

31 August 2018

Project Officer Application A1157
Food Standards Australia New Zealand
PO Box 10559
The Terrace
WELLINGTON 6036

Dear Sir/Madam

Application A1157 – Enzymatic production of Rebaudioside M – Call for Submissions

Thank you for the opportunity to comment on this application. The Ministry for Primary Industries (MPI) has the following comments to make.

General comments

MPI supports the request made by the applicant, that is, to amend the Australia New Zealand Food Standards Code (the Code) to allow for a novel production method for Rebaudioside M (Reb M). We agree that the Code does not currently permit the applicant's production method for Reb M.

At the March 2018 meeting, the Codex Committee on Food Additives (CCFA) agreed on a number of matters relating to the sweetener steviol glycoside, as follows:

- changes were made to the International Numbering System (INS) numbering for steviol glycosides;
- the tentative status for the Joint FAO/WHO Expert Committee on Food Additives (JECFA) specification for 'Steviol glycosides from *Stevia rebaudiana* Bertoni' was removed (specification was adopted in July by the Codex Alimentarius Commission); and
- three entries relating to new JECFA specifications for steviol glycosides (all produced using novel production methods) were included in the JECFA priority list.

Risk assessment

MPI supports the risk assessment, and agrees that Reb M using this production method should be permitted.

Labelling comments, including INS number

We note that no changes are included for food additive ingredient listing requirements under Standard 1.2.4. This means that all permitted forms of steviol glycosides will be declared as INS 960 or by the name steviol glycosides. The changes made to the INS list at CCFA this year distinguish the steviol glycosides extracted

from the plant, from those made using alternative technologies. This is so consumers are more fully informed. The new numbers are:

960 (a) Steviol glycosides from *Stevia Rebaudiana* Bertoni (Steviol glycosides from Stevia), and

960 (b) Steviol glycosides from fermentation

960 (b)(i) Rebaudioside A from multiple gene donors expressed in *Yarrowia lipolytica*.

The effect of this change is that the parent number (960) is superseded by the more specific numbers (960(a), 960 (b)(i)).

As more sub-categories are added under the parent INS 960 (to reflect the new technologies, including for example the Reb M subject to this application), additional numbers will be added.

We suggest the Approval Report explains that changes to the INS numbers in the Code will be needed in future, to distinguish between plant sources of steviol glycosides, compared to those produced using novel technologies. This is in order to align with the revisions to the INS, enabling consumers to have information about the source of the steviol glycosides.

Draft variation contained in Attachment A to the Call for Submission paper

Schedule 3 – we agree that Schedule 3 should be amended to allow for the novel production method for Reb M.

In July 2018, the Codex Alimentarius Commission adopted the JECFA specification for "Steviol glycosides from *Stevia rebaudiana* Bertoni" (i.e. its tentative status was removed). It is our understanding that this means S3-35 is no longer required (refer to the FSANZ report on A1132, where this is discussed), as the JECFA specification now includes any mixture of steviol glycoside compounds derived from *Stevia rebaudiana* Bertoni, rather than being limited to nine named leaf-derived steviol glycosides. If our understanding is correct, this will affect how the required provisions arising from A1157 are drafted. Any impact on existing subsections S3—31 and S3—32 may also need to be considered.

We appreciate however that Schedule 3 in the Code needs to be updated to the latest publication of JECFA monographs (i.e. monograph number 20) before the above change can be considered.

If the drafting progresses as in Attachment A, the title of subsection S3-35 may need revising, as it will include information specifically for high purity Reb M, as well as for 'Steviol glycosides from *Stevia rebaudiana* Bertoni'.

Schedule 18 – we agree that Schedule 18 should be amended, to permit the enzymes as a processing aid in the manufacture of Reb M.

Comment on the steviol glycoside permissions in the Code

As a further general comment, we note that the way the additional specifications for steviol glycosides are currently listed in Schedule 3 is not easy for Code users to understand, unless you refer back to the applications that led to the

new sub-sections in schedule 3. As more of these novel methods are approved (such as the fermentation methods, enzymatic methods), we assume they will be added to S35, if the same approach is followed. As editorial notes are no longer used in the Code, there is no obvious place to explain how the provisions apply.

Pages 18-19 of Appendix 1 of the Call for Submissions report (informative summary of the relevant current standards in the Code) under *Identity and purity requirements* could be expanded (in the Approval Report) to provide more information on how the provisions apply, and which application generated the sections in Schedule 3.

Alternatively, there could be a place on the FSANZ website for this information, or some extra information could be placed in the relevant schedules. The sort of information that could be helpful is as follows:

- S3-35 was introduced as a result of A1132 (as discussed above), and
- S3-31 and S3-32 were introduced when application A1108 requested a permission for Reb M (produced from the plant, not using any of the newer/novel techniques). As there is no primary source specification for Reb M, S31 and S32 addresses the differences between Reb M and the specification in the primary sources, and both must be read in conjunction. This information is contained in the earlier FSANZ reports.

