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## Approval report – Application A1183

### Enzymatic production of rebaudioside E from stevia leaf extract

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by Blue California to seek approval for a new specification for the steviol glycoside rebaudioside E, produced by an enzymatic conversion method using an enzyme processing aid derived from a genetically modified strain of *Pichia pastoris*.

On 29 November 2019, FSANZ sought [submissions](#) on a draft variation and published an associated report. FSANZ received six submissions.

FSANZ approved the draft variation on **29 April 2020**. The Australia New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on **12 May 2020**.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

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**Supporting document**

The [following document](#) which informed the assessment of this Application is available on the FSANZ website:

SD1 Risk and technical assessment – Application A1183 – Enzymatic production of rebaudioside E from stevia leaf extract

## Executive summary

Steviol glycosides are currently permitted by the Australia New Zealand Food Standards Code (the Code) to be used in certain foods as food additives up to specified maximum permitted levels. They are used as an intense sweetener or flavour enhancer. Rebaudioside E is known as a 'minor' steviol glycoside as it is present in the stevia leaf at low levels compared to 'major' steviol glycosides.

Blue California submitted an application to amend the Code to include a new production method in Schedule 3 of the Code for rebaudioside E. The enzyme processing aid used in Blue California's enzymatic conversion method is already permitted by the Code to be used in the manufacture of rebaudioside M and rebaudioside D.

The new production method is based on an enzymatic conversion process using an enzyme processing aid derived from a genetically modified (GM) strain of *Pichia pastoris* (*P. pastoris*). The starting material is purified stevia leaf extract, produced from *Stevia rebaudiana* Bertoni (stevia) leaves using the traditional hot water extraction process. Blue California's product contains no less than 85% rebaudioside E and no less than 95% total steviol glycosides. This preparation is designated as high purity rebaudioside E ( $\geq 85\%$  rebaudioside E;  $\geq 95\%$  total steviol glycosides).

The enzymatic conversion method used by Blue California is technologically justified in that it yields a higher amount of rebaudioside E, compared to the low levels in the stevia leaf. Blue California claims that its high purity rebaudioside E preparation has preferential taste characteristics compared to preparations containing major individual steviol glycosides alone.

FSANZ carried out an assessment to determine whether there are any potential public health and safety concerns associated with Blue California's rebaudioside E preparation. This risk assessment did not identify any health or safety concerns.

After assessing the application, FSANZ prepared a draft variation.

The draft variation sought to amend the specification for steviol glycosides from *Stevia rebaudiana* Bertoni in section S3—35 of the Code to include the steviol glycoside rebaudioside E produced from enzymatic conversion, using a specific protein engineered enzyme derived from a GM strain of *P. pastoris*. The draft variation also sought to amend Schedule 18 to permit the use of the protein engineered enzyme, which contains two components: UDP-glucosyltransferase and sucrose synthase (EC 2.4.1.13), and is sourced from *P. pastoris*, as a processing aid - for the production of rebaudioside E.

The draft variation was released with a call for submissions and an assessment report for consultation from 29 November 2019 to 23 January 2020. Six submissions were received in response; five of which were fully supportive of the draft variation. One submitter made a number of comments, these comments have been addressed.

After having regard to these submissions and the requirements of the FSANZ Act, FSANZ approved the draft variation with one minor amendment. The draft variation was amended to remove a variation that had already been made to the Code.

The approved draft variation will allow the use of Blue California's high purity rebaudioside E preparation ( $\geq 85\%$  rebaudioside E;  $\geq 95\%$  total steviol glycosides) in accordance with the Code's existing permissions and limits for steviol glycosides.

# 1 Introduction

## 1.1 The Applicant

Blue California is a developer, producer and distributor of intense sweeteners, including steviol glycosides for the global food and beverage industry.

## 1.2 The Application

Blue California (the applicant) sought to amend the Australia New Zealand Food Standards Code (the Code) to permit an enzymatic conversion process to produce rebaudioside E. The production process results in a highly purified preparation containing no less than 85% rebaudioside E and no less than 95% total steviol glycosides. This preparation is designated as high purity rebaudioside E ( $\geq 85\%$  rebaudioside E;  $\geq 95\%$  total steviol glycosides). The enzymatic conversion process is enabled by a processing aid, designated as UGT-A<sup>1</sup>. UGT-A is a protein engineered enzyme that contains two plant enzymes expressed as a fusion protein, derived from a genetically modified (GM) strain of *Pichia pastoris* (*P. pastoris*). The plant enzymes include an uridine diphosphate (UDP)-glucosyltransferase and a sucrose synthase.

The current permission for rebaudioside E in the Code is for rebaudioside E isolated from *Stevia rebaudiana* Bertoni leaves by hot water extraction. Conversely, the applicant uses an enzymatic conversion method to produce a high purity rebaudioside E preparation, using purified stevia leaf extract as the starting material. Whilst the rebaudioside E produced using enzymatic conversion is identical to that produced by the plant, this production method for rebaudioside E has not previously been assessed by FSANZ. The production method has however been assessed for two other rebaudiosides, rebaudioside M and rebaudioside D, under applications A1157 and A1172 (FSANZ 2018, FSANZ 2019a, respectively).

The applicant did not request to change the purity specification ( $\geq 95\%$  steviol glycosides on a dried basis, under section S3—35 of the Code) or propose extending the use of rebaudioside E in additional food products. Nor did it propose to increase or alter the quantities of rebaudioside E in existing food products.

## 1.3 The current standard

### 1.3.1 Australia and New Zealand standards

Australian and New Zealand food laws require food for sale to comply with the following requirements of the Code, as relevant to this application.

#### 1.3.1.1 Food additives

Paragraph 1.1.1—10(6)(a) provides that, unless expressly permitted by the Code, a food for sale must not have, as an ingredient or component, a substance that is 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) – this includes a substance identified in the table to section S15—5 as a

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<sup>1</sup> UGT is an abbreviation of UDP-glucosyltransferase

permitted food additive or a permitted substance (food additive) listed in section S16—2, S16—3 or S16—4 of the Code.

Section 1.3.1—3 details when substances are permitted to be used as food additives in food.

Schedule 14 lists the permitted technological purposes of food additives. The table in section S14—2 provides that use as an intense sweetener is a permitted purpose.

Schedule 15 lists the specific food additive permissions for different categories of foods in the table to section S15—5. 'Steviol glycosides' is listed in that table as a permitted food additive for various food categories.

Schedule 16 sets out the types of substances that may be used as food additives in any food at Good Manufacturing Practice (GMP) levels. As 'steviol glycosides' is not a GMP food additive, it is not listed in Schedule 16.

### **1.3.1.2 Processing aids**

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

Section 1.1.2—13 defines the expression 'used as a processing aid'. A substance is 'used as a processing aid' if that substance:

- is used in the course of processing to perform a technological purpose in the course of processing; and
- does not perform a technological purpose in the food for sale; and
- is either a substance listed in Schedule 18 of the Code or an additive permitted at GMP.

Standard 1.3.3 sets out when substances may be used as processing aids with *any* foods and *specific* foods.

Schedule 18 lists permitted processing aids and any applicable conditions such as the substance's source, maximum permitted level and technological purpose(s).

Enzymes used in food processing and manufacturing are considered processing aids as although they may be present in the final food, they no longer perform a technological purpose in the final food. Specifically, 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.

### **1.3.1.3 Food produced using gene technology**

Paragraph 1.1.1—10(6)(g) requires that the presence of a food produced using gene technology as an ingredient or component in a food for sale must be expressly permitted by the Code.

Paragraph 1.5.2—3(b) of the Code provides that permission in the Code for a substance to be used as a food additive or processing aid also constitutes the permission required by paragraph 1.1.1—10(6)(g).

#### **1.3.1.4 Identity and purity requirements**

Paragraphs 1.1.1—15(1)(a) and (b) require substances used as food additives and processing aids respectively, to comply with any relevant identity and purity specifications listed in Schedule 3.

Section S3—35 of Schedule 3 provides a specification for steviol glycosides prepared from the leaves of *Stevia rebaudiana* Bertoni.

#### **1.3.1.5 Labelling requirements**

Paragraph 1.1.1—10(8) of the Code provides that the labelling of a food for sale must comply with all relevant labelling requirements imposed by the Code for that food.

The Code's labelling requirements which apply to foods for retail sale and to foods sold to a caterer are set out in Divisions 2 and 3 of Standard 1.2.1 respectively.

The Code requires the labels of most packaged food to contain a statement of ingredients. Subsection 1.2.4—7(1) requires food additives to be declared in the statement of ingredients by one of the following methods: if the food additive can be classified in accordance with Schedule 7—the relevant class name followed in brackets by the name or code number of the food additive specified in Schedule 8; or else, the name of the food additive specified in Schedule 8.

Schedule 7 lists the food additive class names that can be used in the statement of ingredients. Schedule 8 lists the names and code numbers of food additives that are to be used for labelling purposes.

Section 1.5.2—4 of Standard 1.5.2 outlines requirements for labelling of certain foods for sale that consist of or have as an ingredient, food that is a genetically modified food. For labelling purposes, *genetically modified food* is defined in subsection 1.5.2—4(5) as a *food produced using gene technology* that contains novel DNA or novel protein; or is listed in section S26—3.

### **1.3.2 International standards**

Steviol glycosides are approved for use in a number of other jurisdictions, including the European Union, Canada, United States of America (USA), South America, Asia, the Middle East and Africa (PureCircle Stevia Institute, 2019). The applicant's rebaudioside E preparation is considered Generally Recognised as Safe (GRAS) in the USA for use as a table top sweetener and as a general purpose non-nutritive sweetener in foods (USFDA 2019). Information regarding the USA, Canada and European Union regulations, and standards developed by the international bodies Joint FAO/WHO Expert Committee on Food Additives (JECFA) and Codex Alimentarius is provided below.

#### **1.3.2.1 Codex Alimentarius**

Codex Alimentarius is an international body, incorporating the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO), that sets international food standards. Codex Alimentarius has a General Standard for Food Additives (GSFA, CODEX STAN 192-1995) that contains provisions for food additives in various food categories (Codex 2019a). The GSFA contains permissions for the addition of steviol glycosides to a wide variety of food categories up to maximum permitted levels.

### **1.3.2.2 Joint FAO/WHO Expert Committee on Food Additives (JECFA)**

FAO JECFA Monograph 20 includes a specification for steviol glycosides obtained from a hot water extraction from the leaves of *S. rebaudiana* Bertoni ('Steviol glycosides from *Stevia rebaudiana* Bertoni') (JECFA 2017). This specification does not apply to steviol glycosides produced by enzymatic conversion. The specification includes a mixture of any of the steviol glycosides extracted from the stevia leaf rather than an earlier defined list of steviol glycosides. The purity of steviol glycosides from *S. rebaudiana* Bertoni must be no less than 95% total steviol glycosides on the dried basis.

JECFA considered specifications for steviol glycosides at their 87<sup>th</sup> meeting in June 2019. At the time of writing the call for submissions, the summary framework that had been adopted for developing specifications for steviol glycosides produced by four different methods, including enzyme modified steviol glycosides had been published (FAO/WHO 2019a). The full report from the 87<sup>th</sup> JECFA meeting has now been published (FAO/WHO 2019b). The specifications will be considered at the next Codex Committee on Food Additives (CCFA) meeting, after which they will be forwarded to the Codex Alimentarius Commission for adoption.

### **1.3.2.3 United States of America (USA)**

In the USA, there have been over 50 GRAS notifications relating to steviol glycosides submitted to the USA Food and Drug Administration (FDA) for review. GRN No. 823 relates to the same production method and preparation as this application. GRN No. 823 was submitted by the applicant in 2018 and the US FDA responded with 'no questions' to the GRAS status<sup>2</sup>. Therefore, the applicant's rebaudioside E is considered GRAS for use as a table top sweetener and as a general purpose non-nutritive sweetener in foods (USFDA 2019).

### **1.3.2.4 Canada**

In Canada, 'Steviol glycosides from *Stevia rebaudiana* Bertoni' are permitted in a variety of foods, provided they comply with the relevant international specifications for steviol glycosides (either JECFA or Food Chemicals Codex) and relevant conditions for use and requirements of the Food and Drug Act (Health Canada 2019).

### **1.3.2.5 European Union**

Steviol glycoside preparations are permitted as food additives in a variety of different food categories (European Commission 2011) provided they comply with the European Commission specifications for steviol glycosides (European Commission 2016). The specification applies only to steviol glycoside preparations extracted from the leaves of the *S. rebaudiana* Bertoni plant using hot water extraction methods.

## **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 FSANZ Act; and
- it related to a matter that warranted the variation of a food regulatory measure.

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<sup>2</sup> 'No questions' response means the FDA does not question the basis for the notifier's GRAS conclusion (USFDA 2016).

## 1.5 Procedure for assessment

The Application was assessed under the General Procedure.

## 1.6 Decision

The draft variation as proposed following assessment was approved with one consequential amendment as described below. The variation takes effect on gazettal. The approved draft variation is at Attachment A.

The draft variation proposed following assessment included a proposed amendment to the sweetness range in paragraph S3—35(4)(a) of the Code. The same amendment was included in the variation made and approved for A1176. As the A1176 amendment is now in force, there is no need for the A1183 variation to make the same amendment. Therefore, this amendment was removed from the A1183 variation. Further information is available in section 2.3.1

For information purposes, Attachment C contains the A1183 draft variation which had been the subject of the call for submissions report.

The related 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.

## 2 Summary of the findings

### 2.1 Summary of issues raised in submissions

FSANZ sought public comments on the draft variation included in the call for submissions report between 29 November 2019 and 23 January 2020.<sup>3</sup>

FSANZ received six submissions from government agencies and industry groups. Issues raised in three submissions have been addressed in Table 1 below. Supportive submissions that did not raise any issues were received from one government agency and two industry associations.

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<sup>3</sup> These submissions are on the FSANZ website at [A1183 - Enzymatic production of rebaudioside E](#)



**Table 1: Summary of issues raised in submissions**

Issue	Raised by	FSANZ response
<p>Note from the Call for Submissions that the use of enzymatic conversion methods for steviol glycosides are not approved in Canada or Europe. The consideration of international standards is important when assessing Applications of this type, and FSANZ should have included information as to why these methods are not approved in those jurisdictions.</p>	<p>Victoria Department of Health and Human Services and the Victorian Department of Jobs, Precincts and Regions</p>	<p>FSANZ had regard to international standards in assessing this application and the draft variation. See sections 1.3.2 and 2.5.3.</p> <p>Enzymatic conversion is a newer method of production. As such, it is yet to be incorporated into the JECFA specification (refer section 1.3.2.2). This is also reflected in the fact that it has been considered and approved in some countries and not others. As stated in section 1.3.2, the applicant's product and method has been approved in the United States</p> <p>FSANZ conducted an independent risk assessment which did not identify any potential public health and safety concerns with the product. (see section 2.2). This assessment and conclusion were based on the best available scientific evidence (see section 2.5.3 and SD1).</p> <p>FSANZ is not aware of any evidence that the use of enzymatic conversion methods for steviol glycosides, including the method which is the subject of this application, has been rejected or prohibited overseas on the ground of public health and safety.</p> <p>Other reasons exist for differences between jurisdictions in terms of approved food additives. These include:</p> <ul style="list-style-type: none"> <li>• local market needs</li> <li>• regulatory approval processes (legislation, policies and timeframes)</li> <li>• when applications are submitted to national food authorities for assessment.</li> </ul>
<p>The departments note the previously raised concerns about FSANZ's decision to delay the use of a numbering system to distinguish steviol glycosides from different sources, and different technologies in</p>	<p>Victoria Department of Health and Human Services and the Victorian Department of Jobs, Precincts and Regions</p>	<p>An INS (international numbering system) number for steviol glycosides produced by an enzymatic conversion process has not yet been incorporated into the Codex Alimentarius Guideline <i>International Numbering System for Food Additives (INS)</i>. FSANZ</p>

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Issue	Raised by	FSANZ response
<p>the responses to Application A1172<sup>4</sup>. Codex Alimentarius has already adopted a classification system to distinguish steviol glycosides from fermentation through the INS number, 960b. The Codex's labelling approach enables the source identification of steviol glycosides and enforcement of any applicable consumer laws that might refer to 'natural' or leaf extracts. The departments recommend that FSANZ should more rapidly adopt this classification system to distinguish steviol glycosides and align with international approaches.</p>		<p>cannot include an INS number in the Code specifically for steviol glycosides produced via that method of production until the INS number is available. As noted in response to submitter comments in previous similar applications, FSANZ will consider changes to the INS names and numbers in the Code for different production methods of steviol glycosides in the future, if further changes are made to the INS list. Further information is in section 2.3.3.1 of this report.</p>
<p>It is also noted that an acceptable daily intake (ADI) of 0-4 mg/kg bodyweight for steviol glycosides was established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 2009 and re-confirmed in 2016. Similar ADI for steviol glycosides was established by FSANZ in 2008. Over last few years, FSANZ has approved several applications for steviol glycosides but ADI data and permissions were not reviewed.</p> <p>Before further progressing the Application A1183, the departments would like FSANZ to provide details of FSANZ's plan (if available) to review the ADI data and permissions for steviol glycosides.</p>	<p>Victoria Department of Health and Human Services and the Victorian Department of Jobs, Precincts and Regions</p>	<p>FSANZ in conjunction with New Zealand Food Safety are undertaking a review of intense sweeteners permitted in the Code. Preliminary research and risk assessments have eliminated the need for further detailed work for the majority of the sweeteners. Further work was only identified for steviol glycosides. The next phase of the project will include an analytical survey of food products containing steviol glycosides. The aim of this survey is to obtain accurate concentration data in products available for purchase by consumers so that refinements can be made to dietary exposure assessments that are undertaken in the future.</p> <p>The submitters statement relating to the ADI data and permissions is not correct. For all steviol glycoside applications, FSANZ has reviewed and summarised all new relevant studies provided by the applicant, as well as any new studies that FSANZ has identified in our own literature review. This is stated in the SD1 for each application. FSANZ continues to accept the JECFA ADI, because despite our regular literature review and assessment, FSANZ has yet to locate any evidence that would warrant the ADI being revised.</p>
<p>In relation to the INS numbers for labelling purposes, NZFGC noted</p>	<p>New Zealand Food and Grocery Council</p>	<p>As noted in the A1170 and A1176 Approval Reports, FSANZ</p>

<sup>4</sup> The Approval Report for Application A1172 is available at [A1172 – Enzymatic production of Rebaudioside D](#).

Issue	Raised by	FSANZ response
they had previously suggested that there be an administrative limit set after which the Code should be amended to reflect the novel production methods available at that time <sup>5</sup> . This would give assurance about future transparency in the food supply.	(NZFGC)	understands NZFGC's suggestion and desire to ensure transparency. However, FSANZ considers it is appropriate to wait until further consideration by Codex regarding steviol glycosides before considering making changes to the Code.
<p>The NZBC indicated its strong support, with the following comments<sup>6</sup>:</p> <p>(i) The inclusion of this rebaudioside E within the category of currently permitted foods was supported, as well as foods that will be permitted in the future.</p> <p>Omissions of permissions in any one non-alcoholic beverage class (as per A1149) would need to be avoided.</p> <p>(ii) It was noted that although the rebaudioside E would not require labelling as 'genetically modified', 'GMO free' claims or claims of similar meaning on products using rebaudioside E produced by this method would be inappropriate.</p>	New Zealand Beverage Council	<p>In response to the NZBC comments, FSANZ noted that:</p> <p>(i) Permission for rebaudioside E in any food categories in the future would be subject to the standard pre-market assessment and approval process undertaken by FSANZ.</p> <p>All of the existing permissions for use of steviol glycosides in Schedule 15 of the Code also cover the rebaudioside E that is the subject of this application.</p> <p>(ii) The Code does not regulate 'GMO free' claims or claims of similar meaning. These types of representations are voluntary and are subject to fair trading laws and food acts in Australia and New Zealand, which prohibit representations about food that are, or are likely to be, false, misleading or deceptive.</p>

## 2.2 Risk assessment

FSANZ conducted an assessment to determine whether there were any potential public health and safety concerns associated with the applicant's high purity rebaudioside E preparation ( $\geq 85\%$  rebaudioside E;  $\geq 95\%$  total steviol glycosides), produced using the specified enzyme processing aid (see SD1).

The enzyme processing aid UGT-A has previously been assessed and approved under application A1157 (FSANZ 2018).

An acceptable daily intake (ADI) of 0-4 mg/kg bodyweight for steviol glycosides, expressed as steviol, was established by FSANZ in 2008 and JECFA in 2009, and confirmed at their 82nd meeting in 2016. This ADI is appropriate for rebaudioside E produced using enzymes from GM *P. pastoris* as it is chemically the same as rebaudioside E extracted traditionally from *Stevia rebaudiana* Bertoni and would therefore follow the same metabolic pathway in humans. Toxicological and other relevant data published subsequent to FSANZ's previous assessments of steviol glycosides raised no concerns regarding the safety of steviol glycosides and did not indicate a need to amend the ADI.

FSANZ is aware that a number of research papers have reported on possible links between

<sup>5</sup> FSANZ notes this was suggested in responses to Application A1170 and A1176.

<sup>6</sup> FSANZ notes these comments were also made by the NZBC in responses to A1170, A1172 and A1176.

consumption of intense sweeteners and unwanted metabolic effects resulting in weight gain, but considers that the current weight of evidence does not support a causal relationship. FSANZ will continue to monitor the emerging scientific literature in this area.

The applicant has not requested a change to the foods permitted to contain steviol glycosides as a food additive nor did they propose to increase the maximum permitted levels of steviol glycosides in foods. FSANZ has previously conducted a dietary exposure assessment using the current permissions to use steviol glycosides as a food additive and therefore no dietary exposure assessment was necessary for this application.

In conclusion, FSANZ's risk assessment did not identify any safety concerns associated with the applicant's high purity rebaudioside E preparation ( $\geq 85\%$  rebaudioside E;  $\geq 95\%$  total steviol glycosides), produced using the enzyme processing aid UGT-A.

## 2.3 Risk management

### 2.3.1 Specification for steviol glycosides

The risk management options available to FSANZ, after assessment, were to reject the application or to prepare a draft variation to amend the Code to permit the applicant's rebaudioside E preparation for use as a food additive at levels and in food classes currently permitted in the Code for steviol glycosides.

Based on the conclusion above, that there are no public health and safety concerns, and on supporting submitter comments and other considerations detailed in section 2.5 below, amendments to the specification for steviol glycosides from *Stevia rebaudiana* Bertoni (section S3—35 of the Code) to include rebaudioside E produced by an enzymatic conversion method using a specific enzyme processing aid derived from a GM strain of *P. pastoris* were considered appropriate.

Amending the steviol glycoside specification ensures rebaudioside E produced by enzymatic conversion has the same permissions for use as a food additive as other steviol glycosides already included in specifications in the Code. The new specification refers to the production of rebaudioside E via enzymatic conversion. It was not necessary to add a new specification for the approximately 10% of other steviol glycosides contained in the applicant's rebaudioside E preparation, as they are consistent with section S3—35 of the Code.

The sweetness equivalency to sucrose of the applicant's high purity rebaudioside E product ( $\geq 85\%$  rebaudioside E;  $\geq 95\%$  steviol glycosides) was reported in the application to be 137 times sweeter than sucrose upon evaluation by a sensory panel. The applicant provided additional information, which showed that the sweetness is approximately 179 times sweeter than sucrose. Paragraph S3—35(4)(a) of the Code (at the time following assessment of A1183) described the sweetness level for steviol glycosides as 'approximately 200 to 300 times sweeter than sucrose'. Therefore, following assessment and for the purposes of A1183, FSANZ proposed to amend paragraph S3—35(4)(a) to refer to the sweetness level for steviol glycosides as 'approximately 150 to 300 times sweeter than sucrose'.

However, since the A1183 call for submissions, the A1176 variation has been gazetted (on 26 February 2020) and came into force, amending (among other things) the sweetness potency in paragraph S3—35(4)(a) of the Code to 'approximately 150 to 300 times as sweet as sucrose' (FSANZ 2019b). Consequently, the amendment to paragraph S3—35(4)(a) of the Code proposed for the purposes of A1183 is no longer required, and a consequential change to the A1183 draft variation has been made (see Attachment A).

### 2.3.2 Enzyme processing aids

It was also considered appropriate to propose an amendment to Schedule 18 to extend the use of the protein engineered enzyme UGT-A sourced from a GM strain of *P. pastoris* to include production of rebaudioside E. This will ensure compliance with the Code in regard to the use of the processing aid, and the very low possibility of the processing aid being present in the final rebaudioside E preparation.

This express permission for the enzyme's use as a processing aid will also provide the permission for the potential presence in the rebaudioside E steviol glycoside preparation as a food produced using gene technology. FSANZ considers the processing aid is a food produced using gene technology for Code purposes as it is derived from 'an organism that has been modified using gene technology' (i.e. GM microorganisms).

### 2.3.3 Labelling considerations

#### 2.3.3.1 Ingredient labelling

Under existing labelling requirements in the Code (unless the food is exempt from the requirement for a statement of ingredients) the applicant's rebaudioside E preparation will require declaration as a food additive in the statement of ingredients on the label of foods. These ingredient labelling requirements require steviol glycosides to be identified in the statement of ingredients using the food additive name 'steviol glycosides' or the International Numbering System (INS) code number 960 (as listed in Schedule 8).

The Codex Committee on Food Additives (CCFA) at its 50th Session (March 2018) updated the INS numbers for steviol glycosides, which were subsequently adopted into the Class Names and International Numbering System for Food Additives (CXG 36-1989) by the Codex Alimentarius Commission (Codex 2019b). The new numbers distinguish between steviol glycosides produced from the plant (Steviol glycosides from *Stevia rebaudiana* Bertoni – INS 960a) and those produced by fermentation (INS 960b). As CCFA has not completed its work on the production method described in this application, a new INS number is not assigned at the present time.

When considering A1170, A1172 and A1176, FSANZ decided not to include 960a and 960b in the Code at that stage for various reasons (FSANZ 2019c, FSANZ 2019a, FSANZ 2019b). These reasons included the desire to provide a more coordinated approach and efficient transition for the labelling of steviol glycosides produced by all new novel methods of production compared to an unsystematic or ad-hoc approach for individual methods of production through various applications. This also maintains a level playing field for suppliers of steviol glycosides or for manufacturers of foods containing steviol glycosides produced using novel production methods, given INS numbers are not available for all methods.

For these reasons, FSANZ considers that the most appropriate INS number for labelling purposes, for all steviol glycosides at this stage, is 960. FSANZ will consider changes to this INS number in the future, if further changes are made to the INS list.

The FSANZ website has been updated to provide information on the new production methods for steviol glycosides.<sup>7</sup> Consumers wanting to know the source of any particular steviol glycosides in foods are advised that they may ask the manufacturer who should advise them accordingly.

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<sup>7</sup> [https://www.foodstandards.gov.au/consumer/additives/Pages/Steviol-glycosides-\(960\)-\(intense-sweetener\).aspx](https://www.foodstandards.gov.au/consumer/additives/Pages/Steviol-glycosides-(960)-(intense-sweetener).aspx)

In terms of the enzymes used as processing aids, paragraphs 1.2.4—3(2)(d) and (e) of the Code exempts processing aids from the requirement to be declared in the statement of ingredients. This exemption will apply to the processing aid UGT-A sought to be permitted by this application.

### **2.3.3.2 Labelling as ‘genetically modified’**

Section 1.5.2—4 of the Code requires certain foods for sale that consist of or have as an ingredient, food that is genetically modified to be labelled with the statement ‘genetically modified’. The Code’s labelling requirements imposed by section 1.5.2—4 apply to foods for retail sale and to foods sold to a caterer under subsection 1.2.1—8(1) and section 1.2.1—15 respectively.

FSANZ’s assessment is that Blue California’s rebaudioside E preparation is not a food produced using gene technology as it is not derived from an organism that has been modified using gene technology. This is in contrast to the enzyme processing aid used for its manufacture, which is a food produced using gene technology for Code purposes. As such, Blue California’s rebaudioside E preparation does not require labelling as ‘genetically modified’.

The enzyme used as a processing aid to manufacture Blue California’s rebaudioside E preparation is highly unlikely to be present as an ingredient in food for sale which contains this preparation. Furthermore, it is understood that the rebaudioside E preparation itself would not be sold for retail sale or to a caterer because it is a highly concentrated intense sweetener. As such, it is likely that the requirement to label the processing aid as ‘genetically modified’ would not apply to a food for sale that contains the rebaudioside E preparation because the labelling requirements only apply to food that consists of, or has as an ingredient, a genetically modified food under section 1.5.2—4.

### **2.3.4 Risk management conclusion**

Taking account of the risk assessment conclusions in section 2.2, the risk management considerations in section 2.3, and other considerations outlined in section 2.5 below, the risk management conclusion is to permit the applicant’s method of producing high purity rebaudioside E preparation ( $\geq 85\%$  rebaudioside E;  $\geq 95\%$  total steviol glycosides), i.e. rebaudioside E produced by an enzymatic conversion method using a specific enzymatic processing aid derived from a GM strain of *P. pastoris*.

Although it is FSANZ’s assessment that the protein engineered enzyme proposed to be used as a processing aid (containing a UDP-glucosyltransferase and a sucrose synthase (EC 2.4.1.13)) to produce rebaudioside E is highly unlikely to be present as an ingredient in food for sale, the enzyme will also be listed in the table to subsection S18—9(3). Listing of the enzyme in that table will permit the enzyme to be used as proposed, even if the enzyme is present as a component in the food for sale. The permission is already in place for the enzymatic production of rebaudioside D and is one of the processing aids required for the enzymatic production of rebaudioside M. The A1183 draft variation was drafted subject to proposed amendments by A1176 to section S3—35. A1176 was gazetted on 26 February 2020.

## **2.4 Risk communication**

### **2.4.1 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 Food Standards Notification Circular, media release, FSANZ's social media tools and Food Standards News.

The process by which FSANZ considers standards development matters is open, accountable, consultative and transparent. Public submissions were called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application. All comments are valued and contribute to the rigour of our assessment.

The draft variation was considered for approval by the FSANZ Board having regard to public comments received from the call for submissions.

## **2.5 FSANZ Act assessment requirements**

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

### **2.5.1 Section 29**

#### **2.5.1.1 Consideration of costs and benefits**

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulation Impact Statement for the approval of additional processing aids or food additives (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting additional processing aids or food additives is a minor, deregulatory change and their use is voluntary. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

FSANZ, however, had regard to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act requirements. The FSANZ Act requires FSANZ to have 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 (paragraph 29(2)(a)).

The purpose of this consideration was to determine if the community, government and industry as a whole is likely to benefit, on balance, from a move from the status quo. This analysis involved consideration of whether to approve or reject the application (retain the status quo). In particular, this analysis involved consideration of whether to amend the Code to permit as a food additive, a steviol glycoside preparation containing rebaudioside E produced using a new conversion method, i.e. an enzymatic conversion method using a specific processing aid (in accordance with the existing relevant permissions in the Code for steviol glycosides).

The consideration of the costs and benefits in this section were not intended to be an exhaustive, quantitative economic analysis of the proposed measure and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment sought to highlight the likely positives and negatives of moving away from the status quo by amending the Code as requested.

FSANZ's conclusions regarding costs and benefits of the proposed measure are set out below.

*Costs and benefits of including a new specification for rebaudioside E produced by an enzymatic conversion method using a specific processing aid*

Steviol glycosides, in general, can be used as intense sweeteners in reduced energy and no-added sugar products.

The applicant may have an advantage over other intense sweetener manufacturing businesses from this voluntary permission. The applicant agreed with FSANZ and acknowledged in correspondence after submitting its application that there is an exclusive capturable commercial benefit. The impact on other competing Australia-New Zealand manufacturers is unknown.

The applicant and down-stream retailers may reduce prices for the consumer in some existing products containing the food additive in this application, where there are cost savings from using it. Due to the voluntary nature of the permission, the applicant will only produce, and downstream retailers will only use, the food additive (prepared using the specific enzyme processing aid) where they believe a net benefit exists. There are other methods available to produce steviol glycosides and steviol glycosides of other sweetness profiles are available.

There may also be greater substitution from products containing sugar or other sweeteners that have a less attractive taste, to products containing the steviol glycosides the subject of this application. That may increase the quality and choice of food products available to consumers.

The greater choice for consumers (highlighted above) may allow them to further maximise their purchasing options by choosing a food or drink they may prefer, including more choice of food or drink with reduced energy content. It may also result in some products becoming cheaper.

Permitting the food additive and associated enzyme processing aid may result in a small cost to government in terms of adding these to the current range of food additives and processing aids that are monitored for compliance.

*Conclusions from cost benefit considerations*

FSANZ's assessment was that the direct and indirect benefits that would arise from permitting the use of the food additive and enzyme processing aid in question most likely outweigh the associated costs.

**2.5.1.2 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.

**2.5.1.3 Any relevant New Zealand standards**

The Standards and Schedules relevant to the draft variation apply in both Australia and New Zealand. There are no relevant New Zealand only Standards.

**2.5.1.4 Any other relevant matters**

Other relevant matters are considered below.



## 2.5.2 Subsection 18(1)

FSANZ has also had regard to the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

### 2.5.2.1 *Protection of public health and safety*

FSANZ concluded that there are no public health and safety concerns associated with the use of the high purity rebaudioside E preparation ( $\geq 85\%$  rebaudioside E;  $\geq 95\%$  steviol glycosides) produced by an enzymatic conversion method using a processing aid (a protein engineered enzyme that contains both uridine diphosphate (UDP) glucosyltransferase, and sucrose synthase (EC 2.4.1.13)); derived from a genetically modified strain of *P. pastoris*. For further detail refer to section 2.2 above and SD1.

### 2.5.2.2 *The provision of adequate information relating to food to enable consumers to make informed choices*

The generic labelling requirements will apply when these steviol glycoside preparations are added to food as an ingredient (see section 2.3.3 above).

### 2.5.2.3 *The prevention of misleading or deceptive conduct*

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

## 2.5.3 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 used the best available scientific evidence to conduct the risk assessment which is provided in SD1. The applicant submitted a dossier of scientific studies as part of the application. Other technical information including scientific literature was also identified and used by FSANZ in assessing the application.

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

A number of international jurisdictions and standards permit the use of steviol glycosides in foods, the majority of which relate to steviol glycosides extracted directly from stevia leaves rather than by enzymatic conversion. As outlined in section 1.3.2.2, JECFA recently adopted a framework for developing specifications for steviol glycosides by four different methods of production, including enzyme modified steviol glycosides (FAO/WHO 2019a), and has published draft specifications for consideration by the CCFA (FAO/WHO 2010b).

The applicant's rebaudioside E is permitted for use in the USA.

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

Permission to use this particular rebaudioside E preparation as a food additive will provide additional choice to Australian and New Zealand food manufacturers, enabling access to an intense sweetener with preferential taste characteristics compared to preparations containing major individual steviol glycosides alone.

- **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 Forum on Food Regulation**

The Policy Guideline ‘Addition to Food of Substances other than Vitamins and Minerals’<sup>8</sup> includes specific order policy principles for substances added to achieve a solely technological function, such as food additives. 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
- 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 has determined that the addition of the applicant’s rebaudioside E preparation to food would be consistent with these specific order policy principles.

## 4 References

Codex 2019a, General Standard for Food Additives,  
<http://www.fao.org/gsfaonline/index.html;jsessionid=64CA5BB29D301405C4DD6FA3239EA22D>  
Accessed 7 October 2019

Codex 2019b, CXG 36-1989, Class Names and the International Numbering System for Food Additives <http://www.fao.org/fao-who-codexalimentarius/codex-texts/guidelines/en/> Accessed 7 October 2019

European Commission 2011, Commission Regulation (EU) No 1131/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council with regard to steviol glycosides. Available at <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R1131&from=EN> Accessed 7 October 2019

European Commission 2016, Commission Regulation (EU) 2016/1814 of 13 October 2016 amending the Annex to Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards specifications for steviol glycosides (E 960). Off J Eur Union 59(L278):37-41. Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1570415600099&uri=CELEX:32016R1814> Accessed 7 October 2019

FAO/WHO (2019a) Joint FAO/WHO Expert Committee on Food Additives, Eighty-seventh meeting, Rom, 4-13 June 201. Summary and Conclusions. Available at [https://www.who.int/foodsafety/areas\\_work/chemical-risks/JECFA87\\_Summary\\_Report.pdf?ua=1](https://www.who.int/foodsafety/areas_work/chemical-risks/JECFA87_Summary_Report.pdf?ua=1) Accessed 7 October 2019

FAO/WHO (2019b) Joint FAO/WHO Expert Committee on Food Additives. (2019) . Evaluation of certain food additives: eighty-seventh report of the Joint FAO/WHO Expert Committee on Food Additives. World Health Organization. Available at <https://apps.who.int/iris/handle/10665/330612> Accessed 19 February 2020

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<sup>8</sup> <http://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Addition-of-Substances-other-than-Vitamins-and-Minerals>

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FSANZ (2018) Application A1157 [Enzymatic production of rebaudioside M](#). Food Standards Australia New Zealand, Canberra.

FSANZ (2019a) Application A1172 [Enzymatic production of rebaudioside D](#). Food Standards Australia New Zealand, Canberra.

FSANZ (2019b) Application A1176 [Enzymatic production of steviol glycosides](#). Food Standards Australia New Zealand, Canberra.

FSANZ (2019c) Application A1170 [Rebaudioside MD as a steviol glycoside from \*Saccharomyces cerevisiae\*](#). Food Standards Australia New Zealand, Canberra.

Health Canada 2019, 9. List of Permitted Sweeteners (Lists of Permitted Food Additives). Available at <https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/9-sweeteners.html> Accessed 7 October 2019

JECFA (2017). Steviol glycosides from *Stevia rebaudiana Bertoni* [New specifications prepared at the 84th JECFA, 2017), Superseding tentative specifications prepared at the 82nd JECFA (2016)]. In: *Compendium of Food Additive Specifications*. 84th Meeting, Rome, 6-15 June 2017 (FAO JECFA Monographs 20). Rome, Italy: Food and Agriculture Organization of the United Nations (FAO) /Geneva, Switz.: World Health Organization (WHO), pp. 50-69. Available at: <http://www.fao.org/documents/card/en/c/4b06cdda-3e70-4c80-b7e5-56034601836b/> Accessed 7 October 2019

PureCircle Stevia Institute 2019, Map Infographic Where in the World is Stevia Approved? <https://www.purecirclestevia.com/resources/infographics/map-infographic> Accessed 7 October 2019

USFDA (2016) [About the GRAS Notification Program](#), October 2016. Accessed 7 October 2019.

USFDA (2019). GRAS Notices Inventory. Washington (DC): U.S. Food and Drug Administration (U.S. FDA). Available at: <https://www.accessdata.fda.gov/scripts/fdcc/index.cfm?set=GRASNotices> Accessed 7 October 2019

## Attachments

- A. Approved draft variations to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement
- C. Draft variations to the *Australia New Zealand Food Standards Code* (call for submissions)

## Attachment A – Approved draft variations to the *Australia New Zealand Food Standards Code*



### Food Standards (Application A1183 – Enzymatic production of Rebaudioside E) 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 Delegate]

[Insert name and title 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 A1183 – Enzymatic production of Rebaudioside E) 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**

**[1] Schedule 3** is varied by omitting subparagraph S3—35(2)(d)(iii), substituting

- (iii) a sucrose synthase (EC 2.4.1.13) sourced from *Escherichia coli*;
- (e) by enzymatic conversion of purified stevia leaf extract to produce rebaudioside E using a protein engineered enzyme that:
  - (i) contains both of the following components:
    - (A) UDP-glucosyltransferase; and
    - (B) sucrose synthase (EC 2.4.1.13); and
  - (ii) is sourced from *Pichia pastoris* strain UGT-A.

**[2] Schedule 18** is varied by inserting in the table to subsection S18—9(3), in alphabetical order

Protein engineered enzyme that:	For the conversion of purified stevia leaf	GMP
(a) contains both of the following components -	extract to produce rebaudioside E.	
(i) UDP-glucosyltransferase;		
and		
(ii) sucrose synthase (EC		
2.4.1.13); and		
(b) is sourced from <i>Pichia pastoris</i>		
strain UGT-A.		

## Attachment B – 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 A1183 which seeks approval for a new specification for the steviol glycoside rebaudioside E produced by an enzymatic conversion method using a processing aid derived from a genetically modified strain of *Pichia pastoris*. 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 standard, or 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 Authority has approved a draft variation to:

- a. permit steviol glycoside preparations containing rebaudioside E produced by the new enzymatic conversion method to be used as a food additive in accordance with the existing permissions and limits for steviol glycosides in the Code; and
- b. permit a particular substance to be used as a processing aid in the manufacture of the A1183 applicant's rebaudioside E preparation in accordance with Standard 1.3.3 of the Code.

### 3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

### 4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1183 included one round of public consultation following an assessment and the preparation of a draft variation and associated report.

A Regulation Impact Statement was not required because the proposed variations to Schedules 3 and 18 are likely to have a minor impact on business and individuals (OBPR

reference 12065).

## 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 Item [1]

**Item [1]** amends section S3—35 of the Code which sets out the specification for steviol glycosides from *Stevia rebaudiana* Bertoni.

In particular, subsection S3—35(2) is amended by omitting subparagraph S3—35(2)(d)(iii) and inserting in its place amended subparagraph S3—35(2)(d)(iii) and new paragraph S3—35(2)(e).

Paragraph S3—35(2)(d) was inserted into the Code by the variation for Application A1176, which came into force on 26 February 2020. The amendment made by **item [1]** changes the punctuation at the end of that paragraph to reflect the addition of new paragraph S3—35(2)(e).

New paragraph S3—35(2)(e) specifies the following process by which a steviol glycosides preparation can be obtained from the leaves of the *Stevia rebaudiana* Bertoni plant—the enzymatic conversion of purified stevia leaf extract to produce rebaudioside E using a protein engineered enzyme that: contains both uridine diphosphate (UDP) glucosyltransferase and sucrose synthase (EC 2.4.1.13); and is sourced from *Pichia pastoris* (strain UGT-A).

### 6.2 Item [2]

**Item [2]** amends Schedule 18 by inserting a new entry into the table to subsection S18—9(3). This table lists permitted substances that may be used as processing aids for specific technological purposes.

The new entry lists a protein engineered enzyme containing both of the following components: UDP-glucosyltransferase and sucrose synthase (EC 2.4.1.13); and which is sourced from *Pichia pastoris* strain UGT-A.

The specified technological purpose for this protein engineered enzyme processing aid is the conversion of purified stevia leaf extract to produce rebaudioside E.

The maximum permitted level at which the enzyme may be present in food must be consistent with Good Manufacturing Practice (as defined by section 1.1.2—2(3) of the Code).

The cumulative effect of the amendments in items **[1]** and **[2]** above is to permit the following substance to be used as a food additive (in accordance with the existing relevant permissions in the Code): a steviol glycoside preparation containing rebaudioside E produced by the enzymatic conversion of purified stevia leaf extract using the above protein engineered enzyme as a processing aid.

## Attachment C – Draft variations to the *Australia New Zealand Food Standards Code* (call for submissions)



### Food Standards (Application A1183 – Enzymatic production of Rebaudioside E) 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 Delegate]

[Insert name and title 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.



Schedule

**1 Name**

This instrument is the *Food Standards (Application A1183 – Enzymatic production of Rebaudioside E) 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

**[1] Schedule 3** is varied by

[1.1] omitting subparagraph S3—35(2)(d)(iii), substituting

- (iii) a sucrose synthase (EC 2.4.1.13) sourced from *Escherichia coli*;
- (e) by enzymatic conversion of purified stevia leaf extract to produce rebaudioside E using a protein engineered enzyme that:
  - (i) contains both of the following components:
    - (A) UDP-glucosyltransferase; and
    - (B) sucrose synthase (EC 2.4.1.13); and
  - (ii) is sourced from *Pichia pastoris* strain UGT-A.

[1.2] omitting paragraph S3—35(4)(a), substituting

- (a) Description—white to light yellow powder, approximately 150 to 300 times sweeter than sucrose;

**[2] Schedule 18** is varied by inserting in the table to subsection S18—9(3), in alphabetical order

Protein engineered enzyme that:	For the conversion of purified stevia leaf	GMP
(a) contains both of the following components -	extract to produce rebaudioside E.	
(i) UDP-glucosyltransferase;		
and		
(ii) sucrose synthase (EC		
2.4.1.13); and		
(b) is sourced from <i>Pichia pastoris</i>		
strain UGT-A.		