11 November 2026
420-26

Call for submissions – Application A1357

Steviol glycosides (rebaudioside M and rebaudioside D) produced by enzymatic conversion using enzymes produced by *Escherichia coli* BL21

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Adorvia Biotechnology Co Ltd (a subsidiary of Abiochem Biotechnology Co Ltd) to permit the use of steviol glycosides with a high rebaudioside M (Reb M) or rebaudioside D (Reb D) content, produced by enzymatic conversion using enzymes derived from genetically modified strains of *Escherichia coli* BL21, as a food additive and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

Submissions on this application need to be made through the Consultation Hub. All submissions on applications and proposals will be published on the Consultation Hub. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published following consultation and before the next stage in the statutory assessment process.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at Making a submission. For information on how FSANZ manages personal information when you make a submission, see FSANZ's Privacy Policy.

FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices. There is no need to send an email or hard copy of your submission if you have submitted it through the FSANZ Consultation Hub.

DEADLINE FOR SUBMISSIONS: 11:59pm (Canberra time) 23 December 2026

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

For information about making a submission, visit the FSANZ website at current calls for public comment and how to make a submission. Questions about making a submission or application and proposal processes can be sent to standards.management@foodstandards.gov.au. Submissions in hard copy may be sent to the following addresses:

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Supporting document

The following document which informed the assessment of this application is available on the FSANZ website[1]:

SD1 Risk and technical assessment report

[1] https://www.foodstandards.gov.au/food-standards-code/applications/a1357-steviol-glycosides-rebaudioside-m-and-rebaudioside-d

Executive summary

Food Standards Australia New Zealand (FSANZ) has assessed an application from Adorvia Biotechnology Co Ltd (a subsidiary of Abiochem Biotechnology Co Ltd) seeking amendments to the Australia New Zealand Food Standards Code (the Code) to permit the use of steviol glycosides with a high rebaudioside M (Reb M) or rebaudioside D (Reb D) content as a food additive. In particular, these steviol glycosides are produced by enzymatic conversion using enzymes derived from genetically modified (GM) strains of *Escherichia coli* BL21, which are used to convert purified stevia leaf extract to produce the Reb M or Reb D.

Steviol glycosides are already permitted for use as food additives (sweeteners) in certain foods up to specified maximum permitted levels in the Code. In addition, a number of enzymes used in the manufacture of steviol glycosides are already permitted as processing aids in Schedule 18, including sucrose synthase (EC 2.4.1.13) and uridine diphosphate (UDP)-glucosyltransferase produced using *E. coli* BL21 production strains. Two of the enzymes that are the subject of this application are produced by GM strains of *E. coli* BL21 that contain genes sourced from donor organisms that are not included in existing permissions in the Code. Specifically, the application seeks permission for a sucrose synthase derived from *Methylocaldum szegediense* and a UDP-glucosyltransferase derived from *Solanum tuberosum*, expressed in *E. coli* BL21 production strains. The third enzyme, a UDP-glucosyltransferase sourced from *E. coli* BL21 containing the UDP-glucosyltransferase gene from *Stevia rebaudiana,* has an existing permission in the Code. However, that permission is limited to the conversion of purified stevia leaf extract to produce Reb M only. Accordingly, the enzymes and their proposed uses required assessment.

In addition, there are specifications in Schedule 3 of the Code with which certain substances, e.g. substances used as food additives and substances used as processing aids, must comply with whenever the substances are added to food in accordance with the Code or sold for such use. In particular, there is a specification specifically for steviol glycosides produced by enzymatic conversion. However, this specification does not cover the applicant's particular method of enzymatic conversion.

FSANZ assessed whether the proposed enzymes achieve their intended technological purpose and whether any public health and safety concerns arise from their use. The assessment concluded that the technological purpose is justified and that the proposed use of the enzymes as processing aids in the production of Reb M and Reb D does not raise safety concerns.

Following assessment, for the reasons set out in this report, FSANZ has prepared a draft variation to the Code to amend Schedule 3 and Schedule 18 to include the applicant's particular method of enzymatic conversion in section S3—35 and to list the applicant's enzymes as processing aids to produce Reb M and Reb D using the enzymatic conversion production method as permitted processing aids in the table to subsection S18—9(3) (respectively).

The overall effect of the draft variation, if approved, would be to permit the applicant's steviol glycosides preparation containing Reb M or Reb D, which is produced by enzymatic conversion using the above-mentioned enzymes derived from GM strains of *E. coli* BL21, to be used as a food additive in accordance with the Code.

FSANZ now seeks submissions on the draft variation to the Code.

1 Introduction

1.1 The applicant

The applicant is Adorvia Biotechnology Co Ltd, a subsidiary of Abiochem Biotechnology Co Ltd, and is a manufacturer of food ingredients.

1.2 The application

The purpose of the application is to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of steviol glycosides with a high rebaudioside M (Reb M) or rebaudioside D (Reb D) content produced by enzymatic conversion using enzymes derived from genetically modified (GM) strains of *Escherichia coli* BL21. The enzymes are sucrose synthase and two uridine diphosphate (UDP)-glucosyltransferases as follows:

- sucrose synthase (EC 2.4.1.13) produced by *E. coli* BL21, containing the gene for sucrose synthase from *Methylocaldum szegediense*

- β-1,2-glucosyltransferase (EC 2.4.1.-) produced by *E. coli* BL21, containing the gene for β-1,2-glucosyltransferase from *Solanum tuberosum*

- β-1,3-glucosyltransferase (EC 2.4.1.-) produced by *E. coli* BL21, containing the gene for β-1,3-glucosyltransferase from *Stevia rebaudiana*.

The enzymes convert the naturally occurring steviol glycosides in an extract of *S. rebaudiana* Bertoni leaves (e.g. the 'major glycoside' rebaudioside A) to Reb M and Reb D. These are categorised as 'minor glycosides' but have more favourable sensory characteristics. The final product is a steviol glycoside preparation containing high amounts of Reb M (≥95%) or Reb D (≥85%, with a total steviol glycoside content of ≥95%).

1.3 The current standard

Australian and New Zealand food laws require food for sale to comply with relevant requirements in the Code. The requirements relevant to this application are summarised below.

1.3.1 Permitted use – food additives

The use of steviol glycosides in food as an intense sweetener is regulated by the provisions of the Code relating to food additives.

Paragraph 1.1.1—10(6)(a) of the Code provides that, unless expressly permitted by the Code, a food for sale cannot contain, as an ingredient or component, a substance used as a food additive.

Section 1.1.2—11 defines the expression 'used as a food additive'. Subsection 1.1.2—11(1) provides that a substance is 'used as a food additive' in relation to a food if both of the following conditions are met:

- the substance is added to the food to perform one or more technological functions listed in Schedule 14; and
- the substance is identified in subsection 1.1.2—11(2). The substances listed in that subsection include a substance identified in the table to section S15—5 as a permitted food additive.

Schedule 14 lists the permitted technological purposes of food additives. The table in section S14—2 lists 'Intense sweetener' as a permitted technological purpose.

Section 1.3.1—3 provides that a substance may be used as a food additive in relation to food if (among other things) the substance is permitted to be used as a food additive for that food by Schedule 15. The table to section S15—5 of Schedule 15 lists the specific food additive permissions for different classes of foods. Steviol glycosides is already a permitted food additive for a range of food classes. It has the International Numbering System (INS) number 960.

Therefore, the focus of this application is on the three enzymes derived from a GM *E. coli* BL21 used to produce steviol glycosides via the applicant's enzymatic conversion method of production.

Schedule 16 sets out the types of substances that may be used as food additives in any food at Good Manufacturing Practice (GMP)[2] levels. Where a food class in Schedule 15 has *'Additives permitted at GMP'* listed beneath it, this means that food additives listed in Schedule 16 may be used in that food class, subject to any applicable conditions. Steviol glycosides is not such a food additive and therefore not listed in Schedule 16.

1.3.2 Permitted use – processing aids

Paragraph 1.1.1—10(6)(c) of the Code provides that a food for sale must not have as an ingredient or component, a substance used as a processing aid unless the use of that substance as a processing aid is expressly permitted by the Code.

Section 1.1.2—13 provides that a substance 'used as a processing aid' in relation to a food is a substance used during the course of processing that meets all of the following conditions:

- it is used to perform a technological purpose during the course of processing
- it does not perform a technological purpose in the food for sale, and
- it is a substance listed in Schedule 18 or identified in section S16—2 as an additive permitted at GMP.

Standard 1.3.3 and Schedule 18 list the permitted processing aids. Enzymes of microbial origin permitted to be used as processing aids are listed in the table to subsection S18—4(5) or in the table to subsection S18—9(3) of Schedule 18, depending on whether a technological purpose has been specified. An enzyme of microbial origin listed in the table to subsection S18—4(5) is permitted for use as a processing aid to perform any technological purpose if the enzyme is derived from the corresponding source specified in the table. The table to subsection S18—9(3) lists those substances, including enzymes derived from particular sources, that are permitted to be used as processing aids for specific technological purposes in relation to:

- if a food is specified—that food, or
- if no food is specified—any food.

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[2] GMP is defined in section 1.1.2—2 of the Code as follows: ***GMP*** *or* ***Good Manufacturing Practice****, with respect to the addition of substances used as food additives and substances used as processing aids to food, means the practice of:*
(a) limiting the amount of substance that is added to food to the lowest possible level necessary to accomplish its desired effect; and
(b) to the extent reasonably possible, reducing the amount of the substance or its derivatives that:
*(i) remains as a *component of the food as a result of its use in the manufacture, processing or packaging; and*
(ii) is not intended to accomplish any physical or other technical effect in the food itself;
(c) preparing and handling the substance in the same way as a food ingredient.

Additionally, paragraph 1.3.3—11(c) specifies that the substance may only be used as a processing aid if it is not present in the food at greater than the maximum permitted level for that substance indicated in the table to section S18—9.

There are a number of permissions for enzymes listed in the table to subsection S18—9(3) for the production of different steviol glycosides, including the following sourced from *E. coli* BL21:

- sucrose synthase (EC 2.4.1.13) sourced from *E. coli* BL21 containing the gene for sucrose synthase from *Arabidopsis thaliana,* to produce Reb M

- UDP-glucosyltransferase sourced from *E. coli* BL21 containing the gene for UDP-glucosyltransferase from *S. rebaudiana,* to produce Reb M.

However, the proposed enzymes are not covered by the existing permissions in the table to subsection S18—9(3). Two of the proposed enzymes are sourced from GM strains of *E. coli* BL21 that contain genes sourced from donor organisms that are not included in existing permissions in the Code. While a permission does exist for the third enzyme, a UDP-glucosyltransferase sourced from *E. coli* BL21 containing the gene for UDP-glucosyltransferase from *S. rebaudiana*, that permission is limited to use in the production of Reb M. Therefore, the proposed use of these enzymes to produce both Reb M and Reb D is not currently permitted under Standard 1.3.3 and Schedule 18.

1.3.3 Identity and purity requirements – food additives

Paragraph 1.1.1—15(1)(a) requires substances used as food additives to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code when added to food in accordance with the Code or sold for use in food.

Paragraphs S3—2(1)(b), (c) and (d) of Schedule 3 incorporate by reference the specifications listed in the Joint Food and Agriculture Organization/World Health Organization (FAO/WHO) Expert Committee of Food Additives (JECFA) Combined Compendium of Food Additive Specifications (FAO JECFA Monographs 34 (2025), explicitly FAO/WHO (2006)), the United States Pharmacopeial Convention (2024) Food Chemicals Codex (FCC 14th edition), and Commission Regulation (EU) No 231/2012. These include specifications for steviol glycosides.

Specifically, JECFA has prepared a Specifications Monograph (JECFA Framework for Steviol Glycosides), the latest version of which was published in FAO JECFA Monographs 31 (2023). Annex 3 of the JECFA Framework is focussed on steviol glycosides produced by enzymatic conversion using sucrose synthase and glucosyltransferase. The production method described in the application is consistent with Annex 3 of the JECFA Framework. This is with the exception of a donor organism used by the applicant in the production of sucrose synthase, *M. szegediense*, which is not currently listed in Annex 3.

Schedule 3 of the Code also contains several specifications specifically for certain types of steviol glycosides in addition to the steviol glycosides listed in paragraph S3—2(1)(b) and (c) of Schedule 3. Section S3—35 of the Code provides a specification for steviol glycosides preparations obtained from the leaves of *S. rebaudiana* Bertoni and produced by enzymatic conversion. The specification states that the preparation may contain different individual steviol glycosides, with total steviol glycosides present at levels not less than 95% (on the dried basis) (subsections S3—35(3) and (4)). An amendment to section S3—35 is required to permit Reb M and Reb D produced using the particular enzymes listed in the application.

1.3.4 Identity and purity requirements – processing aids

Paragraph 1.1.1—15(1)(b) requires substances used as processing aids to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code when added to food in accordance with the Code or sold for use in food.

As mentioned in section 1.3.3 of this report, subsection S3—2(1) incorporates by reference specifications listed in the JECFA Combined Compendium of Food Additive Specifications and the FCC. These also include general specifications for enzyme preparations used in food processing for identity and purity parameters.

1.3.5 Labelling requirements

Subsection 1.1.1—10(8) of the Code provides that food for sale must comply with all relevant labelling requirements in the Code.

Standard 1.2.1 sets out the labelling requirements for food for sale.

Standard 1.2.4 generally requires packaged food to be labelled with a statement of ingredients. Subsection 1.2.4—7(1) requires food additives to be declared in the statement of ingredients in one of the following ways:

- if the food additive can be classified into a class of additives listed in Schedule 7—by referring to the relevant class name, followed in brackets by the name or code number of the food additive indicated in Schedule 8
- otherwise—by referring to the name of the food additive as indicated in Schedule 8.

Schedule 7 lists the food additive class names that can be used in the statement of ingredients, including the class name ‘sweetener’. Schedule 8 lists the names and code numbers of food additives that are to be used for labelling purposes. The name ‘steviol glycosides’ and corresponding code number 960 are listed in Schedule 8.

Paragraphs 1.2.4—3(2)(d) and (e) exempt processing aids from the requirement to be declared in the statement of ingredients, unless other requirements apply.

1.3.6 International standards

In developing food regulatory measures, FSANZ must have regard to the promotion of consistency between domestic and international food standards. In terms of food safety, the relevant international standard setting body is the Codex Alimentarius Commission (Codex).

Codex STAN 192-1995 (also referred to as the General Standard for Food Additives, or GSFA) contains food additive listings by food category[3]. Only food additives that have been assigned an Acceptable Daily Intake or determined, based on other criteria, to be safe by JECFA and have an INS designation by Codex are considered for inclusion in the GSFA.

The GSFA contains provisions for the use of steviol glycosides produced by enzymatic conversion (as steviol equivalents) as a food additive in a range of foods and maximum permitted limits.

In addition, the Codex Guideline *Class Names and the International Numbering System (INS) for Food Additives* (CXG 36-1989)[4] lists the names and INS numbers of food additives,

[3] https://www.fao.org/gsfaonline/foods/index.html
[4] https://www.fao.org/fao-who-codexalimentarius/sh-proxy/it/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B36-1989%252FCXG_036e.pdf

including steviol glycosides.

There is no Codex 'general standard' for processing aids. However, as noted in section 1.3.4 of this report, there are internationally recognised specifications for enzyme preparations established by JECFA and the FCC.

In addition, there is a Codex guideline, *Guidelines on Substances used as Processing Aids* (CAC/GL 75-2010), which sets out general principles for the safe use of substances used as processing aids, including that substances used as processing aids shall be used under conditions of GMP.

1.4 Reasons for accepting application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act)
- it related to a matter that warranted the variation of a food regulatory measure.

1.5 Procedure for assessment

The application is being assessed under the General Procedure in accordance with the FSANZ Act.

2 Summary of the assessment

FSANZ has undertaken an assessment to determine whether the enzymes achieve their technological purpose as processing aids during the production of steviol glycosides, namely, Reb M and Reb D, and to evaluate potential public health and safety risks that may arise from their use (see Supporting Document 1 (SD1)). A summary of the assessment is provided below.

2.1 Risk assessment

The 3 enzymes are technologically justified for the production of Reb M and Reb D by enzymatic conversion and are appropriately considered processing aids for the purposes of the Code.

Processing and purification steps undertaken ensure residual protein and DNA of the production organism and enzymes are below quantifiable and detectable levels, respectively. Exposure to any of the enzymes through use of the final product will be negligible or low.

There are relevant identity and purity specifications listed in Schedule 3 of the Code with which the enzymes will have to comply. These are detailed in section 2.4.1 of SD1. Analytical data provided by the applicant showed that the enzymes meet the relevant specifications. The steviol glycosides also comply with relevant identity and purity specifications in Annex 3 of the JECFA Framework and Schedule 3 of the Code.

No public health and safety concerns were identified in the assessment of the enzymes and production organisms. The enzymes have a history of safe use for steviol glycosides production. Recent bioinformatic searches were conducted and there are no homologies of the three enzymes to known toxins or allergens.

The host organism is a strain of *E. coli* BL21, an organism with a long history of safe use as an enzyme production organism, including for steviol glycosides. Analysis of the production strains confirmed the presence and stability of the genes for the three enzymes used to produce Reb M and Reb D.

2.2 Risk management

The risk management options available to FSANZ after assessment were to either:

- reject the application, or
- prepare a draft variation of the Code.

For the reasons listed in this report, FSANZ decided to prepare a draft variation to the Code to permit the use of the following three enzymes as processing aids in Schedule 18 for use in the conversion of purified stevia leaf extract to produce Reb M and Reb D:

- sucrose synthase (EC 2.4.1.13) sourced from *E. coli* BL21, containing the sucrose synthase gene from *M. szegediense*

- β-1,2-glucosyltransferase (EC 2.4.1.-) produced by *E. coli* BL21, containing the gene for β-1,2-glucosyltransferase from *S. tuberosum*

- β-1,3-glucosyltransferase (EC 2.4.1.-) produced by *E. coli* BL21, containing the gene for β-1,3-glucosyltransferase from *S. rebaudiana*.

The draft variation would also include the applicant's method of enzymatic conversion as a permitted process by which a steviol glycoside preparation may be obtained from the leaves of the *Stevia rebaudiana* Bertoni plant for the purposes of the specification set out in section S3—35 of the Code. If the draft variation is approved, a steviol glycosides preparation obtained using the applicant's enzyme conversion process would have to comply with the specification at section S3—35 when the preparation is added to food in accordance with the Code or sold for such use.

The draft variation would combine β-1,2-glucosyltransferase and β-1,3-glucosyltransferase in one entry – being UDP-glucosyltransferase, in a manner that is consistent with other entries for the same enzyme in section S18—9(3) and section S3—35 of the Code.

The enzymatic conversion method of production of steviol glycosides is comparable to methods already considered and permitted by FSANZ (see Applications A1157, A1172, A1176, A1183, A1268 and A1318).

FSANZ's assessment is that amending the Code as proposed is the only option that can provide express permission for the steviol glycosides containing Reb M and Reb D, produced by the applicant's enzymatic conversion process, as a food additive in accordance with the Code. There are no non-regulatory options that can appropriately address the regulatory request. In making its assessment, FSANZ had regard to the criteria prescribed in the FSANZ Act (see section 2.4 of this report).

Other risk management considerations for this application are related to enzyme and source microorganism nomenclature, specifications and labelling. These are discussed below.

2.2.1 Enzyme nomenclature, source microorganism nomenclature and specifications

FSANZ notes the International Union of Biochemistry and Molecular Biology (IUBMB) lists the accepted name 'sucrose synthase' for the enzyme EC 2.4.1.13 (see section 2.1 of SD1). This is the name used in the proposed draft variation.

β-1,2-glucosyltransferase and β-1,3-glucosyltransferase are not yet fully classified by the IUBMB and fourth-level EC numbers have not been assigned. Both enzymes are therefore appropriately classified as EC 2.4.1.-. As outlined above, the draft variation combines

β-1,2-glucosyltransferase and β-1,3-glucosyltransferase in one entry to maintain consistency with previous entries.

Nomenclature for the host and gene donor organisms – *Escherichia coli* BL21 and *Methylocaldum szegediense, Solanum tuberosum,* and *Stevia rebaudiana* respectively – is in accordance with accepted international norms for bacterial taxonomy (see section 1.2 of this report).

There are relevant identity and purity specifications listed in Schedule 3 for steviol glycosides and enzymes used in food processing (refer to sections 1.3.3 and 1.3.4 of this report and section 2.4 of SD1). The steviol glycoside preparations of Reb M and Reb D, and the enzymes used to produce them, would have to comply with their relevant specifications when added to food in accordance with the Code or sold for such use.

2.2.2 Labelling

The existing labelling provisions in the Code would apply to foods for sale that contain steviol glycosides produced from the enzymes specified in this application. See section 1.3.5 of this report (above).

2.2.3 Risk management conclusion

For the reasons set out in this report, FSANZ has prepared a draft variation to the Code (Attachment A) to amend Schedule 3 (section S3—35) and Schedule 18 (subsection S18—9(3)) as proposed so as to permit steviol glycosides containing Reb M and Reb D, produced by the applicant's enzymatic conversion process, as a food additive in accordance with the Code.

2.3 Risk communication

2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a standard communication strategy to this application. All calls for submissions are notified via the FSANZ Notification Circular, digital channels and Food Standards News.

The process by which FSANZ approaches standards development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on the draft variation.

The draft variation will be considered for approval by the FSANZ Board taking into account all public comments received from this call for submissions.

2.3.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are not substantially the same as existing international standards and the proposed measure may have a significant effect on trade.

As noted in sections 1.3.3 and 1.3.6 of this report, the method of production used in this application is described in the JECFA Framework for Steviol Glycosides, and steviol glycosides produced by enzymatic conversion are listed in the Codex GSFA.

While there is no Codex 'general standard' for enzymes, the enzymes in this application are comparable to already permitted forms listed in the JECFA Framework and perform the same function.

FSANZ considers that the proposed draft variation would facilitate trade in steviol glycosides and food containing steviol glycosides rather than restrict it, thus not having an inhibiting effect on trade.

Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 FSANZ Act assessment requirements

When assessing this application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

2.4.1 Section 29

2.4.1.1 Consideration of costs and benefits

FSANZ has assessed that a regulation impact statement (RIS) is not required for this application. This is because applications relating to permitting the use of food additives and processing aids that have been determined to be safe, such as with this application, are considered to be minor in impact or deregulatory in nature as their use will be voluntary if the draft variation concerned is approved. Therefore, a RIS has not been prepared.

FSANZ however had regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (as per paragraph 29(2)(a) of the FSANZ Act).

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the potential positives and negatives of moving away from the status quo by permitting the proposed use of the applicant's enzymes to produce Reb M and Reb D.

FSANZ's conclusions regarding the costs and benefits of the proposed measure are set out below. However, information received from the call for submissions may result in FSANZ arriving at a different outcome.

2.4.1.2 Costs and benefits of permitting the proposed use of steviol glycosides containing Reb M and Reb D, produced by the applicant's enzymatic conversion process

If the draft variation is approved, industry might benefit from several improvements and efficiencies from the use of steviol glycosides containing Reb M and Reb D, produced by the applicant's enzymatic conversion process, as a food additive. Due to the voluntary nature of the permission, industry would only use these food additives where they believe a net benefit exists for them.

If industry experiences cost savings from the use of steviol glycosides preparations produced using the applicant's enzymes, industry might pass on some of the cost savings to consumers.

Permitting the proposed use of the applicant's enzymes might result in a small, inconsequential cost to government in terms of an addition to the current range of processing aids that are already monitored for compliance.

Conclusions of costs and benefits

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting the proposed use of these enzymes as processing aids are likely to outweigh the associated costs.

2.4.1.3 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the application.

2.4.1.4 Any relevant New Zealand standards

The relevant standards in the Code apply in Australia and New Zealand. There are no relevant New Zealand only standards.

2.4.1.5 Any other relevant matters

Other relevant matters are considered below.

2.4.2 Subsection 18(1)

FSANZ has also considered the 3 objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.4.2.1 Protection of public health and safety

FSANZ has completed a risk and technical assessment (refer to SD1 which is summarised in section 2.1 of this report). The assessment concluded there are no public health and safety concerns associated with the proposed use of the applicant's enzymes as processing aids to produce Reb M and Reb D.

2.4.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

The labelling requirements for the provision of information to consumers are discussed in sections 1.3.5 and 2.2.2 of this report.

2.4.2.3 The prevention of misleading or deceptive conduct

No issues have been identified with this application relevant to this objective.

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ has used risk analysis and the best available scientific evidence to conduct the risk and technical assessment (refer to SD1). The applicant submitted supporting information, including scientific studies and relevant literature as part of their application. FSANZ had regard to that information, and to other technical information including scientific literature in assessing the application.

- **the promotion of consistency between domestic and international food standards**

In terms of food safety, the relevant international standard setting body is Codex. As noted in section 1.3.6 of this report, the Codex GSFA contains provisions for steviol glycosides produced by enzymatic conversion and the Codex guideline CXG 36-1989 lists steviol glycosides with the INS number 960.

As outlined in section 1.3.3 of this report, JECFA has adopted a framework for developing specifications for steviol glycosides categorised by their specific method of production, including enzymatic conversion. The applicant's method of production is consistent with Annex 3 of the JECFA Framework.

Regarding the enzyme processing aids, there is no Codex 'general standard', however, as noted in section 1.3.6 of this report, there are internationally recognised specifications for enzyme preparations established by JECFA and Food Chemicals Codex, with which the applicant's enzymes would have to comply when added to food in accordance with the Code or sold for use in food. There is also Codex guideline CAC/GL 75-2010 which sets out general principles for the safe use of substances used as processing aids, including that substances used as processing aids shall be used under conditions of GMP.

- **the desirability of an efficient and internationally competitive food industry**

Permission to use the applicant's enzymes as processing aids to produce Reb M and Reb D would enable Australian and New Zealand food manufacturers to access and use steviol glycosides preparations assessed as safe that are available to some overseas competitors. This will improve domestic food manufacturers' capacity to compete in overseas markets (see discussion in section 2.4.1.1 of this report).

The conclusion of the risk and technical assessment is that there are no public health and safety concerns associated with the proposed use of the applicant's enzymes as processing aids in the production of Reb M and Reb D, using the enzymatic conversion method of production described by the applicant. It is therefore appropriate that Australian and New Zealand food industries are given the opportunity to benefit from the use of steviol glycoside preparations produced using the applicant's enzymes as food additives. Ultimately, the food industry will make their own economic decisions, taking into account the costs and benefits, to determine the overall benefits to their particular business.

- **the promotion of fair trading in food**

No issues were identified for this application relevant to this objective.

- **any written policy guidelines formulated by the Food Ministers' Meeting**

The Ministerial Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*[5] includes specific order policy principles for substances added to achieve a solely technological function, such as processing aids. These specific order policy principles state that permission should be granted where:

- the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (i.e. the 'stated purpose')
- the addition of the substance to food is safe for human consumption
- the amounts added are consistent with achieving the technological function

[5] https://www.foodregulation.gov.au/resources/publications/policy-guideline-addition-substances-other-vitamins-and-minerals

- the substance is added in a quantity and a form which is consistent with delivering the stated purpose
- no nutrition, health or related claims are to be made in regard to the substance.

FSANZ determined that permitting the proposed use of the applicant's enzymes to manufacture Reb M and Reb D is consistent with these specific order policy principles for 'technological function'. All other relevant requirements of the policy guideline would be similarly met.

3 Draft variation

The draft variation to the Code is at Attachment A and is intended to take effect on gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

Attachments

A. Draft variation to the Australia New Zealand Food Standards Code
B. Draft Explanatory Statement

Attachment A – Draft variation to the Australia New Zealand Food Standards Code

Food Standards (Application A1357 – Steviol glycosides (rebaudioside M and rebaudioside D) produced by enzymatic conversion using enzymes produced by GM *Escherichia coli* BL21) Variation

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by the Delegate]

[Name and position of Delegate]
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1357 – Steviol glycosides (rebaudioside M and rebaudioside D) produced by enzymatic conversion using enzymes produced by GM* Escherichia coli *BL21) Variation*.

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

Schedule

Schedule 3—Identity and purity

[1] Subparagraph S3—35(2)(g)(ii)

Repeal the subparagraph, substitute:

(ii) sucrose synthase (EC 2.4.1.13) from *Arabidopsis thaliana* sourced from *Escherichia coli* BL21;

(h) by enzymatic conversion of purified stevia leaf extract to produce rebaudioside M or rebaudioside D using both of the following enzymes:

(i) UDP-glucosyltransferases sourced from *Escherichia coli* BL21 containing the UDP-glucosyltransferase gene from *Solanum tuberosum* or *Stevia rebaudiana*; and

(ii) sucrose synthase (EC 2.4.1.13) sourced from *Escherichia coli* BL21 containing the sucrose synthase gene from *Methylocaldum szegediense*.

Schedule 18—Processing aids

[2] Subsection S18—9(3) (table, after the table item dealing with 'Sucrose synthase (EC 2.4.1.13) sourced from *Escherichia coli* BL21 containing the gene for sucrose synthase from *Arabidopsis thaliana*')

Insert:

Sucrose synthase (EC 2.4.1.13) sourced from *Escherichia coli* BL21 containing the sucrose synthase gene from *Methylocaldum szegediense*	For the conversion of purified stevia leaf extract to produce: (a) rebaudioside M; or (b) rebaudioside D.	GMP

[3] Subsection S18—9(3) (table, table item dealing with 'Uridine diphosphate (UDP) glucosyltransferases sourced from *Escherichia coli* BL21 containing the UDP glucosyltransferase gene from *Stevia rebaudiana*')

Repeal the entry, substitute:

Uridine diphosphate (UDP)-glucosyltransferases sourced from *Escherichia coli* BL21 containing the UDP-glucosyltransferase gene from *Solanum tuberosum*	For the conversion of purified stevia leaf extract to produce: (a) rebaudioside M; or (b) rebaudioside D.	GMP
Uridine diphosphate (UDP)-glucosyltransferases sourced from *Escherichia coli* BL21 containing the UDP-glucosyltransferase gene from *Stevia rebaudiana*	For the conversion of purified stevia leaf extract to produce: (a) rebaudioside M; or (b) rebaudioside D.	GMP

Attachment B – Draft Explanatory Statement

DRAFT EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1357 – Steviol glycosides (rebaudioside M and rebaudioside D) produced by enzymatic conversion using enzymes produced by* Escherichia coli *BL21) Variation

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (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 A1357 which seeks an amendment of the Code to permit steviol glycosides with a high rebaudioside M (Reb M) or rebaudioside D (Reb D) content produced by enzymatic conversion using enzymes derived from genetically modified strains of *Escherichia coli* BL21 to be used as a food additive. The Authority considered the application in accordance with Division 1 of Part 3 and has prepared a draft variation – the *Food Standards (Application A1357 – Steviol glycosides (rebaudioside M and rebaudioside D) produced by enzymatic conversion using enzymes produced by* Escherichia coli *BL21) Variation* (the draft variation).

2. Variation will be a legislative instrument

If approved, the draft variation would be a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and be publicly available on the Federal Register of Legislation (www.legislation.gov.au).

If approved, this instrument would not be subject to the disallowance or sunsetting provisions of the *Legislation Act 2003.* Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunsetting if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunsetting legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the FSANZ Act establishes the Authority to develop food standards for consideration and endorsement by the Food Ministers Meeting (FMM). The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become

part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority has prepared a draft variation to amend the table to subsection S18—9(3) of the Code to permit the use of new enzymes sourced from genetically modified strains of *Escherichia coli* BL21 (permitted enzymes) as processing aids for the conversion of purified stevia leaf extract to produce Reb M and Reb D.

The draft variation would also amend section S3—35 of the Code setting out the specification for a steviol glycosides preparation produced by enzymatic conversion so that the specification would also apply to a steviol glycosides preparation containing Reb M or Reb D, which is produced by enzymatic conversion using the permitted enzymes. If the draft variation is approved, when used as a food additive, the preparation would have to comply with the specification in section S3—35 when it is added to food in accordance with the Code or sold for such use.

4. Documents incorporated by reference

The draft variation does not incorporate any documents by reference.

However, existing provisions of the Code incorporate documents by reference that would prescribe identity and purity specifications for the processing aids and food additive (a steviol glycosides preparation containing Reb M or Reb D, which is produced by enzymatic conversion) that would be permitted by the draft variation. Section 1.1.1—15 of the Code requires substances used as processing aids and food additives to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code when added to food in accordance with the Code or sold for use in food. Section S3—2 of Schedule 3 incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Combined Compendium of Food Additive Specifications (FAO/WHO 2025, explicitly FAO/WHO 2006), the United States Pharmacopeial Convention Food Chemicals Codex (FCC) (14th edition) (FCC 2024), and Commission Regulation (EU) No 231/2012. These include specifications for the identity and purity parameters of steviol glycosides and/or general specifications for the identity and purity parameters of food additives and enzyme preparations used as processing aids in the production of those additives.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1357 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. A call for submissions (including the draft variation) will be open for a 6-week consultation period. Further details of the consultation process, the issues raised during consultation and by whom, and the Authority's response to these issues are available in an approval report published on the Authority's website at www.foodstandards.gov.au.

A regulation impact statement (RIS) has not been prepared. This is because applications relating to permitting the use of processing aids that have been determined to be safe are considered to be minor and deregulatory in nature, as their use will be voluntary if the draft variation relating to the application is approved. Therefore, the Authority's assessment is that a RIS is not required for this application.

6. Statement of compatibility with human rights

If approved, this instrument would be exempt from the requirements for a statement of compatibility with human rights as it would be a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

7. Variation

References to 'variation' in this section are references to the draft variation.

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application A1357 – Steviol glycosides (rebaudioside M and rebaudioside D) produced by enzymatic conversion using enzymes produced by GM* Escherichia coli *BL21) Variation*.

Clause 2 of the variation provides that the Code is amended by the Schedule to the variation.

Clause 3 of the variation provides that the variation will commence on the date of gazettal of the instrument.

Schedule to the variation

Item [1] of the Schedule to the variation would amend subsection S3—35(2) of Schedule 3.

Section S3—35 sets out the specification for steviol glycosides produced by enzymatic conversion. Subsection S3—35(2) sets out the processes by which a steviol glycoside preparation must be obtained from the leaves of the *Stevia rebaudiana* Bertoni plant.

Item [1] would repeal subparagraph S3—35(2)(g)(ii) and substitute the repealed subparagraph with a revised subparagraph S3—35(2)(g)(ii) and a new paragraph S3—35(2)(h).

Existing subparagraph S3—35(2)(g)(ii) is the last provision of subsection S3—35(2) and, as such, the provision ends with a full stop.

Revised subparagraph S3—35(2)(g)(ii) ends with a semi-colon instead. This is because revised subparagraph S3—35(2)(g)(ii) is followed by new paragraph S3—35(2)(h).

New paragraph S3—35(2)(h) states:

'(h) by enzymatic conversion of purified stevia leaf extract to produce rebaudioside M or rebaudioside D using both of the following enzymes:
  (i) UDP-glucosyltransferases sourced from *Escherichia coli* BL21 containing the UDP-glucosyltransferase gene from *Solanum tuberosum* or *Stevia rebaudiana*; and
  (ii) sucrose synthase (EC 2.4.1.13) sourced from *Escherichia coli* BL21 containing the sucrose synthase gene from *Methylocaldum szegediense*.'

If the variation is approved, the effect of the amendment in **item [1]** would be that the specification in section S3—35 would apply to a steviol glycosides preparation obtained from the leaves of the *Stevia rebaudiana* Bertoni plant using the process in new paragraph S3—35(2)(h). Consequently, when used as a food additive, this preparation would have to comply with the specification in section S3—35 whenever it is added to food in accordance with the Code or sold for use in food.

Items [2] and **[3]** of the Schedule to the variation would amend the table to subsection S18—9(3) of the Code, which sets out processing aids that are permitted to be used for specified technological purposes.

Item [2] would insert a new item into the table after the table item dealing with 'Sucrose synthase (EC 2.4.1.13) sourced from *Escherichia coli* BL21 containing the gene for sucrose synthase from *Arabidopsis thaliana*'.

The new table item would consist of the following enzyme in column 1 of the table:

- Sucrose synthase (EC 2.4.1.13) sourced from *Escherichia coli* BL21 containing the sucrose synthase gene from *Methylocaldum szegediense.*

The permitted technological purpose for this enzyme would be prescribed in column 2 of the table i.e. for the conversion of purified stevia leaf extract to produce Reb M or Reb D.

The permission for this enzyme would be subject to the condition, as prescribed in column 3 of the table, that the maximum permitted level or amount of the enzyme that may be present in the food must be consistent with GMP.

Item [3] would repeal the existing table item dealing with 'Uridine diphosphate (UDP) glucosyltransferases sourced from *Escherichia coli* BL21 containing the UDP glucosyltransferase gene from *Stevia rebaudiana*' and substitute the repealed item with two new items.

The new table items would consist of the following enzymes in column 1 of the table:

- Uridine diphosphate (UDP)-glucosyltransferases sourced from *Escherichia coli* BL21 containing the UDP-glucosyltransferase gene from *Solanum tuberosum*;
- Uridine diphosphate (UDP)-glucosyltransferases sourced from *Escherichia coli* BL21 containing the UDP-glucosyltransferase gene from *Stevia rebaudiana.*

The permitted technological purpose for each enzyme would be prescribed in column 2 of the table i.e. for the conversion of purified stevia leaf extract to produce Reb M or Reb D.

The permission for each enzyme would be subject to the condition, as prescribed in column 3 of the table, that the maximum permitted level or amount of the enzyme that may be present in the food must be consistent with GMP.

If the variation is approved, the effect of the amendments in **items [2]** and **[3]** would be that the listed enzymes would be permitted to be used as processing aids for the conversion of purified stevia leaf extract to produce Reb M or Reb D in accordance with the Code.

If the variation is approved, the overall effect of the variation would be to permit a steviol glycosides preparation containing Reb M or Reb D, which is produced by enzymatic conversion using enzymes derived from genetically modified strains of *Escherichia coli* BL21, to be used as a food additive in accordance with the Code.