

**ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES**

**NONI JUICE PRODUCED BY LEAP OF FAITH FARMS**

**Issue**

An application has been received from Leap of Faith Farms for an opinion on equivalence of their noni juice products compared with the approved noni juice produced by Tahitian Noni International (formerly Morinda Inc) which was approved for sale in the EU in June 2003. This application has been submitted in accordance with article 3(4) of the Novel Foods Regulation (EC) 258/97.

The Committee is asked to consider whether these noni juice products are substantially equivalent to those from Tahitian Noni International.

**Background**

1. Regulation (EC) 258/97 includes a provision for novel foods and ingredients, which are substantially equivalent to an existing product to be placed on the market once the applicant has notified the Commission. In cases to date a company must first obtain an opinion from a Member State before notifying. A US company Leap of Faith Farms is requesting such an opinion from the UK Competent Authority for noni juice produced in Panama. The application dossier, including appendices, is attached as Annex 1.
2. 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.”
3. The Committee will wish to note that the application dossier was published on the ACNFP’s web-site for a 21-day public consultation on 5 January 2006. Any comments received will be tabled at the meeting or forwarded to Members by post.

## Evaluation

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

Annex 1, pages 4-19 and 22

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 also indigenous to Panama and the applicant has stated that they use the same species, *Morinda citrifolia* L which is an arboreal fruit, and is a botanically stable species. The applicant notes that botanical experts such as Will McClatchey (University of Hawaii) have extensively reviewed and characterised the noni plant. Dr McClatchey provided the expert botanist opinion for Neways who obtained a positive opinion on equivalence from the UK in June 2003 for noni juice from Hawaii.
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 employed at figure 2.3 (Annex 1 page 9):

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

Noni juice or noni juice mixed with other fruit juices. Both the pure ('fresh') and mixed ('fresh') 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 solely for ease of transport. The drying method, which not only removes water by a means of heat but a reduction in water activity, provides an environment in which neither pathogens nor spoilage organisms can multiply. The dried juice will be re-constituted with water and pasteurised before bottling and sale.

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 are described using these terms. The applicant would therefore have to clearly state that their noni juice has been dried and reconstituted so that the product is accurately described and does not mislead the consumer. The applicant cannot market the dried juice to the consumer, as the authorisation for Morinda's noni juice does not extend to dried products. This point will be clearly stated in any opinion in order to avoid any confusion with the as yet unapproved product being evaluated by Germany.

7. Members will wish to note that the dried noni ingredient (iv) is similar to a product that is currently being assessed by the German Competent Authority for use as a dietary supplement. The Secretariat has discussed the dried product with colleagues in Germany who have confirmed that the product that they are considering is produced from the whole noni fruit. As the application made to Germany was made by Leap of Faith farms the Secretariat is reassured that the two products are different.
8. 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.
9. 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.

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

Annex 1, page 15-19

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 assumption is based on the fact that they are both produced from the same species using a similar process that is at least as hygienic as the approved noni ingredient, whilst the supporting analytical data indicates that they are compositionally comparable.
11. Compositional analyses have been provided on the fresh juice and the dried juice which has been reconstituted with water. These have been compared with a commercially available Tahitian noni juice (Annex 1, Appendices A2-A5). The applicant is of the view that these compositional analyses demonstrate the equivalence of their ingredient with the approved product.
12. To enable a more meaningful comparison to be carried out the applicant has summarised the compositional data in table 3.1 (Annex1 page 16).

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

Annex 1, pages 20 and 22

13. Microbiological analysis has been conducted on two samples each of the applicant's noni juice and dried powder and the certificate of analyses is attached as Appendix A2-A5 in Annex 1. 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 a sample of the juice and dried powder. These analyses indicate that neither of these anthraquinones is present in either product at the limit of detection. The results of these analyses can be found in Annex 1, Appendix A7.

### **Committee Action Required**

16. The Committee is asked whether it has any comments or objections to raise or whether Members are content to agree that substantial equivalence has been established between Leap of Faith Farms ingredient and that of Tahitian Noni International.
17. If so, the Secretariat will prepare a formal draft opinion for consideration by the Committee. If not, the Committee is asked to state what additional information the applicant could supply in order to demonstrate equivalence.

**Secretariat  
January 2006**

### **Annex attached:**

**Annex 1:** Leap of Faith Farms application dossier.

**ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES**

Leap of Faith Farms application dossier.

This application has been published on the ACNFP website at:

<http://www.acnfp.gov.uk/assess/simproc/noniloff>

**Secretariat  
January 2006**