

# codex alimentarius commission E



FOOD AND AGRICULTURE  
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Agenda Item 6

CX/NASWP 08/10/8

September 2008

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### FAO/WHO COORDINATING COMMITTEE FOR NORTH AMERICA AND THE SOUTH WEST PACIFIC

Tenth session

Nuku'alofa, Tonga, 28-31 October 2008

#### DISCUSSION PAPER ON THE DEVELOPMENT OF A STANDARD FOR NONU (NONI) PRODUCTS

(prepared by an electronic group led by Tonga with the Assistance of Cook Islands, Federated States of Micronesia, Fiji, Papua New Guinea, Kiribati, Samoa, Solomon Islands, Vanuatu and a group meeting led by Tonga with the Assistance of Cook Islands, Fiji, Samoa, Vanuatu)

Governments and international organizations in Observer status with the Codex Alimentarius Commission wishing to submit comments on the following subject matter are invited to do so **no later than 30 September 2008** to: Dr Viliami T. Manu, Ministry of Agriculture, Food, Forests and Fisheries, PO Box 14, Nuku'alofa, Tonga (Fax: +676 24271; Email: [mafsoils@kalianet.to](mailto:mafsoils@kalianet.to), preferably), with a copy to the Secretary, Codex Alimentarius Commission, Joint FAO/WHO Food Standards Programme, Viale delle Terme di Caracalla, 00153 Rome, Italy (Fax No + 39.06.5705.4593; E-mail: [codex@fao.org](mailto:codex@fao.org) - preferably).

#### Background

1. The 9<sup>th</sup> session of the Coordinating Committee of North America and South West Pacific (Apia, Samoa, October 2006) during its consideration of possible new work, noted that Samoa<sup>1</sup>, is intending to present a proposal for the committee to consider the need to undertake new work on the development of a Standard for Nonu (noni).
2. During its discussion of the new work, the Committee noted that Samoa is in the preliminary stage of preparation to prepare a formal proposal for the new work. Therefore, the Committee agreed to establish an electronic Working Group, led by Tonga<sup>2</sup>, on Objective 6 of the Strategic Plan to add to its terms of reference, to prepare a discussion paper on the need to undertake new work on the development of the Standard for Nonu, for consideration at its next session

#### Rationale for development of a standard for nonu (noni)

3. In the last ten years, Nonu is an increasing traded products of the Pacific Islands mainly as a raw material to countries outside the region such as New Zealand, Australia, United States of America, Japan and European countries. The majority of the production in the Pacific Islands is nonu plants existing in natural vegetations, with a much lesser production in the planted orchards.
4. Currently Tahiti Noni Juice is marketed in the European Union, after safety testing approval was granted in 2002 as a novel food.<sup>3</sup> In their report, the European Commission's Scientific Committee made no endorsement of health claims.

<sup>1</sup> CRD 10

<sup>2</sup> With the assistance of Cook Islands, Fiji, Micronesia, Papua New Guinea, Samoa, Solomon Islands, Vanuatu

<sup>3</sup> European Commission Health and Consumer Protection Directorate-General (December 11, 2002). Opinion of the Scientific Food Committee on Tahitian Noni Juice.

**Scope of the proposed work****Conclusion and recommendation**

5. The working group agreed that there are benefits to standardizing nonu (noni) production. It was noted that several industry standards are already in existence.<sup>4</sup> However, in view of factors identified in the attached discussion paper<sup>5</sup> it is recommended that wider consultation with producing countries and the industry take place prior to deciding on the need for Codex to initiate new work on a standard for nonu (noni). Based on this consultation, the attached discussion paper should be revised for consideration by the next session of CCNASWP if a standard is to be developed. This is recommended in view of the need for more resources and time to conduct a region wide consultation.

**Request for Comments**

6. Governments and international organizations in Observer status with the Codex Alimentarius Commission are invited to submit comments on this discussion paper, as directed above, for further consideration by the 10<sup>th</sup> Session of the CCNASWP.

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<sup>4</sup> Pacific Island Noni Association SOP, HACCP guidelines, IRETA draft Noni standard

<sup>5</sup> Including the need to identify most suitable varieties for processing, a wide range of processing methods, use of different plant parts

## DRAFT PROJECT DOCUMENTATION

### Proposal to develop a Codex Standard for Nonu (Noni)

#### 1. The Purpose and Scope of the Standard:

The purpose of this document is to request a Codex standard for nonu (noni) products, intended for human consumption. This proposal is intended to cover nonu products whether processed, semi-processed or in raw form intended as a food for human consumption in accordance with the codex definition.<sup>6</sup>

#### Definition of Nonu (Noni)

*Morinda citrifolia*, commonly known as Great morinda, Indian mulberry, Beach mulberry, Tahitian Noni, or since recently: Noni (from Hawaiian), Nono (in Tahitian), Mengkudu (from indonesia), Nonu (in Tongan), and Ach (in Hindi), is a shrub or small tree in the family *Rubiaceae*. *Morinda citrifolia* is native to Southeast Asia but has been extensively spread by man throughout India and into the Pacific islands as far as the islands of French Polynesia, of which Tahiti is the most prominent. It can also be found in parts of the West Indies.

#### Description

Product definition

Nonu juice is classified in 3 categories depending on how it is processed.

- 1.1 Fermented/Fresh/Reconstitute fruit juice
- 1.2 Dried fruit powder
- 1.3 Dried leaves powder

#### Safety of Nonu Products

Nonu products are currently being sold world-wide as a novel food item.

The European Commission Scientific Committee on Food which evaluated the Tahitian Noni Juice (TNJ) application for registration of its noni juice as a novel food item-delivered its opinion on the 4 December 2002<sup>7</sup>, “stated:

- The committee evaluated the safety aspects of TNJ as a novel food
- There was no indication of adverse effects from lab animal studies on sub acute and sub chronic toxicity, genotoxicity and allergenicity.
- The product has been marketed for several years, the observed level of intake 30ml/day as acceptable”

This decision was reassessed in 2006 by the European Food Safety Authority’s (EFSA) NDA Panel, which considered various data including studies conducted with humans and laboratory animals to test potential toxicity, as well as data on noni juice consumption in Europe. In conclusion, the Panel confirmed the findings of the Scientific Committee on Food regarding the studies on toxicity as well as genotoxicity and allergenicity. From a toxicological point of view, noni juice has been adequately tested. On the basis of the available information, it is unlikely that consumption of noni juice at the observed levels of intake induces adverse human liver effects. The Panel concluded that there is no convincing evidence for a causal relationship between the acute hepatitis observed in the case studies reported and the consumption of noni juice.<sup>8</sup>

In addition, the Pacific Islands Noni Association (PINA) applied to export different nonu juice products to EU countries, which was accepted in 2004 by the British Food Safety Authority (FSA) on the grounds of it’s

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<sup>6</sup> Codex Alimentarius Commission (FAO/WHO): Procedural Manual, 17<sup>th</sup> Edition, Rome 2007, p.41

<sup>7</sup> European Commission (2002): Opinion of the scientific committee on food on Tahitian noni juice (SCF/CS/NF/DOS/18 ADD 2 Final)

<sup>8</sup> [http://www.efsa.europa.eu/en/science/nda/nda\\_opinions/nda\\_op\\_ej376\\_noni.html](http://www.efsa.europa.eu/en/science/nda/nda_opinions/nda_op_ej376_noni.html)

substantially equivalent, as defined in Article 3(4) of regulation (EC) 258/97, to the accepted Tahitian noni juice ingredient<sup>9</sup>.

The FSA emphasized that any noni juice products introduced to the member countries market will need to comply with existing EU legislation, including rules on the composition and labeling of fruit juices (2001/112/EEC) and on mycotoxins (Regulation 466/2001).

Consequently, the PINA has developed and adopted an Operating Standard for Nonu Production in the Pacific and USP has drafted a product standard<sup>10</sup>. A HACCP guideline has also been developed and the PIC nonu (noni) producers are beginning to adopt and audited on an annual basis.

## 2. Its Relevance and Timeliness:

There is a significant volume of production in the Pacific Island Countries, as well as in some countries outside of the region (e.g. Vietnam, South America). Currently, there are approximately 300 companies marketing nonu (noni) juice in a global market estimated at more than \$2 billion annually<sup>12</sup>.

Raw materials such as fruits, leaves and juices are exported from Pacific Island Countries including Tahiti, Cook Island, Samoa, Tonga, Fiji, Vanuatu, Solomon Islands, etc., to be processed for nonu products in large number of countries including Australia, NZ, USA, Japan and Europe.

### Annual Production (Volume/Value MT and/or \$ for past 10 years)

Cook Islands: In 2002, production is about 141 acres of Nonu orchards, and about 350 acres of natural vegetation with a potential of 2400 metric tons of Nonu juice.<sup>11</sup>

Fiji

FSM

Papua New Guinea

Samoa

Tonga

Vanuatu

The export of nonu is estimated as follows.

**Table 1. Export countries of the pacific with the export values, volumes and importing countries**

	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006
<i>Export Value (US\$ Thousands)</i>										
<i>Cook Island</i>								3,337	1,807	1,395
<i>Tonga</i> <sup>12</sup>				68	0.6	11	13	1,170	2	0.7
<i>Samoa</i> <sup>13</sup>	84	31	169	327	494	628	1,911	3,291	3,411	1,695
	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006
<i>Export Volume (metric tons)</i>										
<i>Cook Island</i>								555,952	352,322	241,052
<i>Tonga</i>				56	0.1	1	40	527	1	0.4
<b>Importing Countries</b>	New Zealand, Australia, USA, Japan	New Zealand, Australia, USA, Japan	New Zealand, Australia, USA, Japan	New Zealand, Australia, USA, Japan	New Zealand, Australia, USA, Japan	New Zealand, Australia, USA, Japan	New Zealand, Australia, USA, Japan	New Zealand, Australia, USA, Japan	New Zealand, Australia, USA, Japan	New Zealand, Australia, USA, Japan

<sup>9</sup> FSA letter to PINA, ref. NFU 502, October 2004

<sup>10</sup> USP/IRETA (Draft Noni Standard)

<sup>11</sup> Department of Quarantine, Cook Islands

<sup>12</sup> Department of Statistics, Tonga

<sup>13</sup> Bureau of Statistics, Samoa

### 3. The Main Aspects to be covered:

New work should be initiated to develop a Codex Standard for Nonu (noni), which will be drafted in accordance with the Codex standard layout for food products and will cover nonu products as defined above. This should build on existing industry standards and guidelines.

### 4. An Assessment against the *Criteria for the Establishment of Work Priorities*:

The proposal for drafting a Codex Standard for nonu is consistent with the *Criteria for the Establishment of Work Priorities*, in particular the criterion:

- i. There is a significant volume of production in Pacific Island Countries, as well as in some countries outside of the region (e.g. Vietnam). There are now approximately 300 companies marketing nonu (noni) juice in a global market estimated at more than \$2 billion annually<sup>14</sup>. Raw materials for nonu products on the world market mainly come from the Pacific Island Countries, and are exported to large number of countries including Australia, NZ, USA, Japan and Europe.
- ii. While there are currently no national standards / legislation for nonu, an operating standard has been developed and adopted for use by the industry. Furthermore, a hygienic standard for nonu products has been developed by USP for PINA under EU funding. It is noted that .
- iii. Regional market potential – the majority of nonu (noni) is being exported from PICs to countries outside of the region. It is expected that this market will continue to grow.
- iv. While nonu is grown in almost all PICs, the varieties used for human consumption have not been identified. It is also noted that various parts (fruits, leaves) are processed and exported. A recent study by USP also found that processing methods also vary widely between different countries and producers.
- v. The proposed standard would aim promote standardization of the processing methods, with a view to enhancing quality control/assurance and application of HACCP.

### 5. Relevance to the Codex Strategic Objectives:

The proposed standard meets the criteria outlined in Objectives 1, 2 and 5 of the Codex Strategic goals.<sup>15</sup>

*Goal 1:* It will contribute goal 1 by providing a sound regulatory framework harmonized across growing and processing countries;

*Goal 2:* It will promote wide and consistent application of scientific principles and risk analysis, including promoting the collection of data from developing countries and from all regions of the world so that the risk analysis is based on global conditions and requirements. The standard will be based upon existing industry guidelines and standard operating procedures, emphasizing HACCP principles.

*Goal 5:* It will promote maximum and effective participation of members - Pacific producers are actively collaborating through the PINA and it is expected that this collaboration will continue during the development of a nonu (noni) standard.

### 6. Information on the Relation between the Proposal and Other Existing Codex

#### Documents:

This proposal is an initiative of PICs to promote safe production of nonu, as there is currently no such existing standard within codex. It will refer as much as possible to other general codex standards (e.g. hygiene, labeling, food additive and contaminants, etc).

### 7. Identification of Any Requirement for and Availability of Expert Scientific Advice:

Scientific advice is required on the following:

- Mapping/Identification of nonu varieties suitable for human consumption.

<sup>14</sup> Tahitian Noni International - The Manufacturer.com - Promoting best practice in Manufacturing Tahitian Noni International: History

<sup>15</sup> Codex Alimentarius Commission Strategic Plan 2008–2013

- Identifying key pre and post harvest moulds and mycotoxin (if any) on the fruits that affect nonu (noni) products.
- Identification of the bacteria that promote fermentation.
- Numerous health claims made in nonu (noni) juice marketing are not supported by scientific research and in human clinical trials. As such findings need to be confirmed by laboratory experiments or demonstrated in expert-reviewed human clinical trials, no inference can therefore be made about whether noni has anti-cancer properties, as claimed.

**8. Identification of Any Need for Technical Input to the Standard From External Bodies so That This Can Be Planned For:**

Technical assistance by WHO and/or FAO to substantiate scientific advice in Section 7 above, as appropriate.

**9. The Proposed Time-line for Completion the New Work, Including the Start Date, the Proposed Date for Adoption at Step 5, and the Proposed Date for Adoption by the Commission”**

Start Date: 2010

Proposed Date for Adoption at Step 5: 2012

Proposed Date for Adoption by the Commission: 2014