CODEX ALIMENTARIUS COMMISSION

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Agenda Item 6 **CX/NASWP 14/13/6 Add.1**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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

13th Session, Kokopo, Papua New Guinea

PROPOSED DRAFT REGIONAL STANDARD FOR FERMENTED NONI JUICE

COMMENTS AT STEP 3

(*Replies of Australia, Canada, Solomon Islands, Tonga and the United States of America*)

AUSTRALIA

Australia would like to congratulate Tonga for its work in developing the initial draft standard. As a general comment we note that the project document for the new work which was approved by the Commission in 2013 indicates a need for expert scientific advice from WHO/FAO. It is unclear whether FAO/WHO has been formally requested to provide the technical assistance in time for the 2014 Session, as mentioned in paragraph 9 of the Project Document. We note that if the advice has not been formally requested from the FAO/WHO this could delay progress on the work on this regional standard and the Codex Executive Committee should be informed of potential delay in completion of the work.

Australia wishes to provide the following specific comments with regard to CX/NASWP 14/13/6 Proposed Draft Regional Standard for Fermented Noni Juice.

Specific Comments

Para 4 – Noni Fruits

Australia proposes that 'seeds' be included in the list of materials to be excluded from the production of fermented nobi juice. The section would then read as follows:

'…..Fruits that are: over-ripe, fallen fruits, green, bruised and or damaged fruit, noni fruit seeds 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'.

Rationale

Research has found that the production process (fermentation/juice production versus drying/lyophilization) has no effect on the anthraquinone content. The source product, however, does have implications: noni fruit puree from which seeds had been removed as well as consumer products produced from such puree had no detectable amounts of any anthraquinones. Products that did contain seed or leaf material in all cases did contain partly significant amounts of anthraquinones. To alleviate safety concerns, we suggest that noni products, whether fermented or unfermented juice or powder, should be derived only from fully ripe noni fruits, and that any seed material needs to be removed during the production process.

Para 5 – Fermentation Noni Fruit Juice

Australia proposes the following inclusion in section 5:

'Whole fruits or fruit pulp**, excluding seeds,** should be fermented for a minimum of….'

Rationale

Research has found that the production process (fermentation/juice production versus drying/lyophilization) has no effect on the anthraquinone content. The source product, however, does have implications: noni fruit puree from which seeds had been removed as well as consumer products produced from such puree had no detectable amounts of any anthraquinones. Products that did contain seed or leaf material in all cases did contain partly significant amounts of anthraquinones. To alleviate safety concerns, we suggest that noni products, whether fermented or unfermented juice or powder, should be derived only from fully ripe noni fruits, and that any seed material needs to be removed during the production process.

Para 8 – Definition of Defects

Australia proposes the following inclusion to the section on defects:

'a) Presence of Noni leaves, **seeds,** stems, barks and roots'

Rationale

Research has found that the production process (fermentation/juice production versus drying/lyophilization) has no effect on the anthraquinone content. The source product, however, does have implications: noni fruit puree from which seeds had been removed as well as consumer products produced from such puree had no detectable amounts of any anthraquinones. Products that did contain seed or leaf material in all cases did contain partly significant amounts of anthraquinones. To alleviate safety concerns, we suggest that noni products, whether fermented or unfermented juice or powder, should be derived only from fully ripe noni fruits, and that any seed material needs to be removed during the production process.

Para 15 - Minimum fill

Australia considers a reference to OIML R871[1] may be appropriate instead of a detailed procedure, plus consideration of whether an 'Average requirement' plus an 'Individual prepackage requirement' should be specified (as per OIML R87).

Methods of Analysis and Sampling

The proposed draft regional standard could be improved by incorporating sampling plan(s) plus method of analysis for all the quality factors listed in para 7, Australia would suggest the Codex General Standard for Fruit Juices and Nectars (CODEX STAN 247-2005) and Recommended Methodsof Analysis and Sampling (CODEX STAN 234-1999, PART A, Commodity Category - Fruit Juices and Nectars) as source of suitable endorsed methods, which would then provide consistency with similar products.

The sampling plans need to be specified based on the commodity and how the product is traded e.g. isolated lots or a continuous series of lots. Further information can be found in the General Guidelines on Sampling (CAC/GL 50-2004) see section 3.1, where for Qualitative/quantitative characteristics/sensory inspections consideration should be given to an Inspection by attributes using a Limiting Quality (LQ) for isolated lots, or an inspection level plus Acceptable Quality Level (AQL) for a continuous series of lots (for the Microbiological parameters for which an attribute plan may not be suitable).

For the methods provided in Appendix A, B and C; some method performance data is provided in the referenced text, however acceptance may also be enhanced by undertaking an international collaborative trial using these methods for Fermented Noni Juice. This would support the methods validity and ensure consistency in outcomes between trading partners of Fermented Noni Juice.

DETERMINATION OF MOISTURE

This method is for Loss on Drying (Moisture) in sugars which lists four techniques for different applications, the exact technique may have to be specified. An alternatively to consider AOAC Method 934.06 Loss on Drying (Moisture in Dried Fruits) with the preparation for juices in AOAC Method 920.149; or if the parameter was to change from "Moisture" to "Total Dry matter", the Determination of Total Dry Matter (vacuum-oven drying at 70°C); EN 12145 (1996); IFU Method No 61 (1991).

DETERMINATION OF ASH

This is an old AOAC reference, Australia believe AOAC Method 940.26 A may be relevant; alternatives could be EN 1135 (1994); IFU Method No 9 (1989)

DETERMINATION OF BRIX

This parameter is normally expressed as "Soluble solids" with a method principle "Indirect by refractometry". If included, methods which could be considered are: AOAC 983.17; EN 12143 (1996); IFU Method No 8 (1991); ISO 2173: 2003

Australia suggests the addition of the following:

DETERMINATION OF pH

If included, methods which could be considered are: Determination of pH-value: NMKL 179:2005; EN 1132 (1994); IFU Method No 11 (1989); ISO 1842: 1991

DETERMINATION OF ACIDITY

If included, a method which could be considered is: AOAC Method 942.15

[1] International Organization of Legal Metrology (OIML), Bureau International de Métrologie Légale 11, rue Turgot - 75009 Paris - France, Publication OIML R 87 Edition 2004 (E).

DETERMINATION OF ETHANOL

If included, a method which could be considered is: Determination of alcohol (ethanol) - IFU Method No 52 (1996)

We understand that our comments in relation to methods of analysis are complex and highly technical and possibly not appropriate to be discussed in CCNASWP, but we want to bring these to the attention of the committee at this early stage so that there is an opportunity for the committee to seek advice from the Codex Committee on Methods of Analysis and Sampling at an early point in the development of the standard in order to avoid delays in its adoption.

CANADA

Canada is pleased to offer the following comments on the Draft Regional Standard for Fermented Noni Juice for consideration at the 13th Session of CCNASWP. We would note that we had submitted comments on the draft standard in August 2013 and November 2013. Paragraph 4 of the background document (CX/NASWP 14/13/6) does not acknowledge the comments submitted by Canada in November 2013.

1. The methods proposed for moisture and ash are published AOAC methods and may be considered for Type I method status:

- the method proposed for ash is the same as the Codex Type I method for ash in fruit products but the reference number should be changed from 37.1.18 to AOAC 940.26
- the method proposed for moisture is AOAC 925.45 which is for sugar products and may be considered or alternatively aligned with the Codex Type I method for fruit juices and nectars as in STAN 234

2. The methods listed in the annexes A, B and C appear to be single lab validated methods and therefore may only be suggested as Type IV methods.

3. There is a problem with the “Quality Factors” in the proposed draft standard because they imply a zero tolerance, i.e. free of patulin mycotoxins and free of lucidin, alizarin and rubiadin. There is no method suggested for patulin but that is not absolutely necessary for Type II/III methods because method performance criteria can be elaborated as per the Procedural Manual. As the methods in the standard will need to be endorsed by CCMAS, there is a problem with these "free of" provisions in that CCMAS cannot deal with zero as a maximum limit. CCMAS needs a ML to determine if a method proposed is fit for purpose or to calculate performance criteria. We also believe that CCMAS might also be reluctant to endorse methods for zero tolerance since it implies that CCMAS has established an ML by way of the method Limit of Detection or Limit of Quantitation. If there are ML established, it would be preferable if these were for each individual compound rather than a sum or total ML. CCMAS has not yet established how to elaborate criteria for a sum of components. Consideration might also be given to referring the standard to CCCF for its view on any ML established for mycotoxin contaminants.

4. The standard should also specify a method for Brix since this is a Type I defining method. Different methods may give different results, so, a naming the method may be desirable.

5. It is also likely that CCMAS would expect a method for Acidity to be identified and could request clarification for the units intended in the standard. The standard does indicate Acidity as 0.095-0.135% but does not indicate as % of what particular acid. Eg. for orange juice it is customary to report as Acidity as citric acid or in oils as oleic acid. There are Type I methods in STAN 234 applicable to Acidity in Fruit Juice and Nectar which may be considered.

SOLOMON ISLANDS

General Comments

Solomon Islands do take note of the revised version for the 13th session of CCNASWP.

Specific Comments:

1. Paragraph 2: Definition: Propose adding the word PRODUCTS.

Rationale: word Products is mentioned in further into the standard. (To be consistent all through).

2. Paragraph 4 Line 3: Proposed the deletion of word FRUIT after the word damaged.

Rationale: word fruit is already stated at the beginning of the sentence.

3. Paragraph 4 Line 3: Proposed replacing word SHOULD with SHALL.

Rationale: would be proper to put shall so that it is mandatory.

4. Paragraph 7 Line 1: proposed inserting SHALL to replace Must. Therefore would propose the same to be applicable to later texts.

Rationale: although must is mandatory shall is preferred.

5. Paragraph 7 Line 2 Replace word may be with SHOULD.

Rationale: maybe is seen as assumption and not definite.

6. Paragraph 12: Line 1 replace word Must with Shall.

7. Paragraph 14: Line 1, 3 & 6. Replace word Must with Shall.

TONGA

Specific Comments

DESCRIPTION

2. Product Definition

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

*Common names of noni are great morinda, beach mulberry, Indian mulberry, ach, mengkudu, nono, nonu and noni.

Tonga comment- from the The Manual of the Flowering Plants of Hawaii by Wagner, Herbst and Sohmer (Copyright 1990, Bishop Museum, Honolulu) described 3 varieties of noni (citrifolia, Potteri, bracteata). The noni variety citrifolia of two types (large fruit with oval leaves and small size fruits with elongated leaves) is the traditional variety commonly used. Therefore, in the product definition above insert the variety citrifolia, ***Morinda citrifolia* L. var citrifolia of the Rubiceae** family.

FOOD ADDITIVES

10. Food additives listed in Tables 1 and 2 of the General Standard for Food Additives in Food Categories 14.1.2.1 (Fruit juice) may be used in foods subject to this Standard.

11. Use of flavouring substances should be consistent with the Guidelines for the Use of Flavourings CAC/GL 66-2008).

12. Section 4.1 of the General Standard for Food Additives (CODEX STAN 192-1995) referring to the conditions applying to carry over of food additives from ingredients and raw materials in food shall apply.

UNITED STATES OF AMERICA

General Comments

As you may recall, the United States had some concerns regarding the safety of Noni products at the last CCNASWP (2012) and in our recent comments submitted to the eWG. All of the safety data cited is based on a maximum daily consumption of 30 ml (see the project document and EFSA novel food discussion). However, in the United States, a single serving of fruit juice is 8 times higher (240 ml). The safety of noni juice at a maximum of 30 ml per day has been previously commented on in the project document. The U.S. labeling rules require that juice containers bear a label identifying a serving size as 240 ml of the juice. Therefore, Noni juice would potentially be consumed in the United States (and perhaps elsewhere in the region) in the same quantities as other juices with 240 ml serving sizes. This could be dangerous and misleading because consumers frequently assume that they can consume as many servings as they wish – fruit juice is expected to be safe even if consumed in quantity.

In looking at the safety of noni fruit juice, one needs to consider purity, volume and duration of consumption, drug interactions, with special attention to susceptible populations which includes children (because of their higher exposure on a per body weight basis), pregnant and lactating women and individuals with preexisting medical conditions such as liver disorders or those on blood thinners. While Noni juice may be considered safe for the general population under specified conditions, it could pose adverse health effects to susceptible populations when consumed in quantities typical of juice. The presence of a Codex standard may be reassuring to consumers when, in fact, the levels of consumption on which the safety is based, are not what is likely if the standard is adopted without a limitation.

Additionally, noni is often used as an additive in other foods such as dietary supplements. Accordingly, we are concerned that the safety of this product should be considered and evaluated by JECFA before moving

any further in the Step process. As the report of the eWG indicates, there is a clear need for expert scientific advice from WHO/FAO on the following:

- Mapping/Identification of noni varieties suitable for human consumption.
- Identifying key pre and post harvest molds and mycotoxin (if any) on the fruits that affect noni (noni) products.
- Identification of the bacteria that promote fermentation.
- Recommended maximum daily intake of the fermented noni fruit juice products.
- Recommended safe maximum level of "scopoletin;" as well as the method of analysis.

Specific Comments

3.2 QUALITY FACTORS

US Comment: Please identify the Method of Analysis to determine that Noni raw materials must be "free of patulin mycotoxins."

3.2.1 Fermented Noni Fruit Juice

g) Deacetylasperulosidic acid > 0.95 mg/mL

US Comment: This needs a quantitative method since a minimum quantity (> 0.95 mg/mL) is specified. If there is no quantitative method for this substance, there is no way to determine whether the fermented noni juice actually meets this requirement and suggests that a minimum quantity should not be specified.

h) Scopoletin > 0.95 mg/mL

US Comment: This needs a quantitative method since a minimum quantity (> 0.95 mg/mL) is specified. If there is no quantitative method for this substance, there is no way to determine whether the fermented noni juice actually meets this requirement and suggests that a minimum quantity should not be specified.

3.3 DEFINITION OF DEFECTS

The following defects shall be applied to the Fermented Noni Fruit Juice:

a) Presence of Noni leaves, stems, barks, and roots

b) Insects

c) Bacterial aerobic total viable count exceeding 1000 cfu/mL

d) Yeast exceeding 100 cfu/mL

e) Mold exceeding 10 cfu/mL

fe) Presence of Escherichia coli & Patulin mycotoxins

gf) Presence of lucidin, alizarin and rubiadin.

US Comment: With regard to c) - f) highlighted and underlined above, are these analyses performed before or after the pasteurization step (82.2° C for 1 to 2 minutes) as specified in footnote #7 of the draft standard? One would not expect these organisms to be present after pasteurization but the issue is whether they are "defects" if present before pasteurization?

Noni raw materials that fail to meet one or more of the applicable quality requirements, set out above shall be considered "defective" noni raw materials or products and should not be used for manufacturing of Fermented Noni Fruit Juice products. The presence of any of these anthraquinones indicates the fermented noni fruit juice is adulterated with noni roots and/or bark. Also see Annex A

US Comment: The suggestion here is that the testing is applied before fermentation while the sentence preceding the lettered list suggests they are applied to the "fermented noni juice".

6.4 IDENTIFICATION OF SCOPOLETIN

According to method described in Annex B

US Comment: As mentioned above in 3.2.1, this needs a quantitative method since a minimum quantity is specified.

6.5 IDENTIFICATION OF DEACETYLASPERULOSIDIC ACID

According to method described in Annex C

US Comment: As mentioned above in 3.2.1, this needs a quantitative method since a minimum quantity is specified.

ANNEX A

DETERMINATION OF LUCIDIN, RUBIADIN AND ALIZARIN

1. PREPARATION OF SAMPLES

Two grams of mashed fruit is extracted with methanol twice (125 milliliters, 30 min each) using a sonicator. The methanol extract is evaporated under vacuum in a rotary evaporator. The extracts are then re-dissolved in 10 milliliters of methanol.

One gram of noni fruit powder is extracted with methanol twice (125 milliliters, 30 min each) using a sonicator. The methanol extract is evaporated under vacuum in a rotary evaporator. The extracts are then re-dissolved in 10 milliliters of methanol

One hundred milliliters of noni juice is partitioned three times with 100 milliliters of dichloromethane (CH2Cl2) each time to obtain a CH2Cl2 extract. The extract is concentrated by evaporation of the solvent in a rotary evaporator under reduced pressure at 45 °C. The dried extract is dissolved with 5 mL of MeOH.

One gram of milled dry noni leaf is extracted with methanol twice (125 milliliters, 30 min each) using a sonicator. The methanol extract is evaporated under vacuum in a rotary evaporator. The extracts are then re-dissolved in 10 milliliters of methanol.

All sample solutions are filtered through a nylon membrane filter (0.45 µm pore size) before HPLC experiments. The injection volume is 50 µL each of the sample solutions.

US Comment: The presence of the substances highlighted and underlined above is supposedly prohibited in "fermented noni fruit juice" per 3.2.1 and 3.3. This method appears to be intended for use on "fruit", dried "noni fruit powder," "noni juice", and "milled dry noni leaf". Is this method applicable and has it been validated for "fermented noni fruit juice"? Should CCMAS evaluate the suitability of this method for a "fermented" product?

ANNEX B

IDENTIFICATION OF SCOPOLETIN

US Comment: The Identification of Scopoletin is not a quantitative method. It is a qualitative method that can determine whether scopoletin is present, but it cannot tell whether scopoletin is present at greater than 0.95mg/g as required by 3.2.1(h).

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.

US Comment: The presence of the substances highlighted and underlined above is supposedly prohibited in "fermented noni fruit juice" per 3.2.1 and 3.3. This method appears to be intended for use on "fruit", dried "noni fruit powder," "noni juice", and "milled dry noni leaf". Is this method applicable and has it been validated for "fermented noni fruit juice"? Should CCMAS evaluate the suitability of this method for a "fermented" product?

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 colors on developed plate under UV lamp, 365 nm. Identify scopoletin in samples by comparing Rf values and colors to the standard.

US Comment: Dichloromethane is a hazardous chlorinated solvent. Should CCMAS be consulted about the use of a method requiring this solvent?

ANNEX C

IDENTIFICATION OF DEACETYLASPERULOSIDIC ACID

US Comment: The identification of Deacetylasperulosidic Acid is not a quantitative method. It is a qualitative method that can determine whether deacetylasperulosidic acid is present but it cannot determine whether deacetylasperulosidic acid is present at greater than 0.95mg/g as required by 3.2.1(g).

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.

US Comment: The presence of the substances highlighted and underlined above is supposedly prohibited in “fermented noni fruit juice” per 3.2.1 and 3.3. This method appears to be intended for use on “fruit”, dried “noni fruit powder, “noni juice”, and “milled dry noni leaf”. Is this method applicable and has it been validated for “fermented noni fruit juice”? Should CCMAS evaluate the suitability of this method for a “fermented” product?

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.

US Comment: Dichloromethane is a hazardous chlorinated solvent. Should CCMAS be consulted about the use of a method requiring this solvent?