

MonkFruit corp.

The World's Leading Monk Fruit Company



1226 American Way
Libertyville, IL 60048
USA
Tel: +1 847 367 6665

8 B De Leeuw Place
Te Rapa, Hamilton 3200
New Zealand
Tel: +64 7 849 6731

5 Liangfeng Road, Yanshan,
Guilin, Guangxi 541006
People's Republic of China
Tel: +86 773 355 0105

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6143
NEW ZEALAND

Dear Sir / Madam,

SUBMISSION

A1129 -Monk Fruit Extract as a Food Additive

Monk Fruit Corp is a leading manufacturer of monk fruit ingredients. We have been supplying the world's leading food and beverage companies with monk fruit ingredients since 2006 and have been at the forefront of the monk fruit industry for more than a decade.

Monk Fruit Corp would like to provide the following comments in relation to application A1129 by Saraya Co., Ltd. (Saraya) to permit the use of monk fruit extract as a food additive to perform the technological purpose of an intense sweetener.

Monk fruit provides a natural alternative to other intense sweeteners currently available, and is recognised as having a number of benefits compared to currently approved natural sweeteners including better taste than stevia without the bitter and metallic off-flavours which limit the use of stevia in many applications. Since 2006 more than 2,000 products have been launched worldwide containing monk fruit as an ingredient.

Monk Fruit Corp supports the approval of monk fruit extract as an intense sweetener, however, we are surprised at the narrow scope of food categories submitted by Saraya for approval (refer table 4.1 of application) and included in the draft variation in Attachment A of the Call for Submissions. The narrow scope of food categories requested provides limited benefit to industry and consumers relative to the potential benefits as several of the major categories for monk fruit use are not included in the food categories requested by Saraya. In particular dairy, non-alcoholic beverage, and formulated supplementary sports foods which we estimate make up nearly 70% of the food (non-supplement) use of monk fruit extract are not in the food categories requested. See Appendix 2 for a breakdown of global product launches containing monk fruit since 2008 by category.

In the USA, China and Japan monk fruit is available as a general food additive available to be added to most foods and supplements. Monk Fruit Corp therefore requests FSANZ to consider the expansion of the permitted food categories for Monk Fruit Extract as a food additive. Monk Fruit Corp proposes the categories in Appendix 1.



Expanding the number of categories in which monk fruit extract is permitted will provide greater benefit to both consumers and industry. Industry will be able to formulate a wider range of products containing lower sugar with natural additives, giving consumers a wider choice of lower kilojoule products. The requested expansion of categories would not result in any further costs to consumers, industry or government.

Monk fruit is a traditional food in China that has been consumed for hundreds of years. Monk fruit has also been recognised by Health Canada as a traditional food in Canada, and the FSANZ Novel Foods Advisory Committee has also recognised monk fruit as a traditional food in Australia and New Zealand. Monk fruit extract has a long history of use in Japan, and has been available as a GRAS food ingredient in the USA since 2010. No adverse effects on human health or development associated with monk fruit extract consumption has 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. On page 7 of the Call for Submissions and page 22 of the Risk Assessment it is stated:

“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.”

According to JECFA, “an ADI of “not specified” is a term applicable to a food additive of very low toxicity that, on the basis of the available chemical, biochemical and toxicological data, as well as the total dietary exposure of the additive (from its use at the levels necessary to achieve the desired effect and from its acceptable background in food), does not represent a hazard to health. For that reason, the establishment of an ADI expressed in numerical form is not necessary. An additive meeting this criterion must be used in accordance with GMP: that is, it should be technologically efficacious and should be used at the lowest level necessary to achieve this effect, it should not conceal inferior food quality or adulteration, and it should not create a nutritional imbalance”. (EHC 240, Annex 1 – Glossary of Terms, p. 2)

Based on monk fruit approvals and use in other countries, and the very low toxicity exhibited in all toxicology studies undertaken to date (resulting in FSANZ declaring an ADI of “not specified” for monk fruit extract), it is reasonable to assume that expanding the categories in which monk fruit extract can be used should not result in any further safety concerns. Approving the other categories requested now will also save the government time and reduce costs, as it will avoid the need to review a complete new submission for approval of monk fruit extract as a sweetener in the missing food categories which we will have to submit if the additional categories are not approved at this time.

We sincerely hope that you consider the above request.

Should you have any questions, please do not hesitate to contact us.

Your sincerely,



Appendix 1: Monk Fruit Proposed Food Categories

Category No	Food Description	Proposed Maximum Use Levels	Proposed Typical Use Levels
1.1.2	Liquid milk products and flavoured milk	800	400
1.2.2	Fermented milk products and renneted milk products	800	400
3	Ice cream and edible ices	2000	500
4.3.2	Fruits and vegetables in vinegar, oil, brine, or alcohol	800	400
4.3.3	Commercially sterile fruits and vegetables in hermetically sealed containers	1000	500
4.3.4	Fruit and vegetable spreads including jams, chutneys and related products	1100*	550*
4.3.4.1	Low joule chutneys, low joule jams, and low joule spreads	2400	1200
4.3.6	Fruit and vegetable preparations including pulp	1000	500
5	Confectionary	1000*	500*
5.1	Chocolate and cocoa products	2500	1250
5.2	Sugar confectionary	5000	2500
6.3	Processed cereal and meal products	1000*	500*
6.4	Flour Products	1000*	500*
7.1	Breads and related products	800	400
7.1.1	Fancy breads	800	400
7.2	Biscuits, cakes, and pastries	1000*	500*
11.4	Tabletop sweeteners	8000*	4000*
12.6	Vegetable protein products	800	400
13.2	Foods for infants	800	400
13.3	Formula meal replacements and formulated supplementary foods	800	400
13.4	Formulated supplementary sports foods	800	400
13.5	Food For Special Medical Purposes	1000*	500*
14.1.2.1	Fruit and vegetable juices	800	400
14.1.2.2	Fruit and vegetable juice products	800	400



Category No	Food Description	Proposed Maximum Use Levels	Proposed Typical Use Levels
14.1.3	Water based flavoured drinks	800	400
14.1.4	Formulated beverages	800	400
14.1.5	Coffee, coffee substitutes, tea, herbal infusions, and similar products	800	400
14.2	Alcoholic beverages	800	400
14.3	Alcoholic beverages not included in item 14.2	800	400
20.1	Beverages	800	400
20.2.0.1	Custard mix, custard powder, and blancmange powder	800	400
20.2.0.2	Jelly	1250	625
20.2.0.3	Dairy and fat based desserts, dips, and snacks	1000*	500*
20.2.0.4	Sauces and toppings (including mayonnaises and salad dressings)	5000*	2500*
20.2.0.5	Soup bases (the maximum permitted levels apply to soup made up as directed)	800	400

*items in red proposed by Saraya



Appendix 2 – Global Product Launches Containing Monk Fruit Since 2008

Food category	Number of Products Launched*
Alcoholic Beverages	2
Baby & Toddlers	5
Bakery	94
Cereals	196
Confectionery	101
Dairy	135
Desserts & Ice Cream	186
Fruit & Vegetables	17
Hot Drinks	74
Pet Food	6
Ready Meals	10
Sauces & Seasonings	6
Snacks	26
Soft Drinks	372
Soup	4
Sports Nutrition	553
Spreads	9
Sugar & Sweeteners	70
Supplements	513
Grand Total	2,379

*Data from Innova Product Database

