

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

NONI JUICE: NOTIFICATIONS UNDER ARTICLE 5 OF THE NOVEL FOOD REGULATION (EC) 258/97.

Issue

Five notifications have been received via the European Commission for noni juice products to be marketed in the EU in accordance with Article 5 of the novel food regulation (EC) 258/97. Members are therefore invited to consider these four notifications and to raise any concerns they may have on the marketing of these products.

Background

1. The Committee will recall being asked to consider whether Hawaiian noni juice (juice of the fruit of *Morinda citrifolia* L) was substantially equivalent to the noni juice ingredient that was approved as a novel food in June 2003. This application was discussed most recently at the February meeting and the Committee is awaiting further data on the composition of the new and existing products before concluding its assessment. A number of similar applications have been submitted and have received positive opinions from other Member States.
2. These opinions should be considered separately as each refers to a separate product from a different manufacturer, from noni fruits grown in different parts of the Pacific region.

(a) GSE Vertrieb

3. The company notified the Commission in December 2003 of its intention to market its pasteurised fresh noni juice product called "100% Cook Islands Noni Juice" in accordance with Article 5 of the Novel Food Regulation (EC) 258/97. The notification was supported by an opinion on substantial equivalence from the German Competent Authority (CA). A translation of the German opinion is attached at Annex 1.
4. **Product specification.** The specification of the product corresponds with that laid down in Commission Decision of 5th June 2003 (2003/426/EC). Using the results from laboratory compositional tests (number of samples not supplied) and taking into account natural variations between fruits, the German CA was of the opinion that this product was substantially equivalent to the product currently on the market. Tests were carried out for genotoxic anthraquinones and these proved negative (limit of detection not supplied).
5. **Manufacturing process.** The German CA was of the opinion that the harvesting and manufacturing process as described by the Applicant was substantially equivalent to that described in the opinion of the Scientific Committee on Food (SCF) of 4th December 2002 regarding Tahitian Noni Juice. They were also satisfied that only the fruits of the plant *Morinda citrifolia* were present in the "100% Cook Islands Noni Juice".

6. **Anticipated intake.** The noni juice product produced by GSE Vertrieb is intended for direct distribution to the consumer and was initially labelled with a recommended daily intake of 30-50ml to be taken alone or with other fruit juices. The applicant was instructed by the German CA to reduce this recommendation to a daily intake in line with the SCF opinion that is equal to 30ml of juice diluted with a low level of other fruit juices.
7. **Conclusions.** The German CA are of the opinion that this product is equivalent to the noni product already on the market in terms of origin, harvesting, processing (including pasteurisation) and chemical composition. As long as the labelling of the product is in line with that recommended in the Commission Decision (2003/426/EC) permitting the marketing of noni juice, the German CA are content to allow this product on the market.

(b) Svane Trading ApS

8. The company notified the Commission in January 2004 of its intention to market its pasteurised fresh noni juice produced by “Tahiti Naturel” in accordance with Article 5 of the Novel Food Regulation (EC) 258/97. The notification was supported by an opinion on substantial equivalence from the Danish Competent Authority (CA). A translation of the Danish opinion is attached at Annex 2.
9. **Product specification.** The Danish CA are of the opinion that a compositional specification provided by the applicant including details of the appearance, taste, microbiological and chemical characteristics demonstrates that the product is substantially equivalent to the product currently on the market in the EU. Five samples of pure juice and two of blended juice were analysed. It is not clear whether these samples were from separate batches.
10. **Manufacturing process.** The Danish CA is of the opinion that the “Svane Tahiti Noni Juice” produced by “Tahiti Naturel” is substantially equivalent in terms of the production process used in its manufacture. The juice is pasteurised and not fermented, and is mixed with 10% grape and blackcurrant juice and then pasteurised again. The product currently on the market contains 11% grape and blueberry juice.
11. **Anticipated intake.** The applicant states that the recommended daily intake of their product is 30ml. As this is the same as that recommended in the SCF report of 4th December 2002 the Danish CA are content with this level of intake.
12. **Chemical composition/nutritional considerations.** The applicant has provided results for compositional analyses carried out on five samples of pure juice and two of blended juice. These analyses included details of water, protein, fat and ash content. For the pure juice, details of fibre content and details of the sugar fraction are supplied, although it is unclear whether these are actual or calculated results. Levels of some vitamins and minerals are also supplied. A discrepancy between the carbohydrate levels of the “Tahiti Naturel” product and that already on the market has been justified by the applicant and the Danish CA are content that the two products are substantially equivalent with regards to composition and nutritional value.

13. **Chemical composition/toxicological considerations.** The Danish CA are content that the “Tahiti Naturel” product is substantially equivalent to the product already on the market with respect to its specification, manufacturing process, anticipated intake and chemical composition. This product therefore poses no health effects that were not already considered during the application process for the product already on the market.
14. The Danish CA requested that the applicant carry out analysis for anthraquinones that are present in parts of the *M. citrifolia* plant other than the fruits and some of which are thought to be genotoxic. The results demonstrated that levels of these substances were below the limit of detection of 0.05% and therefore the Danish CA were of the opinion that this posed no risk to human health.
15. **Labelling/claims.** The product will be marketed under the name of “Svane Tahiti Noni Juice. The applicant has provided a labelling suggestion that describes the product as “a juice that strengthens the whole body so as to restore and maintain the inner and outer person”. As this is an unfounded claim the Danish CA have recommended that this be removed and advised the applicant to review the current labelling legislation on fruit juices.
16. **Conclusions.** The Danish CA are of the opinion that this product is equivalent to the noni product already on the market in terms of origin, harvesting, processing (including pasteurisation) and chemical composition. As long as the labelling of the product is in line with that recommended in the Commission Decision (2003/426/EC) permitting the marketing of noni juice the Danish CA are content to allow this product on the market.

(c) Botanical Products International/FM Brenner GmbH

17. The company notified the Commission in January 2004 of its intention to market its pasteurised noni juice concentrate produced in Hawaii in accordance with Article 5 of the Novel Food Regulation (EC) 258/97. The notification was supported by an opinion on substantial equivalence from the Austrian Competent Authority (CA). A translation of the Austrian opinion is attached at Annex 3.
18. **Product Specification.** The applicant has provided a view from an expert at the University of Hawaii at Manoa, stating that *Morinda citrifolia* plants grown in Hawaii are of the same species as those grown in Tahiti.
19. The juice concentrate is to be reconstituted with water or other fruit juices. The recommended dilution factor is six times that of the concentrate, therefore one litre of concentrate will form six litres of reconstituted juice at the same concentration as the product that is currently on the market.
20. Compositional analyses have been carried out on an unspecified number of samples and the Austrian CA is of the opinion that these are substantially equivalent to those for the product currently on the market taking into account the dilution factor. The compositional analyses included quantification of protein, fat, ash, total carbohydrate, total sugar, energy, sodium, potassium, vitamins, minerals and trace elements. The Austrian CA requested Anthraquinone analysis and the results demonstrated that levels were below the detectable limit of 1mg/kg also isoflavone levels were very low.

21. **Production process.** The Austrian CA are of the opinion that the harvesting and manufacturing process are substantially equivalent to that described in the SCF opinion of 4th December 2002. The ripe fruits are washed, after harvesting and stored for 2-3 days until fully ripe. After inspection and removal of any rotten or damaged fruits the juice is pressed and concentrated to a sixth of its original volume at 60°C and then pasteurised at 90°C for 10 minutes and decanted into containers. Each batch is tested for polysaccharide content and microbiological status.
22. **Anticipated intake.** The applicant has stated that their noni fruit concentrate is not to be sold directly to the consumer, but to juice manufacturers for dilution with water or other fruit juices. The daily intake is recommended to be 25-30ml of the diluted product. The Austrian CA is content that this intake is equivalent to that outlined in the SCF opinion of 4th December 2002.
23. **Microbiological information.** The microbiological analysis carried out by the applicant demonstrates no cause for concern and the Austrian CA are content that this product is substantially equivalent to the product already on the market in terms of microbial content.
24. **Conclusions.** The Austrian CA concluded that this Hawaiian noni juice concentrate is substantially equivalent after reconstitution in terms of the fruits used, the production process and composition. The Austrian CA stated that the dilution factor must be stated on the packaging of the concentrate.

(d) Paracelsus Haus

25. The company notified the Commission in December 2003 of its intention to market its pasteurised noni juice "Bula Noni" produced in the Fiji Islands by the manufacturer Frezco Beverages Ltd in accordance with Article 5 of the Novel Food Regulation (EC) 258/97. The notification was supported by an opinion on substantial equivalence from the Austrian Competent Authority (CA). A translation of the Austrian opinion is attached at Annex 4.
26. **Product Specification.** The applicant intends to market a 100% pure fermented noni juice obtained entirely from the species *M. citrifolia*. The fruit originates from the Fiji Islands that are geographically close to Tahiti and where the applicant has stated that the climate is very similar. The applicant has included an opinion from an expert at the University of Hawaii in Manoa stating that the *Morinda citrifolia* plants in Fiji came from Tahiti via human intervention.
27. Compositional analyses have been carried out and the Austrian CA is of the opinion that these are substantially equivalent to those for the product currently on the market. The compositional analyses included quantification of water, protein, fat, ash, pH value, energy content, total carbohydrate, fructose and glucose, vitamins and minerals. The Austrian CA requested anthraquinone and isoflavone analysis and the results demonstrated that levels were below the detectable limit (limit of detection not specified).
28. The Austrian CA is content that the parameters investigated are enough to demonstrate that the Fijian product is substantially equivalent to the product already on the market.

29. **Production process.** The applicant states that “Bula Noni” is made in the traditional way where the ripe fruits are “fermented” for a number of days (exact time frame not specified) and the fermented juice is then filtered. The Austrian CA are of the opinion that the rest of the harvesting and manufacturing process are substantially equivalent to that described in the SCF opinion of 4th December 2002.

30. The Advisory Committee to the Austrian CA stated that they did not believe that the fermentation procedure produced any adverse effects on wholesomeness or safety, especially as no rotten or damaged fruits were used and the pH of the juice is very low so that no contaminants such as mycotoxins would be expected in the product. The Secretariat requested further information from the Austrian CA with regards to this fermentation procedure. The Austrian CA stated that the product was compositionally equivalent to the noni juice currently on the market and that as the product was pasteurised it could not be thought of as fully fermented. The Austrian CA has also analysed other noni juices which are described as “fermented” and found that these have a markedly different composition. The Paracelsus product may be more similar to freshly-prepared juice because the period of “fermentation” or “maturation” is relatively short compared with other fermented noni juice products.

31. **Microbiological information.** The microbiological analysis carried out by the applicant demonstrates no cause for concern and the Austrian CA are content that this product is substantially equivalent to the product already on the market in terms of microbial content.

32. **Anticipated intake.** The “Bula Noni” product is to be sold to manufacturers for use in pasteurised fruit juice drinks and initially the applicant did not provide a recommended daily intake level on the label. The applicant was instructed by the Austrian CA to recommend a daily intake in line with the SCF opinion that is equal to 30ml of juice.

33. **Conclusions.** The Austrian CA are of the opinion that “Bula Noni” manufactured by Paracelsus Haus GmbH is substantially equivalent to the product already on the market in terms of the fruit used, the manufacturing process and composition. The Austrian CA drew the applicants attention to the labelling requirements set out in the Commission Decision of 5 June 2003 (2003/426/EC) with regards to noni juice products.

(e) NCT Nord Trading

34. The company notified the Commission in November 2003 of its intention to market its pasteurised 100% noni juice “Noni-Saft in accordance with Article 5 of the Novel Food Regulation (EC) 258/97. The notification was supported by an opinion on substantial equivalence from the German Competent Authority (CA). A translation of the German opinion is attached at Annex 5.

35. **Product Specification.** The applicant intends to market a 100% pure noni juice obtained entirely from the species *M. citrifolia*. The German CA has not mentioned the origin of the fruit in their opinion.

36. Compositional analyses have been carried out and the German CA is of the opinion that these are substantially equivalent to those for the product currently on the market taking into account natural variation and the pure nature of the product. The German CA requested anthraquinone and isoflavone analysis and the results demonstrated that levels were below the detectable limit (limit of detection not specified).
37. The German CA is content that the parameters investigated are sufficient to demonstrate that the "Noni-Saft" product is substantially equivalent to the product already on the market.
38. **Production process.** The German CA are of the opinion that the harvesting and manufacturing process are substantially equivalent to that described in the SCF opinion of 4th December 2002. No further details of the manufacturing process were provided by the German CA.
39. **Anticipated intake.** The "Noni-Saft" product is to be sold to manufacturers for use in pasteurised fruit juice drinks and the applicant did not provide a recommended daily intake level on the label. The applicant was instructed by the German CA to recommend a daily intake in line with the SCF opinion that is equal to 30ml of juice and to state this intake on the product labelling.
40. **Conclusions.** The German CA concluded that "Noni-Saft" manufactured by NCT Nord Trading GmbH is substantially equivalent to the product already on the market in terms of the fruit used, the harvesting and manufacturing process and composition. The German CA drew the applicant's attention to the labelling requirements set out in the Commission Decision of 5 June 2003 (2003/426/EC) with regards to noni juice products.

Committee action required

41. The Committee is asked to consider whether they agree with the conclusions that these five noni juice products can be considered to be "substantially equivalent", as defined in Article 3(4) of the novel food regulation, to the existing product.
42. Based on the information provided, the Committee is asked whether it has any concerns over the marketing of these five noni juice products.

**Secretariat
March 2004**

Annexes :

- 1** Notification from the Commission referring to the opinion from the German CA for the noni product produced by GSE Vertrieb.
- 2** Notification from the Commission referring to the opinion from the Danish CA for the noni product produced by Svane Trading ApS.
- 3** Notification from the Commission referring to the opinion from the Austrian CA for the noni product produced by Botanical Products Intl/F.M. Brenner GmbH.
- 4** Notification from the Commission referring to the opinion from the Austrian CA for the noni product produced by Paracelsus Haus.
- 5** Notification from the Commission referring to the opinion from the German CA for the noni product produced by NCT Nord Trading GmbH.