## CODEX ALIMENTARIUS COMMISSION





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Agenda Item 8

**CX/NASWP 16/14/9** 

#### JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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

14th Session, Port Vila, Vanuatu

19 - 22 September 2016

#### PROPOSED DRAFT REGIONAL STANDARD FOR FERMENTED NONI JUICE

Prepared by the electronic Working Group led by Tonga<sup>1</sup>

Governments and interested international organizations are invited to submit comments on the attached Proposed Draft Regional Standard for Fermented Noni Juice at Step 3 (see Appendix I) and the comments should be in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (see *Procedural Manual of the Codex Alimentarius Commission*) to: The Secretariat, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Rome, Italy, email <a href="mailto:codex@fao.org">codex@fao.org</a> by 1 August 2016.

Format for submitting comments: In order to facilitate the compilation of comments and prepare a more useful comments document, Members and Observers, are requested to provide their comments in word file and following the format outlined in the Appendix III to this document.

#### **Background**

- 1. The 13<sup>th</sup> Session of the FAO/WHO Regional Coordinating Committee for North America and South West Pacific (CCNASWP) agreed to establish an Electronic Working Group (EWG) led by Tonga to redraft the proposed draft Regional Standard for Fermented Noni Juice, taking into account the discussion and decisions as well as comments for the circulation of draft standard at Step 3 and for consideration at the next Session of CCNASWP (REP15/NASWP para 53).
- 2. The CCNASWP also agreed to request advice from the Committee on Contaminants in Food (CCCF) on the safe level for scopoletin as well as the methods of analysis (<u>REP15/NASWP</u> para 51).
- 3. Tonga, as the lead country of the eWG, invited Codex Members and Observers interested in participating in this work, in March 2016. Seven countries replied their interest in participating, namely Australia, Canada, Federated State of Micronesia, Papua New Guinea, Samoa, Solomon Islands and United State of America.

#### Proceedings of the electronic working group

4. Two rounds of comments were requested. Comments were received from Australia and United States of America (first round) and Canada and United States of America (second round). All the responses received were considered and integrated into this Proposed Draft Regional Standard for Fermented Noni Juice.

#### **Discussion**

- 5. In preparing the Draft Standard, the eWG considered the sixteen discussion points and decisions from 13<sup>th</sup> Session of CCNASWP (<u>REP15/NASWP</u> para 38-53).
- 6. The Proposed Draft has been revised to address the above discussion points and decisions plus other comments from Australia, Canada and USA that were considered by the eWG and agreed to the proposed draft. The following points summarize the recommended revisions made to various sections of the Proposed Draft:
  - a) In the Product Definition, the capital "C" was replaced lower case in citrifolia.
  - b) In the Fermentation Noni Fruit Juice, the "exclusion of seeds" was added in addition to eight other comments from Australia, Canada and USA.
  - c) The Quality Factors was re-drafted with two comments from USA.
  - d) The Fermented Noni Juice was amended with four comments from USA. USA also relayed that the request for a full risk assessment of scopoletin to JECFA concluded that there is very limited data on scopoletin available (<u>REP15/CCCF</u> para 149).
  - e) The Definition of Defects was redrafted with an extra comment from USA
  - f) The Food Additives was redrafted with an extra comment from USA

<sup>&</sup>lt;sup>1</sup> Members of EWG: Australia, Canada, Federated State of Micronesia, Papua New Guinea, Samoa, Solomon Islands, United States of America

- g) The Packaging was re-drafted with an extra comment from Canada
- h) The Minimum Fill was also re-drafted.
- i) The Labelling was redrafted with a comment from Canada.
- j) The Method of Analysis and Sampling was also redrafted with suggestions from Australia, Canada and USA.
- k) The method for Identification of Scopoletin in Annex A was re-drafted with comments from USA, which also indicates that the method may be a qualitative method, which only detect the presence of Scopoletin but not its amount.

#### Recommendation

7. The 14<sup>th</sup> Session of CCNASWP is invited to consider the Proposed Draft Regional Standard for Fermented Noni Juice as presented in Appendix I.

Appendix I

# PROPOSED DRAFT REGIONAL STANDARD FOR FERMENTED NONI FRUIT JUICE (STEP 3)

#### **SCOPE**

This standard applies to Fermented Noni Fruit Juice products, as defined in Section 2 below, which is used as a food or food ingredient. This standard does not apply to non-fermented or other Noni products from fruit and leaves or noni products for medicinal purposes.

#### **DESCRIPTION**

#### 1. Product Definition

The fermented noni fruit juice is derived from the fermenting of fresh fruits of noni plants<sup>2</sup>, *Morinda citrifolia* L. variety *citrifolia*<sup>3</sup> of the Rubiceae family, with suitable processes that maintain it's essential physical, chemical, organoleptic and nutritional characteristics.

#### 1.1 Noni Fruits

Fresh, firm and mature to ripe noni fruits, with greenish-yellow to white colour, are harvested, washed and left to dry. Optionally, the fruits may be crushed to a pulp<sup>4</sup>. Fruits that are: over-ripe, fallen fruits, green<sup>5</sup>, bruised and or damaged fruit<sup>6</sup>, or foreign material such as sticks, stem, leaves, bark and root material should be rejected and not used in the production of Fermented Noni Fruit Juice.

#### 1.1.1 Fermentation Noni Fruit Juice

Whole fruits or fruit pulp should be fermented for a minimum of 10 days to a maximum of 60 days. The requirement for a starter viable microorganism for fermentation may not apply<sup>7</sup> due to the heat pasteurization that follows. The fermented products are pressed, strained, filtered, re-filtered if required to a finer degree. The filtered fermented juice product is substantially free of extraneous materials (e.g., noni leaves, stems, seed fragments, fruit skins, and insects). The resultant 100% fermented noni fruit juice is pasteurized by heat<sup>8</sup>.

#### 2. ESSENTIAL COMPOSITION AND QUALITY FACTORS

#### 2.1 INGREDIENTS

The Fermented Noni Fruit Juice as define in section 2.

#### 2.2 QUALITY FACTORS

Noni raw materials must be:

- whole, with the peduncle intact; the peduncle may be trimmed;
- sound, produce affected by rotting or deterioration such as to make it unfit for consumption is excluded:
- clean and practically free of any visible foreign matter;
- practically free of pests and damage caused by them affecting the general appearance of the produce;
- free of abnormal external moisture, excluding condensation following removal from cold storage;
- free of any foreign smell and/or taste;
- free of damage caused by low and/or high temperatures; and
- free of cracking.

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<sup>&</sup>lt;sup>2</sup> Common names of noni are great morinda, beach mulberry, Indian mulberry, ach, mengkudu, nono, nonu, noni and cheesefruit.

<sup>&</sup>lt;sup>3</sup> Two types of large fruits with oval leaves and small fruits with elongated leaves (Wagner, Herbst and Sohmer, 1990,

<sup>&</sup>quot;The Manual of the Flowering Plants of Hawaii" (Copyright 1990, Bishop Museum, Honolulu)

<sup>&</sup>lt;sup>4</sup> Crush with a Hammer mill to increase surface area expediting fermentation

<sup>&</sup>lt;sup>5</sup> Green immature noni fruits has a brix level of less than 4% making it very susceptible to growth of mould

<sup>&</sup>lt;sup>6</sup> Susceptible to develop moulds, that might produce mycotoxin such as patulins [Note that para 40 REP15/NASWP explicitly deleted patulin as not relevant to the product]

Standard for Fermented Milk (CODEX STAN 243-2003)

<sup>&</sup>lt;sup>8</sup> Pasteurized at 82.2°C for 1 to 2 minutes

#### 2.3 FERMENTED NONI FRUIT JUICE

a) Moisture: 89-96.7 %

b) Ash: 0.2-0.8 g/100 mL

c) Brix 7-14 % d) pH 3.55-4.00

e) Acidity 0.095-0.135%

f) Ethanol 0.3% v/v

g) Deacetylasperulosidic acid > 0.95 mg/mL h) Scopoletin > 0.95 mg/mL

#### 2.4 DEFINITION OF DEFECTS

Fermented noni juice shall be prepared in accordance with good manufacturing practices (GMPs) from such materials and under such practices that the product is substantially free of extraneous materials (e.g. noni leaves, stems, insects, etc.).

#### 2.5 FOOD ADDITIVES

All food additives used in accordance with Table 1 and 2 of the *General Standard for Food Additives* (CODEX STAN 192-1985) in food category 14.1.2.1.

The flavourings used in products covered by this standard should comply with the *Guidelines for the Use of Flavourings* (CAC/GL 66-2008).

Processing aids used in products covered by this standard shall comply with the *Guidelines on substances used as processing aids* (CAC/GL 75-2010).

#### 3. CONTAMINANTS

The products covered by this standard shall comply with the Maximum Levels for contaminants that are specified for the product in the *General Standard for Contaminants and Toxins in Food and Feed* (CODEX STAN 193-1985); and the Maximum Residue Limits for pesticides established by the Codex Alimentarius Commission.

#### 4. HYGIENE

Fermented noni juice products covered by this Standard must be prepared and handled in accordance with appropriate sections of the *General Principles of Food Hygiene* (CAC/RCP 1-1969), *Code of Hygienic Practice for Fresh Fruits and Vegetables* (CAC/RCP 53-2003), and other relevant Codex texts such as Codes of Hygienic Practice and Codes of Practice.

The product should also comply with any microbiological criteria established in accordance with the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CAC GL 21-1997).

#### 5. PACKAGING

The Fermented Noni Juice products must be packed in containers that safeguard its hygienic, nutritional and organoleptic quality, and also comply with the *Code of Practice for Aseptically Processed and Prepackaged Low acid Food* (CAC/RCP 40 1993). The materials used for packaging must be new (for the purposes of this Standard, this includes recycled material of food-grade quality.) The containers shall meet the quality, hygiene, ventilation and resistance characteristics to ensure suitable handling, shipping and preserving of the Fermented Noni Juice. Packages must be free of all foreign matter and smell.

#### 6. WEIGHTS AND MEASURES

#### **6.1 FILL OF THE CONTAINER**

#### **6.1.1 MINIMUM FILL**

The container shall be well filled<sup>9</sup> with the product and the product shall occupy not less than 90% of the water capacity of the container. The water capacity of the container is the volume of distilled water at 20°C which the sealed container will hold when completely filled.

<sup>&</sup>lt;sup>9</sup> International Organization of Legal Metrology (OIML), Bureau International de Métrologie Légale 11, rue Turgot – 75009 Paris – France, Publication OIML R87 Edition 2004 (E)

#### 7. LABELLING

The product shall be labelled in accordance with the *General Standard for Labelling of Prepackaged Food* (CODEX STAN 1-1985). In addition, the following specific provisions apply:

#### 7.1 NAME OF THE PRODUCT

The name of the food product shall be "Fermented Noni Juice".

#### 8. METHODS OF SAMPLING AND ANALYSIS

#### **8.1 DETERMINATION OF MOISTURE**

According to AOAC 925.45

### **8.2 DETERMINATION OF ASH**

According to AOAC 940.26

#### **8.3 IDENTIFICATION OF SCOPOLETIN**

According to method described in Annex A

#### 8.4 IDENTIFICATION OF DEACETYLASPERULOSIDIC ACID

According to method described in Annex B

ANNEX A

#### **IDENTIFICATION OF SCOPOLETIN**

#### 1. PREPARATION OF SAMPLES

- **1.1** Noni fruit is mashed. Two grams of mashed fruit is extracted twice with 125 milliliters methanol. The methanol extract is concentrated by evaporation of the solvent under vacuum. The extract is then redissolved in a small quantity of methanol, such as 10 milliliters.
- **1.2** Noni juice is filtered through a 0.45 µm membrane filter and then purified by solid-phase extraction (SPE) with Waters OASISS® extraction cartridges, or similar solid-phase extraction cartridge.
- **1.3** One gram of noni fruit powder is extracted with 5 milliliters of methanol. The methanol extract is filtered and evaporated to dryness under vacuum at 50°C. The extract is dissolved into one milliliter of methanol.

#### 2. PREPARATION OF STANDARD

- 2.1 A standard is prepared by dissolving 1 mg scopoletin in 1 milliliter of methanol.
- **2.2** Alternately, certified *Morinda citrifolia* reference plant material may be prepared in the same manner as the samples to be analyzed. The certified *Morinda citrifolia* reference material should be from the same part of the plant as the samples to be analyzed.

#### 3. IDENTIFICATION

#### 3.1 THIN LAYER CHROMATOGRAPHY

Spot 5 microliters of sample solutions and standard solution on a silica gel thin layer chromatography (TLC) plate, previously dried at 110 °C for 15 minutes in a drying oven. Develop the plate with a lower solution mobile phase of dichloromethane: methanol: water (13:6:1, v/v/v). View bright fluorescent blue colours on developed plate under UV lamp, 365 nm. Identify scopoletin in samples by comparing Rf values and colours to the standard.

#### **REFERENCES**

- **1.** Deng S, West BJ, Jensen J. A Quantitative Comparison of Phytochemical Components in Global Noni Fruits and Their Commercial Products. Food Chemistry 2010, 122 (1): 267-270.
- **2.** Potterat O, et al. Identification of TLC markers and quantification by HPLC-MS of various constituents in noni fruit powder and commercial noni-derived products. Journal of Agricultural and Food Chemistry 2007, 55(18):7489–7494.
- **3.** Basar S, Westendorf J. Identification of (2E, 4Z, 7Z)-Decatrienoic Acid in Noni Fruit and Its Use in Quality Screening of Commercial Noni Products. Food Analytical Methods. Published online 23 February 2010. DOI: 10.1007/s12161-010-9125-9.
- **4.** Chan-Blanco Y, et al. The ripening and aging of noni fruits (Morinda citrifolia L.): microbiological flora and antioxidant compounds. Journal of the Science of Food and Agriculture 2007, 87:1710 1716.
- **5.** West BJ, Deng S. Thin layer chromatography methods for rapid identity testing of Morinda citrifolia L. (noni) fruit and leaf. The Open Agriculture Journal. Under review. 2010.

ANNEX B

#### IDENTIFICATION OF DEACETYLASPERULOSIDIC ACID

#### 1. PREPARATION OF SAMPLES

- **1.1** Noni fruit is mashed. Two grams of mashed fruit is extracted twice with 125 milliliters methanol. The methanol extract is concentrated by evaporation of the solvent under vacuum. The extract is then redissolved in a small quantity of methanol, such as 10 milliliters.
- **1.2** Noni juice is filtered through a 0.45 µm membrane filter and then purified by solid-phase extraction (SPE) with Waters OASISS® extraction cartridges, or similar solid-phase extraction cartridge.
- **1.3** One gram of noni fruit powder is extracted with 5 milliliters of methanol. The methanol extract is filtered and evaporated to dryness under vacuum at 50°C. The extract is dissolved into one milliliter of methanol.

#### 2. PREPARATION OF STANDARD

- 2.1 A standard is prepared by dissolving 1 mg deacetylasperulosidic acid in 1 milliliter of methanol.
- **2.2** Alternately, certified *Morinda citrifolia* reference plant material may be prepared in the same manner as the samples to be analyzed. The certified *Morinda citrifolia* reference material should be from the same part of the plant as the samples to be analyzed.

#### 3. IDENTIFICATION

**3.1** Thin layer chromatography Spot 5 microliters of sample solutions and standard solution on a silica gel thin layer chromatography (TLC) plate, previously dried at 110 °C for 15 minutes in a drying oven. Develop the plate with a lower solution mobile phase of dichloromethane:methanol (19:1, v/v). Spray developed plate with 2% anisaldehyde, 10% sulfuric acid-EtOH solution then heat in oven at 110 °C for 1 minute to reveal blue color. Identify deacetylasperulosidic in samples by comparing Rf values and colors to the standard.

#### References

- **1.** Potterat O, et al. Identification of TLC markers and quantification by HPLC-MS of various constituents in noni fruit powder and commercial noni-derived products. Journal of Agricultural and Food Chemistry 2007, 55(18):7489–7494.
- **2.** Deng S, et al. Determination and comparative analysis of major iridoids in different parts and cultivation sources of Morinda citrifolia. Phytochemical Analysis. In press. 2010.
- **3.** West BJ, Deng S. Thin layer chromatography methods for rapid identity testing of Morinda citrifolia L. (noni) fruit and leaf. The Open Agriculture Journal. Under review. 2010.

**Annex** 

#### GENERAL GUIDANCE FOR THE PROVISION OF COMMENTS

In order to facilitate the compilation and prepare a more useful comments' document, Members and Observers, which are not yet doing so, are requested to provide their comments under the following headings:

- (i) General Comments
- (ii) Specific Comments

Specific comments should include a reference to the relevant section and/or paragraph of the document that the comments refer to.

When changes are proposed to specific paragraphs, Members and Observers are requested to provide their proposal for amendments accompanied by the related rationale. New texts should be presented in **underlined/bold font** and deletion in **strikethrough font**.

In order to facilitate the work of the Secretariats to compile comments, Members and Observers are requested to refrain from using colour font/shading as documents are printed in black and white and from using track change mode, which might be lost when comments are copied / pasted into a consolidated document.

In order to reduce the translation work and save paper, Members and Observers are requested not to reproduce the complete document but only those parts of the texts for which any change and/or amendments is proposed.