

Application

Claiming

SUBSTANTIAL EQUIVALENCE of

**LEAP OF FAITH FARMS NONI JUICES
(Skin- and seed-free expressed juices of *Morinda
citrifolia L*)**

To 'Tahitian Noni Juice' of Morinda Inc.

(Non-Confidential)

Application made to:

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21 December 2005

SUMMARY

An application is submitted claiming Substantial Equivalence of Leap of Faith Farms (LoFF) noni (*Morinda citrifolia L*) juices to Morinda Inc's Tahitian Noni Juice (TNJ), which was approved as a Novel Food within the EU in 2003.

The Claim of Equivalence is based upon using equivalent plant material to produce juices that are similar in composition, free from potentially harmful compounds and processed in at least as hygienic a manner as TNJ.

LoFF noni juice is the seed- and skin-free expressed juice of *Morinda citrifolia L*. The fruit are grown at certified organic farms in Panama under rigorous GAP conditions and processed under GHP and GMP regimes. The success of these measures is proven by microbiological assays.

Nutrient and amino acid assays are also presented for three samples of LoFF juices and, for comparison, a commercially-available Tahitian noni juice unadulterated by additional fruit juices and sugars. These show that LoFF juice is similar in composition to Tahitian juices, except for having lower concentrations of sugars than TNJ (TNJ is know to contain admixtures of other sweet fruit juices and sugars), and higher concentrations of some vitamins, especially vitamin C. We attribute the latter result partly to a superior processing and storage regime.

Our product has been tested for the potentially harmful anthraquinones rubiadin and lucidin; both are shown to be absent, to the limits of analytical technique.

Recommended usage quantities are the same as for TNJ.

Taking all these factors into account we submit that Leap of Faith Farms noni juices are Substantially Equivalent to TNJ.

1. INTRODUCTION

Leap of Faith Farms (LoF Farms) grow *Morinda citrifolia* L(noni) fruit at Boquerón Chiriqui, Panama, for the food ingredients wholesale market. Noni fruit are processed in Panama into seed- and skin-free juice products which LoF Farms wish to market to countries of the European Union.

LoF Farms juices are similar in composition to Morinda Inc.'s 'Tahitian Noni Juice' (TNJ), which was approved as a Novel Food for sale in the EU in June 2003 (Official Journal, 2003), and are produced to the highest standards of quality and hygiene. We the Applicants provide this document as evidence in support of Substantial Equivalence to TNJ. This application describes the origin, harvesting and processing of the product, expected consumption, and analyses for nutrients and undesirable compounds.

The toxicity, genotoxicity and allergenicity of TNJ were extensively animal tested by Morinda Inc. in multiple separate studies, the results of which have been summarised by Wang *et al.* (2002). The results of Morinda's testing programme are discussed by the EU Scientific Committee on Food (2002b) in a published 'Opinion'. The No-Observable-Adverse-Effect-Limit (NOAEL) was equivalent to 8% of the subjects' body weight per day.

We claim that LoF Farms' noni juices are Substantially Equivalent to TNJ, because they are produced from the same species of fruit using similar processes that are at least as hygienic as those used by Morinda Inc., and this Substantial Equivalence is borne out by analysis.

We claim Substantial Equivalence for the following seed- and skin-free juice products:

1. Pure fresh juice;
2. Fresh juice with an admixture of 3-15% other fruit juices for taste;
3. Fresh juice concentrated and frozen (for transport and subsequent reconstituting);
4. Dried fresh Juice (for transport and subsequent reconstituting).

1.1 Brief Description, History of Consumption and Availability Outside the EU

Morinda citrifolia is a tropical continuously cropping non-seasonal tree bearing avocado-sized fruit, the juice of which is the subject of this Application.

Noni juices and other noni products are available commercially in the USA, primarily of Hawaiian origin, and the US FDA has found no cause to restrict the marketing and sales of such products. Noni products are also available in Central and South America and in Asia.

While not having been a traditional food ingredient in Europe, noni fruit and all its products have been consumed in Polynesia and the Hawaiian Islands for hundreds of years, primarily for medicinal purposes, but also in some communities and in time of famine as a staple. In Panama and other tropical countries noni fruit are eaten, as well as being processed into local products such as noni wine.

During the Second World War, noni fruit were classified as 'Generally Regarded as Safe' (GRAS) by the US military for service personnel stationed on Pacific islands.

The extensive information regarding ingestion of the fruit (as both medicine and food) in Polynesia and the Hawaiian islands is rigorously reviewed by McClatchey (2002). Despite being highly critical of certain specific medicinal claims, McClatchey reports no detriment to human health.

It is not the purpose of this Application to prove beneficial effects or to identify alleged beneficial components; the objective is to prove Substantial Equivalence to Morinda Inc's 'Tahitian Noni Juice' (TNJ), which has already been proven as not causing harm.

2. ORIGIN AND PRODUCTION PROCESS

2.1 Specification

The source of the product is the unripe and ripe fruit of *Morinda citrifolia L.*, which is a member of the Rubiaceae family:

Order: *Rubiales*

Family: *Rubiaceae* (Madder family; 66 genera, including coffee, quinine).

Genus: *Morinda L.*

Species: *Morinda citrifolia L.* (Indian mulberry, noni)

Morinda citrifolia L., has been a botanically stable species for hundreds of years, and is well-characterised. The plants used for LoF Farms juice products have not been subject to genetic modification (GM).

A description of the plant can be found in Wagner *et al.* (1990). Each noni 'fruit' as picked and processed comprises many connate drupes forming a fleshy syncarp or multiple fruit. The fruit contain multiple single-seeded cartilaginous pyrenes. Under optimum cultivation the fruit are typically 10-12 cm long and 5-6 cm in diameter.

Plant and fruit are illustrated in Figure 2.1. The fully-ripe fruit are cream-coloured.



Figure 2.1 *Morinda citrifolia L.* and Detail of Underripe Fruit. ©J.S. Peterson. USDA NRCS NPDC. Royal Botanic Gardens, Sydney, NSW, Australia. 2002.

LoF Farms juice products comprise the whole expressed juice of noni fruit, without seeds, skin or pulp.

LoF Farms juice products are classed as a novel food ingredient in pasteurised fruit drinks. The dried juice will be sold to consumers only as a reconstituted product in pasteurised fruit drinks, and labelling instructions will make this clear.

2.2 Hygiene Principles

LoF Farms' noni juices are produced under hygienic conditions, according to Council Directive 93/43/EEC (1993), by a combination of Good Agricultural Practice (GAP), Good Hygiene Practice (GHP) and Good Manufacturing Practice (GMP). In addition, cultivation has been certified as Organic; this ensures that there can be no synthetic chemical residues on the fruit.

Good Agricultural Practices as defined globally (FAO, 2003), comprise a range of measures for agriculture which is sustainable, efficient and non-polluting by taking a life cycle approach to environmental hygiene, hygienic production (water, manure, soil, agricultural chemicals, biological control, indoor facilities, personal hygiene); handling; storage; transport; cleaning; maintenance; and sanitation.

But within this framework, specific guidance is available for minimising microbial contamination of fruit and vegetable products. The standards applied to LoF Farm juices are those recommended for best practice in the USA, by the US FDA (1998) and in an excellent presentation from Cornell University (2001).

The focus of GAP in microbial hygiene of fruit is upon faecal *Salmonella*, *Shigella* and coliforms, and prevention is rightly regarded as more effective than cure. In accordance with the guidelines, LoF Farms practice centres upon:

- Cultivation;
- Harvesting; and
- Post-harvest treatment.

As Beuchat (1998) points out, removal of heavy microbial contamination on fruit arising from cultivation and/or harvest is much more difficult and less satisfactory than minimising contamination in the first place. It is the role of Good Agricultural Practices to achieve this. The complementary role of Good Manufacturing Practices is to prevent contamination (or growth, from very low levels, of existing contamination) during subsequent processing.

Although the juices are subsequently pasteurised, the microbial protection strategy up to the point of juice expression actually follows published best practice in the cultivation, harvesting and post-harvest treatment of *fruit and vegetables to be eaten raw*. The EU view on the needs (though not the means) for microbial safety in this type of product are described by the EU Scientific Committee on Foods (2002a).

2.3 Origin, Cultivation and Harvesting

LoF Farms grows *Morinda citrifolia L.* (noni) trees on three farms in Panama in a rich dark volcanic soil. Noni trees were first planted at these farms in 2001. Cultivation has been certified as organic by Bio-Latina, the regulatory body from South America with a presence throughout Latin American countries, and affiliated to the German Deutscher Akkreditierungs Rat (DAR). Bio Latina's requirements follow EEC Regulation 2092/91 'Organic Production of Agricultural Products'. Current certificates of organic production and processing are shown in shown in Figures 2.2a and 2.2b.



Figure 2.2a Certificate of Organic Production for LoF Farms in Panama

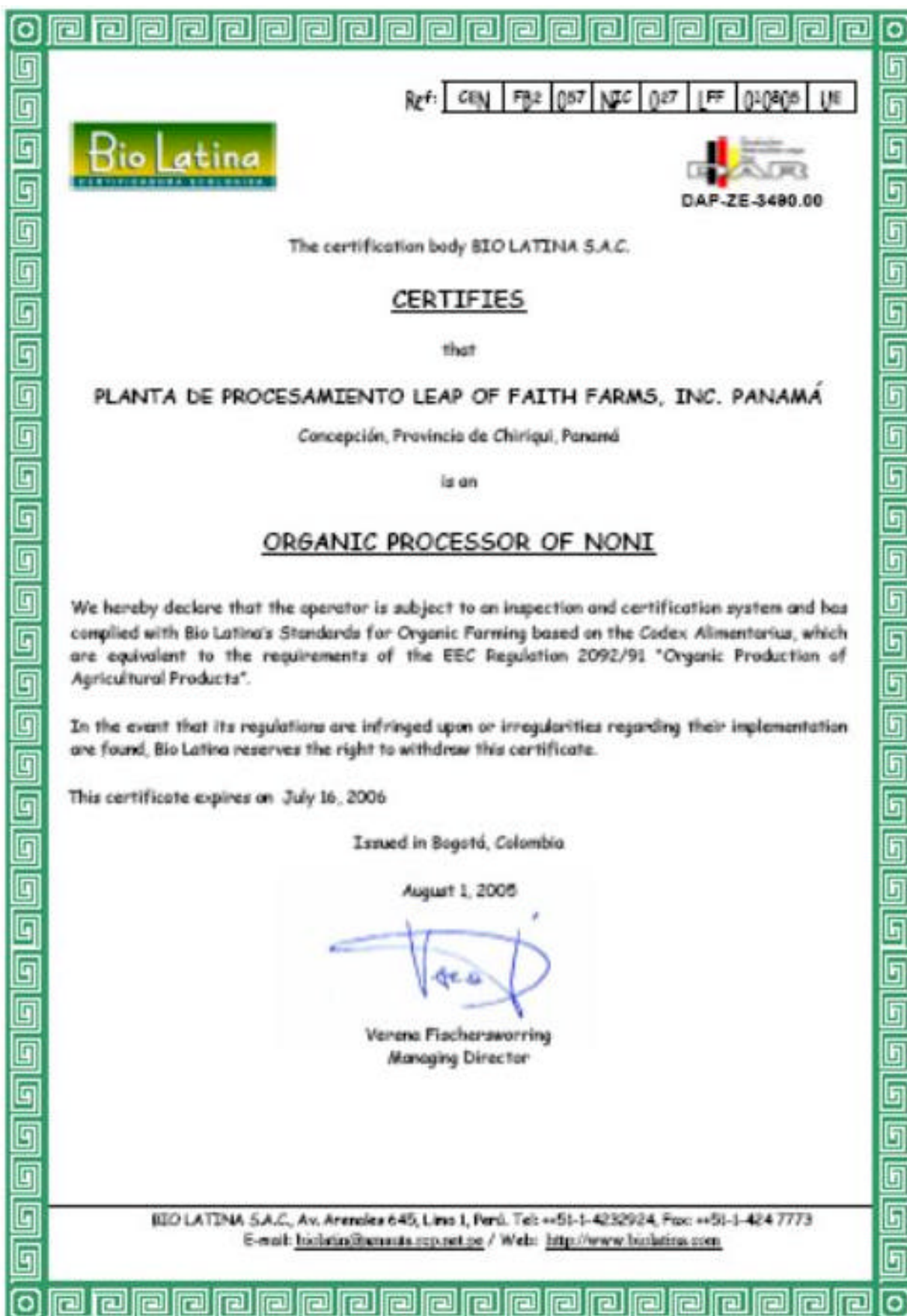


Figure 2.2b Certificate of Organic Processing for LoF Farms in Panama

The aims of GAP in cultivation are to prevent contact of the fruit with manure or with wildlife, human or pet faeces whether ground- or water-based. The noni fruit is an above-ground arboreal crop, and has no direct contact with the soil or terrestrial faeces.

LoF Farms use natural but not animal fertilizers; fertilizers comprise coffee bean and rice husks and decomposing plant matter. No chemical fertilizers are used. All water for irrigation, required during the dry season, is from a private river of fresh water from mountain streams, uncontaminated by fertilizer or animal manure runoff.

Only certified organic pesticides are used. Pesticides are made up using local municipal water of potable quality. Pesticides are used principally to control ants and other insects on immature, non-fruit-bearing, plants to ensure proper growth. No pesticides are applied to mature, fruit-bearing, trees except in cases of severe infestation. In such cases, affected trees are marked and quarantined, and the fruit is not picked for processing but allowed to fall before disposal. The quarantine period is 60 days.

Harvesting is carried out by hand by workers trained in personal hygiene, to prevent human faecal contamination. Fruit is picked dry. All fruit is picked from the tree; no fruit is used if it has touched the ground. Fruit visibly contaminated by bird droppings is left on the tree at harvest. The fruit is inspected when picked for insects or portions that have spoiled or bruised; all damaged fruit is discarded.

During harvesting at LoF Farms, noni fruit are picked by hand, and twigs and leaves do not normally enter the harvesting containers. There is, further, no possibility of root material being present.

The noni fruit are picked when near but not completely ripe. At picking they are cream in colour, not green, but are still hard in texture to prevent handling damage.

Receptacles for carrying fruit to the processing plant are washed daily using potable municipal water.

2.4 Processing

The processing of the fruit is illustrated in Figure 2.3.

The noni fruit are delivered directly to an enclosed processing plant where they are graded and inspected. All post-harvest treatment takes place in an enclosed workroom, which is separated from any gross dust created by vehicles etc in the loading bay. Any bruised or damaged fruit not rejected at harvest is removed at inspection. Any twig or leaf material that is inadvertently harvested is removed at the inspection stage.

Fruit are then washed by a brush washer in fresh potable municipal water. Water is not recirculated. The fruit are blown with clean air to remove superficial liquid.

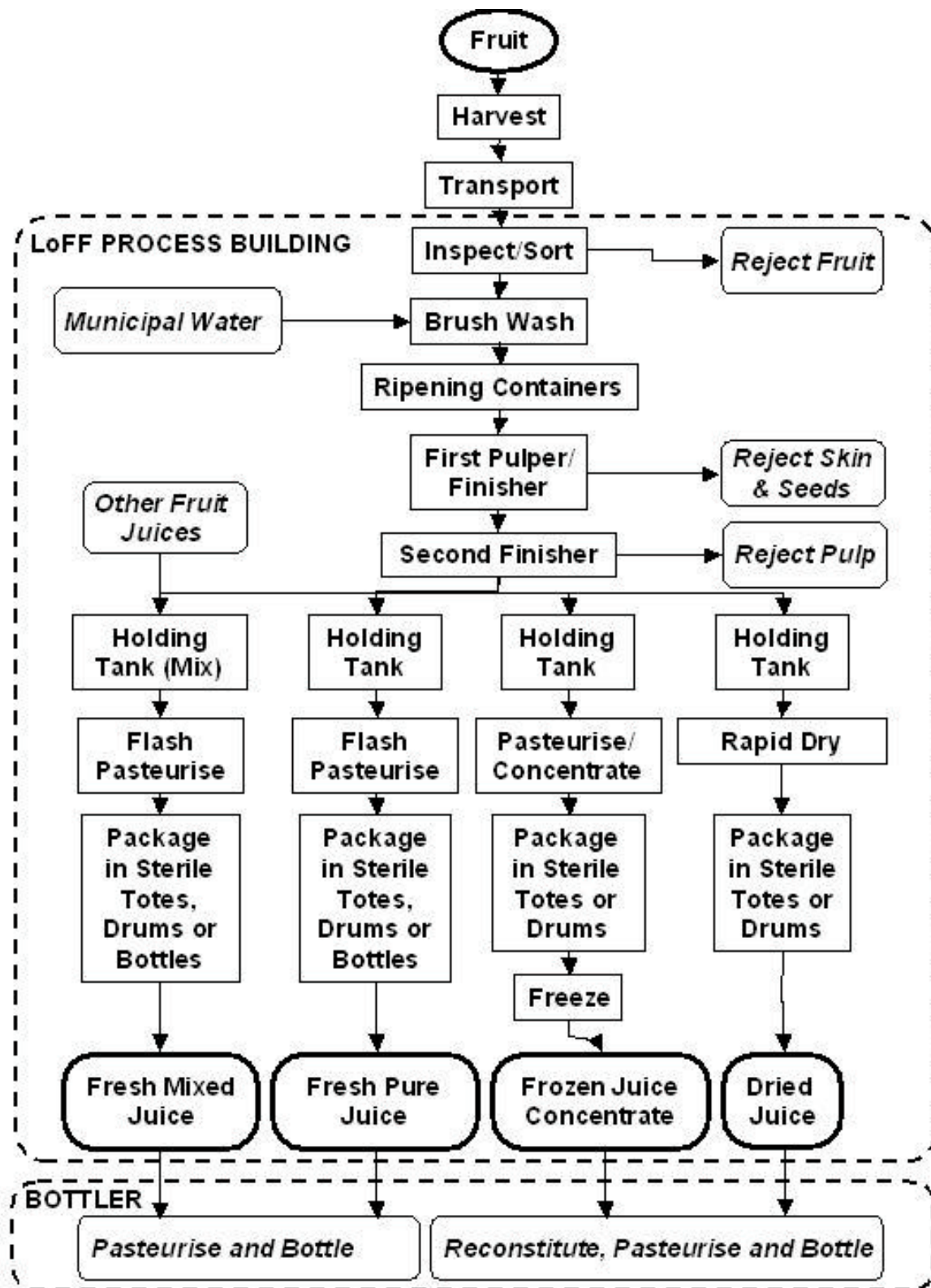


Figure 2.3 Schematic of the Process.

Process water temperature is regulated to near ambient, to ensure that it is never more than 5.6°C (10°F) cooler than the fruit. This is done in accordance with GAP to reduce water and potential contaminant ingress to the fruit pulp via minor scars and skin blemishes.

The product is untouched by hand after washing of the fruit.

After inspection, the fruit are conveyed to disinfected/sterilized containers, and covered for a period of 2 - 4 weeks to ripen naturally. By completing ripening within the process facility, harvesting damage to softened fruit is minimized. This also minimizes loss of fruit due to falling and maximizes juice yield as fibres in the fruit break down. Once the fruit has ripened according to LoF Farms' standards, and has been tested for quality, it is processed by a Brown Model 202 Pulper/Finisher or equivalent machine. This removes skin and seeds and breaks the remaining flesh into a puree. The Pulper/ Finisher is of the paddle type, and the concentricity of paddle and screen prevent breakage of seeds.

The puree and juice produced by the first Pulper/Finisher is pumped to a second Finisher, a Brown Model 303 or equivalent. The Brown Model 303 is of the twin-screw type, and is equipped with a very fine screen that separates the juice from the pulp. The excess pulp is expelled and pumped to a receiving vessel for processing into animal feed.

The noni juice is pumped from the Second Finisher to one of several Holding Tanks. The juice may be flash pasteurised directly from the holding tanks or subjected to three minor variations:

- 1) Mixed with other (non-noni) juices for palatability, then flash pasteurised. The proportion of Noni juice in such cases would be no less than 85%, and typically no more than 97%.
- 2) Concentrated by thermal evaporation and subsequently frozen;
- 3) Dried for subsequent reconstituting at a bottlers.

These variations have negligible influence on the general composition of the juices, which are all similar and equivalent to Morinda TNJ.

Fresh and Mixed Juices:

Fresh and mixed juices are pasteurised under a 'flash' or High Temperature Short Time (HTST) regime that raises the temperature to 88°C for 4 seconds. Pasteurization destroys pathogens. Pasteurised juice is filled into: 1,000 litre aseptic totes; aseptic 200 litre (55 US gal) drums; or bottled in controlled conditions into sterile washed and rinsed glass or PET plastic containers.

Concentrated Juice:

Where evaporative concentration is practiced, the degree of concentration is determined partly by customer specifications, but always to a total sugars concentration of at least 45 Brix. The high temperatures of evaporative concentration also destroy and inactivate pathogens, and high sugar concentrations are a well-established means to inhibit further bacterial growth. Bacterial growth depends on adequate water activity a_w , and if water activity can be reduced below approximately 0.91 most infectious, spoilage and food poisoning organisms are inactivated. Figure 2.4 shows how a_w changes with concentration for glucose (Gibbs and Gekas, 2004); similar values apply for fructose.

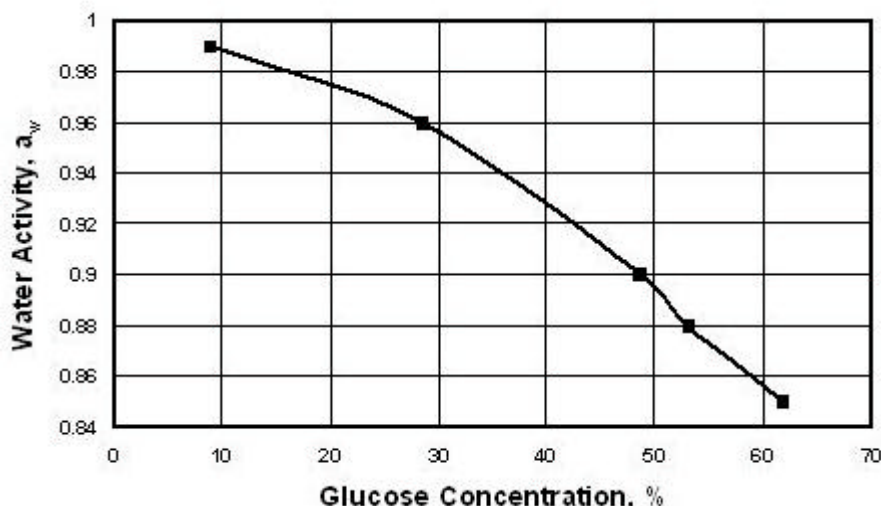


Figure 2.4 Dependence of Water Activity on Concentration in a Glucose Solution.

Concentrated juice is filled into bulk aseptic drums or totes and then frozen for transport. Freezing is purely precautionary – due to the high sugar content and the lack of any tendency on the part of noni juice to ferment. The concentrate is subsequently reconstituted with water and pasteurized before bottling.

Dried (for Reconstituting) Juice:

Some juice is dried for subsequent reconstituting by a bottler, to a water content of less than 4% by weight. Drying kills pathogens and reduces water activity to a level at which microbial activity is extremely low.

2.5 Process Hygiene

The processing plant meets GMP standards, and all FDA and HACCP principles are strictly adhered to from the time the fruit arrives at the plant to the time it is shipped.

The pulper-finishers and other equipment are designed for food use and constructed internally of food-grade stainless steels. Pumps are of the positive-displacement lobe type specified for food or pharmaceuticals use. Pumps etc. are connected by a combination of stainless steel pipe and food-grade flexible polymer hoses with rapid disconnects.

All equipment is CIP (clean in place) and is daily emptied, washed and sanitized using approved food industry cleaning products, and inspected.

The processing facility is monitored and inspected at least once per month by the local health ministry.

All personnel are tested and certified by the health ministry on an annual basis. Clean laboratory-type smocks or coats are worn at all times while in the processing areas, as well as mandatory hairnets and gloves. Footwash (for rubber boots) and hand wash is at any entry point to the processing area as well as sanitizer wash and rinses at each toilet facility.

Each employee is trained by management in proper sanitary methods and understands the operating procedures for their position or task.

Processing personnel are periodically checked by their foreman to ensure strict adherence to all sanitary and operating policies and procedures.

2.6 Standard Microbial Analyses of Products

In its 'Opinion' on TNJ the SCF does not repeat any microbiological information presented to it by Morinda Inc., relying, it would appear, on the assertion of GAP, GHP and GMP.

The efficacy of the agricultural and processing regimes used for the production of LoFF juices is confirmed by the range of microbiological tests reported in the appendices.

Appendix A2 gives microbiological data for LoFF fresh and dried juices measured in December 2004, and Appendices A3 and A4 provide similar data for those measured in July/August 2005. Appendix A5 lists microbiological data for the commercial pure Tahitian noni juice sampled.

All samples show very low levels of *Bacillus cereus* and *Clostridium perfringens*. In addition, all three LoFF samples (Appendices A2, A3 and A4) display a complete absence of coliforms, *E. coli*, *Listeria*, *S. aureus*, yeasts and moulds. That these species are absent compares favourably with the commercial Tahitian noni juice (which has low levels of all these) and is proof of the effectiveness of the processing regime. Total Viable Count at 20-40 colony-forming units (cfu) per gram is very low. These counts compare favourably with counts of commercially-advertised products of natural foodstuffs on the open market. A typical example is cocoa powder from an Asian source, which had a maximum Standard Plate Count of 2,000 cfu/g.

3. COMPOSITION AND COMPARISON WITH TAHITIAN NONI JUICES

In order to establish equivalence, the following analyses were undertaken:

- Proximate, vitamin and amino acid analyses of fresh and reconstituted dried juice. Fresh juice samples from Leap of Faith Farms were analysed in December 2004 and again in July/August 2005.
- Proximate, vitamin and amino acid analysis of a commercially-available Tahitian noni juice free from other juices and additives (unlike Morinda's TNJ which does contain additional juices).
- Analysis of the anthraquinones rubiadin and lucidin in fresh and dried (ie. powder) LoF Farms juices.

Appendices A1 to A5 list proximate nutritional parameters plus vitamin, amino acid and microbiological data.

Appendix A6 reiterates data for TNJ that are given in the EU 'Opinion' (2002b).

Appendix A7 reproduces analytical data for rubiadin and lucidin in LoFF fresh and dried juices.

All three analyses of LoFF juices *and* the commercial Tahitian juice were undertaken in the same laboratory, at the Laboratorio de Recursos Naturales of the Universidad Autonoma de Chiriqui, Panama. (The raw analytical reports presented in Appendices 3 – 5 were given in Spanish and have been translated).

We claim that LoF Farms' noni juices are Substantially Equivalent to TNJ, because they are produced from the same species of fruit using similar processes that are at least as hygienic as those used by Morinda Inc., and this Substantial Equivalence is borne out by analysis.

Microbiological data have been discussed in Section 2.6 above.

3.1 Major Nutritional Parameters

The juice analyses given in Appendices A1 – A6 are compared in Table 3.1.

Appendix A1 gives a proximate analysis of LoFF juice without water sampled in December 2004, and the first column of data in Table 3.1 summarises this information with the following minor changes in presentation:

- The total proportion of carbohydrates, protein, vitamins and ash in Appendix A1 is 97.49%: the remaining 2.51% is presumed to be fat, and this accords well with previous analyses of LoFF noni products.
- Total sugars and fibre have been subtracted from the 'total carbohydrates' figure to give a figure of 36.25% for starch.
- The recorded metals content is detailed separately at the bottom of the table.

In the second column of the table, the 'dry' analysis of column 1 is converted to a wet basis using the same moisture content (95.86%) of recent fresh samples.

Appendices A3 and A4 give analyses of samples collected in July/August 2005 of fresh LoFF noni juice and of juice which has been dried and then reconstituted with water. These

samples were analysed 'wet' and the data are compared in the next two columns of Table 3.1. In other respects the presentation is the same as for the earlier sample.

Appendix A5 records 'wet' analytical data for a commercially-available Tahitian noni juice unadulterated by other juices or sugars. These data are recorded in the fifth column of data in Table 3.1 in the same way as for the Panamanian juices.

Comparison with Morinda Inc.'s TNJ is more difficult because Morinda are known to add other juices and sugars to their product. In the SCF 'Opinion' (given in Appendix A6), ranges are given for the nutritional parameters on a 'wet' basis. It is clear that the major difference between LoFF juices and TNJ is that the latter contains far more sugar.

If the additional sugar levels in TNJ were to be discounted, then the levels of other nutrients would mostly 'bracket' those found for LoFF products. However, such a quantitative comparison was not considered justified.

Overall, the data show broadly similar products across the samples studied. The two Tahitian products adduced for comparison are similar in composition, though the fructose levels in the 'Pure' Tahitian juice are somewhat high compared to fibre and starch.

The compositions of the fresh juices sampled in December 2004 and in July/August 2005 are very similar in composition except in respect of dietary fibre, and are close to the recorded ranges for TNJ.

The dried juice is more similar in composition to the pure Tahitian juice.

Levels of minerals are broadly similar, especially calcium, iron and zinc, though the more volatile elements are relatively low in the dried product.

Vitamins are discussed in the next section.

Table 3.1 Comparison of Leap of Faith Farms Noni Juices and a Commercial Unadulterated Tahitian Juice; Major Nutritional Parameters.

All figures as percentage by weight (ie. g/100g)

	LoFF Juice 12/04	LoFF Juice, Wet Basis 12/04	LoFF Juice 07-08/05	LoFF Dried 07-08/05	Tahitian Pure 07-08/05
Moisture	0	95.86	95.86	96.3	95.1
Total Carbohydrates	79.8	3.30	3.3	3.10	3.86
Fibre, Dietary, Total	18.1	0.75	0.07	0.52	0.07
<i>Fructose</i>	14.9	0.62	0.71	1.05	2.07
<i>Glucose</i>	9.36	0.39	0.33	0.55	0.94
<i>Sucrose</i>	1.21	0.05	0.03	0.80	0.09
Total Sugars	25.47	1.06	1.07	2.4	3.1
Other Carbs. (Starch)	36.23	1.5	2.16	0.18	0.69
Protein - Combustion	7.59	0.31	0.38	0.40	0.43
Ash - Food	5.89	0.24	0.36	0.15	0.51
Vitamins, Total Recorded	4.21	0.17	0.038	0.037	0.0051
Other (Inc. fat)	2.51	0.10	0.10	0.013	0.2
TOTAL	100.00	100.00	100.04	100.00	100.11
Minerals :					
Sodium			0.0142	0.00458	0.0297
Magnesium	0.1300	0.0054	0.0048	0.00388	0.0162
Phosphorus	0.1400	0.0060	0.0129	0.0017	0.0166
Potassium	3.6600	0.151	0.169	0.0303	0.118
Calcium	0.2500	0.010	0.0121	0.00954	0.0152
Manganese			0.00004	0.00004	0.00005
Iron	0.0052	0.0002	0.00031	0.00025	0.00038
Copper	0.0021	0.00007	0.00007	0.00003	0.00003
Zinc			0.00006	0.00006	0.0001
Total Minerals	4.187	0.173	0.213	0.0504	0.196

3.2 Vitamin Profile

Table 3.2 compares the profiles of individual reported vitamins for LoFF juices and pure Tahitian juice. As in Table 3.1 above, the data in the first column of figures are converted to a 'wet' basis in the second.

A significant feature of these data is the similarity in vitamin profile between the July/August 2005 samples of fresh and dried juice. For every vitamin measured, the 'dried' value is the same or only slightly lower than the 'fresh' value. This appears to indicate that drying denatures some of the vitamin content of the juice, but only by a small proportion.

The profiles of all samples are dominated by vitamin C. The vitamin C content measured for LoFF juice in December 2004 is exceptionally high for any fruit, but is very close to values previously measured by another laboratory for other LoFF noni products from the same source, and should therefore be considered genuine. Probable reasons are good choice of fruit variety/strain and a processing regime which optimises retention of the characteristics of the fresh fruit.

Table 3.2 Comparison of Vitamin Profiles of Leap of Faith Farms Noni Juices, and a Commercial Unadulterated Tahitian Juice.

	Unit	LoFF Juice 12/04	LoFF Juice Wet Basis 12/04	LoFF Juice 07-08/05	LoFF Dried 07-08/05	Tahitian Pure 07-08/05
B1	mg/100g	0.76	0.031	0.015	0.015	0.0006
B2	mg/100g	4.4	0.18	0.015	0.015	0.0005
B6	mg/100g	0.30	0.012	0.12	0.10	0.08
B12	mcg/100g	0.44	0.018	0.2	0.18	0.18
Niacin	mg/100g	*6.0	0.25			
Folic acid	mcg/100g	62	2.57	18.0	18.0	10.0
C	mg/100g	4,200	174	38	37	5
E	IU/100g	12	0.501	1.25	1.20	0.25

(*Comparison with previous analyses of LoFF noni products, as well as levels recorded in the general open literature for a wide variety of fruit, indicates that the units of measurement for niacin have been incorrectly recorded by Chiriqui University laboratories as micrograms per 100g, not milligrams per 100g; this has been corrected in the table.)

3.3 Amino Acid Profile

Table 3.3 compares the amino acid profiles for LoFF juices and pure Tahitian juice. As in Tables 3.1 and 3.2, the data in the first column of figures are converted to a 'wet' basis in the second.

The clearest trend in these data is for the amino acid content of the dried juice to be slightly lower than that of the fresh juice, and this applies to every amino acid measured. This is similar to the trend found for vitamins. Thus the act of drying lowers the amino acid content, but only slightly and in a very consistent fashion. This underlines the similarities of fresh and dried juice.

For the most part, concentrations for the candidate juices tend overall to be similar or somewhat higher than the pure Tahitian juice.

Table 3.3 Comparison of Amino Acid Profiles of Leap of Faith Farms Noni Juices and a Commercial Unadulterated Tahitian Juice.

All figures in mg/100g

	LoFF Juice 12/04	LoFF Juice Wet Basis 12/04	LoFF Juice 07-08/05	LoFF Dried 07-08/05	Tahitian Pure 07-08/05
Cystine	140	6	6	6	7
Methionine	60	2	3	2	3
Aspartic acid	650	27	65	65	15
Threonine	210	9	6	6	6
Serine	230	10	9	8	9
Glutamic acid	720	30	32	32	10
Proline	220	9	22	21	5
Glycine	280	12	10	10	8
Alanine	270	11	27	26	22
Valine	320	13	17	17	10
Isoleucine	220	9	7	7	5
Leucine	340	14	18	18	11
Tyrosine	150	6	9	9	8
Phenylalanine	180	7	8	8	7
Lysine, total	140	6	8	7	7
Histidine	110	5	7	7	8
Arginine	320	13	18	18	22
Tryptophane	130	5	1	1	1

3.4 Analysis of Anthraquinones

Much has been made in the noni (not just TNJ) promotional literature of the wide variety of natural and allegedly beneficial compounds in noni products, among them anthraquinones. But certain anthraquinones, notably the hydroxyanthraquinones rubiadin and lucidin, are known for a degree of genotoxic potential. The adverse side-effects of hydroxy-anthraquinones in herbal medicines have been reviewed by Westendorf (1993). And Westendorf *et al.* (1998) found that anthraquinone-containing root of madder (*Rubia tinctorum*) caused non-neoplastic and neoplastic changes to liver and kidneys in rats. While the published studies of toxicity for herbal products rely on chronic animal tests at very high doses, on the precautionary principle the possibility of chronic high-level use by consumers cannot be ruled out.

Anthraquinones have been detected in some tissues of the noni plant, such as the roots, leaves and bark. However, anthraquinones have been shown not to be present in TNJ.

During harvesting at LoF Farms, noni fruit are picked by hand, and twigs and leaves do not normally enter the harvesting containers. Any twig or leaf material that is inadvertently harvested is removed at the inspection stage. There is, further, no possibility of root material being present.

Nonetheless, analyses were undertaken of Leap of Faith Farms juice products for the following species:

- Rubiadin
- Lucidin,

Separate analyses were undertaken by HPLC for both rubiadin and lucidin in fresh and dried noni juice.

The method was that of Westendorf *et al.* (1998). 20 ml of the juice is extracted twice with 20 ml ethyl acetate. The organic phase is combined, evaporated and redissolved in 100 µl methanol. 20µl of this solution is injected on an RP-18/10µ HPLC column and eluted with a gradient of acetonitrile/water. The detection wavelength is 410 nm.

The results of the analyses are shown in Appendix 7. Anthraquinone concentrations have been measured in micrograms per kilogram, equivalent to parts per billion (ppb), with an effective limit of detection for juices of 10 ppb. In neither of the samples was either rubiadin or lucidin found at the limit of detection. A higher limit of detection applies to dried product, but again neither anthraquinone was detectable.

3.5 Conclusions on Composition

In this section we have compared analyses for three LoFF juice products with a commercial pure Tahitian noni juice.

We have shown that nutritional analyses are broadly similar for all four products considered, though LoFF products tend to be somewhat high in vitamin C. Our analyses of vitamin and amino acid profiles of fresh and dried LoFF juice show that drying has a measurable but small effect on composition.

We have also shown conclusively that good regimes for keeping fruit separate from leaves, roots and twigs means that no rubiadin or lucidin is present in LoFF products.

4. INTENDED USAGE AND QUANTITIES

The intended use of the juices are as ingredients in pasteurised fruit drinks. The dried juice will be sold to consumers only as a reconstituted product in pasteurised fruit drinks, and labelling instructions will make this clear.

The pure juices are not intended or expected to be consumed for their taste, and will not replace other nutritionally significant foods in the diet.

The products will be supplied as pure or mixed juices in conventional sized bottles, typically 250 – 750 ml according to the requirements of the local market.

The recommended daily usage will be 30 ml. Though small, this is in keeping with the dose recommended by Morinda Inc. for TNJ, but recognising that some customers will over-use the product on the false principle that 'more is better'. It is worth noting that in his trials of the benefits or otherwise of noni consumption, Solomon (1999, 2000) used a daily starting dose of 4 ounces (113 g) of whole noni juice, without ill effect.

Compared to 'conventional' fruit juices, accidental ingestion to excess by children is very unlikely due to the unpleasant taste.

6. EVALUATION AND CONCLUSION

In evaluating Substantial Equivalence with existing products, the UK Competent Authority (the FSA) along with all EU member states require a request for an opinion to meet the requirements as defined in Article 3(4) of Regulation (EC) 258/97.

In establishing equivalence, we the applicants have first shown that we use the same species, *Morinda citrifolia* L (noni). Because noni is an arboreal fruit it does not come into contact with soil, and hence soil-borne faecal contamination prior to harvesting is avoided. Harvesting and washing use the strictest adherence to the high standards of Good Agricultural Practices (GAP) normally reserved for fruit and vegetables to be eaten raw.

The fruit as it enters the processing plant is therefore free from faecal contamination.

While not here claiming organic status in the UK context, the fact that our farming practices have also been approved as organic by internationally recognised certifying bodies means that fruit is also free from synthetic chemical contamination.

In the processing plant, the noni fruit are thoroughly washed, damaged fruit is rejected and undamaged fruit allowed to ripen. The subsequent processing, firstly by a paddle pulper-finisher and subsequently by a screw finisher, produces a high-quality juice free of seeds, skin and gross pulp fibre. The action of the paddle pulper-finisher is such that the tough seeds are not broken, so no seed material enters the juice.

Subsequent processing of the juice, whether fresh, mixed with other juices for flavour or dried, also follows the strictest standards of hygiene. Final processing of juice by LoF Farms comprises rapid pasteurisation or evaporative concentration or drying. Both concentration and drying not only destroy pathogens but reduce water activity to the point at which spoilage is halted.

Processing also meets the highest standards of general hygiene. Comminution, pumping and storage take place in contact only with stainless steels and food-grade polymers. All equipment is of food grade construction, and is cleaned daily. Personnel are trained in personal hygiene, and protective clothing is worn. The facility is subject to regular inspection by local authorities.

Juice has been analysed for nutritional parameters and amino acids, as well as standard microbiological indicators. Unlike TNJ, our 'standard' juice product does not contain added sugars or sweeter fruit juices, so comparison has been made with a commercial pure Tahitian noni juice. Compositions are broadly similar.

The exception lies in the measured levels of certain vitamins, notably vitamin C which is exceptionally high – but we argue that this is partly the result of a less damaging processing regime.

The effect of drying juice is to lower the levels of vitamins and amino acids consistently but only slightly.

Microbiological measurements of our products gave Total Viable Counts of 20 - 40 cfu/g, and absence of coliforms, *Listeria*, and *S.aureus*, confirming the efficacy of the cultivation and processing regime.

Promotional literature for some noni products claims the presence of certain anthraquinones. Examples include rubiadin, which is known to be present in noni root but has been implicated in carcinogenicity. The EU Committee on the Safety of Food is concerned particularly with

the hydroxyanthraquinones rubiadin and lucidin. We have carried out analyses for rubiadin and lucidin, and these were found to be absent to the limits of detection by highly reputable academic analysts.

Our product is not expected to replace other items in the European diet, but is intended as an ingredient in pasteurised fruit drinks and is marketed as such. The dried juice will be sold to consumers only as a reconstituted product in pasteurised fruit drinks, and labelling instructions will make this clear. The recommended daily dose of 30 ml is the same as recommended by Morinda Inc. for TNJ.

Taking all these factors into account we submit that LoF Farms noni juices, fresh, fresh mixed with other juices, or reconstituted from concentrate or powder, are Substantially Equivalent to TNJ.

7. REFERENCES

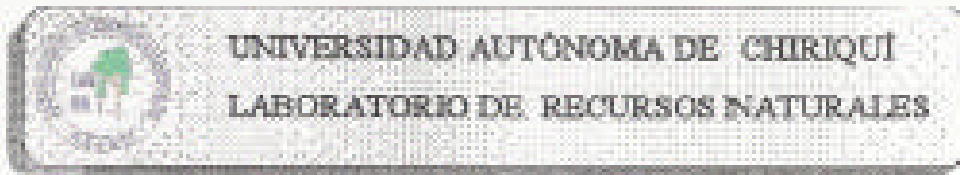
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APPENDICES – ORIGINAL ANALYTICAL DATA

Appendix A1. Analysis of LoFF Fresh Panamanian Noni Juice, December 2004; Major Nutrients and Vitamins



Date: 10/12/2004
Product Sample: Noni Fruit Juice

Client: Leap of Faith Farms
Mr. Michael Vorderburg

RESULTS OF ANALYSIS

	Result	Unit
Protein	7.59	%
Fiber	18.1	%
Ash - Food	5.89	%
Carbohydrates	79.8	%
Calories	368.0	100 g
Fructose	14.9	%
Glucose	9.36	%
Sucrose	1.21	%
Calcium	253	mg/100g
Copper	0.0018	%
Iron	0.0056	%
Magnesium	0.13	%
Phosphorus	144	mg/100g
Potassium	3,644	mg/100g
pH	4.04	
Folic Acid	62.3	mcg/100g
Niacin	6.01	mcg/100g
Vitamin B1	0.760	mg/100g
Vitamin B2	4.43	mg/100g
Vitamin B6	0.300	mg/100g
Vitamin B12	<0.441	mcg/100g
Vitamin C	4,194	mg/100g
Vitamin E	12.10	IU/100g

Analista Responsable

Aracely Vega
MSc. Aracely Vega

Appendix A2. Analysis of LoFF Fresh Panamanian Noni Juice, December 2004; Microbial and Amino Acid Analysis



AGRICULTURAL/BULK DIVISION
NEW ORLEANS, LA

MARCH 22, 2005
NOAB05-31218.7146-7147/mr

ANALYSIS REPORT

DATE SUBMITTED: DECEMBER 20, 2004
SUBMITTED BY: LEAP OF FAITH
MARKS/REFERENCES: JUICE "A" & JUICE POWDER "B"

Samples were submitted for analysis, results as follows:

<i>Laboratory Nos.</i>		<i>31218.7146</i>	<i>31218.7147</i>
METHOD	TEST	JUICE "A"	JUICE POWDER "B"
AOAC 990.12	Total Viable Count, cfu/g	40	20
BAM	Bacillus Cereus, mpn	*4	<0.3
BAM	Clostridium Perfringens, cfu/g	<10	<10
AOAC 991.14	Coliforms, cfu/g	Negative	Negative
AOAC 991.14	E. Coli, cfu/g	Negative	Negative
BAM	Listeria	Negative	Negative
AOAC 2001.05	Staphylococcus Aureus, cfu/g	Negative	Negative
AOAC 997.02	yeasts, cfu/g	Negative	Negative
AOAC 997.02	Molds, cfu/g	Negative	Negative

*Confirmed result from Analytical Food Lab.

Cystine	0.14 %	0.01 %
Methionine	0.06 %	<0.01 %
Aspartic Acid	0.63 %	0.08 %
Threonine	0.21 %	0.02 %
Serine	0.23 %	0.02 %
Glutamic Acid	0.72 %	0.04 %
Proline	0.22 %	0.02 %
Glycine	0.28 %	0.02 %
Alanine	0.27 %	0.04 %

Appendix A2. Analysis of LoFF Fresh Panamanian Noni Juice, December 2004; Microbial and Amino Acid Analysis (Contd.)



SAMPLE A & B

NOAB05-31218.7146-7147/mr

ANALYSIS REPORT - CONTINUED:

<i>Laboratory Nos.</i>	<i>31218.7146</i>	<i>31218.7147</i>
TEST	JUICE "A"	JUICE POWDER "B"
Valine	0.32 %	0.02 %
Isoleucine	0.22 %	0.02 %
Leucine	0.34 %	0.02 %
Tyrosine	0.15 %	0.01 %
Phenylalanine	0.18 %	0.01 %
Lysine, Total	0.14 %	0.02 %
Histidine	0.11 %	0.01 %
Arginine	0.32 %	0.01 %
Tryptophane	0.13 %	0.003 %

Above results are based upon sample submitted to INTERTEK AGRICULTURAL SERVICES, New Orleans Laboratory, for analysis. Any sample identification is reported as submitted and is not verified by INTERTEK AGRICULTURAL SERVICES, New Orleans Laboratory as a representative sample.

INTERTEK AGRICULTURAL SERVICES

Munazz Haider
Chief Chemist
Agricultural/Bulk Division
New Orleans, LA
/ma

Appendix A3. Compositional and Microbiological Analysis of LoFF Fresh Panamanian Noni Juice, July/August 2005

The sample was analyzed (July/August 2005) by standard procedures and the results are reported below.

Test	Results	Units
Moisture	95.86	g/100 g
Protein	0.38	g/100 g
Ash	0.36	g/100 g
Total Fat	0.10	g/100 g
Total Carbohydrate	3.3	g/100 g
Total Dietary Fibre	0.07	g/100 g
Fructose	0.71	g/100 g
Glucose	0.33	g/100 g
Sucrose	0.03	g/100 g
Energy	65.4	kJ/100 g
Sodium	14.2	mg/100 g
Specific Gravity	1.02	g/ml
pH	3.80	
<i>Minerals</i>		
Calcium	12.1	mg/100 g
Iron	0.31	mg/100 g
Phosphorus	12.9	mg/100 g
Magnesium	4.80	mg/100 g
Manganese	0.04	mg/100 g
Potassium	169	mg/100 g
Copper	0.07	mg/100 g
Zinc	0.06	mg/100 g
<i>Vitamins</i>		
Vitamin C	38	mg/100 g
Vitamin B1	0.015	mg/100 g
Vitamin B2	0.015	mg/100 g
Vitamin B6	0.12	mg/100 g
Vitamin E	1.25	IU/100 g
Vitamin B12	0.2	mcg/100 g
Folic Acid	18.0	mcg/100 g
<i>Amino Acids</i>		
Aspartic Acid	65	mg/100 g
Threonine	6	mg/100 g
Serine	9	mg/100 g
Glutamic Acid	32	mg/100 g
Proline	22	mg/100 g
Glycine	10	mg/100 g
Alanine	27	mg/100 g
Cystine	6	mg/100 g
Valine	17	mg/100 g

Methionine	3	mg/100 g
Isoleucine	7	mg/100 g
Leucine	18	mg/100 g
Tyrosine	9	mg/100 g
Phenylalanine	8	mg/100 g
Histidine	7	mg/100 g
Lysine	8	mg/100 g
Arginine	18	mg/100 g
Tryptophan	1	mg/100 g

Microbiological

Total Viable Count	< 20	cfu/g
Bacillus cereus	< 20	cfu/g
Clostridium perfringens	< 10	cfu/g
Coliforms	Negative	
Escherichia coli	Negative	
Listeria	Negative	
Staphylococcus aureus	Negative	
Yeast	Negative	
Moulds	Negative	

Appendix A4. Compositional and Microbiological Analysis of Dried and Reconstituted Fresh LoFF Panamanian Noni Juice, July/August 2005

The sample was analyzed (July/August 2005) by standard procedures and the results are reported below.

Test	Results	Units
Moisture	96.30	g/100 g
Protein	0.40	g/100 g
Ash	0.15	g/100 g
Total Carbohydrate	3.10	g/100 g
Total Dietary Fibre	0.52	g/100 g
Fructose	1.05	g/100 g
Glucose	0.55	g/100 g
Sucrose	0.8	g/100 g
Energy	52.55	kJ/100 g
Sodium	4.58	mg/100 g
Specific Gravity	1.00	g/ml
pH	4.65	
<i>Minerals</i>		
Calcium	9.54	mg/100 g
Iron	0.25	mg/100 g
Phosphorus	1.70	mg/100 g
Magnesium	3.88	mg/100 g
Manganese	0.04	mg/100 g
Copper	0.03	mg/100 g
Zinc	0.06	mg/100 g
Potassium	30.3	mg/100 g
<i>Vitamins</i>		
Vitamin C	37	mg/100 g
Vitamin B1	0.015	mg/100 g
Vitamin B2	0.015	mg/100 g
Vitamin B6	0.10	mg/100 g
Vitamin E	1.20	IU/100 g
Vitamin B12	0.18	mcg/100 g
Folic Acid	18.0	mcg/100 g
<i>Amino Acids</i>		
Aspartic Acid	65	mg/100 g
Threonine	6	mg/100 g
Serine	8	mg/100 g
Glutamic Acid	32	mg/100 g
Proline	21	mg/100 g
Glycine	10	mg/100 g
Alanine	26	mg/100 g
Cystine	6	mg/100 g
Valine	17	mg/100 g
Methionine	2	mg/100 g

Isoleucine	7	mg/100 g
Leucine	18	mg/100 g
Tyrosine	9	mg/100 g
Phenylalanine	8	mg/100 g
Histidine	7	mg/100 g
Lysine	7	mg/100 g
Arginine	18	mg/100 g
Tryptophan	1	mg/100 g

Microbiological

Total Viable Count	< 20	cfu/g
Bacillus cereus	< 0.2	cfu/g
Clostridium perfringens	< 10	cfu/g
Coliforms	Negative	
Escherichia coli	Negative	
Listeria	Negative	
Staphylococcus aureus	Negative	
Yeast	Negative	
Moulds	Negative	

Appendix A5. Compositional and Microbiological Analysis of a Commercial Pure Noni Juice from Tahiti

A purchased bottled sample of unadulterated Noni juice produced in Tahiti was supplied for analysis. The samples were analyzed by standard procedures and the results are reported below:

Test	Results	Units
Moisture	95.1	g/100 g
Protein	0.43	g/100 g
Ash	0.51	g/100 g
Total Fat	0.2	g/100 g
Total Carbohydrate	3.86	g/100 g
Total Dietary Fibre	0.07	g/100 g
Fructose	2.07	g/100 g
Glucose	0.94	g/100 g
Sucrose	0.09	g/100 g
Energy	75.6	kJ/100 g
Sodium	29.7	mg/100 g
Specific Gravity	1.015	g/ml
pH	3.5	
<i>Minerals</i>		
Calcium	15.2	mg/100 g
Iron	0.38	mg/100 g
Phosphorus	16.6	mg/100 g
Magnesium	16.2	mg/100 g
Manganese	0.05	mg/100 g
Potassium	118	mg/100 g
Copper	0.03	mg/100 g
Zinc	0.1	mg/100 g
<i>Vitamins</i>		
Vitamin C	5	mg/100 g
Vitamin B1	0.0006	mg/100 g
Vitamin B2	0.0005	mg/100 g
Vitamin B6	0.08	mg/100 g
Vitamin E	0.25	IU/100 g
Vitamin B12	0.18	mcg/100 g
Folic Acid	10.0	mcg/100 g
<i>Amino Acids</i>		
Aspartic Acid	15	mg/100 g
Threonine	6	mg/100 g
Serine	9	mg/100 g
Glutamic Acid	10	mg/100 g
Proline	5	mg/100 g
Glycine	8	mg/100 g
Alanine	22	mg/100 g
Cystine	7	mg/100 g
Valine	10	mg/100 g

Methionine	3	mg/100 g
Isoleucine	5	mg/100 g
Leucine	11	mg/100 g
Tyrosine	8	mg/100 g
Phenylalanine	7	mg/100 g
Histidine	8	mg/100 g
Lysine	7	mg/100 g
Arginine	22	mg/100 g
Tryptophan	1	mg/100 g

Microbiological

Total Viable Count	< 10	cfu/g
Bacillus cereus	< 50	cfu/g
Clostridium perfringens	< 10	cfu/g
Coliforms	< 10	cfu/g
Escherichia coli	< 10	cfu/g
Listeria	< 20	cfu/g
Staphylococcus aureus	< 40	cfu/g
Yeast	< 10	cfu/g
Moulds	< 10	cfu/g

Appendix A6. Data for Morinda Inc.'s Tahitian Noni Juice ("TNJ") as Reported in EU Scientific Committee on Food "Opinion" (2002b)

The following data are taken from the EU "Opinion" for TNJ, which is known to be adulterated with other sources of fruit sugar.

	Low	High	Units
Proximate:			
Moisture	89.00	90.00	%
Total Carbohydrate (<i>sic</i>)	9.0	11.0	%
Fibre, Dietary, Total	0.50	1.00	%
<i>Fructose</i>	3.00	4.00	%
<i>Glucose</i>	3.00	4.00	%
<i>Sucrose</i>	0.00	0.1	%
Total Sugars	6.00	8.00	%
Protein - Combustion	0.20	0.50	%
Ash - Food	0.20	0.30	%
Vitamins, Total Recorded	0.003	0.025	%
Other (Inc. fat)	0.10	0.20	%

Minerals :

Calcium	0.0200	0.0250	%
Magnesium	0.0030	0.0120	%
Iron	0.0001	0.0003	%
Phosphorus	0.0020	0.0070	%
Potassium	0.0300	0.1500	%

Vitamins:

B1	0.003	0.01	mg/100g
B2	0.003	0.01	mg/100g
B6	0.04	0.13	mg/100g
B12	0.1	0.3	mcg/100g
Niacin	0.1	0.5	mg/100g
Folic acid	7	25	mcg/100g
C	3	25	mg/100g
E	0.25	1	IU/100g

Amino Acids:

Cystine	7	11	mg/100g
Methionine	1	4	mg/100g
Aspartic acid	30	77	mg/100g
Threonine	8	11	mg/100g
Serine	9	12	mg/100g
Glutamic acid	25	44	mg/100g
Proline	24	33	mg/100g
Glycine	10	22	mg/100g
Alanine	17	33	mg/100g
Valine	10	22	mg/100g

Isoleucine	7	11	mg/100g
Leucine	10	22	mg/100g
Tyrosine	6	11	mg/100g
Phenylalanine	5	8	mg/100g
Lysine, total	7	11	mg/100g
Histidine	4	6	mg/100g
Arginine	30	44	mg/100g
Tryptophane	1	3	mg/100g

Appendix A7. Analyses for the Anthraquinones Rubiadin and Lucidin. Fresh Juice

LarsReimann@eurofinsUS.com

Dr. Wiertz - Dipl. Chem. Eggert - Dr. Jörissen GmbH
Handels- und Umweltschutzzlaboratorium

Stenzelring 14 b, 21107 Hamburg, Tel.: 040/752709-0, Fax -35

Wiertz/Eggert/Jörissen - Stenzelring 14B - 21107 Hamburg

LEAP OF FAITH FARMS
Box 94

Your reference : ./.
Person in charge : Mr. Krück -37

PA-BOQUERON, CHIRIQUI / PANAMA

page : 1/1 Hamburg, 21.06.2004

TEST REPORT 436218A / 155

Ref. : Noni Juice
Marked : as per letter:
Noni Juice
Ordered by : LEAP OF FAITH FARMS
Received from : your firm, letter of May 14, 2004
Received on : 21.05.2004 by : FedEx (8453 1799 1099)
Packing : plastic bags
Number / quantity : 2 / 459 + 484 g
Type of sealing : without Seal/lead
Sample/storage temperature : room temperature
Start/end of analyses : 21.05.2004 / 21.06.2004

TEST RESULTS

Anthraquinone in noni-juice
HPLC/DAD after extraction
Analysis at the laboratory Chemische
Chemie Universität Hamburg

- Rubiadin µg/kg : < 10 **
- Lucidin µg/kg : < 10 **

** the given value corresponds to the limit of detection

JUDGEMENT

On basis of the performed analysis there is no reason about
complaint.

(Dr. Hummert / Dr. Gatermann / Dr. Winkelmann)
Dr. Wiertz - Dipl. Chem. - Eggert - Dr. Jörissen GmbH
Trade and environmental protection laboratory Hamburg

Orders are accepted and completed according to our General Trading Terms. Place of execution and place of jurisdiction is Hamburg - Lower district court Hamburg 66, HRB 31 746
General Manager: Dr. Christian Hummert, Signing Clerks: Dr. Robert Gatermann, Dr. Wilfried Winkelmann. The results of examination refer exclusively to the checked samples.
Duplicates - even in parts - must be authorized by the test laboratory in written form.

Appendix A7. Analyses for the Anthraquinones Rubiadin and Lucidin (Contd.). Dried Juice

LarsReimann@eurofinsUS.com

Dr. Wiertz - Dipl. Chem. Eggert - Dr. Jörissen GmbH
Handels- und Umweltschutzzaboratorium

Stenzelring 14 b, 21107 Hamburg, Tel.: 040/752709-0, Fax -35

Wiertz/Eggert/Jörissen - Stenzelring 14B - 21107 Hamburg

LEAP OF FAITH FARMS
Box 94

Your reference : M Vorderburg
Person in charge : Mr. Krück -37

PA-BOQUERON, CHIRIQUI / PANAMA

page : 1/1 Hamburg, 21.06.2004

TEST REPORT 433214A / 155

Ref. : Noni Fruit Samples
Marked : as per letter:
Noni Powder
Ordered by : LEAP OF FAITH FARMS
Received from : your firm, letter of April 28, 2004
Received on : 10.05.2004 by : FedEx (8453 1799 1114)
Packing : tin bags
Number / quantity : 3 / 122, 123, 124 g
Type of sealing : without Seal/lead
Sample/storage temperature : room temperature
Start/end of analyses : 10.05.2004 / 21.06.2004

TEST RESULTS

Anthraquinone in noni-juice
HPLC/DAD after extraction
Analysis at the laboratory Chemische
Chemie Universität Hamburg

- Rubiadin µg/kg : < 50 **
- Lucidin µg/kg : < 250 **

** the given value corresponds to the limit of detection

JUDGEMENT

On basis of the performed analysis there is no reason about
complaint.

(Dr. Hummert / Dr. Gatermann / Dr. Winkelmann)
Dr. Wiertz - Dipl. Chem. - Eggert - Dr. Jörissen GmbH
Trade and environmental protection laboratory Hamburg

Orders are accepted and completed according to our General Trading Terms. Place of execution and place of jurisdiction is Hamburg -lower district court Hamburg 95, HRB 31746
General Manager: Dr. Christian Hummert, Signing Clerks: Dr. Robert Gatermann, Dr. Wilfried Winkelmann. The results of examination refer exclusively to the checked samples.
Duplicates - even in part - must be authorized by the test laboratory in written form.