

22 August 2018

Food Standards Australia New Zealand
PO Box 5423
KINGSTON ACT 2604
AUSTRALIA

Dear FSANZ

Re: Application A1129 – Monk Fruit Extract as a Food Additive

Thank you for giving us the opportunity to comment on the draft food regulatory measure that has been proposed by FSANZ as a result of our application, A1129. Saraya recognises and is grateful for the considerable time and effort that has gone into assessing the application.

Saraya **supports** the draft food regulatory measure proposed by FSANZ. However, we would like to take this opportunity to propose some additional food groups be permitted to contain monk fruit extract. This would require a modification to the draft food regulatory measure.

Our original application in March 2016 proposed a limited number of food groups to contain monk fruit extract. We took a conservative approach to the number of food groups selected, as we anticipated that FSANZ may set a potentially restrictive acceptable daily intake (ADI). Having a large number of food groups—with relatively high proposed maximum concentrations—may have resulted in a dietary exposure assessment concluding that estimated dietary exposures exceeded the ADI considerably. This was a result we wished to avoid. However, as the risk assessment completed by FSANZ has determined that ‘an [ADI] of “not specified” is appropriate for monk fruit extract’, and that ‘a dietary exposure assessment is therefore not required’, it is clear now that this conservative approach was not necessary.

Saraya now proposes that the food groups (and maximum permitted levels) listed in Table 1 of this submission be added to the draft food regulatory measure, in addition to those of our original application.

We believe this proposal has the following benefits:

- *Greater benefits to consumers*

As noted in the call for submissions, the introduction of new products containing monk fruit extract will benefit Australia and New Zealand consumers by providing broader choice of low- and no-sugar products. Permitting monk fruit extract in the proposed additional food groups will extend these benefits to wider range of consumers.

Table 1 - Proposed additional food groups to be permitted to contain monk fruit extract

Food group name and number	Proposed maximum permitted level, mg/kg
1.1.2 Liquid milk products and flavoured liquid milk	1,000
1.2.2 Fermented milk products and renneted milk products	1,000
3 Ice cream and edible ices	2,000
4.3.2 Fruits and vegetables in vinegar, oil, brine or alcohol	4,000
4.3.3 Commercially sterile fruits and vegetables in hermetically sealed containers	1,000
13.3 Formulated meal replacements and formulated supplementary foods	1,000
13.4 Formulated supplementary sports foods	1,000
14.1.2.2 Fruit and vegetable juice products	1,000
14.1.2.2.2 Low joule fruit and vegetable juice products	5,000
14.1.3 Water based flavoured drinks	6,000
14.1.3.0.1 Electrolyte drink and electrolyte drink base	1,000
14.1.3.3 Brewed soft drink	2,000
14.1.4 Formulated Beverages	6,000
14.1.5 Coffee, coffee substitutes, tea, herbal infusions and similar products	1,000
20.2.0.1 Custard mix, custard powder and blancmange powder	1,000
20.2.0.2 Jelly	2,000
20.2.0.5 Soup bases	5,000

- *Greater benefits to industry*

Similarly, the call for submissions also identified benefits to the Australian and New Zealand food industry by enabling the development and marketing of new products making use of the unique properties of monk fruit extract. Permitting monk fruit extract in the proposed additional food groups will provide these opportunities to a greater number of manufacturers. Saraya has already had expressions of interest from a number of local food manufacturers looking to utilise monk fruit extract in future products. This includes products that will only be possible if the proposed additional food groups are permitted to contain the extract.

- *More internationally competitive food industry*

The expansion of opportunities for Australian and New Zealand manufacturers to develop a wider range of products for the domestic market would also lead to greater opportunities to export those products. Saraya believes permitting the proposed additional food groups would

strengthen the draft food regulatory measure with regard to Subsection 18(2)(c) of the FSANZ Act—‘the desirability of an efficient and internationally competitive food industry’.

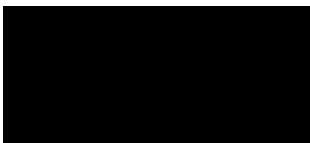
- *Avoids the need for another application*

If the draft food regulatory measure were to be adopted in its current form—without the additional food groups—it is highly likely that Saraya or other manufacturers would make another application at a later date to request the approval of additional food groups. Even though this application would be of relatively low complexity for FSANZ to assess, according to Section 2.1.5 of the latest FSANZ Application Handbook the total cost of assessing an application under the ‘general procedure’ is approximately A\$50,000. Since there would be no ‘exclusive capturable commercial benefit’ to the applicant, this cost would be borne by FSANZ. Avoiding the need for another application at a later date presents a significant cost saving for FSANZ.

Saraya acknowledges that adding additional food groups to the draft food regulatory measure at this stage may be inconvenient for FSANZ, due to the short statutory timeframe within which FSANZ is working. However, Saraya believes the above benefits and potential cost saving to FSANZ outweigh the inconvenience of implementing the proposed changes.

Thank you once again on behalf of Saraya.

Yours sincerely



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Saraya Co., Ltd.