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Reference: NFU 569

Dear Mr Martin,

**REQUEST FOR AN OPINION ON THE SUBSTANTIAL EQUIVALENCE OF NONI JUICE  
PRODUCED BY LEAP OF FAITH FARMS**

The Advisory Committee on Novel Foods and Processes (ACNFP) has now completed your request for an opinion on the equivalence of noni juice produced by Leap of Faith Farms used as a fruit juice ingredient in pasteurised fruit juice drinks, compared with the existing noni juice ingredient from Tahiti. The Committee's opinion is enclosed.

I am pleased to inform you that, in view of the positive opinion given by the ACNFP, the Food Standards Agency, which is the UK Competent Authority for all novel food issues, is content that noni juice products produced by Leap of Faith Farms meets the criteria for equivalence, as defined in Article 3(4) of regulation (EC) 258/97. This conclusion applies to the fresh pasteurised juice (to be sold as such or combined with other fruit juices) and to reconstituted products prepared from the frozen concentrate or the dried juice. Each product should be appropriately labelled to inform consumers of the nature of the processing 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, you should notify the European Commission when you first intend to market your noni juice products. You should send this notification to Mr Andreas Klepsch at the following address:

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

If you have any query, please contact me.

Yours sincerely,

*(By e-mail only)*

**Michelle Young**

Novel Foods, Additives and Food Supplement Division

# OPINION ON SUBSTANTIAL EQUIVALENCE OF NONI JUICE PRODUCED BY LEAP OF FAITH FARMS CONSIDERED UNDER ARTICLE 5 OF THE NOVEL FOODS REGULATION

**Applicant** Leap of Faith Farms  
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**Responsible Person** Mr Peter Martin  
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## Introduction

1. A request was submitted by Perspekt Consulting, on behalf of Leap of Faith Farms, to the UK Competent Authority on 5 January 2006 for an opinion on equivalence of noni juice products produced in Panama to the approved noni juice produced by Tahitian Noni International (formerly Morinda Inc), which was approved for sale in the EU in 2003 by Commission Decision 2003/426/EC.
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 (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.”
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## Evaluation

### (a) Composition and (d) Intended use

4. The approved ingredient marketed by Tahitian Noni International is produced using noni fruit grown in French Polynesia, whereas the noni fruit used by the applicant is grown and harvested in Panama. The noni plant is indigenous to both regions and the applicant has stated that they use the same species, *Morinda citrifolia* L. which is a botanically stable species. The applicant notes that botanical experts such as Dr Will McClatchey (University of Hawaii) have extensively reviewed and characterised the noni plant. Dr McClatchey provided the expert botanist opinion for a previous applicant who obtained a positive opinion on equivalence from the UK in June 2003 for noni juice from Hawaii. Although there is morphological diversity within the species, the applicant has provided evidence that the plants used for production of juice in Panama are very similar to those in French Polynesia.
  
5. The noni fruit is hand picked in order to ensure that no leaves or twigs enter the production process and washed in potable water. The skin and seeds are mechanically separated from the flesh. The flesh of the fruit is then pureed and the juice separated from the pulp and pasteurised. The juice will be produced in four forms and the applicant has provided a flow chart detailing the production processes in the application dossier:

#### (i) and (ii) Pure and mixed noni juice

Noni juice or noni juice mixed with other fruit juices. Both the pure and mixed noni juice are then subject to 'flash' pasteurisation before being packaged and bottled.

#### (iii) Concentrated and frozen juice

Noni juice is concentrated by thermal evaporation and frozen. The applicant states that the temperature involved in this process would also destroy pathogens. The concentrated juice would be reconstituted with water and pasteurised before bottling.

#### (iv) Dried juice

The juice is dried for ease of transport. The drying method, removes water by reducing water to a point where neither pathogens nor spoilage organisms can multiply. The dried juice will be reconstituted with water and pasteurised before bottling and sale.

The applicant has stated that the recommended shelf life of the dried noni product is 2 years when stored in dry, cool conditions and away from direct sunlight, as indicated on the packaging. However, in practice the dried noni ingredient is normally reconstituted between 60 and 90 days.

6. Fruit juices and nectars which are sold in the UK must comply with the provisions of the Fruit Juices and Nectars Regulation 2003. This Regulation clearly defines the terms 'fruit juice' and 'dehydrated or powdered fruit juice' and requires that such products be described using these terms.
7. Compositional analyses have been provided on the fresh juice and the dried juice, reconstituted with water. The dried product was stored for more than 12 months prior to reconstitution and analysis. These have been compared with a commercially available Tahitian noni juice. As with previous applications, a pure noni juice from Tahiti was used in the compositional analysis as a surrogate for the product marketed by Tahitian Noni International, as the latter is a noni juice-based drink containing additional ingredients that would invalidate the comparison.
8. The Scientific Committee on Food (SCF) opinion of 4 December 2002 refers to a daily intake of 30 ml for TNI's noni juice containing 89% noni juice and 11% fruit juice concentrate. The applicant intends to market all four of their products as an ingredient in pasteurised fruit drinks with a recommended daily intake of 30ml, which is in accordance with both the SCF opinion and all other opinions issued for noni juice products.
9. **Discussion:** *The Committee was content that the fresh and reconstituted products have an equivalent composition to the Tahitian juice. The Committee noted that the applicant will not market the dried juice directly to the consumer and noted that the products must be clearly labelled to indicate that the juice has been dried and reconstituted so that it is accurately described and does not mislead the consumer.*

*Members noted that there is considerable diversity in noni trees and noni fruit in the Pacific region<sup>1</sup>, and the information provided by the applicant did not fully establish the genetic identity of the plants found in Panama compared with those in French Polynesia. However, the applicant has demonstrated that the plants are similar and Committee agreed that any small variations would not in-validate a case for substantial equivalence.*

*The Committee also noted that the dried noni ingredient (iv) is similar to a dried noni product that is currently being assessed by the German Competent Authority for use as a dietary supplement. However, the latter product is produced from the whole noni fruit (including peel and seeds) and is consumed in a different form. The Committee's conclusions about the dried and reconstituted juice cannot therefore be extended to the material that is under evaluation in Germany is intended for use in food supplements.*

*Regarding the stability and the shelf-life of the dried noni juice, Members noted that the tested material was drawn from stock of approximately 12 months. Members noted that the manufacturer should not recommend shelf life without the stability data to support it and therefore the maximum recommended shelf life should be 12 months.*

*The Committee confirmed that the applicant's noni juice is to be consumed at the same levels as the approved product, and in line with the SCF recommendation that intake should not exceed 30 ml/day (see paragraph 8 above).*

#### **(b) (c) Nutritional value and metabolism**

10. The applicant considers the nutritional value and metabolism of their noni ingredient to be substantially equivalent to the noni juice produced by Tahitian Noni International. This conclusion is based on the fact that they are both produced from fruits of the same species using a similar process that is at least as hygienic as the approved noni ingredient, and supporting analytical data indicates that they are compositionally comparable.

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<sup>1</sup> "Diversity of Uses and Growth Forms in the *Morinda citrifolia* Complex" W. McClatchey. Proceedings of the 2002 Hawai'i Noni Conference, available at [www.botany.hawaii.edu](http://www.botany.hawaii.edu)

11. *Discussion: The Committee was content that the evidence provided by the applicant demonstrates that the nutrient content was substantially equivalent to the existing product.*

#### **(e) Levels of undesirable substances**

12. The products are manufactured according to GMP standards and the applicant has a HACCP system in place in order to minimise the risk of contamination throughout all stages of the production. The procedures involved are monitored and inspected at least once a month by the local health ministry.

13. Microbiological analysis has been conducted on two samples each of the applicant's noni juice and dried powder and the certificate of analyses. The results of this analysis demonstrated a total viable count of 20 and 40 cfu/g for the powder and juice respectively, along with the absence of coliforms, *E. coli*, *Listeria*, *S.aureus*, yeast, and moulds.

14. The potential presence of anthraquinones in noni juice has previously been raised as a potential concern due to their presence in other parts of the noni plant, namely the leaves and twigs. The applicant highlights the fact that their noni fruit is hand picked and an additional inspection stage is employed after harvesting to ensure that no leaf or twig material is processed.

15. The applicant has also analysed for anthraquinones, namely rubiadin and lucidin, using HPLC on samples of the juice and dried powder. These analyses indicate that neither of these anthraquinones is present in either product at the limit of detection.

16. *Discussion: The Committee was content that the applicant had provided sufficient information that their product was substantially equivalent in terms of undesirable substances and that the quality control procedures would minimise the risk of extraneous part of the plant being used.*

#### **Conclusion**

17. The Committee is content that Leap of Faith Farms has demonstrated the equivalence of their noni juice products with the existing noni juice ingredient according to the criteria set out in Article 3(4) of the Novel Foods Regulation (EC)

258/97. This conclusion applies to the fresh pasteurised juice (to be sold as such or combined with other fruit juices) and to reconstituted products prepared from the frozen concentrate or the dried juice. Each product should be appropriately labelled to inform consumers of the nature of the processing.

18. Therefore, noni juice produced by Leap of Faith Farms can be considered to be substantially equivalent to the existing noni juice produced by Tahitian Noni International.

**September 2006**