

**12 February 2019**  
**[73–19]**

## **Call for submissions – Application A1172**

### **Enzymatic production of rebaudioside D**

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FSANZ has assessed an application made by SweeGen, Inc. to amend the Australia New Zealand Food Standards Code (the Code) to include a new specification for rebaudioside D (Reb D) produced by an enzymatic conversion method 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.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that that we accept as confidential, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

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 [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to [submissions@foodstandards.gov.au](mailto:submissions@foodstandards.gov.au).

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

### **DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 26 March 2019**

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.

Questions about making submissions or the application process can be sent to [standards.management@foodstandards.gov.au](mailto:standards.management@foodstandards.gov.au).

Hard copy submissions may be sent to one of the following addresses:

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### Supporting document

The [following document](#)<sup>1</sup> which informed the assessment of this application is available on the FSANZ website:

SD1        Risk and technical assessment report

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<http://www.foodstandards.gov.au/code/applications/Pages/A1172EnzymaticproductionofRebaudiosideD.aspx>

## Executive summary

The SweeGen, Inc. application seeks to add permission in the Australia New Zealand Food Standards Code (the Code) for a rebaudioside D (Reb D) produced by a novel production method. The method is based on an enzymatic conversion process using an enzyme processing aid (UGT-A) sourced from a genetically modified (GM) strain of *Pichia pastoris*.

The Code permits the use of Reb D and other steviol glycosides as food additives in various food categories subject to prescribed limits and also imposes identity and purity specifications with which Reb D and other steviol glycosides must comply. These current specifications do not allow for SweeGen's production method.

SweeGen's application seeks to amend Schedule 3 – Identity and Purity to include a reference to this new production method. This will allow the use of SweeGen's Reb D in accordance with the Code's existing permissions and limits for currently permitted steviol glycosides.

FSANZ's risk assessment—based on the best available scientific evidence—confirmed that neither SweeGen's Reb D nor the enzyme used to manufacture that Reb D posed a public health and safety risk. The risk assessment also found that the use of the enzyme to manufacture the Reb D in the way proposed by SweeGen (i.e. as a processing aid) is technologically justified.

FSANZ has therefore prepared a draft variation to amend Schedule 3 to include a reference to the production method for SweeGen's Reb D in the specifications for steviol glycosides. The draft variation will also amend Schedule 18 to permit the use of the enzyme as a processing aid in the manufacture of that Reb D, ensuring compliance with the Code.

The express permission for the enzyme's use as a processing aid will also provide the required permission for the enzyme's potential presence in the Reb D as a food produced using gene technology. The enzyme is a food produced using gene technology for Code purposes as it is derived from 'an organism that has been modified using gene technology'.

# 1 Introduction

## 1.1 The applicant

SweeGen, Inc. is a science-based developer, producer, and distributor of non-caloric sweeteners for the food, flavour and beverage industries. The applicant has indicated that all rights of Blue California (the applicant for A1157, being a comparable application) have been granted to SweeGen, Inc. in relation to steviol glycosides.

## 1.2 The application

This application is very similar to application A1157 which sought a new production method to produce rebaudioside M<sup>2</sup>. However, this application uses the same production method to produce rebaudioside D (Reb D).

The application seeks to change the Code to permit an alternative production method for the food additive, Reb D, a type of steviol glycoside. Steviol glycosides are traditionally produced using hot water extraction of the *Stevia rebaudiana* Bertoni (stevia) leaf, followed by purification and recrystallisation using methanol or ethanol. In this application, SweeGen uses the enzyme processing aid UGT-A, previously assessed and approved in A1157, to convert stevia extract into Reb D.

The Code currently permits the use of steviol glycosides as food additives with the INS number 960. They are permitted in a wide range of food classes listed in the table to section S15—5 at maximum permitted levels (MPLs), and at Good Manufacturing Practice (GMP) for tabletop sweeteners only.

However, the current specifications for identity and purity do not allow for SweeGen's production method. SweeGen has not asked to change the purity specification or proposed extending the use of Reb D in additional food products. Nor has it proposed to increase or alter the permitted quantities of Reb D in permitted food products.

Current permissions for steviol glycosides in the Code and international permissions for SweeGen's Reb D are provided below.

## 1.3 The current 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.

### *Permitted use*

Subsection 1.1.1—10(6) 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'; a substance that was 'used as a processing aid'; or a food produced using gene technology'.

### *Food additives*

Section 1.3.1—3 of the Code details which substances are permitted to be used as a food additive for the purposes of the Code. The permitted food additives for different food categories are listed in the table to section S15—5 of the Code.

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<sup>2</sup> <http://www.foodstandards.gov.au/code/applications/Pages/A1157-EnzymaticproductionofRebaudiosideM.aspx>

Section 1.1.2—11 also provides that a substance is ‘used as a food additive’ if it is added to a food to perform one or more technological functions listed in schedule 14 of the Code and is one of a number of substances listed in that section. These 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 of that schedule provides that use as an intense sweetener is a permitted purpose.

Schedules 15 and 16 list the specific food additive permissions for different categories of food products.

### *Processing aids*

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

Standard 1.3.3 and Schedule 18 list the permitted processing aids. The table to subsection S18—9(3) lists those substances, including enzymes, that are permitted to be used as processing aids for specific technological purposes.

Section 1.1.2—13 defines the expression ‘used as a processing aid.’ That definition imposes requirements on substances permitted by Standard 1.3.3 and Schedule 18 to be used as a processing aid, such that it does not perform a technological purpose in the final food for sale.

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

### *Identity and purity requirements*

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

Section S3—35 of Schedule 3 provides a specification for steviol glycosides prepared from the leaves of *Stevia rebaudiana* Bertoni. The specification permits only one method of production, namely extraction using the traditional hot water extraction method. The SweeGen Reb D does not comply with this specification due to its different method of production.

## **1.3.1 International standards**

Steviol glycosides, which includes Reb D, are approved for use as food additives with the technological purpose of sweetener around the world including in Europe, Central/South America, Asia, Africa and the Middle East (PureCircle Stevia Institute, 2018). Permissions for some of these countries are provided in the following sections. Safety assessments have also been performed on steviol glycosides by international expert committees such as the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

### **1.3.1.1 Codex Alimentarius**

Codex Alimentarius is an international body that incorporates the Food and Agriculture Organisation 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 2018). The GSFA contains provisions for steviol glycosides in a wide variety of food categories.

#### **1.3.1.2 JECFA**

JECFA has assessed the safety and specifications of steviol glycosides a number of times, most recently at the 82<sup>nd</sup> meeting in 2016 (JECFA 2017a). That meeting re-evaluated the safety, dietary exposure and specifications of steviol glycosides, as well as updated its Chemical and Technical Assessment. The safety and Acceptable Daily Intake (ADI) of steviol glycosides were confirmed. New, amended tentative specifications for “steviol glycosides from *Stevia rebaudiana* Bertoni” were produced at the 82<sup>nd</sup> meeting and finalised at its 84<sup>th</sup> meeting (JECFA 2017b). The definition in this specification includes a production method that the steviol glycosides are obtained from a hot water extraction from the leaves of *S. rebaudiana* Bertoni. The specification has expanded the definition to include a mixture of any of the steviol glycosides extracted from the stevia leaf rather than the 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.

#### **1.3.1.3 United States**

In the United States there have been over 50 Generally Recognised as Safe (GRAS) notices relating to steviol glycosides submitted to the US Food and Drug Administration (FDA) for review. To date, excluding pending notifications, the US FDA has not raised any objections to the GRAS status of these steviol glycoside products for use as a sweetener in foods. GRN No. 715 relates to the same production method and product as this application. GRN No. 715 was submitted by Blue California (all rights have now been granted to SweeGen, Inc., the applicant for this application) in 2017 and the US FDA responded with no questions to the GRAS status. Therefore, SweeGen’s Reb D is considered GRAS for use as a table top sweetener and as a general purpose non-nutritive sweetener in foods (US FDA 2017).

#### **1.3.1.3 Canada**

Health Canada expanded the definition of steviol glycosides as permitted food additive sweeteners to include all steviol glycosides in the *S. rebaudiana* Bertoni plant in 2017 (Health Canada 2017). The applicant has Health Canada correspondence confirming that this includes SweeGen’s Reb D. Item S.1.2 of the *List of Permitted Sweeteners* in the Canadian *Food and Drugs Act* permits the use of this Reb D as a sweetener food additive in a variety of food categories provided it complies with the relevant international specifications for steviol glycosides (either JECFA or Food Chemicals Codex) and relevant conditions for its use and requirements of the Food and Drug Act (Health Canada 2018).

#### **1.3.1.4 European Union**

Steviol glycosides 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). This European specification applies to steviol glycosides preparations that contain eleven named steviol glycosides which include Reb D at levels not less than 95% on the dried basis. The specification applies only to steviol glycosides preparations extracted from the leaves of the *S. rebaudiana* Bertoni plant, similar to the JECFA and Food Chemicals Codex specifications.

## **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

- 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.

## 2 Summary of the assessment

### 2.1 Risk assessment

FSANZ has conducted an assessment of the public health and safety risks associated with the SweeGen's Reb D as a food additive (see SD1) and concluded:

- Recent assessments by FSANZ, Health Canada and JECFA have confirmed that all steviol glycosides undergo the same metabolic pathway to steviol, which is then glucuronidated and excreted in the urine.
- A group ADI, expressed as steviol, is therefore appropriate to cover dietary exposure to all steviol glycosides. Toxicological and other relevant data published subsequent to FSANZ's most recent steviol glycosides assessment (Application A1157, assessment completed in October 2018), raised no concerns requiring a change to the existing ADI of 0-4 mg/kg bodyweight (bw)/day steviol.
- SweeGen's Reb D that is the subject of this application is chemically the same as Reb D extracted directly from *S. rebaudiana* Bertoni and would therefore follow the same metabolic pathway.
- SweeGen's Reb D complies with international purity specifications for steviol glycosides.
- No major allergens are used to culture the yeast or at any other stage of the production process.
- The enzyme processing aid UGT-A has previously been assessed and approved under application A1157.

In conclusion, FSANZ's risk assessment has not identified any safety concerns associated with SweeGen's Reb D produced using the enzyme processing aid UGT-A.

### 2.2 Risk management

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 SweeGen's Reb D for use as a food additive at levels and in food classes currently permitted in the Code for steviol glycosides.

Based on the risk assessment conclusion that there are no public health and safety risks, it was considered appropriate to propose to amend Schedule 3 of the Code in order to permit the use of SweeGen's Reb D as a food additive at the levels and in the foods currently permitted for steviol glycosides in the Code. Amending the steviol glycosides specification in Schedule 3 to allow SweeGen's production method for Reb D ensures this steviol glycosides preparation has the same permissions as other steviol glycosides preparations already listed in the Code.

It was also considered appropriate to include an amendment to Schedule 18 permitting the use of the enzyme UGT-A produced from a GM *Pichia pastoris* strain as a processing aid used for the production of Reb D to ensure regulatory certainty, in a similar way and for similar reasons to that determined in FSANZ's assessment of A1157.

Paragraph 1.1.1—10(6)(g) of the Code requires that the presence as an ingredient or component in a food for sale of a food produced using gene technology must be expressly permitted by the Code. Section 1.5.2—3 of the Code provides that permission for use as a processing aid also constitutes the permission required by paragraph 1.1.1—10(6)(g).

FSANZ's assessment is that the enzyme's use as a processing aid to manufacture Reb D does not itself, make the Reb D a GM food. As the Reb D itself is not derived from an organism that has been modified using gene technology, FSANZ's determination is that SweeGen's Reb D is not itself a food produced using gene technology.

## **2.2.1 Labelling considerations**

### **2.2.1.1 Ingredient labelling**

Under existing labelling requirements in the Code (unless the food is exempt from the requirement for a statement of ingredients) SweeGen's Reb D would require declaration as a food additive in the statement of ingredients on the label of foods. These ingredient labelling requirements currently require steviol glycosides to be identified in the statement of ingredients using the food additive name 'Steviol glycosides' or the code number 960 (as listed in Schedule 8). As the proposed change to the Code is to the production method and specification for Reb D rather than approval of Reb D itself as a food additive, the existing labelling requirements relating to steviol glycosides would apply.

The Codex Committee on Food Additives (CCFA) at its 50th Session (March 2018) updated the International Numbering System (INS) numbers for steviol glycosides, which were subsequently adopted into the Class Names and International Number System for Food Additives (CXG 36-1989) by the Codex Commission at its meeting in July 2018 (CCFA 2018). 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). The CCFA has not completed its work (for example, the production method used under this application does not have a new INS number assigned at the present time). For this reason, the most appropriate INS number is 960. FSANZ will consider changes to the INS number for Reb D in the future, if changes are made to the INS list.

In terms of the enzyme used as a processing aid to manufacture SweeGen's Reb D, the Code exempts processing aids from the requirement to be declared in the statement of ingredients.

### **2.2.1.2 Labelling as 'genetically modified'**

Section 1.5.2—4 requires certain foods for sale that consist of or have as an ingredient, food that is a genetically modified to be labelled as 'genetically modified'. The Code's labelling requirements, including those imposed by section 1.5.2—4, generally apply only 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 SweeGen's Reb D is not a food produced using gene technology as it is not derived from an organism that has been modified using gene technology, in contrast to the enzyme processing aid used for its manufacture, which is a food produced using gene technology for Code purposes. As such, SweeGen's Reb D does not require labelling as 'genetically modified'.

The enzyme used as a processing aid to manufacture SweeGen's Reb D is highly unlikely to be present as an ingredient in a food for sale which contains Reb D. Furthermore, it is understood that SweeGen's Reb D itself would not be sold for retail sale or to a caterer because it is a highly concentrated intense sweetener. As such, the requirement to label the

processing aid as 'genetically modified' would not apply to a food for sale that contains Reb D because the labelling requirements only apply to food that consists of, or has as an ingredient, a GM food under section 1.5.2—4(1).

### **2.2.2 Risk management conclusion**

Taking account of the risk assessment conclusions in (section 2.1), the risk management considerations (section 2.2) along with the benefits to industry and consumers (section 2.4.1.1), the risk management conclusion is to permit the use of SweeGen's Reb D as a food additive manufactured using the novel enzymatic production method.

To provide that permission, section S3—35 of Schedule 3 of the Code will be amended to refer to the specific manufacturing method for SweeGen's Reb D.

The permitted technological purpose of SweeGen's Reb D's use as a food additive is that of an intense sweetener and will be permitted in Schedule 15. These permissions are those currently permitted for steviol glycosides at the current MPLs and specified food classes, and at GMP levels for tabletop sweeteners. It will similarly utilise the current INS number 960.

The protein engineered enzyme used to produce Reb D will also be listed as an enzymatic processing aid in subsection S18—(9)(3). Permission for this enzyme processing aid will be limited to the specific purpose of producing Reb D from purified stevia leaf extract only at the use level of GMP.

## **2.3 Risk communication**

### **2.3.1 Consultation**

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a basic 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 standard development matters is open, accountable, consultative and transparent. Public submissions are 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.

The draft variation will be considered for approval by the FSANZ Board taking into account 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 inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are relevant international standards for Reb D. Amending the Code to permit Reb D produced by an enzymatic conversion method is unlikely to have a significant effect on international trade as the identity and purity is identical to currently permitted Reb D and other steviol glycosides produced by the traditional hot water extraction method. 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**

### **2.4.1 Section 29**

#### **2.4.1.1 Consideration of costs and benefits**

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory 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, has given consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. 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 (S.29 (2)(a)).

The purpose of this consideration is 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 considers to either approve or reject the application (retain the status quo). This analysis considers the option of permitting the use of Reb D produced by an enzymatic conversion method as a food additive in certain foods. FSANZ is of the view that no other realistic food regulatory measures exist, however information received may result in FSANZ arriving at a different outcome.

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 likely positives and negatives of moving away from the status quo by permitting the use of Reb D produced by an enzymatic conversion method as a food additive in certain foods.

*Costs and benefits of permitting the use of Reb D produced by an enzymatic conversion method as a food additive in certain foods.*

The use of SweeGen's Reb D as a food additive in the manner proposed will not pose a health or safety risk for consumers. The benefits to the consumer would mirror those for other steviol glycosides currently permitted for use in Australia and New Zealand. SweeGen's Reb D, like other steviol glycosides, would be used in foods and beverages to replace sugar, which will benefit consumers seeking products that have reduced sugar and/or energy content.

Consumers may also benefit from the choice of additional food products which have more favourable sensory characteristics, compared to those using other major glycosides (i.e., stevioside, rebaudioside A). They will also be able to access products manufactured with this particular Reb D, which are currently manufactured overseas.

The development of the new technology to produce a steviol glycoside with preferential sensory characteristics for product development can provide a benefit in terms of product and/or competitive advantage to food manufacturers.

In the US, SweeGen's Reb D produced via enzymatic conversion of purified stevia leaf extract has GRAS status for use as a table top sweetener and a general purpose non-

nutritive sweetener in foods. Permission to use SweeGen's Reb D as a food additive, will enable Australia/New Zealand food manufacturers to access and use a product assessed as safe that is available to their overseas competitors. This will improve their capacity to compete in overseas markets. Use by industry is voluntary, therefore it will only be used where industry believe a net benefit exists above using existing intense sweeteners.

Since SweeGen's does not intend to propose an extension for the use of Reb D in additional food products nor does it wish to propose to increase the permitted quantities of Reb D in permitted food products, there is no perceived benefit or added cost to governments.

However, the approval of the enzyme as a processing aid may result in a small cost to government in terms of adding the enzyme to the current range of enzymes that are monitored for compliance.

#### *Conclusions from cost benefit considerations*

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting the use of Reb D produced by an enzymatic conversion method as a food additive in certain foods most likely outweigh the associated costs.

#### **2.4.1.2 Other measures**

FSANZ considers 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.

#### **2.4.1.3 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.

#### **2.4.1.4 Any other relevant matters**

Other relevant matters are considered below.

#### **2.4.2 Subsection 18(1)**

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

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

FSANZ concluded that there are no safety concerns associated with SweeGen's Reb D produced using an enzyme from GM *P. pastoris*. For more detail, see SD1.

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

The generic labelling requirements will apply to the use of Reb D in food (see section 2.2.1).

##### **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 used the best available scientific evidence when undertaking the risk analysis, which is provided in SD1 – the risk and technical assessment report. The applicant submitted a dossier of scientific studies and other technical information including scientific literature. This information dossier, together with other technical information including scientific literature, was used in assessing the application.

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

The SweeGen's Reb D specifications (identity and purity, but not production method) are identical to those established by JECFA (JECFA 2017a) and the Food Chemicals Codex (Food Chemicals Codex 2018).

SweeGen's Reb D is permitted for use in the USA and Canada.

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

Permission to use this particular Reb D as a food additive will enable Australian and New Zealand food manufacturers to access and use a product assessed as safe that is available to some overseas competitors. This will improve their capacity to compete in overseas markets. See discussion at section 2.4.1.1 above.

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

SweeGen's Reb D has been assessed as safe and is permitted for use in the USA and Canada. It is therefore appropriate that Australian and New Zealand food manufacturers can also benefit by gaining permission to use this particular Reb D, which is claimed to provide more favourable sensory characteristics.

- **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>3</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 permitting SweeGen's Reb D produced by an enzymatic conversion method, is consistent with these specific order policy principles.

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<sup>3</sup> <http://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Addition-of-Substances-other-than-Vitamins-and-Minerals>

### 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.

### 4 References

Codex 2018, General Standard for Food Additives,  
<http://www.fao.org/gsfaonline/index.html;jsessionid=64CA5BB29D301405C4DD6FA3239EA22D>  
Accessed 25 October 2018

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>

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## **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 A1172 – Enzymatic Production of Rebaudioside D) 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 Delegate's details]

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 A1172 – Enzymatic Production of Rebaudioside D) 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 paragraph S3—35(2)(b), substituting

- (b) by enzymatic conversion of purified stevia leaf extract to produce rebaudioside M using protein engineered enzymes that:
  - (i) contain both UDP-glucosyltransferase (EC 2.4.1.17) and sucrose synthase (EC 2.4.1.13) components; and
  - (ii) are sourced from both of the following:
    - (a) a *Pichia pastoris* strain expressing UGT-A;
    - (b) a *Pichia pastoris* strain expressing both UGT-B1 and UGT-B2;
- (c) by enzymatic conversion of purified stevia leaf extract to produce rebaudioside D using a protein engineered enzyme that:
  - (i) contains both UDP-glucosyltransferase (EC 2.4.1.17) and sucrose synthase (EC 2.4.1.13) components; and
  - (ii) are 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: contains both UDP-glucosyltransferase (EC 2.4.1.17) and sucrose synthase (EC 2.4.1.13) components; and are sourced from <i>Pichia pastoris</i> strain UGT-A.	For the conversion of purified stevia leaf extract to produce rebaudioside D.	GMP
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## **Attachment B – Draft 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 A1172 which sought an amendment to Schedule 3 of the Code to prescribe a new specification for rebaudioside D (Reb D) produced by a particular enzymatic conversion method. The Authority considered the application in accordance with Division 1 of Part 3 of the FSANZ Act and has prepared a draft variation.

### **2. Purpose**

The Authority has prepared a draft variation to amend subsection S3—35(2) of Schedule 3 of the Code. The amendment will include in the specification provided by that subsection a reference to the enzymatic conversion method used to produce the A1172 applicant's Reb D. The amendment's effect would be to permit Reb D produced by that production method to be used as a food additive in accordance with the existing permissions and limits for steviol glycosides (including containing Reb D) in the Code.

The Authority has also prepared a draft variation to amend Schedule 18 of the Code to permit the use of the specific enzyme as a processing aid in the processing of the A1172 applicant's Reb D 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 A1172 will include one round of public consultation following an assessment and the preparation of a draft Standard and associated assessment summary.

A Regulation Impact Statement was not required because the proposed variations to Schedule 3 are likely to have a minor impact on business and individuals.

### **5. Statement of compatibility with human rights**

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

### **6. Variation**

*Item [1]*

Item [1] amends Schedule 3 of the Code. The item adds a new paragraph (c) to the subsection S3—35(2).

The new paragraph S3—35(2)(c) includes a reference to the enzymatic conversion of purified stevia leaf extract to produce Reb D using a protein engineered enzyme that: contains both UDP-glucosyltransferase (EC 2.4.1.17) and sucrose synthase (EC 2.4.1.13) components; and is sourced from *Pichia pastoris* strain UGT-A.

The effect of this amendment is to permit Reb D produced using this method to be used as a food additive in accordance with the existing food additive permissions in the Code for steviol glycosides (including steviol glycosides containing Reb D).

*Item [2]*

Item [2] amends Schedule 18. The item inserts a new entry into the table to subsection S18—9(3). The effect of the new entry would be to permit the use of a specific enzyme as a processing aid in the manufacture of Reb D for the following technological purpose: the conversion of purified stevia leaf extract to produce Reb D. The permitted enzyme is a protein engineered enzyme that: contains both UDP-glucosyltransferase (EC 2.4.1.17) and sucrose synthase (EC 2.4.1.13) components; and is sourced from *Pichia pastoris* strain UGT-A. The permission includes the condition that the maximum permitted amount used as a processing aid must be consistent with Good Manufacturing Practice (as defined by section 1.1.2—2(3) of the Code).