximum concentrations (mg/kg) proposed by the applicant.

There is a primary source of specifications in Schedule 3 (Identity and purity) for monk fruit extract. The current labelling requirements in subsection 1.2.4—7 apply for ingredient labelling of products containing the food additive.

1 Introduction

1.1 The applicant

Saraya Co., Ltd. focusses on the manufacture and sale of 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 purpose of this application is to request Food Standards Australia New Zealand (FSANZ) to assess monk fruit extract for approval for use 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 proposed to contain monk fruit extract are outlined in Table 4.1 of the application, together with the proposed maximum concentrations at which the extract is to be added to these foods. The applicant seeks to amend 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 Australia New Zealand Food Standards Code (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 exhibits a number of advantages over other already approved intense sweeteners. It has a less bitter taste relative to other intense sweeteners; it makes for a versatile table-top 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 flavouring, 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 GRAS 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, followed by the individual additive name or code number in brackets.

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.

1.3.1 Other relevant international regulations

Monk fruit extract has 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.

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 is being assessed under the General Procedure.

2 Summary of the assessment

2.1 Risk assessment

There are no public health and safety issues associated with the proposed use of the food additive as an intense sweetener because:

- 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 on monk fruit extract at the highest doses tested which were 5 g/kg 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. Furthermore, 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.

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 is 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.

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

2.2 Risk management

The hazard assessment conclusions 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 is 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 2.4.1.1 take account of the safety of the food additive.

Although monk fruit extract is already permitted as a flavouring substance in the Code, if this application is permitted, it will allow the use of monk fruit extract 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 usage levels proposed by the applicant for table-top sweeteners and other ready-to-consume food products are within the limits of use of intense sweeteners, as specified in the Code (see section 1.3 above).

The applicant provided information about the specific food groups proposed to contain monk fruit extract and the proposed maximum concentrations at which the extract is to be added to these foods. Based on the outcomes of the risk and technical assessment, FSANZ proposes that monk fruit extract be included as a permitted food additive in the table at section S15—5 in Schedule 15 for all of the food groups and at the maximum concentrations (mg/kg) proposed by the applicant. One of the proposed food groups is Food for special medical purposes (food group number 13.5). There are three intense sweeteners permitted for use in this particular group of foods, at specified maximum permitted levels. Approval of monk fruit extract will provide manufacturers an alternative to these approved intense sweeteners.

The applicant has proposed that 'luo han guo extract' could be used by FSANZ as the common name, for the purposes of regulation. However, FSANZ is proposing that 'monk fruit extract' be the food additive name in the Code for permissions (with 'luo han guo extract' in brackets) (Standard 1.3.1 and Schedule 15). Codex has not assigned an INS code number to monk fruit extract, so a dash ('-') in the column for INS numbers will be used in Schedule 15.

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. The final food additive preparation meets Food Chemicals Codex and Code specifications, with the exception of exceedances of the Food Chemicals Codex arsenic limits (but not the Code limits) for two samples. The applicant will need to ensure that the final preparation meets all specifications, including the arsenic limits set in Food Chemicals Codex.

2.2.1 Labelling requirements

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 is proposing that the class name 'sweetener' be used, with the food additive names of 'monk fruit extract' or 'luo han guo extract' (both will be 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. If and when an INS number is provided by the Codex Committee on Food Additives this can be added into the Code in the future.

2.3 Risk communication

FSANZ has developed a basic communication strategy for this Application.

2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process. The process by which FSANZ considers standards' 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. The call for submissions is notified via the FSANZ Notification Circular, media release, FSANZ's social media tools and Food Standards News. Subscribers and interested parties are also notified.

The draft variation will be considered for approval by the FSANZ Board taking into account public comments received from this call for submissions.

2.3.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are no relevant international standards (i.e. Codex) but amending the Code to approve monk fruit extract as a food additive is unlikely to have a significant effect on international trade as it is already permitted for use in a number of other countries overseas, in line with their respective regulations covering the use of food additives (see section 1.3.1). Therefore, a notification to the WTO as per Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 FSANZ Act assessment requirements

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

2.4.1 Section 29

2.4.1.1 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, has given 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 (S.29 (2)(a)).

The purpose of this consideration is 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. FSANZ is of the view that no other realistic food regulatory measures exist, however information received may result in FSANZ arriving at a different outcome.

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 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.

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. Due to the voluntary nature of the permission, industry will only use the extract 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 extract 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.

2.4.1.2 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.

2.4.1.3 Any relevant New Zealand standards

The Standards described in section 1.3 above apply in both Australia and New Zealand and there are no relevant New Zealand only standards.

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2 Subsection 18(1)

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

2.4.2.1 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.

2.4.2.2 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 2.2.1 – Labelling requirements. 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.

2.4.2.3 The prevention of misleading or deceptive conduct

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

2.4.3 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. The applicant submitted a dossier of scientific studies as part of their application. Other technical information 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 1.3.1). In addition, there are specifications for monk fruit extract in the United States Pharmacopeial Convention (2016) Food Chemicals Codex (10th edition) (see Section 2.2).

- **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. 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](#)³ 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 Draft variation

The draft variation to the Code is at Attachment A and is intended to take effect on gazettal.

A draft 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.

4 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-

³ <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

[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>

US Food and Drug Administration (2011), GRAS notices - GRN no. 359. Viewed 3 May 2017.
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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. Draft variations to the *Australia New Zealand Food Standards Code*
- B. Draft Explanatory Statement

Attachment A – Draft variations to the *Australia New Zealand Food Standards Code*



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]

General Manager
Risk Management and Intelligence
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 |
|--|------|

Attachment B – Draft 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.

FSANZ 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 prepared a draft Standard.

2. Purpose

The Authority has prepared a draft amendment to the table at section S15—5 in Schedule 15 of the Code 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 in the food groups and at the maximum concentrations (mg/kg) listed in the table below:

Food class number	Food class name	Maximum monk fruit extract concentration (mg/kg)
4.3.4	Fruit and vegetable spreads including jams, chutneys and related products	1100
5	Confectionery	1000
6.3	Processed cereal and meal products	1000
6.4	Flour products	1000
7.2	Biscuits, cakes and pastries	1000
11.4	Table-top sweeteners	8000
13.5	Food for special medical purposes	1000
20.2.0.3	Dairy and fat based desserts, dips and snacks	1000
20.2.0.4	Sauces and toppings	5000

The Authority has also prepared an amendment to Schedule 8 to prescribe the use of 'monk fruit extract' or 'luo han guo extract' to describe the permitted intense sweetener food additive for labelling purposes.

3. Documents incorporated by reference

The approved draft variations to food regulatory measures do 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 draft 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 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary.

A call for submissions (including the draft variation) will occur for a six-week consultation period.

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.

Subitem [1.1] inserts in the table to subsection S8—2 (alphabetical listing) in alphabetical order, a new entry for “monk fruit extract or luo han guo extract” into column 1 and “-” into column 2.

Subitem [1.2] inserts in the table to subsection S8—2 (numerical listing) in numerical order, a new entry for “monk fruit extract or luo han guo extract” into column 1 and “-” into column 2.

The effect of these amendments is that “monk fruit extract” or “luo han guo extract” are food additive names for monk fruit extract, for labelling purposes. The “-” is inserted into column 2 as monk fruit extract has no assigned INS code number.

6.2 Variation to Schedule 15

Item [2] varies Schedule 15.

Subitem [2.1] inserts in item 4.3.4 of the table to subsection S15—5, after the heading ‘Fruit and vegetable spreads including jams, chutneys and related products’

monk fruit extract (luo han guo extract)	1100
--	------

Subitem [2.2] inserts in item 5 of the table to subsection S15—5, after the heading ‘Confectionery’

monk fruit extract (luo han guo extract)	1000
--	------

Subitem [2.3] inserts in item 6.3 of the table to subsection S15—5, after the entry for ‘Colourings permitted to a maximum level’

monk fruit extract (luo han guo extract)	1000
--	------

Subitem [2.4] inserts in item 6.4 of the table to subsection S15—5, after the entry for

'Colourings permitted to a maximum level'

monk fruit extract (luo han guo extract)	1000
--	------

Subitem [2.5] inserts in item 7.2 of the table to subsection S15—5, after the heading 'Biscuits, cakes and pastries'

monk fruit extract (luo han guo extract)	1000
--	------

Subitem [2.6] inserts in item 11.4 of the table to subsection S15—5, after the entry for 'Colourings permitted to a maximum level'

monk fruit extract (luo han guo extract)	8000
--	------

Subitem [2.7] inserts in item 13.5 of the table to subsection S15—5, after the entry for 'Colourings permitted to a maximum level'

monk fruit extract (luo han guo extract)	1000
--	------

Subitem [2.8] inserts in item 20.2.0.3 of the table to subsection S15—5, after the heading Dairy and fat based desserts, dips and snacks

monk fruit extract (luo han guo extract)	1000
--	------

Subitem [2.9] inserts in item 20.2.0.4 of the table to subsection S15—5, after the heading Sauces and toppings

monk fruit extract (luo han guo extract)	5000
--	------

The effect of these amendments will be 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 in the above mentioned classes of foods subject to the specified (mg/kg) maximum concentration for each class.