

ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES

NONI JUICE PRODUCED BY THE PACIFIC ISLANDS NONI ASSOCIATION

Issue

Pacific Islands Noni Association (PINA) has submitted additional data in response to the questions raised at the Committee's May 2004 meeting (ACNFP/66/7). The Committee is asked whether the additional data provides sufficient reassurance to answer the questions raised and whether it considers that noni juice described by the applicant is substantially equivalent to the approved product.

Background

1. The Committee will recall considering an initial opinion from the Belgian Competent Authority (CA) in 2001 for Morinda's Tahitian Noni Juice (ACNFP/52/1). The noni ingredient of this product was authorised by Commission Decision 2003/426/EC (June 2003). A number of other noni juice ingredients have since gained approval under article 5 of the Novel Foods Regulation and these have either been considered by the ACNFP in the first instance or Members have had the opportunity to review the opinions given by other Member States.

2. The Secretariat contacted the applicant after the May meeting and advised the company that they had provided insufficient data for an opinion on equivalence to be given. The Secretariat requested that additional compositional analyses be supplied by the applicant, and also requested further information to clarify the nature of the fermentation process that takes place during the maturation process. Unlike previous applications for noni considered by the Committee, all of the applicants apply an 8-10 week maturation process to their product prior to producing the juice (ACNFP/66/4).

3. In line with standard practice for novel food dossiers, the original request from PINA was published on the Food Standards Agency's website for public comment. Two responses were received, both from companies who have already obtained novel food approval for their own noni juice (Annex C) and the issues they have raised are discussed below.

Applicant's Response

4. The applicant has provided further compositional analyses using two samples of juice produced by members of PINA (Herbex Ltd and CCK Trading) and two samples of a 100% pure juice from Tahiti Noni which is used as a direct comparative. The applicant has not annotated these data but is of the view that the additional studies demonstrate that the noni juice products are comparable and that any

difference seen are due natural variation. To enable a more meaningful comparison to be carried out, the Secretariat has carried out comparative analysis (attached in Annex A).

5. The production process of the two samples of juice produced by members of PINA is the same as that stated in the original application dossier. The applicant initially provided analyses of one sample of their product and one sample of noni juice from Polynesia (Tahiti Noni 100% pure juice) for comparison.

6. Members should be aware that the application for approval is on behalf of producers from a number of separate Pacific Islands. The data provided by the applicant compares the composition of juice from two of these islands (Fiji and Samoa) with the same Tahitian Noni juice. The applicant considers that the data supplied also provides reassurance that the maturation process has no effect on composition, although some manufacturers claim that there is a change in colour and flavour (see Annex C, page 4)

7. The Applicant has also provided an amended version of the application dossier (Annex B) in response to the Committee's earlier comments on further information to clarify the nature of the fermentation process that takes place during the maturation process. This incorporates slight amendments to the text on the comparison with authorised juice and the addition of another applicant company (Panacea Pacific Products Ltd). The amended text is highlighted (see Annex B page 6)

Responses to public consultation (Annex C)

8. The principal points raised in these comments were:

(a) The application does not provide adequate data demonstrating a lack of undesirable substances, such as anthraquinones and mycotoxins.

The potential presence of anthraquinones in juice obtained from noni fruit is an issue because these toxic compounds are reported to be present in other parts of the noni plant, such as the leaves and the roots. This question was addressed in the original novel food dossier for noni juice by analysis of representative batches of the final product (i.e. noni juice combined with other concentrated fruit juices and other ingredients) showing that anthraquinones were not present in detectable amounts. The Committee has examined an earlier application for an opinion on substantial equivalence and was satisfied that this issue was being effectively addressed through quality control procedures that excluded material other than fruits from entering the production process. Similarly, the current applicants have addressed this question via the latter route.

The question of mycotoxins is not addressed by the current applicants. Their production process differs from earlier applications as it involves a period of enclosed storage. The principal mycotoxin normally associated with fruit juices is patulin, which could be produced under these conditions. It is also possible that other mycotoxin-producing fungi could proliferate, depending on the ambient temperature and the presence of oxygen in the container. (Earlier

applications addressed the question of mycotoxins through analysis of representative batches, or by quality control that excludes damaged fruit. However, the results of these earlier evaluations cannot be applied to the current application due to the difference in storage procedures).

(b) More data from PINA members is needed to ensure that the claims made in the application are true for each supplier and that each processor adheres to PINA's processing criteria.

The application from the Association, on behalf of the named companies, is accepted on the understanding that the statements and descriptions apply to all the companies involved in manufactures of the final product. Any opinion issued by the Food Standards Agency as the competent body under the relevant legislation (and advised by the Committee) would be strictly on this basis.

(c) The data provided by the applicant are less than would be required for the full assessment of a novel food (e.g. as provided by the company that initially gained novel food authorisation for noni juice).

This is an intentional feature of the procedures laid down in the novel foods regulation. A "full" application requires the applicant to demonstrate that their product meets the three criteria for acceptance of novel foods (safety, consumer information and nutritional quality). The "simplified" procedure requires applicants to demonstrate that the food or food ingredient is substantially equivalent to an existing product., thereby reducing the need to additional testing.

(d) There is a relatively high degree of genetic variability of the leaf and fruit within the species.

The Committee considered this issue in relation to the earlier application for an opinion on substantial equivalence of noni juice from Hawaii and Tahiti, and was satisfied by a statement from an expert local botanist that the plants from these two regions were comparable. However, no similar reassurances have been provided for the current application.

Committee action required

9. In accordance with Article 3(4) of Regulation (EC) 258/97 an opinion on “substantial equivalence” should be made on the basis of composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein.

10. The Committee is therefore, asked if it is content that the additional information supplied by the applicant provides sufficient evidence of equivalence of the ingredient noni juice, juice from the fruit of *Morinda citrifolia* L grown and processed in a range of Pacific Islands, to the existing noni juice ingredient in accordance with Article 3(4) of (EC) 258/97.

11. If not, the Committee is asked to identify what additional information the applicant could supply in order to demonstrate equivalence.

**Secretariat
July 2004**