

Anthony Bush  
CAMedica Ltd  
Brook House  
Tarrington  
Herefordshire  
HR1 4EU

16<sup>th</sup> December 2004

Reference: NFU 502

Dear Mr Bush

**REQUEST FOR AN OPINION ON SUBSTANTIAL EQUIVALENCE OF NONI JUICE PRODUCED ON A NUMBER OF PACIFIC ISLANDS.**

The Advisory Committee on Novel Foods and Processes (ACNFP) has now finalised its assessment of your request for an opinion on the substantial equivalence of 'Noni Juice produced by a number of Pacific Islands' used as a fruit juice ingredient in pasteurised fruit juice drinks, compared with the existing noni juice ingredient from Tahiti.

I am pleased to inform you that, in view of the ACNFP's positive opinion, the Food Standards Agency, the UK Competent Authority for all novel food issues, is content that the 'Noni Juice produced by a number of Pacific Islands' ingredient meets the criteria for equivalence, as defined in Article 3(4) of regulation (EC) 258/97. This conclusion is on the basis that the ingredient is manufactured in the way described in your request

and all quality control procedures mentioned in your request and the ACNFP opinion are followed.

This opinion applies solely to the 26 companies named at Annex A of the ACNFP Opinion. I wish to stress that each company should ensure that it has measures in place to ensure compliance with this opinion before they market a product in any Member State. Companies should also ensure that all products are marketed and labelled in accordance with European Community Law and any relevant national provisions.

Please note that, in accordance with Article 5 of (EC) 258/97, each applicant company should notify the European Commission when their product is first marketed. This notification should be sent (with the UK opinion) to Mr Andreas Klepsch at the following address:

**European Commission  
DG SANCO  
Rue de la Loi 200  
B-1049  
Brussels  
Belgium**

If you have any other queries, please do not hesitate to contact me.

Yours sincerely,

**Dr Chris Jones**  
Novel Foods Division

Enc.: ACNFP's opinion

Cc Mr A Klepsch, DG SANCO



4. According to Article 3(4) of (EC) 258/97, the notification procedure applies to “foods or food ingredients... which on the basis of scientific evidence available and generally recognised or on the basis of an opinion delivered by one of the competent bodies... are substantially equivalent to existing foods or food ingredients as regards their:
  - Composition
  - Nutritional value
  - Metabolism
  - Intended use
  - Level of undesirable substances contained therein”.
5. The legal implication of a trade association applying for approval under (EC) 258/97 has been investigated and no issues were raised.

## **Composition, Nutritional Value and Metabolism**

### **(a) Major Constituents**

6. The applicant is claiming equivalence to the approved noni juice produced in Tahiti and marketed by Morinda, which was authorised by Commission Decision 2003/426/EC in June 2003.
7. The noni juices produced by the applicant are produced on a variety of islands in the Pacific region and use a traditional ‘maturation’ process to condition the fruit prior to pressing. The applicant has produced an expert opinion, which states that the plant and fruits are the same as those grown in Tahiti.
8. The Noni juice produced by the applicant is intended to be consumed as a 100% pure juice. The applicant initially provided compositional data for one noni juice produced in Fiji. The Committee requested that additional compositional data be provided to demonstrate that the composition of the Fijian juice was typical of juice produced by all the named companies. The Committee also requested that the compositional specification should also be compared to a noni juice produced in Tahiti. The applicant provided further compositional analysis consisting of two samples of juice produced by the named companies in Fiji and Samoa. These were compared with two samples of a 100% pure noni juice from Tahiti. The results of these analyses indicate that whilst there were a number of differences these were within the limits of variation and the major constituents were comparable.

## **Composition, Nutritional Value and Metabolism**

### **(b) Effect of the production process**

9. The fruit is collected, and leaves, twigs and roots are excluded from the production process in order to prevent a build up of anthraquinones. The fruit is then washed, and graded and they are then left to mature in sealed, food-grade stainless steel drums for 8-10 weeks. The fruit is then pressed and the juice is filtered and pasteurised. This production process used by the applicant differs from the approved product. The applicant has explained that the maturation process is used to alter the colour and flavour, and also increases the amount of juice yield by the fruit. In contrast, the juice prepared by Morinda Inc. is prepared from fresh fruit without any intentional delay beyond what might normally occur during transportation from the field to the processing plant. The applicant does not believe that there are any significant compositional differences between juice produced from matured fruits and those produced using the process employed by Morinda Inc.
10. The Committee requested further information to clarify the nature of the maturation process, specifically whether the process produced alcohol. In response the applicant demonstrated that the product is not fermented and provided analyses of ethanol levels. Ethanol levels in the final product were 0.3% v/v which is comparable to both fruit juices in general and the authorised noni juice (0.2% v/v). The applicant also noted that 'pasteurisation, would arrest any further fermentation and also ensure microbiological safety'.

## **Composition, Nutritional Value and Metabolism**

### **(c) Amino acid profile**

11. In their consideration of the data described in para 8, the Committee noted that the levels of free amino acids, measured by an ion exchange chromatographic technique, were consistently higher in the applicant's products than in the Tahitian product. Members requested further information to clarify the nature of these differences and also requested information regarding the analytical methods employed. The applicant noted that the differences in amino acid levels are due to proteolysis occurring during the maturation stage and this leads to raised levels of free amino acids in the juice. The applicant agrees that whilst the values are higher than in the approved noni juice, they remain within the ranges seen for a number of other fruit juices.

## **12. Discussion:**

- (a) *The Committee agreed with the expert opinion that the plant and fruit was the same as the one used in the approved product. Members also agreed that the major components were present at levels that were typical of those seen in the approved noni product.*
- (b) *The Committee accepted that the maturation process did not produce an alcoholic beverage. The Committee also agreed with the applicant that the production process had no significant effect on the composition of the final product and was produced in a manner that would not result in anthraquinones being present in the final product.*
- (c) *The Committee accepted that the increased levels of amino acids were likely to be as a result of enzymic degradation, and agreed with the applicant that there was no evidence to suggest that the nutritional value and metabolism will alter significantly from the noni juice currently permitted on the EU market.*

## **Intended Use**

13. The applicant intends to market their product in a similar way to the approved product. The juice will be sold as a pure 100% pasteurised noni juice along with a recommended daily intake of 30ml. This recommendation is in line with Morinda Inc's approval, although the Morinda juice is consumed along with other ingredients in juice-based drinks.

14. *The Committee was content that the applicant's noni juice is to be consumed in similar manner to the approved product.*

## **Level of Undesirable Substances**

15. In the first instance the applicant provided microbiological analyses on a single representative sample of noni. The Committee requested further microbiological analysis be provided in order to demonstrate that the levels of microorganisms seen were typical of those seen in juice produced by other named producers. The Committee also requested clarification as to how the applicant intended to ensure that the fungal and yeast contamination was minimised during the maturation period. The applicant provided additional microbiological analyses on the same samples as those described in para 8. Although not as detailed as those provided

in the original data set, these gave a value of <10 CFU/g (Total viable count) . The applicant has also provided clarification as to how a quality assurance procedure will minimise fungal contamination during the maturation period Regular microbiological analyses will be carried out on all noni batches to show that the mould and yeast count is within acceptable levels and there will be regular visual inspections throughout the processing. Batches, which do not meet the quality assurance checks, will be discarded. Data provided by the applicant indicates that there is little growth of yeasts and mould throughout the maturation period

16. The Committee received two comments during a 21-day public consultation which related to the lack of adequate data provided by the applicant to demonstrate the lack of undesirable substances such as anthraquinones and mycotoxins and the requirement that all of the named companies adhere to the same QA procedures. The Committee agreed with both comments and requested that analyses be carried out on a range of products in order to demonstrate the absence mycotoxins (in particular patulin). Four samples of the applicant's noni juice have been tested for the presence of patulin and were found to be free from mycotoxins. The applicant is aware of Regulation (EC) 1425/2003<sup>1</sup> which set the maximum levels for patulin in fruit juices at 50ppb, along with a "code of practice for the prevention and reduction of patulin contamination in apple juice and apple juice ingredients in other beverages", which details maximum levels of patulin along with the sampling method and reference analysis method.

17. In addition to the QA measures described above, the applicant companies are introducing a HACCP system in accordance with Codex Alimentarius principles in order to minimise the risk of contamination throughout all the stages of production of the juice. These procedures will be independently audited on an annual basis.

***Discussion*** *The Committee agreed that the additional data provided demonstrates that the final pasteurised product is free from microbial contamination. Concerning the presence of mycotoxins, and in particular patulin, Members accepted there was little yeast and mould contamination during the maturation period and that the four patulin analyses demonstrated that the final product was within the levels described in Commission Regulation (EC) 466/2001. Given the lengthy maturation period, the Committee were also reassured with the applicant's assurance that the quality control procedures will prevent the growth of fungi. The applicant's intention to ensure that all parties who are named at annex 1 implement a HACCP system provides further*

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<sup>1</sup> OJ L 203, 12.8.2003, p.1.

*reassurance that the product will be produced in a manner that minimised the risk of contamination.*

### **Conclusion**

18. The Committee is content that sufficient data have been provided to evaluate the equivalence of the noni juice, produced by the applicant companies on a variety of islands in the Pacific region, with the existing noni juice ingredient, according to the criteria set out in Article 3(4) of the Novel Foods Regulation (EC) 258/97.
19. The noni juice produced by the applicant companies is manufactured and marketed in such a way that is not identical to the approved noni juice. However, the compositional data provided indicates that the maturation process has no significant effect on the nutrient composition of the final product, when compared with the approved product. Also, consumption in the form of pure juice, rather than as a component of juice-based drinks, does not invalidate the comparison.
20. Therefore the committee is content that noni juice produced by the named producers [Annex A] is substantially equivalent to the existing noni juice ingredient. The Committee would like to emphasize that any noni juice products introduced on the market will need to comply with existing EU legislation, including rules on the composition and labelling of fruit juices (2001/112/EEC) and on mycotoxins (Regulation 466/2001).

**October 2004**

**Annex A**

**Applicant companies**

<b>Company</b>	<b>Contact</b>	<b>Address</b>
*Pure Pacific Nin Juice *	Francis Reimers	P.O. Box 786 Majuru, Marshall Islands
*C-View Investments Ltd	Lynn-Lu	Lautoka Fiji
Pacific Fabrication	Carmen Bigler	P.O. Box 424 Majuru, Marshall Islands
*Noni PNG Ltd.	Brendan Chan	P.O. Box 246 , Lae Morobe Province, PNG
*Royale Noni Ltd*.	William Brull	P.O. Box 5842, Navutu Lautoka, Fiji
*Herbex Ltd *.	Gerhard Stemmler	P.O. Box 516 Lautoka, Fiji
*Bioteknology Ltd.*	Jeff Liew	P.O. Box 13617 Suva, Fiji
*Owlfiji Ltd .	George Patterson	P.O. Box 149 Levuka, Fiji
*Frezco Beverages Ltd .	Mohammed Altaaf	P.O. Box 9303 Nadi, Fiji
*Nonu Supplies Fiji Ltd .	David A. Khan	P.O. Box 10664 Suva, Fiji
*Lita Noni Juice Co.	T. Takataka	P.O. Box 1584 Nuku'alofa, Tonga
*Industrial Botanicals Co Ltd	Simon Agius	P O Box 1584, PKF House Port Vila, Vanuatu
*Cook Islands Noni Marke.	Teava Iro Jnr.	P.O. Box 184 Rarotonga, Cook Islands
Sunline Noni Ltd.	Taura Tukaroa	P.O. Box 295

		Rarotonga, Cook Islands
*Cook Islands Prem. Noni Nonimana Inc. Ltd.	Danny Mataroa	P.O. Box 78 Rarotonga, Cook Islands
Noni Ltd.	Richard Browne	P.O. Box 144 Rarotonga, Cook Islands
*CCK Trading	Ken Newton	P.O. Box 3043 Apia, Samoa
*Wilex	Eddie Wilson	P.O. Box 3428 Apia, Samoa
Nonu Samoan Ent.	Tia Siaosi	P.O. Box 1099 Apia, Samoa
Richard Keil Holdings	Richard Keil	P.O. Box 977 Apia, Samoa
Belau Agro Ind. Dev. Corp	Minoru Ueki	P.O. Box 8013/1197 Koror, Palau
*Tima Ltd	Ian Simpson	Taveuni Fiji
*Urabuta Ltd	John May	Lautoka Fiji
*King Solomon Noni *	Morgan Wairiu	Honiara, Solomon Islands
*Panacea Pacific Products Ltd	Ed Eves	P.O.Box 600 Port Vila, Vanuatu I
*Nauru Noni	Nelson Tamakin	P.O. BOX 452 Buada District, Republic of Nauru

**\* PINA Members**