

## Opinion on the safety of Tahitian Noni® ‘*Morinda citrifolia* (noni) fruit puree and concentrate’ as a novel food ingredient<sup>1</sup>

### Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies

(Question No EFSA-Q-2007-181)

Adopted on 13 March 2009

#### SUMMARY

Following a request from the European Commission, the Panel on Dietetic Products, Nutrition and Allergies was asked to deliver a scientific opinion on the safety of ‘*Morinda citrifolia* (Noni) fruit puree and concentrate’ as a novel food ingredient.

Noni fruit puree manufactured according to the procedure described in this application is the same as the noni fruit material used to produce Tahitian Noni® Juice. Noni fruit concentrate is also made directly from noni fruit puree. The compositional data provided demonstrate that the manufacture of noni fruit concentrate results in an increase of the proportions of more hydrophilic components (carbohydrates, sugars, minerals) and in a decrease of the fat content. The Panel considers that the two steps involved in the production of the noni fruit concentrate (removal of the pulp by centrifugation and concentration by evaporation) are not expected to result in qualitative or quantitative compositional changes which might be of toxicological or nutritional relevance.

According to the applicant, the quantity of noni fruit puree or noni juice concentrate to be included in products will be equivalent to 30 mL of *Morinda citrifolia* fruit juice per serving. The highest estimate at the 97.5th percentile is 504 mL *Morinda citrifolia* fruit juice/day for adults, excluding Tahitian Noni® Juice. Adding the 97.5th percentile for consumption of Tahitian Noni® Juice by adults (120 mL/day) results in a total 97.5th percentile estimate of 624 mL *Morinda citrifolia* fruit juice/day. The average combined intake for adult males, from all sources, is estimated to be no more than 161 mL *Morinda citrifolia* fruit juice.

In children, the highest quantity estimated for any high consumer group is equivalent to 416 mL *Morinda citrifolia* fruit juice/day. Combining this with the high consumption (97.5<sup>th</sup> percentile) estimate of 132 mL Tahitian Noni® Juice/day by children provides a total of 548 mL *Morinda citrifolia* fruit juice/day. The highest average combined intake in children is estimated to be 169 mL *Morinda citrifolia* fruit juice/day.

In a previous opinion adopted in 2006, the Panel considered four case studies to investigate a possible association between the consumption of noni juice and hepatotoxicity. On the basis of the available toxicological information and against the background of the data provided on consumption of noni juice without the reporting of hepatotoxic effects, the Panel considered it

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unlikely that consumption of noni juice, at the observed levels of intake, induces adverse human liver effects. This would also apply to the anthraquinones potentially present in the commercially produced noni juice. The Panel concluded that there was no convincing evidence for a causal relationship between the acute hepatitis observed in the case studies reported and the consumption of noni juice.

Since then, the Panel has been made aware of five additional case reports on a possible association between the consumption of noni juice and hepatotoxicity, and one case report on the consumption of a non-specified noni preparation. The Panel noted that in most of the case studies reported the source of the noni product consumed remained unclear. While the Panel considers that available data are not sufficient to establish a causal relationship between the consumption of Noni Juice and hepatotoxicity, the increasing number of case reports might indicate that some individuals have a particular sensitivity for hepatotoxic effects to noni fruit products.

The Panel concludes that '*Morinda citrifolia* (Noni) fruit puree and concentrate as novel food ingredients' under the specified conditions are considered safe for the general population. However the Panel considers that the increasing number of case reports might indicate that some individuals have a particular sensitivity for hepatotoxic effects to noni fruit products.

**Key words:** Morinda citrifolia, Tahitian Noni<sup>®</sup> Juice, noni puree, noni concentrate, hepatotoxicity