

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda item 7

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME
FAO/WHO COORDINATING COMMITTEE FOR NORTH AMERICA AND THE SOUTH WEST PACIFIC
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DRAFT REGIONAL STANDARD FOR FERMENTED NONI FRUIT JUICE

Comments in reply to CL 2022/83/OCS-NASWP

Comments of Canada, Egypt, European Union, Iraq, Mauritius and USA

Background

1. This document compiles comments received through the Codex Online Commenting System (OCS) in response to CL 2022/83/OCS-NASWP issued in December 2022.

Explanatory notes on the Annex

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

Annex I**GENERAL COMMENTS**

Canada would like to thank the EWG chairs, Tonga and Samoa, for preparing the draft regional standard and note with appreciation the progress made on it. Canada offers the following comments for consideration.	Canada
Egypt agrees on the draft of the standard with no comments	Egypt
In the EU, the juice of the noni fruit (<i>Morinda citrifolia</i> L.) was authorised by Commission Decision 2003/426/EC (1) and it was subsequently included in the Union list of novel foods (2) once the current Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods (3) became applicable. Under that authorisation the fermentation step is optional. (1) https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32003D0426 (2) https://eur-lex.europa.eu/eli/reg_impl/2017/2470/oj (3) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32015R2283	European Union
No comments	Iraq
Thank you for the opportunity to comment. The document seems fine. we have two minor comments inserted below.	Mauritius
The United States supports the final adoption at Step 8 of the Draft Regional Standard for Fermented Noni Fruit Juice despite missing information in Section 3.2 High Performance Liquid Chromatography (HPLC) of Annex A -Identification of Scopoletin and of Annex B - Identification of Deacetylasperulosidic Acid. The United States welcomes the opportunity to participate in further discussions about the methods for which details remain to be provided-- Chromatographic system and HPLC identification test and the HPLC identification test – acceptance criteria.	USA

SPECIFIC COMMENTS**2.3 Fermentation of Noni Fruit Juice**

Whole fruits or fruit pulp are fermented spontaneously-naturally or by starter culture. Juice is extracted from the fermented products. The resultant 100% fermented noni fruit juice is pasteurized or otherwise treated to eliminate pathogens of public health significance.	Mauritius
To readjust the second sentence by "Juice is extracted or collected from the fermented fruit and filtered". The words resultant 100%to be deleted from the sentence.	

3.2 Fermented noni fruit juice

Footnote <i>Scopoletin is present naturally in fermented noni fruit juice. Some reports have shown potential toxicity of scopoletin. Therefore, the scopoletin levels should be kept as low as technologically feasible until a safe level is established by JECFA.</i>	Canada
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10.1 Methods of Analysis

Provision	Method	Principle	Type	Notes	Canada
Ethanol	IFUMA 52 AOAC2017_AOAC 2017.07	Enzymatic determination	IV		
	AOAC Method2016.12	Headspace GC-FID	IV		
Identification of scopoletin	Annex A*	Thin layer chromatography (TLC) or [or], [High-performance liquid chromatography (HPLC)]	IV		
Identification of deacetylasperulosidic acid	Annex B*	Thin layer chromatography (TLC) or [or], [High-performance liquid chromatography (HPLC)]	IV		
<p><i>Identification of scopoletin</i> Suggest placing square brackets [] around "or," as the HPLC method has not been defined yet in Annex A. While the HPLC method would be the preferred method, Canada would suggest placing HPLC method in square brackets [], since the method has not been defined yet in Annex A</p> <p><i>Identification of deacetylasperulosidic acid</i> Suggest placing square brackets [] around "or," as the HPLC method has not been defined yet in Annex B. While the HPLC method would be the preferred method, Canada would suggest placing HPLC method in square brackets [], since the method has not been defined yet in Annex B.</p>					

ANNEX A - IDENTIFICATION OF SCOPOLETIN**1. PREPARATION OF SAMPLES**

Noni fruit 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. [SPE cartridges (**specify type of cartridge in terms of solid phase**) is first equilibrated with water (**mls mLs**), followed by methanol (**mls mLs**). The samples are then loaded onto the cartridge and washed with 5% (**mls mLs**) methanol (**MeOH)MeOH**) in water, followed by 100% (**mls mLs**) MeOH. The MeOH eluate is retained for TLC analysis.]

- The type of cartridge should be specified.
- Suggest that “mls” be changed to “mLs” for consistent expression of milliliters throughout the method of analysis.
- Propose adding "in water" to clarify that this is a 5% solution of methanol in water.
- The volume of water and methanol should be specified.

2. PREPARATION OF REFERENCE STANDARD

2.1 A reference standard is prepared by dissolving 1 mg scopoletin in 1 ~~milliliter~~mL of methanol.

[3.2 HIGH PERFORMANCE LIQUID CHROMATOGRAPHY

Preparation of samples for HPLC identification test

For the HPLC analysis of analytes, 1 mL of noni fruit juice mixed with 1 mL of MeOH, vortex for 1 min, and prepared into a concentration of 0.5 mL/mL solution. All samples were filtered through a nylon microfilter (0.45 µm pore size) before HPLC analysis.

Chromatographic system and HPLC identification test

[Details to be provided]

HPLC identification test – acceptance criteria

[Details to be provided]

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- Canada would suggest that Section 3.2 HPLC be placed in square brackets [] for the time being since the method has not been defined yet.

Canada

ANNEX B - IDENTIFICATION OF DEACETYLASPERULOSIDIC ACID**1. PREPARATION OF SAMPLES**

Noni fruit 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. [SPE cartridges (specify type of cartridges in terms of solid phase) is first equilibrated with water (mls mLs), followed by methanol (mls mLs). The samples are then loaded onto the cartridge and washed with 5% MeOH (mls mLs) in water, followed by 100% MeOH (mls mLs). The MeOH eluate is retained for TLC analysis.]

- The type of cartridge should be specified.
- Suggest that “mls” be changed to “mLs” for consistent expression of milliliters throughout the method of analysis.
- Propose adding "in water" to clarify that this is a 5% solution of methanol in water.
- The volume of water and methanol should be specified.

2. PREPARATION OF REFERENCE STANDARD

2.1 A reference standard is prepared by dissolving 1 mg deacetylasperulosidic acid in 1 milliliter mL of methanol.

[3.2 HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC)

Preparation of samples for HPLC identification test

One gram of the fresh fruit juice diluted with 5 mL of H₂O-MeOH (1:1), and mixed thoroughly; the solution collected into a 5 mL volumetric flask, mixed thoroughly and then filtered through a 0.2 µm PTFE filter for HPLC analysis.

Chromatographic system and HPLC identification test

[Details to be provided]

HPLC identification test – acceptance criteria

[Details to be provided]

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Canada would suggest that Section 3.2 HPLC be placed in square brackets [] for the time being since the method has not been defined yet.

Canada