

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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

*Fifteenth Session  
Port Vila, Vanuatu  
16 – 20 September 2019*

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

*(Prepared by the Electronic Working Group chaired by Tonga)*

*(At Step 3)*

#### 1. Background

- 1.1. In September 2016, the 14th Session of the FAO/WHO Regional Coordinating Committee for North America and South West Pacific (CCNASWP14) agreed to reconvene the Electronic Working Group (EWG), led by Tonga, to redraft the proposed draft Regional Standard for Fermented Noni Juice, taking into account the outstanding issues surrounding the scope, fermentation, methods of analysis, contaminants, especially the safe intake level of scopoletin and all written comments submitted at CCNASWP14<sup>1</sup> and urged CCNASWP Members to actively participate in the EWG.
- 1.2. CCNASWP14 further agreed to request CCEXEC to postpone completion of this work to 2020 given the timeframe for completion of work on a regional standard for fermented noni juice was 2017.
- 1.3. CCNASWP14 also agreed to inform CCCF on the status of development of the standard and urged CCNASWP members to provide to JECFA the data of safety/toxicity of scopoletin (toxicity, occurrence and consumption data).
- 1.4. CCNASWP furthermore agreed to return the proposed draft standard to Step 2/3 for redrafting by the abovementioned EWG, circulation for comments and consideration by the next session of CCNASWP

#### 2. EWG process

- 2.1 Tonga, as the lead country, invited Codex Members and Observers interested in participating in this work to join the EWG in February 2017. Seven (7) countries registered to participate in the EWG and these are listed in Appendix II.
- 2.2 Three rounds of comments were requested. Comments were received from Australia, Canada, New Zealand and United States of America (US) (first round), Canada, Fiji, Vanuatu and US (second round), and Canada and US (third round).
- 2.3 Verbal comments on the draft Standard were also provided by the Cook Islands and Niue, Samoa and Vanuatu at the CCNASWP workshop held in October 2018.
- 2.4 All the responses received were considered and integrated into this Proposed Draft Regional Standard for Fermented Noni Juice.

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<sup>1</sup> [REP15/NASWP](#), para 68

### 3. Issues considered

1. The Proposed Draft Regional Standard for Fermented Noni Juice has been revised to address the discussion points and decisions from CCNASWP14<sup>2</sup>, plus subsequent comments from Australia, Canada, Cook Islands and Niue, Fiji, New Zealand, Samoa, US and Vanuatu that were considered by the EWG and agreed to. The following points summarise the responses to the recommended revisions:
  - a) Redrafting of the scope now clarifies that the standard covers fermented noni fruit juice and does not apply to non-fermented juice or noni fruit or any other noni products from fruit, leaves, bark or flowers or noni products for medicinal purposes.
  - b) The product definition clarifies what parts of the noni fruit can be used and what should not. Only essential process requirements are now set out in the draft standard. Further information on the manufacturing methods is included in Annex C to the draft Standard. This annex is advisory in nature to allow flexibility for the variety of processes that exist or have been proposed. Additional information can be included if it is available, such as filtration methods.
  - c) After extracting the juice, the resultant 100% fermented noni fruit juice is pasteurized to eliminate pathogens of public health significance. Various methods of pasteurisation have been proposed, e.g. heat or UV, but there has not been a proposal to replace pasteurisation with something else. The Committee may wish to consider if pasteurisation is the only acceptable process that would render the product safe for consumption. In addition the committee might want to consider the performance criterion for pasteurization (see comment in square brackets in Annex C).
  - d) The performance criterion for pasteurization in square brackets is a microbiological criterion from Fiji's noni regulation, which was mentioned at the Oct 2018 meeting. It is not in the main body of this standard because the presence of *E coli* is not necessarily a food safety matter, but nevertheless the criterion could be a useful "performance objective", for the efficacy of pasteurization, if members agree.
  - e) Only the essential composition and quality factors for fermented noni fruit juice need to be listed. Ash and acidity have been removed but it may be that Moisture, pH and Ethanol can also be removed if they are not essential to determine composition. Some attendees at the Vanuatu workshop recommended that the range in the pH level be changed from 3.55-4.00 to 3.5-3.9%, moisture from 89-96.7% to 70-90%, and Brix from 7-14° to 5.5-7.0°. A greater understanding on why the ranges provided are so wide would be helpful. It has been noted that the moisture and Brix levels may not correspond. A rationale for the composition changes has been requested. It would for example be useful to have a data source reference that defines the basic quality criteria for the finished product. The composition and quality factors will be a discussion point for the Committee.
  - f) Some suggestions were made around limiting the composition factors for ethanol, however no toxicological basis was provided to justify this. Alcohol duties are a national tax issue rather than an issue for Codex.
  - g) In the absence of data on scopoletin, the US (and others) recommended scopoletin is listed as 'present' in the compositional section. The US suggestion has been adopted to include a footnote with wording around that fact that scopoletin is on the priority list for JECFA evaluation. Similarly the US suggestion that deacetylasperulosidic acid should also be listed as 'present' rather than a set level has been adopted.
  - h) A definition of defects has been added to provide more clarity on what is acceptable quality for fermented noni juice and is consistent with other Codex standards.
  - i) A requirement that food additives be used in accordance with Table 1 or 2 of the General Standard for Food Additives is now included given these tables both apply. Since fermented noni fruit juice does not fit any of the current food categories, the Committee on Food Additives should be asked to create or amend a category to include the product. Further, given processing aids and flavourings are not permitted in the Standard reference to these additives has been removed.
  - j) The wording in the hygiene section has been changed to better reflect a fermented product.

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<sup>2</sup> [REP15/NASWP](#), para 61-69

- k) The reference, in the packaging section, to the Code of Practice for low acid food was removed as fermented noni fruit juice does not fall within the definition of a low acid product. Consideration should be given to whether any storing conditions need to be included in the packaging section, such as refrigeration.
- l) The wording around the fill of the container been changed to align with other Codex standards.
- m) With regard to methods of sampling and analysis, it has been suggested that the method to determine moisture was not appropriate to this product. We recommend that the method for moisture is left out pending further consideration once the moisture and Brix levels (section 3.2) have been finalised.
- n) This Brix method is described as determination of soluble solids by refractometer, and has been adopted by Codex as a Type I method for fruit juices.
- o) Note that since ash and acidity were removed from the essential composition and quality factors list (in section 3.2), methods for these have been removed.

#### ***Scopoletin toxicity***

- p) To address concerns raised prior to CCNASWP14 regarding the toxicity levels of scopoletin, CCCP agreed to add scopoletin to the JECFA priority list for assessment. However to date noni producing countries in the region have not been in a position to provide the necessary data in order for JECFA to carry out its assessment.
- q) The Standard can still progress however if, for example, adoption was made at step 5/8 pending the results of the safety evaluation. The US have suggested that if JECFA is unable to evaluate toxicity levels for scopoletin, the toxicity of scopoletin could be discussed in the draft standard.
- r) Whether the footnote with wording around that fact that scopoletin is on the priority list for JECFA evaluation is sufficient 'discussion' in the draft standard will be an issue for consideration at CCNASWP15.

#### **4. Conclusion and Recommendations**

**4.1.** The EWG completed its work.

**4.2.** CCNASWP is invited to

- (a) consider the Proposed Draft Regional Standard for Fermented Noni Juice as presented in Appendix I.
- (b) consider adopting the Proposed Draft Regional Standard for Fermented Noni Juice at Step 5/8 pending the results of the safety evaluation
- (c) request CCFA to create a food category for fermented noni fruit juice.

**Appendix I**

This version includes:

- changes recommended by the eWG up to April 2018;
- recommendations of the October 2018 Workshop in Vanuatu and the subsequent Codex forum; and
- comments from the eWG in response to outstanding questions, January 2019.

**PROPOSED DRAFT REGIONAL STANDARD FOR FERMENTED NONI FRUIT JUICE  
(At Step 3)**

## 1. SCOPE

This standard applies to fermented noni fruit juice, as defined in Section 2 below, which is used as a food or food ingredient. This standard does not apply to non-fermented juice of noni fruit or other noni products from fruit, leaves, bark or flowers or noni products for medicinal purposes.

## 2. DESCRIPTION

### 2.1. Product Definition

The fermented noni fruit juice is the juice product that is derived from the fermenting of fresh fruits of noni plants<sup>3</sup>, *Morinda citrifolia* L. variety *citrifolia*<sup>4</sup> of the Rubiaceae family.

### 2.2 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 (excluding seeds). Fruits that are: over-ripe, fallen fruits, green, bruised and or damaged fruit, 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.

### 2.3 Fermentation of Noni Fruit Juice

Whole fruits or fruit pulp are fermented spontaneously or by starter culture. Juice is extracted from the fermented products. The resultant 100% fermented noni fruit juice is pasteurized to eliminate pathogens of public health significance.

## 3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

### 3.1 Ingredients

The fermented noni fruit juice as defined in section 2.

### 3.2 Fermented noni fruit juice

- |                               |  |
|-------------------------------|--|
| a) Moisture                   | [70-90% or delete as may not be necessary in addition to Brix] |
| c) Brix                       | [5.5-7.0°]   |
| d) pH                         | 3.5-3.9 [if this is needed]                                    |
| f) Ethanol                    | 0.01-0.99% v/v [if this is needed or maybe just a maximum]     |
| g) Deacetylasperulosidic acid | Present  |
| h) Scopoletin                 | Present <sup>5</sup>   |

### 3.3 Definition of defects

To the extent possible in Good Manufacturing Practice, fermented noni fruit juice shall be free from objectionable matter (e.g. noni leaves, seed fragments, fruit skin fragments, stems, insects, etc.).

<sup>3</sup> Common names of noni are great morinda, beach mulberry, Indian mulberry, ach, mengkudu, nono, nonu, noni and cheese fruit.

<sup>4</sup> Two types of large fruits with oval leaves and small fruits with elongated leaves (Wagner, Herbst and Sohmer, 1990, "The Manual of the Flowering Plants of Hawaii" (Copyright 1990, Bishop Museum, Honolulu).

<sup>5</sup> Scopoletin in fermented noni juice is on the JECFA priority list for a full evaluation, including toxicological assessment and exposure evaluation.

### 3.4 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 [to be defined].

## 4. 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.

## 5. HYGIENE

It is recommended that the products covered by the provisions of this Standard be prepared and handled in accordance with appropriate sections of the *General Principles of Food Hygiene* (CAC/RCP 1-1969), 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).

## 6. PACKAGING

The fermented noni juice products must be packed in containers that safeguard its hygienic, nutritional and organoleptic quality. 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.

## 7. WEIGHTS AND MEASURES

### 7.1 Fill of the container

#### 7.1.1 Minimum fill

The container should be well filled 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.

## 8. LABELLING

The product shall be labelled in accordance with the *General Standard for Labelling of Prepackaged Food* (CODEX STAN 1-1985).

### 8.1 Name of the product

The name of the food product shall be "Fermented Noni Juice". The term "noni juice" may be replaced by a term which has customarily been used to describe the product in the country in which the product is intended to be sold (e.g., "nonu juice" or "nono juice").

## 9. METHODS OF SAMPLING AND ANALYSIS

### 9.1 Methods of Sampling

[to be determined]

### 9.2 Methods of Analysis

Provision	Method	Principle	Type	Notes
Moisture	[To be defined]			
Brix value	AOAC 983.17	Refractometry	I	Adopted for fruit juices and nectars
pH value	NMKL 179	Potentiometry	II	Adopted for fruit juices and nectars
Ethanol	IFUMA 52	Enzymatic determination	II	Adopted for fruit juices and nectars
Identification of deacetylasperulosidic acid	Annex B	Thin layer chromatography	IV	
Identification of scopoletin	Annex A	Thin layer chromatography	IV	

According to [method to be defined]

## 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 re-dissolved 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 R<sub>f</sub> 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. *Advance Journal of Food Science and Technology* 2010, 2(5):298-302.

## 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 re-dissolved 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 colour. Identify deacetylasperulosidic in samples by comparing R<sub>f</sub> values and colours 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* 2011, 22(1):26-30.
3. West BJ, Deng S. Thin layer chromatography methods for rapid identity testing of *Morinda citrifolia* L. (noni) fruit and leaf. *Advance Journal of Food Science and Technology* 2010, 2(5):298-302.

## ANNEX C

### PROCESS INFORMATION

This annex provides information on the processes involved in the production of fermented noni fruit juice. Fermented noni fruit juice may be regarded as conforming to the standard whether or not it conforms to this annex.

#### Noni fruit

Green immature noni fruit has a brix level of less than 4°, making it very susceptible to growth of mould. Damaged fruit is susceptible to develop moulds, that might produce mycotoxin.

Noni fruit may be fermented whole, or the fruits may be crushed to a pulp (excluding seeds) with a hammer mill to increase surface area expediting fermentation.

#### Fermentation

Whole fruits or fruit pulp are stored in closed containers lined with sterilized plastics. Fermentation conditions may vary, for example fermentation in the sun for a maximum of 60 days with an average temperature of 35° C, or in the shade for at most 180 days with an average temperature of 30° C. The yield levels of phytochemical and other compounds in fermented noni fruit juice products are at least two times higher in the second method than from the first method of fermentation. Fermentation is generally spontaneous, but starter cultures may be used. Longer fermentation times, up to 4 years, have been reported.

#### Juice extraction

Juice is extracted from the fermented products by pressing, straining, filtered, and re-filtering if required to a finer degree, or by other means that result in a fermented juice product that is substantially free of extraneous materials (e.g., noni leaves, stems, seed fragments, pulp, fruit skins, and insects).

#### Pasteurization

Pasteurization of fermented noni fruit juice may be by heat. Different time and temperature combinations are used, e.g. 82.2° C for 1 to 2 minutes or 87.5° C for 3 seconds. Other methods of pasteurization may be used, such as ultraviolet light or high pressure processing.

[The efficacy of pasteurization can be indicated by the following microbiological criterion:

Maximum *E coli* in 50 ml fermented noni fruit juice: n = 2, c = 0, m = 0.]

**List of Participants****CODEX MEMBERS**

- 1 Australia
- 2 Canada
- 3 New Zealand
- 4 Samoa
- 5 Tonga
- 6 United States of America
- 7 Vanuatu