

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

NONI JUICE PRODUCED BY Mi GMBH

Issue

An application has been received from Mi GmbH, on behalf of Mi GmbH Switzerland and Mi EU Ltd United Kingdom, for an opinion on equivalence of their noni juice product compared with an approved noni juice marketed by GSE Vertrieb and on sale in the EU. This application has been with reference to the criteria set out in Article 3(4) of the Novel Foods Regulation (EC) 258/97.

The committee is asked whether they consider that this product is substantially equivalent to the existing product produced by Natures Products and marketed in the EU by GSE Vertrieb and other companies.

Background

1. In 2001 the committee considered an initial opinion from the Belgian Competent Authority (CA) for Morinda's Tahitian Noni Juice (ANCFP/52/1). This application was authorised in June 2003, and since this original application a relatively large number of noni juices have been marketed in the EU following a notification to the Commission in accordance with Article 5 of (EC) 258/97. In the majority of these cases these notifications have included an opinion on equivalence from a competent authority. GSE Vertrieb obtained an opinion from the German CA in December 2003 and Natures Products – the manufacturer who supplies GSE Vertrieb – received an opinion in November 2004 from the UK. (The latter was a technical request for substantial equivalence based on commercial documents and therefore was not discussed by the ACNFP). Mi GmbH obtains its noni fruit from the same supplier as Natures Products and it is the view of Mi GmbH/EU that juice manufactured by Natures Product is the most appropriate comparator for their noni juice products. The Mi GmbH dossier is attached as Annex 1 and the German CA's opinion on GSE Vertrieb's application is attached as Annex 2.

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. In line with standard practice for novel food dossiers, the original request from Mi GMBH was published on the Food Standards Agency's website for public comment.

Evaluation

Composition

Annex 1 p 2-5, 9-10

4. The noni fruit used to produce the applicant's products are from a range of South Pacific islands which include Tahiti, Fiji, Samoa, Tonga, Vanutu and the Cook Islands. The applicant notes that a botanical opinion from the PINA application made to the UK in 2004 (ACNFP/66/7) states that fruit from these islands all come from the same tree recognised as *Morinda citrifolia L.*

5. The applicant has provided a flow chart with harvesting and transporting specifications (Annex 1, Appendix 1). This chart shows that the fruit is handpicked and then sorted to remove all leaves and twigs. It is then washed, dried, packed and pulped before being frozen and shipped to Switzerland. The applicant notes that Natures Products do not routinely freeze their fruit prior to processing, However they state that the freezing is unlikely to have a major impact on the composition of the final juice (Annex 1 p4). Since submitting the dossier the applicant has informed us that the freezing stage is not atypical and is routinely used to transport noni fruit prior to processing in New Zealand, the country where Natures Products' and GSE Vertrieb's juice is made (Annex 3). However, the German CA's opinion on fruit marketed by GSE Vertrieb does not specify whether or not the fruit have been frozen. In addition the applicant has submitted a compositional analysis comparing his noni juice with the GSE Vertrieb product and this indicates that the juices are comparable (Annex 1, appendix 3).

6. The applicant states that all the equipment and processes used to squeeze their noni juice are the same as Natures Products, although there is no information provided to support this. The exception to this is their direct/fresh squeezed product, which is ultrafiltered prior to being pasteurised. The applicant states that ultrafiltration has little effect on the composition of the juice (Annex 1, p6).

Nutritional value and metabolism

Annex 1 p6, 11-16

7. The production process differs in two ways from the production of the existing product from Natures Product and GSE Vertrieb (see paragraphs 3-5). The applicant considers that neither of these processes appears to have an effect on the nutritional composition of the ingredient (see Annex 1, appendix 3).

8. The applicant states that their products are metabolised in a manner similar to all the other noni juice products currently authorised in for sale in the EU, although they have not provided any evidence to support this.

Intended use

Annex1, p8 and 20

9. Mi GmbH intend to sell their pasteurised juice in 5 different forms:
- (1) Pasteurised juice (Direct Squeeze).
 - (2) A juice that is ultrafiltered and then pasteurised (Fresh Squeeze).
 - (3) A concentrate.
 - (4) A frozen concentrate and
 - (5) A frozen pasteurised juice.

We have been informed (Annex 4) that the direct and fresh squeeze juices are the same product. Since submitting the dossier the applicant has also stated that he intends to market a product called pure noni which is the same as Direct/Fresh Squeeze, but with up to 2% added concentrate to give a smoother taste.

10. The Food Standards Agency has issued advice on the use of the term "freshly squeezed", which the applicant intends to use on the labelling of some of their products. Current Agency advice states that the term should only be used to describe juice obtained directly from the fruit (not prepared from a concentrate) and the "use by" date given on the product should be within two weeks of the date of extraction. It also states that if fruit juice described as "freshly squeezed" has been pasteurised, the indication of the treatment should form part of the claim. The Committee may wish to reflect this advice in any opinion it issues in response to the current request.

11. All noni juice products authorised to date have included a recommended daily intake of 30mls a day and this is also the case for the product marketed by the applicant (see sample label Annex 1 Appendix 5). Annex 4 states that the concentrated juice will only be sold to industry to be sold to the consumer in a diluted form with a recommended intake of 30mls a day.

Levels of undesirable substances

Annex 1 p7, 11-19)

12. Annex 1 Appendix 3.1 shows that there are no detectable levels of *Escherichia coli* or *Salmonella* in the ultrafiltered Juice. No aerobic bacteria were detected in the pasteurised juice (Annex 1, Appendix 3).

13. The applicant has provided an analysis of pesticide residues carried out by the supplier of noni fruit to Mi GmbH (Annex 1 Appendix 4). The certificate of analysis shows that no pesticide residues were detected at or above the limits of detection.

14. Anthraquinones are not believed to be present in the juice as all leaves and twigs (the parts of the plant in which anthraquinones are found) are removed by hand post-harvest.

Committee Action Required

15. The Committee are asked if they agree that this product can be considered substantially equivalent to the noni ingredient produced by GSE Vertrieb, approved for sale in the EU, taking into account the production process used by the applicant,

the compositional analyses provided, the nutritional value, intended use and level of undesirable substances.

16. 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 would need to supply in order to demonstrate equivalence.

**ACNFP Secretariat
March 2005
(Revised 24 March)**

Annexes Attached:

Annex 1 - Request for an opinion on the equivalence of noni juice (juice from the fruit of *Morinda Citrifolia L.*).

Annex 2 – Opinion on the determination of substantial equivalence of noni juice from GSE – Vertrieb and noni juice from Morinda Inc.

Annex 3 – Statement confirming that frozen fruit are shipped from the Cook Islands to New Zealand, in accordance with New Zealand requirements.

Annex 4 – Letter of 4 March clarifying various issues raised by the Secretariat.

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

Request for an opinion on the equivalence of noni juice (juice from the fruit of *Morinda Citrifolia* L.).

This application has been published on the Food Standards Agency website at:

<http://www.food.gov.uk/science/ouradvisors/novelfood/assess/simproc/nonimigmbh>

**Secretariat
March 2005**

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

Opinion on the determination of substantial equivalence of noni juice from GSE – Vertrieb and noni juice from Morinda Inc.

**Secretariat
March 2005**

Letter dated:

Berlin, 22/12/2003

From:

Dr Astrid Droß, Office for Consumer Protection and Food Safety

To:

Mr Michael Gracher, GSE-Vertrieb Biologische Nahrungsergänzungs- und Heilmittel GmbH, Saarbrücken

Subject: Opinion on the determination of substantial equivalence of juice from the fruit of the species *Morinda citrifolia* L. from the company GSE-Vertrieb and "noni juice" (juice from the fruit of the species *Morinda citrifolia* L.) from Morinda Inc. authorised as a novel food ingredient

Ref: BVL-105-2211-228014

Dear Mr Gracher,

Please find attached the opinion of the Office for Consumer Protection and Food Safety concerning the application referred to above. Notification of the costs will be forwarded separately.

Yours sincerely,

Dr A Droß

Encl.: Yes

c.c.: Land authorities responsible for food monitoring
Federal Institute for Risk Assessment
Ministry of Consumer Protection, Nutrition and Agriculture

SANCO-2004-00119-00-00-EN-TRA-00 (DE)

Office for Consumer Protection and Food Safety

Berlin, 22.12.2003

Opinion on the determination of substantial equivalence of juice from the fruit of the species *Morinda citrifolia* L. from the company GSE-Vertrieb and "noni juice" (juice from the fruit of the species *Morinda citrifolia* L.) from Morinda Inc. authorised as a novel food ingredient

On 11 September 2003, the company GSE-Vertrieb, 66119 Saarbrücken, applied for the determination of substantial equivalence of pasteurised fresh noni juice from the fruit of the species *Morinda citrifolia* L. and "noni juice". The application by Morinda Inc., 333 W. River Park Drive, Provo, UT 84604, USA, to place "noni juice" (juice from the fruit of the species *Morinda citrifolia* L.) on the market was approved by a Decision of the European Commission on 05.06.2003 (2003/426/EC).

According to Article 3 (4) of Regulation (EC) No 258/97, novel foods and food ingredients which, on the basis of the scientific evidence available and generally recognized or on the basis of an opinion delivered by one of the competent bodies of a Member State, are substantially equivalent to existing foods or food ingredients as regards their composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein, are subject to the procedure laid down in Article 5. The applicant shall then notify the Commission of the placing on the market. Such notification shall be accompanied by the relevant details provided for in Article 3 (4).

According to the *Commission Recommendation of 29 July 1997 concerning the scientific aspects and presentation of information necessary to support applications for the placing on the market of novel foods and novel food ingredients and the preparation of initial assessment reports under Regulation (EC) No 258/97 of the Parliament and of the Council (97/618/EC)*, the principle of substantial equivalence can be extended to the evaluation of foods or food components from novel sources.

On the basis of the documentation provided by the applicant, an assessment was carried out by the Office for Consumer Protection and Food Safety. This was based on the assessment structure set out in the Commission Recommendation for category 2.2 foods: *Complex foods or food components from non-genetically-modified organisms not previously used as foods in the European Community*.

Specification of the novel food

The specification of the pasteurised fresh noni juice, *Morinda citrifolia* L., corresponds to that laid down in the Commission Decision of 05.06.2003 (2003/426/EC), confirming that this is a juice from the species *Morinda citrifolia* L. The juice from the company GSE-Vertrieb GmbH, 66130 Saarbrücken, is to be marketed as "100% Cook Islands noni juice".

The company GSE-Vertrieb GmbH, 66130 Saarbrücken, presented test results which, given the fact that, according to the manufacturer, the case relates to 100% juice from the fruit of the species *Morinda citrifolia* L., and bearing in mind natural variations between fruits, can be regarded as equivalent to the analysis of the "noni juice" from Morinda Inc. The test data were obtained at the Institut Fresenius, 65220 Taunusstein (report dated 08.09.2003). The absence of genotoxicologically relevant substances from the anthrachinone

SANCO-2004-00119-00-00-EN-IRA-00 (DE)

group was confirmed by the Institute for Food and Environmental Research (LEFO), 22926 Ahrensburg (test report dated 12.12.2003).

Description of the manufacturing process

The applicant described the production process in his application dated 11.09.2003. The procedure described both for harvesting and for manufacture is equivalent to the procedure described in the opinion of the Scientific Committee on Food (SCF) of 4 December 2002 regarding Tahitian Noni® juice.

On the basis of the procedure described, together with the test results, it can be assumed that only the fruits of the plant *Morinda citrifolia* L. are used in the manufacture of the applicant's 100% Cook Islands noni juice.

Likely consumption/amount of use of the novel food

"100% Cook Islands noni juice" is intended for direct distribution to the consumer. Recommendations on the daily intake of "100% Cook Islands noni juice" are given by the applicant: "1 x daily 30-50 ml by itself or mixed with other fruit juices". The opinion of the SCF of 4 December 2002 relates to the recommendations by the company Morinda Inc. for a daily consumption of 30 ml. Under these conditions, the consumption of juice from the fruit of the plant *Morinda citrifolia* L. can be regarded as safe. The applicant's intended recommendations for consumption exceed the SCF's recommendations, particularly in view of the fact that they refer to pure noni juice. The applicant is instructed to bring the recommendations on his products into line with those of the SCF.

Conclusions with regard to substantial equivalence

With regard to origin, harvesting, processing (including pasteurisation) and chemical composition, the substantial equivalence of "100% Cook Islands noni juice" from GSE-Vertrieb GmbH, 66130 Saarbrücken, with "noni juice" from Morinda Inc. can be confirmed.

Provided that the labelling requirements in Article 2 of the Commission Decision of 05.06.2003 permitting the marketing of "noni juice" as a novel food within the meaning of Regulation (EC) No 258/97 of the European Parliament and of the Council (2003/426/EC) are met, I consider the determination of substantial equivalence between "100% Cook Islands noni juice" and "noni juice" with regard to their composition, nutritional value, intended use and the level of undesirable substances to be justified.

Dr Astrid Droß
Head of Department 105: consumer
articles, standardisation of methods

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

Statement confirming that frozen fruit are shipped from the Cook Islands to New Zealand, in accordance with New Zealand requirements.

**Secretariat
March 2005**



THE LOGISTICS GROUP

18 Feb 2005

To Whom it May Concern

This letter serves to confirm the The Logistics Group Ltd is the Customs Agent / Import Agent for all Noni Fruit shipped from the Cook Islands

The Rules from the NZ Ministry of Agriculture and Fisheries (MAF) is for product to be shipped and a carriage temperature at -20c for a minimum of 7 days

All shipments to /from the Cook Islands have to date complied with this ruling.

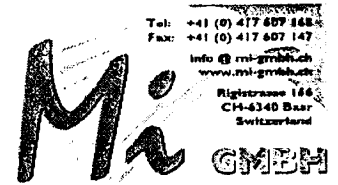
Kind regards

Mike O'Rourke
Import Seafreight Dept

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

Letter of 4 March clarifying various issues raised by the Secretariat.

**Secretariat
March 2005**



Food Standards Agency
Room 515 b
Aviation House,
125 Kingsway
London
WC2B 6NH

Baar Switzerland den 4th March 2005

Dear Katherine Halliwell

As per our request for equivalence against GSE and Natures Products, we would like to clarify a few points raised by the FSA.

Direct and Fresh Squeeze Noni

We would indeed like to confirm that our Direct and Fresh Squeezed products are identical. It is just a labelling difference for the UK and German markets. The juice itself, as per our application is created by squeezing fresh frozen fruits, ultra filtrating (also know as cross flow filtration) with a filter size between 0.45 to 0.02 microns depending on customer requirements. The juice is then bottled/pasteurising.

To confirm, the recommended daily intake for this product as with all Noni juice products is 30ml per day.

Addition of product called Pure Noni Juice

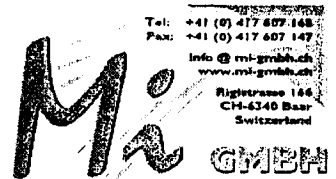
This product is identical to the above Direct/Fresh Squeeze, with the exception of small amount of Noni concentrate (less than 2%) being added to bring up the Brix level creating a smother tasting juice for a very small market segment.

The recommended daily intake for this product as with all Noni juice products is 30ml per day.

Clarification of our concentrated products

As stated in our application to the FSA, we concentrate our Direct/Fresh squeeze to 30 Brix using two widely used process in the EU called Heat Vacuum and Reverse Osmosis concentration. Once the product is concentrated it is hot filled into 500 or 1000ltr food grade storage containers, for our use or sale to industry only under contract.

Concentrated products are only for sale under strict contract to industry (e.g. fruit juice manufacturing companies) that use a diluted form of the concentrate to product fruit juice blends (not cordials). The terms of our sales contract for Noni Concentrate clearly indicate that the product cannot be sold directly to the public without prior dilution back to an original juice Brix level of between 4.0 and 8.0 Brix.



Change in Exporter (not suppliers) of fruit from Cook Islands to obtain Organic status

As stated in our FSA application, at present due to infrastructure, and quality guarantees, all fruit used by Mi is harvested and supplied by the same supplier as Natures Products who in turn supply GSE-Vertrieb.

This is still correct; however we will be using a new company to export out products. The supplier will remain the same as the Island is very small, however to meet our pending organic status obligations we have to use an exporter who is approved by all our organic certifiers such as the Soil Association in the UK. This is a minor change, and is more paperwork than any change to the raw material itself.

Again, I would like to clearly indicate that the fruit is still harvested in the same way, from the same plantations and our local representative inspecting every stage of the process remains the same. The only difference is that our new exporter is registered as an organic exporter under Bio Gro New Zealand

Kind Regards

Garry Martin