



Food and Agriculture  
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Agenda Item 9

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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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

Fifteenth Session

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### PROPOSED DRAFT REGIONAL STANDARD FOR FERMENTED NONI JUICE

Replies to CL 2019/68/OCS-NASWP

*Comments of Canada, Iraq, Syrian Arab Republic, USA*

#### **Background**

This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2019/68/OCS-NASWP issued in June 2019. Under the OCS, comments are compiled in the following order: general comments are listed first, followed by comments on specific sections.

#### **Explanatory notes on the appendix**

The comments submitted through the OCS are hereby attached as Annex I and are presented in table format.

**COMMENTS ON THE PROPOSED DRAFT REGIONAL STANDARD FOR FERMENTED NONI JUICE**  
**Comments at Step 3 (Replies to CL 2019/68/OCS-NASWP)**

<b>GENERAL COMMENTS</b>	
<b>Comment</b>	<b>Member/Observer and Rationale where applicable</b>
We agree with proposed draft of FERMENTED NONI FRUIT JUICE	<b>Iraq</b>
No comments	<b>Syrian Arab Republic</b>
<p>The United States would like to submit the following general comments to the report and proposed draft regional standard for Fermented Noni Fruit Juice:</p> <p>With regard to paragraph e, the United States concurs with the need for a greater understanding on the ranges provided.</p> <p>With regard to paragraph f, the United States would like to know what the level of typical alcohol content is in these products? The United States would suggest that the alcohol level should be less than 0.5% (v/v), as we have commented in the text below, since levels at or above 0.5% by volume would make the product an alcoholic beverage subject to additional regulations.</p>	<b>USA</b>
<b>SPECIFIC COMMENTS</b>	
<b>2.3 Fermentation of Noni Fruit Juice</b>	
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 <u>or otherwise treated</u> to eliminate pathogens of public health significance.	<p><b>USA</b></p> <p>Pasteurization is typically understood as a heat treatment. Another option is to use the words such as “treated” and “processed.”</p>
<b>3.2 Fermented noni fruit juice</b>	
f) Ethanol 0.01-0.99% v/v [if this is needed or maybe just a maximum]	<p><b>Canada</b></p> <p>Canada agrees with the proposal to provide just a maximum ethanol composition criterion (0.99% v/v) rather than a range.</p>
<sup>5</sup> Scopoletin in fermented noni juice is on the JECFA priority list for a full evaluation, including toxicological assessment and exposure evaluation.	<p><b>Canada</b></p> <p>The footnote could be amended, or linked to a note in an annex, with some context from authoritative reviews. Pending either the JECFA evaluation or a separate review of scopoletin toxicity as suggested by the U.S., recent authoritative reviews of noni safety help provide context to the question of risk. In 2006, the European Food Safety Authority's Scientific Panel on Dietetic Products, Nutrition and Allergies reviewed all available evidence on the safety of noni juice. They concluded that they were in agreement with the previous opinion of the European Commission's Scientific Committee on Food (2002) that there were no</p>

	<p>indications of adverse effects from laboratory animal studies on subacute and subchronic toxicity, genotoxicity and allergenicity. From a toxicological point of view, noni juice has been adequately tested and the studies evaluated by the SCF as well as the additional toxicological studies provided to EFSA did not raise concern. Specifically, the Panel considered it unlikely that consumption of noni juice, at the observed levels of intake, induces adverse human liver effects. In a subsequent review of noni fruit puree and concentrate as a novel food, the EFSA Panel (2009) concluded that the ingredients under the specified conditions are considered safe for the general population. However, the Panel considered that the increasing number of case reports might indicate that some individuals have a particular sensitivity for hepatotoxic effects to noni fruit products.</p> <p><a href="https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scf_out151_en.pdf">https://ec.europa.eu/food/sites/food/files/safety/docs/sci-com_scf_out151_en.pdf</a>  <a href="https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2006.376">https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2006.376</a>  <a href="https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2009.998">https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/j.efsa.2009.998</a></p>
f) Ethanol 0.01-0.99% <u>0.5%</u> v/v [if this is needed or maybe just a maximum]	<p><b>USA</b> Suggest the levels should be below 0.5% v/v.</p>
<b>3.4 Food Additives</b>	
All food additives used in accordance with Table 1 and 2 of the <i>General Standard for Food Additives</i> (CODEX STAN 192-1985) in food category [to be defined] <u>are acceptable for use in foods conforming to this standard.</u>	<p><b>Canada</b> This wording would be consistent with the Procedural Manual.</p>
<b>ANNEX A</b>	
<b>3.1 THIN LAYER CHROMATOGRAPHY</b>	
	<p><b>Canada</b> Both Annex A and B set out a TLC methodology for identification of the coumarin scopoletin and the iridoid deacetylasperulosidic acid. So long as detection in comparison to a pure reference standard is the only requirement, TLC is adequate. If in the future a specific limit is set on the concentration of these constituents, as has been discussed, then the HPLC method set out in the references cited in these annexes (e.g., Deng et al. 2010, Deng et al. 2011; Potterat et al. 2007) should be considered for adoption since they will allow quantitation.</p>
<b>REFERENCES</b>	
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. <i>Food Analytical Methods</i> 2011, 4(1):57-65. Published online 23 February 2010. DOI: 10.1007/s12161-010-9125-9.	<p><b>Canada</b> Incomplete reference.</p>
<b>ANNEX B</b>	
<b>3.1 THIN LAYER CHROMATOGRAPHY</b>	

	<p><b>Canada</b> See previous comment on TLC in Annex A (3.1)</p>
<b>ANNEX C</b>	
<p>This annex provides information on the processes involved in the production of fermented noni fruit juice. <del> Fermented noni fruit juice may be regarded as conforming to the standard whether or not it conforms to this annex.</del></p>	<p><b>Canada</b> Annexes form a part of the standard and, as such, become part of the text in the standard. With this in mind, consideration should be given to revising or removing this statement.</p>
<p>[The efficacy pf pasteurization can be indicated by the following microbiological criterion:</p>	<p><b>Canada</b> Canada suggests removing the micro criterion for <i>E. coli</i> as treatments (thermal or non-thermal) that could inactivate <i>E. coli</i> may be insufficient to inactivate pathogens of public health concern. Performance standards should consider the most resistant pathogen of concern relevant in fruit juice produced.</p>
<p>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 <del>a maximum</del> of <u>about 60 days or less</u> with an average temperature of 35° C, or in the shade for <del>at most</del> <u>about 180 days or less</u> 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.</p>	<p><b>USA</b> Is the second sentence even necessary since it states that fermentation conditions may vary? If so, we have provided some edits to the text in track changes. Is there a need to describe the starter culture? With regard to the sentence on yield levels, we question why this language was added. Why is it necessary? Is it accurate? What science is this statement based on?</p>
<p><u>Pasteurization</u> 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.</p>	<p><b>USA</b> US suggested alternative language: Fermented noni fruit juice must be treated with validated processing methods to eliminate pathogens of public health significance. The processing can be done by heat pasteurization or other non-thermal technologies, such as ultraviolet light or high pressure processing.] If the Committee does not agree with the US-proposed alternate text, CCNASWP should consider giving a performance standard, e.g., a 5-log pathogen reduction in the second sentence "Different time and temperature combinations are used..."</p>
<p>[The efficacy pf pasteurization can be indicated by the following microbiological criterion:</p>	<p><b>USA</b> It's best to provide the performance standard, such as log reduction of pathogens of public health significance. The treatment conditions should be validated.</p>