



AUSTRALIAN
**FOOD &
GROCERY**
COUNCIL

AFGC SUBMISSION

FSANZ APPLICATION – A1157
*ENZYMATIC PRODUCTION OF
REBAUDIOSIDE M*

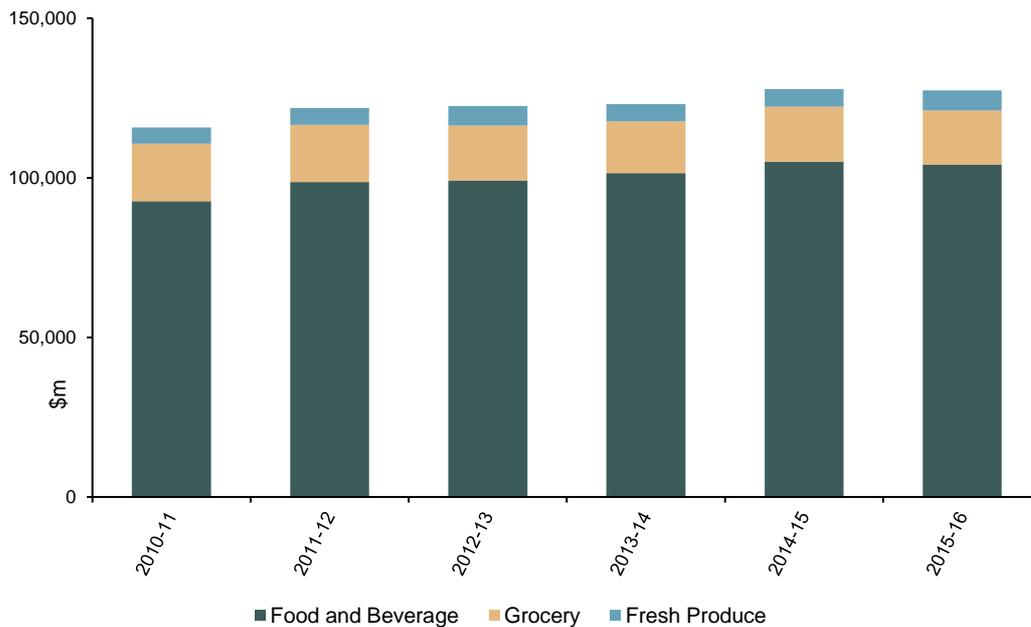
Sustaining Australia

1. PREFACE

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

The membership of AFGC comprises more than 180 companies, subsidiaries and associates which constitutes in the order of 80 per cent of the gross dollar value of the processed food, beverage and grocery products sectors.

Figure 3.1: Composition of the defined industry's turnover (\$2015-16) (million)



With an annual turnover in the 2015-16 financial year of \$127.4 billion, Australia's food and grocery manufacturing industry makes a substantial contribution to the Australian economy and is vital to the nation's future prosperity.

Manufacturing of food, beverages and groceries in the fast moving consumer goods sector is Australia's largest manufacturing industry. Representing 32.4 per cent of total manufacturing turnover in Australia.

The diverse and sustainable industry is made up of over 30,748 businesses and accounts for over \$67.9 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 \$2.9 billion in capital investment in 2015-16 on research and development.

The food and grocery manufacturing sector employs more than 320,300 Australians, representing about 2.6 per cent of all employed people in Australia, paying around \$17.3 billion a year in salaries and wages.

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 for 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.

Australians and our political leaders overwhelmingly want a local, value-adding food and grocery manufacturing sector.

2. SUBMISSION

The Australian Food and Grocery Council (AFGC) provides this submission in response to the Food Standards Australia New Zealand (FSANZ) *Application Paper – A1157: Enzymatic production of Rebaudioside M: to seek approval for a new specification for Rebaudioside M produced by an enzymatic biosynthesis method.*

The AFGC has reviewed the Supporting Document 1 – *Risk and Technical Assessment Report – Application A1157* prepared by FSANZ and supports the positions expressed therein.

The AFGC supports Blue California's application to seek permission in the Australia New Zealand Food Standards Code (the Code) for a Rebaudioside M (Reb M) derived from a novel production method.

The AFGC recognises that Reb M is traditionally produced using hot water extraction of the *Stevia rebaudiana* Bertoni leaf, followed by purification and recrystallization using methanol or ethanol. Blue California however uses an enzymatic process to manufacture Reb M using enzymes sourced from genetically modified strains of *Pichia pastoris*.

The AFGC recognises the FSANZ statement that steviol glycosides extracted from the leaves of *Stevia rebaudiana* Bertoni, including Reb M, are already permitted for use as a food additive in the Code, with maximum permitted levels (MPLs) in a variety of food categories and at GMP levels in commercially available sweeteners as defined in Schedule 15.

The technological purpose of steviol glycosides as a food additive is that of an intense sweetener which replaces the sweetness normally provided by sugars in food, without contributing significantly to their available energy. It is therefore valuable for use in foods such as reduced-energy or no-added sugar products. The technological purpose of the Reb M manufactured by Blue California does not differ from currently permitted steviol glycosides, rather it is the method of manufacture that differs.

In addition, Reb M exhibits preferential sensory characteristics when compared to the major glycosides, being more reflective of sucrose. It is therefore a useful food additive in formulations for reduced-calorie or no-sugar-added products when used as a substitute for sugar.

The AFGC supports the FSANZ position that the *P. pastoris* source organism for the enzymes used to produce Reb M has a long history of industrial use, is commonly used for recombinant gene expression and is not toxigenic. In addition, the Blue California Reb M complies with purity specifications of JECFA.

The AFGC notes that current 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 therefore did not indicate a need to amend the acceptable daily intake (ADI) of 0-4mg/kg.

The AFGC notes that FSANZ's hazard assessment has not identified any safety concerns associated with Blue California's Reb M produced using enzymes from genetically modified *P. pastoris*. FSANZ states that no major allergens are used to culture the yeast or at any other stage of the production process and sufficient information was provided concerning potential homology between the novel enzymes and known allergens. FSANZ acknowledges that there are no concerns in this case with respect to safety or public health.

The AFGC acknowledges that Blue California's Reb M is currently manufactured in China and that all materials and processing aids used in the manufacturing process are food-grade and comply with internationally recognised standards and the relevant Food Chemical Codex. In addition, Blue California's Reb M is manufactured to a high level of purity ($\geq 95\%$) and in compliance with Good Manufacturing Practice (GMP).

The AFGC supports Coca-Cola South Pacific's position regarding consistency in enforcement that 'such foods for sale that contain Blue California's Reb M as an ingredient will not be required to be labelled as *genetically modified*'

The AFGC commends FSANZ on the comprehensive work performed in relation to the evaluation and assessment of the Blue California's production method of Rebaudioside M (Reb M) and supports the approval of the novel manufacturing process using enzymes sourced from genetically modified strains *Pichia pastoris*.