Submission from Sugar Australia Pty Ltd and GLG Life Tech Corporation.

9 February 2011

To: **Food Standards Australia New Zealand**

In Response To: **Assessment Report on Application A1037: Increase in Permitted Use Levels of Steviol Glycosides.**

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1. INTRODUCTION

Sugar Australia Pty Limited (Sugar Australia) was established in March 1998 and operates as an unincorporated joint venture between Sucrogen Limited (formally CSR Sugar) and Mackay Sugar Limited. Sugar Australia is the leading supplier of quality refined Australian sugar products and sweeteners.

Sugar Australia is the largest sugar refiner in Australia and New Zealand with its three sugar refineries capable of producing 970,000 tonnes of sugar annually. Domestically Sugar Australia is the leading sugar refiner operating across multiple business channels including, the supply of sugar as an ingredient into the food and beverage sector, retail in which its CSR consumer brand has the leading market share, as well as foodservice and exports. Sugar Australia also has a market leadership position in the sweetener market being the distributor of market leading brands such as Equal.

Sugar is the second largest export crop in Australia after wheat with an approximate total annual revenue of around $1.5 billion. In 2008, more than 32 million tonnes of cane was crushed in Australia and 4 million tonnes of raw sugar produced. Australia exports about 80 to 85 per cent of raw sugar to buyers overseas. The Australian domestic market for raw sugar is around one million tonnes. The sugar industry generates more than 40,000 jobs, directly and indirectly.

GLG Life Tech Corporation (GLG), a Canadian based company, is a global leader in the supply of high purity stevia extracts, an all natural, zero-calorie sweetener used in food and beverages. The company's vertically integrated operations cover each step in the stevia supply chain including non-GMO stevia seed breeding, natural propagation, stevia leaf growth and harvest, proprietary extraction and refining, marketing and distribution of finished product. GLG have a number of global distribution partnerships with leading agribusiness and food companies, including Cargill.

In 2010 Sugar Australia and GLG entered into a commercial arrangement to sell and market high purity stevia ingredients in Australia and New Zealand, both in their own right and as blends with other ingredients including sugar. The objective of this arrangement was to bring to the market a range of sweet ingredients that will enable food manufacturers to meet the growing consumer demand for natural, good tasting, low and reduced calorie food and beverages.

Sugar Australia and GLG welcome the opportunity to make this submission on Food Standards Australia New Zealand (FSANZ)'s assessment of Application A1037: Increase in the Permitted Use Levels of Steviol Glycosides. In addition to addressing the specific areas requested by FSANZ our submission also makes some other observations that we request you take into consideration in the further development of your recommendation.

In preparing our submission we have drawn on the advice of GRAS Associate LLC (GA) a technical regulatory consulting firm that focuses on food ingredient safety matters (see www.gras-associates.com for more details). GA have prepared six GRAS notifications (GRN 278, GRN 287, GRN 303, GRN 304, GRN 318 and GRN 323) that have successfully cleared the safety evaluation process of the USA Food and Drug Administration and have a working knowledge of the scientific factors that have an important bearing in establishing the safety of steviol glycosides as components in foods and beverages.

2. SUMMARY of OUR POSITION.

Sugar Australia and GLG:

- Support the proposed increase in the maximum permitted levels of steviol glycosides.
- Support the proposed redrafting to provide clarity on the calculation of steviol equivalents and the removal of duplications.
- Request that for the avoidance of confusion the reference to the purity specification of the Cargill preparation be avoided.
- Request for the purposes of clarity that the application specifies that the new permissions apply to all steviol glycoside preparations that met the JECFA monographs endorsed by standard 1.3.4
- Request for the purposes of simplicity and clarity that the indirect permission for the use of steviol glycosides as an additive to ready-to-drink alcoholic mix beverages be replaced with a direct permission.

3. RESPONSE TO QUESTIONS and REQUESTS of FSANZ

1. The scientific and other evidence put forward in support of this application.

In section 4 of the Introduction to the Assessment Report, FSANZ identifies three risk assessment questions.

1. Are the proposed increases in maximum permitted levels in selected foods consistent with achieving the stated purpose?
2. Is there a need to change the ADI of 0-4 mg/kkg body weight established previously by FSANZ?
3. If the maximum permitted levels of steviol glycosides are increased in the proposed foods, would the resulting exposure for all consumers pose an unacceptable risk for the public health and safety?

In-house application work undertaken by Sugar Australia and GLG supports Cargill's claim that the higher permission levels in beverages provides a better taste profile in the final formulation. The higher levels will also allow for the complete replacement of sugar in these applications enabling food manufacturers to meet consumer demands for no-calorie and low-calorie variants.

The analysis undertaken by FSANZ correctly captures the safety information needed to ensure that public health and safety would be properly preserved at the proposed higher permission levels.

Highly qualified entities within the international scientific community have on multiple occasions scrutinized the composite safety information - consisting of acute,

subchronic, chronic, mutagenicity/genotoxicity, reproductive and developmental, pharmacokinetic, and clinical testing of steviol glycosides or component glycosides - to ascertain the potential risks of consumption of high purity sweeteners derived from stevia leaves.

Based on the composite safety studies on steviol glycosides blends, stevioside, and Reb A, JECFA and others have established the ADI to be 4 mg/kg bw/day as steviol which corresponds on a molecular weight adjusted basis to 8 mg/kg bw/day as stevioside and 12 mg/kg bw/day as Reb A. This determination has been embraced by the broader scientific community.

Comparing the estimated dietary intakes with ADI determinations is a critical aspect with these overall safety assessments. The estimated dietary intake assessments as performed independently by multiple parties for steviol glycosides have consistently yielded overestimates to ensure that public health and safety would be preserved.

Despite the different approaches utilized to calculate the dietary intakes of steviol glycosides, the daily consumption estimates for a 60 kg individual tend to converge on about 35 - 100 mg/day as steviol. With the consensus ADI on a steviol basis of 4 mg/kg bw/day, or about 240 mg/day for a 60 kg individual, the calculated EDIs fall in the range of 35 – 100 mg/day; such consumption levels are below what is considered to be an acceptable, or safe, intake level by a factor ranging from 2 to 6.

Sugar Australia and GLG therefore believe that the increased usage levels in the proposed foods will provide consumers with ample protection due to the reliance on safety factors and conservative assumptions that have been built into the analyses as accepted by highly qualified scientists on a world-wide basis.

We also believe that the conservative ADI of 0-4 mg/kg body weight per day established previously by FSANZ should continue for now and that its appropriateness be reviewed in 2 years when more safety and usage data will be available.

2. Potential impact associated with the proposed amendments to steviol glycoside levels

The potential impact on public health and safety has been addressed in the previous section of this submission.

The proposed amendments will provide food manufacturers such as ourselves with an improved ability to innovate and develop products which better meet consumer needs.

3. Data and information on steviol glycoside usage in the food categories where permissions currently exist, and data on actual levels used

While Sugar Australia and GLG recognize the importance of this data to FSANZ's risk assessment we do not currently have this information for the categories for which an increase in permissions is being requested.

Sugar Australia does market a sugar – stevia blend called CSR SMART™ sugar which provides consumers 50 percent less calories by virtue that it is "twice as sweet as normal sugar so you use half as much".

The stevia levels in this product are 0.4% by weight. Our consumer research has indicated that most consumers use this blend to sweeten hot beverages (tea and coffee) or to sweeten their breakfast cereals. Daily consumption is therefore likely to be in the range of 2 – 4 x 5g teaspoons which equates to 4 – 8 teaspoons of standard sugar.

4. Data and information relating to actual market share of steviol glycosides

As the permission to use steviol glycosides as a food additive is relatively new, the market-share of products containing this additive is low. By way of illustration, CSR SMART™ sugar has a market share of <1 percent of the total retail white sugar market (60,000 tonnes).

A significant increase in market share is expected as consumer awareness, understanding and demand for these natural intense sweeteners, and products made from them, grows.

5. Instructions on the calculation for determining steviol equivalents

Sugar Australia and GLG support the inclusion of instructions on how to calculate the steviol equivalent levels for steviol glycosides.

4. FURTHER OBSERVATIONS

Purity reference for the increased permissions.

The executive summary in Application A1037 contains the following paragraph

"The preparation that is subject of this Application comprises not less than 95% of nine steviol glycosides, with rebaudioside A accounting for over 95% of those present"

GLG and Sugar Australia request that ***this reference be removed*** as there is the potential that the new permissions could incorrectly be interpreted to apply only to steviol glycoside extracts that have greater than 90% rebaudioside A content.

To avoid confusion altogether we believe the application would be strengthened by stating that the new permissions apply to all steviol glycoside preparations that comply with the Joint Expert Committee on Food Additives (JECFA) monographs as required by clause 2 of standard 1.3.4.

Permissions for use of steviol glycosides in ready-to-drink alcoholic mix beverages.

The Food Standards Code (FSC) currently provides for ready-to-drink (RTD) alcoholic mixes to be sweetened with the high intensity sweeteners aspartame (951), sucralose (955), and neotame (961) provided these intense sweeteners are only used as a flavour enhancer or in an amount necessary to replace, either wholly or partially, the

sweetness normally provided by sugars.

Category 14.3: *Alcoholic beverages not included in item 14.2**

** Additives in Schedules 2,3 and 4 are permitted.*

The FSC also provides for such beverages to be sweetened with stevia glycosides but through an indirect rather than direct mechanism.

- Category 14.1.3 (water based beverages) and category 14.1.2.1 (Fruit and vegetable juices) permit the use of stevia glycosides as additives.
- Ready to drink beverages are mixtures of spirits and water based beverages and/or fruit juices.
- Clause 7 of Food Standard 1.3.1 provides for the carryover of food additives.

" Other than by direct addition, a food additive may be present in any food as a result of carryover from a raw material or an ingredient, provided that the level of the food additive in the final food is no greater than would be introduced by the use of the raw material or ingredient under proper technological conditions and good manufacturing practice"

- Ready-to-drink beverages can therefore contain steviol glycosides provided the level is not greater than that required to wholly or partially replace the sweetness normally provided by sugars AND the concentration is not higher than in the non-alcoholic component alone.

As illustrated in Appendix 1 to this submission, the current permission of 160 mg/kg steviol equivalents for water based flavoured drinks corresponds to a sugar level of approximately 13g/100g in the final RTD alcoholic mix beverage based on RebA97. The proposed increase in permissions for water based beverages to 200 mg/kg will in turn allow for a higher replacement of 16g/100g in the final RTD alcoholic mix beverage based on RebA 97. This upper limit is sufficient to allow for the complete replacement of sugar at the levels typical in RTD alcoholic mix beverages.

Sugar Australia and GLG believe that the permissions for use of steviol glycoside would be better served by having a direct permission for category 14.3 of the food standards code.

1) It will remove any ambiguity in the interpretation and application of the permissions for steviol glycosides.
2) Under the current provisions strict compliance with the permission would require manufacturers to separately prepare the non-alcoholic beverage with

stevia glycoside and then add this in the appropriate ratio to the spirit. This may not be the most cost effective manufacturing process. A direct permission would eliminate this unnecessary complexity.

3) It would align the permissions for steviol glycosides with other high intensity sweeteners such as aspartame and sucralose. While we would prefer this direct permission to be at GMP, we accept that FSANZ may determine an upper limit based on the ADI of 0-4 mg/kg body weight per day.

Because this is not a request for a new permission but a request to simplify and clarify an existing permission, Sugar Australia and GLG have made the reasonable assumption that FSANZ have already undertaken the required safety and risk assessments for the use of steviol glycosides in RTD alcoholic mix beverages.

If this is NOT the case then we request that FSANZ undertake a further round of consultation with stakeholders prior to the finalization of this application.

5. IN CONCLUSION

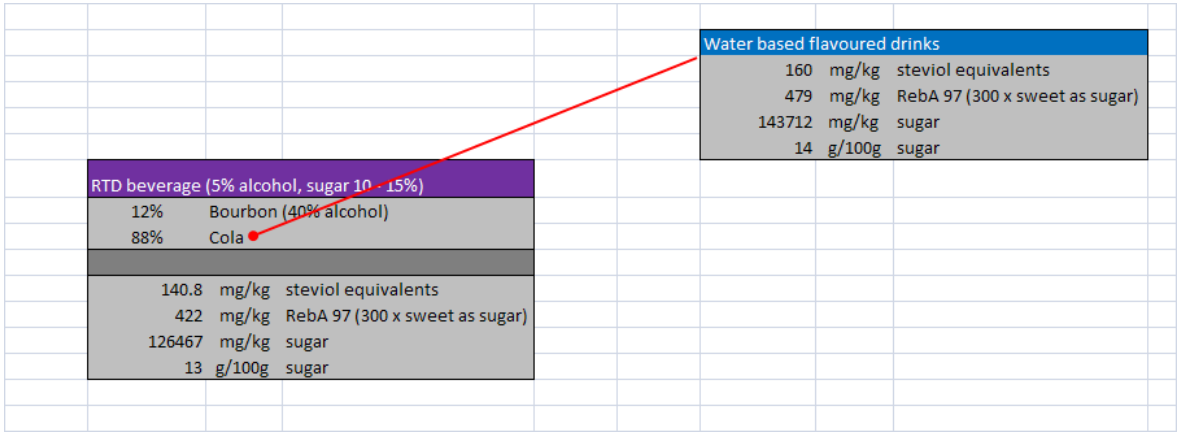
Sugar Australia and GLG would like to thank FSANZ for this opportunity to provide input towards Application A1037.

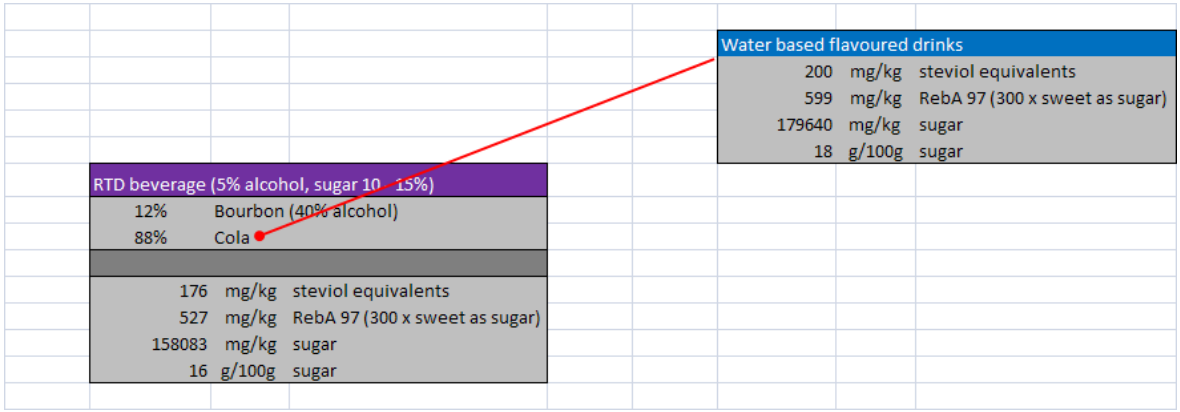
We would be pleased to provide further information to support the review process.

Yours sincerely,

Tim Hart
Chief Executive Officer
Sugar Australia Pty Ltd
(& on behalf of GLG Life tech Corporation)

Appendix 1:


Water based flavoured drinks
160 mg/kg steviol equivalents
479 mg/kg RebA 97 (300 x sweet as sugar)
143712 mg/kg sugar
14 g/100g sugar
RTD beverage (5% alcohol, sugar 10 - 15%)
12% Bourbon (40% alcohol)
88% Cola
140.8 mg/kg steviol equivalents
422 mg/kg RebA 97 (300 x sweet as sugar)
126467 mg/kg sugar
13 g/100g sugar


Water based flavoured drinks
200 mg/kg steviol equivalents
599 mg/kg RebA 97 (300 x sweet as sugar)
179640 mg/kg sugar
18 g/100g sugar
RTD beverage (5% alcohol, sugar 10 - 15%)
12% Bourbon (40% alcohol)
88% Cola
176 mg/kg steviol equivalents
527 mg/kg RebA 97 (300 x sweet as sugar)
158083 mg/kg sugar
16 g/100g sugar