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PROPOSED DRAFT REGIONAL STANDARD FOR FERMENTED NONI JUICE

Comments at Step 3 submitted by Tonga and Brazil

TONGA

General Comments

Tonga acknowledges that since 2008 huge progress has been made to the noni standard with the excellent efforts by the electronic Working Group and members. Therefore, Tonga is pleased to submit the following comments in response to CX/NASWP 16/14/9 and also the comments by United States.

GENERAL COMMENTS

Tonga agrees with the expressed views that the development of the noni standard still needs additional works. Notwithstanding the pursuance by United States of the safety issue of “scopoletin”, Tonga is pleased to report that, to date, no significant adverse health effects has been reported due to the consumption of the noni fruit products. But especially with any direct link to the “scopoletin” compound that is of concern in the noni fruit products.

SPECIFIC COMMENTS

1. 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.

Comments

With regards to the clarity of the main product for this standard, the main product of this standard is the “juice of the fermented noni fruit” as differentiated from other commercial products such as “fermented noni’s leaves, bark or flowers” or “juice of fresh noni fruits” or “puree of fresh noni fruits”, etc. Therefore, Tonga proposes to amend Section 1. Product Definition, to enhance the clarity of the product.

2. DESCRIPTION

1. Product Definition

The fermented noni fruit juice is **the juice product that is** derived from the fermenting of fresh fruits of noni plants¹, *Morinda citrifolia* L. variety *citrifolia*² of the Rubiceae family, with suitable processes ~~that maintain~~ **with minimum changes to** its essential physical, chemical, organoleptic and nutritional characteristics.

Comments

Tonga propose two changes in the product definition: first, by inserting “the juice product that is” in the first line for clarity; in the second line and delete “maintain” and insert “with minimize changes to”.

1.1.1 Fermentation Noni Fruit Juice

Whole fruits or fruit pulp should be **stored in closed containers lined with sterilized plastics and fermented spontaneously in the sun** for a minimum of 10 days to a maximum of 60 days **or in the shade for at most 180 days with a room temperature of 30°C**. ~~The requirement for a starter viable microorganism for fermentation may not apply³ due to the heat pasteurization that follows.~~ The fermented products are

¹ Common names of noni are great morinda, beach mulberry, Indian mulberry, ach, mengkudu, nono, nonu, noni and cheese fruit.

² 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)

³ Standard for Fermented Milk (CODEX STAN 243-2003)

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 heat⁴.

Comments

The first common method use for fermentations involves storing the fruits in closed containers lined with sterilized plastic and left in the sun for at most 60 days with an average temperature of 35°C. The second methods involves storing the fruits in closed containers lined with sterilized plastic and left 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 is at least two times higher in the second method than from the first method of fermentation.

Secondly, all the fermentations practiced and reported for noni fruits are with spontaneous fermentation, that is, no starter viable microorganism culture for fermentation is practiced at all.

Therefore, Tonga proposed changes as in the above paragraph.

2. ESSENTIAL COMPOSITION AND QUALITY FACTORS

2.3 FERMENTED NONI FRUIT JUICE

a) Moisture:	89-96.7%
b) Ash:	0.2-0.8g/100mL
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	>0.95mg/mL
h) Scopoletin	>0.95 mg/ml

Comments

Various reports⁵⁶⁷ found Deacetylasperulosidic acid (DAA) to be a major compound in noni fruit juice, with a range of 1.441 ± 0.027 micro-gram per milliliter of fresh noni fruit juice from Tahiti, Tonga, Hawaii, Thailand, Japan and Dominican Republic. The amount of DAA in different parts of the noni plant decreases from: dried noni fruit > fruit juice > seed > flower > leaf > root. In commercial noni fruit juice products from the 1 company in Asia, 4 in the Pacific and 2 from Europe, found DAA concentration ranges from 0.233 to 2.424 milligram to milliliter of commercial noni fruit juice products.

The same reports found Scopoletin to be another major compound, ranging from 0.064 to 6.87 milligram per gram of fresh noni fruits from 2 sites in Asia, 4 in the Pacific and 1 from Caribbean. From 13 global commercial noni fruit juice products made from Tahiti, El Salvador, Hawaii, Dominican Republic, Costa Rica, China, and Indonesia, reported the Scopoletin content ranges from 0.88 to 34.01 micro-gram to milliliter of commercial juice products.

*Therefore, the inclusion of Deacetylasperulosidic acid and Scopoletin in the noni standard serves as a reference for identification and authentication of noni fruit raw materials and commercial noni fruit juice products. Therefore, Tonga is with the view that these 2 compounds in section 2.3 **are not contaminants** but they are two essential quality phyto-chemicals of the fermented noni fruit juice products.*

The >0.95 mg/mL lower limit is an arbitrary minimum quality marker (prone to changes with the latest science) to the authenticity of the fermented noni fruit juice product.

2.4 DEFINITION OF DEFECTS

Fermented noni juice shall be prepared in accordance with good manufacturing practices (GMPs) from such

⁴ Pasteurized at 82.2°C for 1 to 2 minutes

⁵ Deng S., West B. J., Jensen C. J., 2010: "A quantitative comparison of phytochemical components in global noni fruits and their commercial products" *Food Chemistry* 122, 2010, 267–270

⁶ Deng S., West B. J., Palu A. K., Jensen C. J., 2011: "Determination and Comparative Analysis of Major Iridoids in Different Parts and Cultivation Sources of *Morinda citrifolia*" *Phytochemical Analysis* 2011, **22**, 26–30

⁷ Potterat O., Felten R. von, Dalsgaard W., Hamburger M.: "Identification of TLC Markers and Quantification by HPLC-MS of Various Constituents in Noni Fruit Powder and Commercial Noni-Derived Products" *Journal of Agricultural & Food Chemistry* 2007,

materials and under such practices that the product is substantially free of extraneous materials (e.g. noni leaves, **seed fragments, fruit skin fragments**, stems, insects, etc.).

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

Comments

The two methods of the analysis of fermented noni fruit juice for Deacetylasperulosidic Acid and Scopoletin are qualitative methods for determining the presence of DAA and Scopoletin with concentration above a certain level. The >0.95 mg/mL lower limit is an arbitrary minimum quality marker (prone to changes with the latest science) as an indication of the authenticity of the fermented noni fruit juice product.

BRAZIL

Brazil does not agree with the development of a standard of fermented noni juice because this product has been extensively market with therapeutic proprieties and there are several publications indicating that its consumption may cause hepatotoxicity (BIBRA, 2003; Millonig et al., 2005; Stadlbauer et al., 2005; Yüce et al., 2006; Muller et al., 2007; Andrada et al., 2007; Waldman et al. 2013).

Some authors have suggested that substances naturally present could be responsible for the hepatotoxic effects observed. In this sense, some studies have identified new constituents in fruits and noni juices for which there are few toxicological information, including the identification of anthraquinones whose presence was attributed only to the roots and leaves of the plant (Pawlus et al., 2005; Kamiya et al., 2005; Samoylenko et al., 2006; Akihisa et al., 2007; Deng et al., 2007; Siddiqui et al., 2007).

Additionally, Brazil would like to point that scopoletin, one of the constituents of noni juice, is in the priority list for risk assessment by JECFA.

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