

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

NONI JUICE PRODUCED BY LEAP OF FAITH FARMS

ISSUE

Leap of Faith Farms has submitted further information in response to the questions raised at the Committee's meeting in January 2006. Members are asked to consider this information and whether they consider that substantial equivalence has been established for this product.

Background

1. At the January 2006 meeting, the Committee considered an application 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.
2. The Committee noted that the amount of compositional analytical data provided by the applicant were limited compared to what they would normally expect to see for an application on substantial equivalence for a noni juice. Members queried whether the applicant had set a recommended shelf life for the dried noni juice and if there were any stability data on this product. Members also requested details on how long the analysed product was kept dried before it was reconstituted. The Secretariat forwarded these comments to the applicant on 27 January 2006 (see Annex A).
3. In line with standard practice for novel food dossiers, the original request from Leap of Faith Farms was published on the Food Standards Agency's website for public comment. The Secretariat received one comment asking for confirmation that the frozen noni concentrate would be reconstituted before bottling and sale and has responded accordingly.

Applicant's response

(i) Limited amount of compositional analytical data

4. The applicant has indicated that he does not intend to provide additional compositional data and that he considers that the information already provided adequately demonstrates the equivalence of his noni juice product, as his noni fruit is sourced from a restricted geographical area compared with other noni juice products.

(ii) Shelf life for the dried noni juice

5. The applicant has provided an amended version of his application dossier that includes the following statement: "*The shelf-life of such dried juice is two years if stored under cool dry conditions away from direct sunlight, as directed on the packaging. The typical elapsed time between drying and bottling is 60 – 90 days,*

ie. much less than the shelf-life". The shelf life of the dried noni juice is two years when stored under dry, cool conditions away from direct sunlight as directed on the package (see **Annex B**) The applicant has stated that his noni juice is dried solely for ease of transport

(iii) Stability data on dried noni juice

6. The applicant has provided no information as regards the stability of his dried noni juice, but has commented: "Dried products like this, properly packaged and stored and at a moisture content of less than 4% are known to keep for many years, even decades, ... so the 2-year limit is an arbitrary but totally safe 'shelf life'"

(iv) How long the analysed product was kept dried before it was reconstituted

7. The applicant has not provided an answer to this question.

Committee Action Required

4. The Committee is asked to consider the applicant's response and whether it is content to agree that substantial equivalence has been established between Leap of Faith Farms ingredient and that of Tahitian Noni International.
5. If so, the Committee is asked whether it is content with the text of the draft opinion attached as **Annex C**.
6. If not, the Committee is asked what additional information the applicant should supply in order to demonstrate equivalence.

**ACNFP Secretariat
March 2006**

Annexes attached

Annex A: Email to Applicant

Annex B: Applicant's response (Confidential)

Annex C: Draft Committee opinion (Restricted)

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

Email to Applicant

Dear Mr Martin,

The Committee discussed your request for an opinion on Wednesday 25 January. The Committee was broadly content with your client's application but noted that the analytical data were less than the Committee would normally expect to see.

The Committee queried whether your client has set a recommended shelf life for the dried noni powder and if there are any stability data on this product. Members also requested details on how long the analysed product was (kept) dried before it was reconstituted.

The Committee therefore, also queried whether your client had any additional analytical data.

I look forward to receiving your response to the Committee's questions. Please feel free to give me a call in order to discuss the Committee's Comments and your client's response.

Regards,

Michelle Gardner