



AUSTRALIAN
**FOOD &
GROCERY**
COUNCIL

AFGC SUBMISSION

**CALL FOR SUBMISSIONS APPLICATION A1222 – STEVIOL
GLYCOSIDES FROM *YARROWIA LIPOLYTICA***

22 July 2021

PREFACE

The Australian Food and Grocery Council (AFGC) is the leading national organisation representing Australia's food, beverage and grocery manufacturing sector.

There are over 180 member companies, subsidiaries and associates who together comprise 80 per cent of the gross dollar value of the processed food, beverage and grocery products industries.

With an annual turnover in the 2018-19 financial year of \$127.1 billion, Australia's food and grocery manufacturing sector makes a substantial contribution to the Australian economy and is vital to the nation's future prosperity.

The diverse and sustainable industry is made up of over 15,861 businesses and accounts for over \$75.1 billion of the nation's international trade. These businesses range from some of the largest globally significant multinational companies to small and medium enterprises. Industry made \$2.8 billion in capital investment in 2018-19.

Food, beverage and grocery manufacturing together forms Australia's largest manufacturing sector, representing 31.4 per cent of total manufacturing turnover in Australia.

The food and grocery manufacturing sector employs more than 274,800 Australians, representing 32.2 per cent of total manufacturing employment in Australia.

Many food manufacturing plants are located outside the metropolitan regions. The industry makes a large contribution to rural and regional Australia economies, with almost 40 per cent of the total persons employed being in rural and regional Australia.

It is essential to the economic and social development of Australia, and particularly rural and regional Australia, that the magnitude, significance and contribution of this industry is recognised and factored into the Government's economic, industrial and trade policies.

In Australia, the food and beverage (grocery was not included in the Government's strategy but is recognised as a vital industry) manufacturing sector has been confirmed as an essential service and a National Strategic Priority. The Australian Government through its recently announced Manufacturing Strategy has challenged the sector to develop an industry roadmap describing how it will contribute to the post-COVID-19 recovery through expanding manufacturing, growing jobs, boosting exports and enhancing sovereign capability across the sector.

Food and beverage manufacturing plays an integral role in Australia's economic and social fabric. It is the lifeblood of many regional and rural communities. As such it is well placed to do the heavy lifting in the Manufacturing Strategy through its size, its know-how in adding value to the commodities of the agricultural sector, and to leverage the reputation for safety and quality among consumers in overseas markets.

This submission has been prepared by the AFGC and reflects the collective views of the membership.

OVERVIEW

The Australian Food and Grocery Council (AFGC) welcomes this opportunity to comment on Food Standards Australia New Zealand's (FSANZ) call for submissions on *Application A1222 Steviol Glycosides from Yarrowia lipolytica*.

The AFGC has reviewed both the Application and FSANZ's risk and technical assessment. Both documents provide comprehensive, detailed and convincing scientific evidence that the production of steviol glycosides from *Yarrowia lipolytica* when incorporated into food products presents no consumer food safety or health implications. Consequently, the AFGC supports *Application A1222 steviol glycosides from Yarrowia lipolytica*.

COMMENTS

STEVIOLE GLYCOSIDES MEETING A CONSUMER NEED

Steviol glycosides have been used as intense sweeteners in a range of food products for a number of years. Derived from plants, albeit with various technologies and processing, they have been welcomed by consumers and generally viewed favourably in comparison to some of the earlier generation chemically synthesised intense sweeteners. Industry has used them in food products promoted to consumers on the basis of their reduced sugar and energy content. As such they assist consumers to construct healthy diets aligned to the dietary guidelines across Australia and New Zealand with a primary benefit of helping consumers make choices that meet their nutritional needs so as to maintain an overall healthy and balanced diet.

ALIGNMENT WITH FOFR PRIORITIES

The Food Ministers' Meeting (formerly the Ministerial Forum on Food Regulation) has identified as a priority for the food regulation system "Supporting the public health objectives to reduce chronic disease related to overweight and obesity". The use of intense sweeteners in food products is clearly aligned with that objective. Their value, however, depends heavily on consumer acceptance.

As has been reported in the Application, the steviol glycoside called rebaudioside MD resulting from the use of a genetically modified strain of yeast, *Yarrowia lipolytica*, has an improved sensory profile such as a better sweetness quality compared to other forms of steviol glycosides derived from plant leaves. This will result in greater consumer acceptance of the products with more consumers likely to continue using products with the new steviol glycosides once they have tried them.

The AFGC notes that rebaudioside MD (used as the single of M and D) is already permitted for use as a food additive in the Code with maximum permitted levels in a variety of food categories and at good manufacturing practice levels in table top sweeteners (category 11.4) in [Schedule 15](#).

SAFETY OF THE PRODUCT HAS BEEN CONFIRMED

This purified steviol glycoside preparation, rebaudioside MD, is produced by fermentation of simple sugars using a genetically modified *Y. lipolytica*, expressing steviol glycoside biosynthesis pathway genes.

The safety and risk assessment by FSANZ of this form and method of production of steviol glycoside indicates:

- alignment with international purity specifications
- meeting the purity parameters of specifications for steviol glycosides produced by fermentation listed in [Section S3-39](#)
- no concerns with the host organism *Y. lipolytica* or the novel proteins expressed by the introduced genes for the biosynthesis of rebaudioside MD
- the host *Y. lipolytica* production strain is not pathogenic or toxigenic
- no allergy risk issues
- similar digestion and metabolic fates to other forms of steviol glycosides when ingested
- host organism, residual DNA or residual protein were not detectable in the final rebaudioside MD preparation, and
- other relevant and competent agencies (e.g. JECFA, EFSA, USFDA) overseas have agreed they can be used safely in foods as proposed by the applicant.

The AFGC agrees with the FSANZ safety assessment which has not identified any health or safety concerns associated with the steviol glycosides as described in the application.

Furthermore, the AFGC agrees that Acceptable Daily Intake of 0 – 4 mg/kg body weight expressed as steviol does not need changing as a result of rebaudioside MD preparation produced using genetically modified *Y. lipolytica*. The ADI is appropriate as it is chemically identical to the minor steviol glycosides extracted traditionally from the leaves of *Stevia rebaudiana* Bertoni and follows the same metabolic pathway in humans, as reported in the FSANZ assessment.

LABELLING GENETICALLY MODIFIED

The AFGC notes that while genetic modification techniques were used to prepare this steviol glycoside, no safety issues associated with these techniques (either on the proteins or DNA involved) were identified.

Additionally, host organism, residual DNA or residual protein were not detectable in the final rebaudioside MD preparation. However, under the FSANZ Code, requirement to label it as 'genetically modified' applies if novel DNA or protein is present in the final food, otherwise exemption from labelling applies.

Lastly, under the current Code, the rebaudioside MD preparation will require declaration as a food additive in the statement of ingredients on the label of foods using the name 'steviol glycosides' or the International Numbering System (INS) code number 960.

CONCLUSION

The AFGC commends both the Applicant and FSANZ for the thoroughness with which the science, methodology and safety confirmation of the production and potential use in food products has been described and assessed.

The AFGC has not identified any issues with the application which would warrant its progression through the food regulatory system being delayed or denied.

RECOMMENDATION:

The Australian Food and Grocery Council recommends the amendment to the ANZ Food Standards Code sought in Application A1222 steviol glycosides from *Yarrowia lipolytica* be supported.

- For further information about the contents of this submission contact:

