

**Request for an opinion on the equivalence of Noni Juice (juice from the fruit of *Morinda citrifolia* L)**

**Request made by:**

Hewitsons Solicitors  
Shakespeare House  
42 Newmarket Road  
Cambridge  
CB5 8EP

**On Behalf of:**

Neways Inc.

## Notification

### Non-CONFIDENTIAL VERSION

This notification is being submitted to comply with the procedures laid down in Regulation 258/97 and the requirements of the Food Standards Agency. It follows the Commission Decision of 5 June 2003 addressed to Morinda Inc., authorising the placing on the market of “noni juice (juice of the fruit of *Morinda citrifolia* L.)”, in accordance with the Regulation.

It will aim to show that the noni juice used in the fruit drink Neways intends to market (hereinafter described as the “Noni Juice” or the “Juice”) is substantially equivalent within the terms of Article 3(4) of Regulation 258/97 to the noni juice in respect of which authorisation has been given (hereinafter described as the “Authorised Juice”). It will do so by considering the following:

1. Specification of the Noni Juice
2. Effect of the production process applied to the Noni Juice
3. History of the organism used as the source of the Noni Juice
4. Anticipated intake/extent of use of the Noni Juice
5. Nutritional information on the Noni Juice
6. Microbiological information on the Noni Juice

---

#### 1. **Specification of the Noni Juice**

##### 1.1 *Origin of the Noni Juice*<sup>1</sup>

Noni juice is a juice based on the fruit commonly known as “noni”. The fruit is also known as “Indian mulberry” and “nonu”. Its botanical name is *Morinda citrifolia* L. *Morinda citrifolia* L. is a member of the Rubiaceae plant family.

The plant resembles a small evergreen shrub or tree that grows from 3 to 6 metres tall. Its conspicuous large dark green shiny leaves are generally paired except when forming fruit. The flowers form in globose heads, about 2 to 3 centimetres long bearing many small white flowers. The bumpy, pitted, oblong-shaped fruit are green until maturity, when they rapidly turn to a light yellow and then a translucent white. The fruit grows almost continuously on the trees allowing for several harvests each year. It is a strong smelling fruit and bitter to the taste.

The plant is believed to have originated in Southeast Asia and to have been distributed subsequently by ancient voyagers or other means into the Pacific islands, including Tahiti and Hawaii (*McClatchey, 2002*). Noni has become naturalised in these islands.

It is also found in India, Africa and the West Indies (*International Noni Communication Council*). It seems to favour tropical climes.

---

<sup>1</sup> *University of Hawaii* (save as otherwise specified).

## 1.2 *Comparison with the Authorised Juice*

The noni fruit used to produce the Noni Juice grows in Hawaii. The noni fruit used to produce the Authorised Juice grows in Tahiti. The fruit, in both cases, comes from the plant botanically designated as *Morinda citrifolia* L.

The above is supported by the independent opinion of Will McClatchey, a botanist at the University of Hawaii. The opinion and Mr. McClatchey's curriculum vitae are set out in Schedule A.

## 1.3 *Composition of the Noni Juice*

Neways uses a pureed form of the fruit in the production of its noni-based fruit juice, consisting of *Morinda citrifolia* L. and water. It has already produced such a juice on a commercial scale.

The puree has the same look and texture as canned applesauce, although it can have a slightly darker colour. Its chemical profile is as follows:

**[Confidential – see Annex I]**

## 2. **Effect of the production process applied to the Noni Juice**

### 2.1 *Outline of Process*

The production process is described below. It is also described graphically in Schedule B.

**[Confidential – see Annex II]**

### 2.2 *Comparison with the Authorised Juice*

The food product resulting from this process is a non-fermented noni-based fruit juice.

Pasteurisation serves to arrest any fermentation, and, as described above, it takes place in two stages: the first stage being after the fruit is reduced to a puree and the second stage being after the puree is combined with other ingredients.

The entire manufacturing process is no different from that used in most fruit juice manufacture, including, as far as we are aware, the manufacture of the Authorised Juice.

## 3. **History of the organism used as a source of the Noni Juice**

### 3.1 *Various Uses*

Noni fruit has been used internally as a food and medicine, and, externally as a dye (*Kilham*).

The fruit was traditionally eaten by native cultures in Samoa, Fiji, Burma and Australia. In Hawaii and the Marquesas noni was a famine food and was also fed to livestock. The root and bark of the noni tree were sources of fabric dyes, a use for which noni remained popular in Polynesia, Asia and Europe until the 1950s (*Kilham*).

The fruit, flower, leaves, bark and root of the fruit have all been used for diverse medicinal purposes, as the Scientific Committee on Food's Opinion on Tahitian Noni juice dated 11 December 2002 describes in greater detail.

In Hawaii, no cultivated varieties of the noni plant are recognised in Hawaii, in the sense that the plant has not been subject to manipulations, cross-pollinations or other attempts to alter the fruit's traits; and no germplasm collections are known anywhere (Nelson, 2001). Neways itself requires that its sources of supply have not been subject to genetic modification.

### 3.2 *Traditional Manufacturing Methods*<sup>2</sup>

Noni juice products are processed and prepared by a variety of methods. Traditionally, the juice is both drip-extracted and fermented. First, the fully ripened fruit is placed inside a container. Water is also placed inside the container. The container is tightly sealed and the contents allowed to ferment. After the fermentation process is complete, the juice is drained from the container and filtered. Fresh air is excluded from the container, and contact between the juice and fresh air is minimised throughout the process. A variation on this method is for the juice to be drawn off from the container before it ferments, and, then, refrigerated. Like pasteurisation, refrigeration arrests the process of fermentation.

Consumption of decomposed noni fruit, manufactured according to the above process, is still common in, for example, Hawaii.

By contrast, the non-traditional method of extraction described in paragraph 2.1 above produces a non-fermented juice. The non-fermented juice is considered to be sweeter and fruitier than the fermented juice. Many producers choose to improve the palatability of the juice further by mixing it with flavourings and/or sweeteners.

## 4. **Anticipated intake/extent of use of the Noni Juice**

### 4.1 *Recommended Daily Intake*

As explained above, Neways manufactures a non-fermented Noni Juice. Like many other producers, Neways adds other ingredients to the Juice to improve its palatability. These other ingredients and the proportions in which they are added constitute an important aspect of competition between suppliers of noni-based fruit juices. Neways has in fact sought patent protection in the US for its product formula.

Despite the added ingredients, Neways' end product retains a unique taste. Because of this, consumers are advised to drink no more than 30 ml per day. The recommendation is not based on any scientific data. The recommendation appears to have become standard among manufacturers of noni-based juices, including the manufacturer of the Authorised Juice.

### 4.2 *Past Use*

Neways has been marketing a noni-based fruit juice in a number of key markets, including the United States, Australia and New Zealand. It has done so since October 1999. In total **[Confidential – see Annex III]** bottles containing 1000 ml of juice were purchased over the period January 2002 to December 2002.

It is Neways' intention to continue marketing a fruit juice based on Noni Juice in the above-mentioned markets. Neways additionally hopes to sell significant quantities of the same juice within the European Union.

---

<sup>2</sup> *University of Hawaii*

## 5. Nutritional information on the Noni Juice

The table published by the University of Hawaii at the following web-site provides an indication of the Noni Juice's nutritional quality: [http://www.ctahr.hawaii.edu/ctahr2001/commodities/noni/Res.../nutritional\\_analysis.as](http://www.ctahr.hawaii.edu/ctahr2001/commodities/noni/Res.../nutritional_analysis.as). The analysis in fact concerns a powdered version of the fruit's juice obtained by evaporation.

## 6. Microbiological information on the Noni Juice

The table below provides the relevant data.

**[Confidential – see Annex IV]**

Neways takes the view that the manufacturing process it employs to make the Noni Juice is microbiologically safe. First, the process entails two stages of pasteurization. Second, it entails the use of a technique known as the "aseptic technique". The aseptic technique requires manufacturers to set up an entirely sealed system which prevents the introduction of external contaminants into the product during processing.

Furthermore, the Noni Juice is subject to several quality control checks by the manufacturer and Neways, during and after processing. The facilities currently being used for this purpose by the two sub-contractors, Pharm East Hawaii, Inc. and Beverage Concepts, Inc., respectively are maintained in accordance with Good Manufacturing Practices, as described by the United States Food and Drug Administration, and are inspected weekly by this agency. Neways itself performs periodic inspections of these facilities.

### Literature Cited

University of Hawaii (College of Tropical Agriculture and Human Resources), Manoa, Hawaii. *The Noni Website*; ([www.ctahr.hawaii.edu/ctahr2001/commodities/noni/overview.asp](http://www.ctahr.hawaii.edu/ctahr2001/commodities/noni/overview.asp)).

McClatchey W. *From Polynesian Healers to Health Food Stores: Changing Perspectives of Morinda citrifolia (Rubiaceae)*; 2002.

The International Communication Council. *What is Noni?*; ([www.incc.org/whats\\_noni.htm](http://www.incc.org/whats_noni.htm)).

Kilham C. *Noni (Morinda citrifolia) Fruit And its Uses*; ([www.healthwellexchange.com/manzone/2\\_01/supplier/noni.cfm?path=ex](http://www.healthwellexchange.com/manzone/2_01/supplier/noni.cfm?path=ex))

**Schedule A**  
(Botanist's Opinion)

**Schedule B**

(Production Process)

***[Confidential – see Annex V]***

**Schedule C**

(Quality Control Procedures)

***[Confidential – see Annex VI]***



**Schedule D**

(Quality Control Procedures)

***[Confidential – see Annex VII]***