SUBMISSION FROM SA HEALTH
31 August 2018

Application A1129 Monk Fruit Extract as a food additive (intense sweetener)

SA Health welcomes the opportunity to provide comment on this application. It is noted that this application has only one period of public comment. SA Health is concerned that before supporting this application for the approval of a new intense sweetener that it should be assessed for public health and safety to the same minimum level as described in the FSANZ Application guidelines.

Concerns are related to,

1. being unclear whether the applicant have provided any or relevant safety studies associated with their proprietary extract (1 or possibly 2 are mentioned).

2. the change in the paradigm of assessment for food additives typically from well characterised substance(s) to assessments using poorly defined mixtures to support limited safety data on the intense sweetener considered in the application (pg 76 Section 3.3 B Information related to the safety of the food additive; FSANZ Application Handbook).

3. the assessments by other agencies were not overwhelming and US FDA GRAS determinations are not all that relevant. The European Food Safety Authority (EFSA) has stopped its clock on an application number FIP-2017-0042 on 22/02/2018 requesting additional data for EFSA to perform a risk assessment and to provide a scientific opinion on the safety in the use of Monk Fruit Extract. Approval by the EFSA would provide more surety in safety of this additive. The Codex General Standard for Food Additives does not approve Monk Fruit Extract. In Canada monk fruit extract is approved as a table top sweetener (0.8%) but the application for use in Australia is for a much wider permission in foods. China only approves as a flavouring not as an additive and Japan considers it exempt from requirements of food additives. Japan has a different definition of food additives that allows for a range of substances not considered as food additives elsewhere internationally. The lack of approvals internationally should urge FSANZ to be more cautious in the approval of a new food additive to ensure public health and safety.

4. 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). SA Health supports the use of a single name of identity in the Code as it is unnecessary to list alternative names in the regulations. Most food additives have synonyms that are not included in the current regulations. By including synonyms of food additive names, the regulations become cumbersome to read. Simply by referring to a dictionary, an internet search or guidance documents, alternative names can be found for an additive. By listing in the regulations, does not make the food additive name a prescribed name. The food manufacturer can choose the most appropriate name that is readily understood by the market without it having to be listed in the regulations.

5. 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, with the exception of exceedances of the Food Chemicals Codex arsenic limits for two samples. The applicant needs to ensure that the final preparation meets all specifications, including the arsenic limits set in Food Chemicals Codex. If this is the specification that the applicant is choosing to meet, it cannot pick and choose which parts of the specification that it will meet by saying that it meets part of the regulations in the Food Standards Code. The applicant has not provided evidence of data that shows that it can meet the specification that it is proposing should be applied. In the absence of that evidence, it cannot be assumed that the specification is applicable.

6. if FSANZ concludes based on sufficient evidence that an acceptable daily intake (ADI) "not specified" is appropriate, then to be consistent with this conclusion, the food additive should be permitted for use in all foods consistent with GMP. The levels to be included for a wide range of foods in Schedule 15 are based on proposed usage levels in food rather than providing limits to protect public health and safety. Based on the FSANZ assessment, the additives should be in Schedule 16 -Types of substances that may be used as food additives, as this would be more appropriate.