

William Halterman
Director International Product Registration
Neways International
2089 Neways Drive
Springville
Utah
84663
USA

16th July 2004

Reference: NFU 489

Dear Mr Halterman

REQUEST FOR AN OPINION ON THE SUBSTANTIAL EQUIVALENCE OF HAWAIIAN NONI JUICE

The Advisory Committee on Novel Foods and Processes (ACNFP) has now finalised its assessment of your request for an opinion on the substantial equivalence of Hawaiian noni juice used as a fruit juice ingredient in pasteurised fruit juice drinks, compared with the existing noni juice ingredient from Tahiti.

I am pleased to inform you that, in view of the positive opinion given by the ACNFP, the Food Standards Agency, the UK Competent Authority for all novel food issues is content that your Hawaiian Noni Juice ingredient meets the criteria for equivalence, as defined in Article 3(4) of regulation (EC) 258/97. This conclusion is on the basis that the ingredient is manufactured in the way described in your request and all quality control procedures mentioned in the ACNFP opinion are followed.

You should ensure that all products containing your Hawaiian noni juice ingredient are marketed 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 of your intention to market your Hawaiian Noni Juice when it is first marketed. This notification should be sent (with the UK opinion) to Mr Andreas Klepsch at the following address:

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

If you have any other queries, please do not hesitate to contact me.

Yours sincerely,

Dr Chris Jones
Novel Foods Division

Enc.: ACNFP's opinion

Parameter	Average Tahitian	Average Hawaiian
Moisture	90.05	89.25
Density	1.08	1.08
Protein	8.55	9.21
Ash	15.61	13.67
Total Fat	1.62	1.48
Total Carbohydrate	38.45	38.35
Total Fibre	12.75	11.29
pH	6.87	6.84

6. The product produced by the applicant is manufactured in the same way as the approved noni ingredient with two pasteurisation steps. The applicant has requested that their production process remains confidential.
7. The applicant has not provided details of the growth and processing for the noni juice from Tahiti which is used as the direct comparison.
8. The applicant additionally provided an expert opinion from an independent botanist stating that the noni plants grown on the two islands are the same species.
9. *Discussion: The Committee was content that the expert opinion and the compositional analysis demonstrated that the applicants' product is substantially equivalent to the existing product. Members were content that the variations seen between the different noni juice samples were consistent with differing growth conditions. Members noted the small but consistent differences between protein levels in the Hawaiian and Tahitian samples and the possibility of allergenicity.*

Nutritional Value and Metabolism

10. The applicant has demonstrated that the noni fruit are substantially equivalent to those grown in Hawaii and that the juice is produced through a manufacturing process that is not significantly different to that used by Morinda. There is no evidence in the application to suggest that the nutritional value and metabolism will alter significantly from the product currently permitted on the market in the EU.
11. *Discussion: The Committee was content with the evidence provided by the applicant demonstrating that the nutritional value and metabolism of their product was small and would not be biologically significant when compared with the existing product.*

Intended Use

12. The applicant intends to market their Hawaiian Noni Juice as an ingredient in a fruit juice drink blended with other fruit juices and to be presented in a similar format as that sold by Morinda. The recommended consumption is 30ml/day.
13. *Discussion: The Committee was content that the applicant's noni juice is to be consumed at the same level and in the same form as the existing product.*

Level of Undesirable Substances

14. The applicant has demonstrated that their pasteurised product is free from *Salmonella* and *Escherichia coli*. In order to minimise the risk of anthraquinones being present in the final product, the applicant has provided written assurances that branches, leaves and bark are routinely removed by hand as part of their Good Manufacturing Practice procedures. There is nothing in the ingredients, origin, harvest, or production method to suggest that the applicants noni product would contain any undesirable substances that would not be found in the approved noni ingredient.
15. *Discussion: The Committee was content that the applicant had provided sufficient evidence that their product is substantially equivalent to the existing product in terms of safety with regards to undesirable substances.*

Conclusion

16. The Committee is content that the applicant's approach to demonstrating the equivalence of Neways' Hawaiian Noni Juice with the existing noni juice ingredient is consistent with the criteria set out in article 3(4) of the Novel Foods Regulation (EC) 258/97. The applicant's product is manufactured and marketed in a way that is substantially equivalent to Morinda's Tahitian Noni Juice and data on the composition of noni juice from Hawaii and Tahiti do not indicate any major differences between fruit grown in these two regions of the Pacific.
17. Therefore Hawaiian Noni Juice produced by Neways can be considered to be substantially equivalent to the existing noni juice ingredient.

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