

[REDACTED]
Mi GMBH
[REDACTED]
Switzerland

24 June 2005

Reference: NFU 562

Dear [REDACTED],

**REQUEST FOR AN OPINION ON THE SUBSTANTIAL EQUIVALENCE OF MI
NONI JUICE.**

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 Mi Noni Juice as a food ingredient to be used in pasteurised fruit drinks, compared with an existing noni juice produced by natures products and marketed by GSE Vertrieb.

I am pleased to inform you that, in view of the positive opinion given by the ACNFP, the Food Standards Agency, the UK Competent Authority for all novel food issues is content that your Mi Noni Juice 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.

You should ensure that all products containing Mi Noni Juice are marketed and labelled in accordance with European Community Law and any relevant national provisions.

Please note that, accordance with Article 5 of (EC) 258/97, you should notify the European Commission of your intention to market MI Noni Juice when it 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, Additives and Supplements Division.

Enc: ACNFP's Opinion

ADVISORY COMMITTEE FOR NOVEL FOODS AND PROCESSES
OPINION ON SUBSTANTIAL EQUIVALENCE OF NONI JUICE CONSIDERED
UNDER ARTICLE 5 OF THE NOVEL FOODS REGULATION

Applicant **Mi GmbH**
[REDACTED]
[REDACTED]
Switzerland

On behalf of **Mi GmbH Switzerland and Mi EU Ltd. UK**

Responsible Person [REDACTED]

Introduction

1. A request was submitted by Mi GmbH and Mi EU Ltd. to the UK Competent Authority for an opinion on the equivalence of their noni juice ingredient to the noni juice ingredient produced by Natures Products and marketed by GSE Vertrieb in the EU by substantial equivalence in the UK.
2. Noni juice is produced from the fruit of the plant *Morinda citrifolia* L. that is commonly grown in the Pacific region where the juice is traditionally consumed.
3. According to Article 3(4) of Regulation (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”.

Composition

4. The applicant is claiming equivalence to the Noni Juice produced by Natures Products and marketed for sale in the EU by GSE Vertrieb.
5. The applicant initially provided compositional analysis of two samples of their noni juice and one sample of the Natures Products noni juice. The Committee requested additional samples to be tested in order to demonstrate that their noni

product did not differ from the approved counterparts. The applicant provided three additional sets of compositional data for Mi GmbH noni and three for Natures Products.

	Mi GmbH Mean ± SD (5 Samples)	Natures Products Mean ± SD (4 Samples)
Parameters		
Minerals g per 100ml	0.46 ± 0.04	0.58 ± 0.07
Total Protein NX6.25 per 100ml	0.24 ± 0.04	0.38 ± 0.16
Alcohol vol %	0.26 ± 0.09	0.31 ± 0.08
Potassium mg per 100ml	187.4 ± 20.08	246 ± 28.9
Magnesium mg per 100ml	11.48 ± 1.08	15.4 ± 2.17
Sodium mg per 100ml	11.02 ± 3.13	12.2 ± 2.87
L-(+)-Lactic Acid g per Litre	0.64 ± 0.72	1.71 ± 0.39 (3 Samples)
D-(-)- Lactic Acid g per Litre	0.55 ± 0.87	1.51 ± 0.48 (3 Samples)

6. The product produced by the applicant is manufactured in the same way as the approved noni product. However the fruit is pulped and frozen before being shipped to Switzerland, a process that is routinely used to transport noni prior to processing. It is then shipped to Switzerland where it is bottled using the same processes as Natures Products, except that it is ultrafiltrated before it is pasteurised.

Discussion: The Committee was content that the expert opinion and the compositional analysis demonstrated that the applicant's product is substantially equivalent to the existing product. Members were content that the variations seen between the different noni juice samples were consistent with natural variation.

Intended use

7. The applicant intends to market their noni juice in 5 different forms:
- A pasteurised Juice (Direct Squeeze/ Fresh Squeeze,)
 - Direct/ fresh juice with up to 2% added concentrate (pure noni)
 - A concentrate
 - A frozen concentrate
 - A frozen pasteurised juice
8. The recommended consumption in each case is 30ml/day, which is the same as for the noni juice that has already been authorised. The concentrated juice is to be supplied only to industry and the final product will be sold to the consumer in a diluted form with a recommended intake of 30ml a day.

Discussion: The Committee was content that the applicant's noni juices it to be consumed at the level and in the same form as the existing product.

Nutritional Value and Metabolism

9. The applicant has demonstrated that the noni juice is substantially equivalent to Natures Products noni juice even though the pulp is frozen and the juice is ultrafiltrated before it is bottled. There is no evidence in the application to suggest that the nutritional value and metabolism will differ significantly from the product currently permitted on the market in the EU.

Discussion: The Committee was content with the evidence provided by the applicant demonstrating that nutrient content was equivalent to the existing product.

Level of Undesirable Substances

10. The applicant has demonstrated that there are no detectable levels of *Escherichia coli* or *Salmonella* or aerobic bacteria in the pasteurised juice. In order to minimise the risk of anthraquinones the applicant has informed us that all leaves and twigs are removed by hand post harvest. The applicant has also demonstrated that no pesticide residues were detected in the juice at or above the limits of detection.

Discussion: The Committee was content that the applicant had provided sufficient evidence that their product was substantially equivalent to the existing noni juice product in terms of undesirable substances. Members noted that the applicants will implement measures to ensure that subsequent batches of the juice produced are similarly free from undesirable substances.

Conclusion

11. The Committee is content that the applicant's approach to demonstrating the equivalence of Mi GmbH's noni juice with the existing noni juice ingredient is consistent with the criteria set out Article 3(4) of the Novel Foods Regulation (EC) 258/97. The applicant's product is manufactured and marketed in a way that is substantially equivalent to Natures Products noni juice. Data on the composition of noni juice suggest that freezing and ultrafiltration production steps do not have any major effects on the composition of the juice.
12. Therefore noni juice produced by Mi GmbH and Mi EU Ltd can be considered to be substantially equivalent to the existing noni juice produced by Natures Products.

June 2005

