

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 sunseting 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’.