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Comments of United States of America

At the 14th Session (2016) the FAO/WHO Regional Coordinating Committee for North America and the South West Pacific (CCNASWP) 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. The Committee also agreed to inform the Codex Committee on Contaminants in Foods (CCCF) on the status of development of the standard and urged CCNASWP members to provide to the Joint FAO/WHO Expert Committee on Food Additives (JECFA) data on the safety/toxicity of scopoletin (toxicity, occurrence and consumption data).

JECFA Priority List:

CCCF has requested that CCNASWP confirm if we wish to retain scopoletin on the JECFA priority list, and if so, when suitable data would be forthcoming. In the absence of a JECFA evaluation, the United States suggests removing the footnote referencing the JECFA priority list evaluation and inserting a new footnote to address the potential toxicity of scopoletin:

Scopoletin may be present naturally in fermented noni 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.

The United States supports retaining scopoletin on the JECFA priority list and requesting the JECFA Secretariat to review available data on scopoletin to determine if there are sufficient data to conduct an evaluation and, if not, to identify what data would be needed for an evaluation.

Food Category/Additives Section:

The United States would also like clarification as to what food category from the General Standard for Food Additives (GSFA) will be indicated under the Food Additives section of this draft standard. The current draft of the standard states that the food category is "to be defined."

CX/NASWP 19/15/12 recommends that the Codex Committee on Food Additives (CCFA) be requested to "create" a food category for fermented noni fruit juice. The United States notes that the establishment of a new food category in the GSFA would require a proposal for new work and a project document submitted to the Codex Alimentarius Commission (CAC). However, the United States also notes that the creation of a new food category in the GSFA would not be appropriate, as there is already a food category in the GSFA that corresponds to products such as fermented noni juice.

According to our food additive experts, including the chair of the CCFA working group on the *General Standard for Food Additives* (GSFA), the appropriate food category for fermented noni juice in the GSFA Food Category System is food category 14.2.7 "Aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low-alcoholic refreshers)"¹ :

¹ 14.2.7 "Aromatized alcoholic beverages (e.g. beer, wine and spirituous cooler-type beverages, low-alcoholic refreshers)";

Includes all non-standardized alcoholic beverage products. Although most of these products contain less than 15% alcohol, some traditional non-standardized aromatized products may contain up to 24% alcohol.

Food category 14.2.7 currently permits many food additives with a variety of technological functions. Some of these technological functions may not be appropriate for fermented noni juice. Does the CCNASWP know which functional classes are needed for the manufacture of fermented noni juice (e.g., acidity regulators, antioxidants, preservatives, thickeners)? It may be best if the committee considered what functional classes of additives are needed before going forward. Then the standard could limit the use of food additives in fermented noni juice to those listed in food category 14.2.7 with the appropriate functional class.

In addition to Tables 1 and 2, the GSFA also has Table 3, which lists food additives of low toxicological concern with JECFA Acceptable Daily Intakes (ADIs) of “not specified,” because no numerical limit is needed for food safety. Table 3 additives are permitted for use in foods generally, unless a particular food category is in the annex to Table 3 (in which case a provision would need to be added directly for that food category in Tables 1 and 2) or a commodity standard prohibits their use. Food Category 14.2.7 is not listed in the Annex to Table 3, so Table 3 additives are allowed for use in foods that fall under Food Category 14.2.7 unless specifically excluded. We recommend that the standard for fermented noni juice also allow Table 3 additives of the appropriate functional class.

The United States proposes the following text, in accordance with Section II of the *Codex Procedural Manual* :

Option 1 – if CCNASWP determines that the use of food additives does not need to be limited to specific functional classes:

Food additives used in accordance with Tables 1 and 2 of the General Standard for Food Additives in food category 14.2.7 “Aromatized alcoholic beverages (e.g. beer, wine and spirituous cooler-type beverages, low-alcoholic refreshers)” or listed in Table 3 of the General Standard for Food Additives (CODEX STAN 192-1995) are acceptable for use in foods conforming to this Standard.

Or, if CCNASWP knows what functional classes are needed for the fermented noni juice (e.g., acidity regulators, antioxidants, preservatives, thickeners), a more focused sample text could be:

Option 2 – Reference to Table 3 by Functional Class:

[Functional Classes] used in accordance with Tables 1 and 2 of the General Standard for Food Additives in food category 14.2.7 “Aromatized alcoholic beverages (e.g. beer, wine and spirituous cooler-type beverages, low-alcoholic refreshers)” or listed in Table 3 of the General Standard for Food Additives (CODEX STAN 192-1995) are acceptable for use in foods conforming to this Standard.

Alcohol Content:

The current draft standard specifies an alcohol range of 0.01-0.99% v/v. The United States would like to limit the alcohol content to <0.5% by volume, as we stated in our most recent comments. Otherwise fermented noni juice would have to go through further scrutiny in the United States as it would be treated as an alcoholic beverage. Does the CCNASWP agree that fermented noni juice should be categorized as an alcoholic beverage?

Regardless of whether the product is limited to 0.99% or 0.5% alcohol content in the commodity standard, the food additive section of the commodity standard could still refer to FC 14.2.7 “Aromatized alcoholic beverages (e.g., beer, wine and spirituous cooler-type beverages, low-alcoholic refreshers)” in the GSFA – the descriptor includes the following example: “amazake (a sweet low-alcoholic beverages (<1% alcohol) made from rice” as an example of the types of products included in this food category, so there is precedent for having such a low-alcohol content product in this food category.

Examples include aromatized wine, cider and perry; aperitif wines; americano; batidas (drinks made from cachaça, fruit juice or coconut milk and, optionally, sweetened condensed milk)⁸⁹; bitter soda and bitter vino; clarea (also claré or clary; a mixture of honey, white wine and spices; it is closely related to hippocras, which is made with red wine); jurubeba alcoholic drinks (beverage alcohol product made from the *Solanum paniculatum* plant indigenous to the north of Brazil and other parts of South America); negus (sangria; a hot drink made with port wine, sugar, lemon and spice); sod, soft, and sodet; vermouth; zurra (in Southern Spain, a sangria made with peaches or nectarines; also the Spanish term for a spiced wine made of cold or warm wine, sugar, lemon, oranges or spices); amazake (a sweet low-alcoholic beverages (<1% alcohol) made from rice by koji); mirin (a sweet alcoholic beverage (<10% alcohol) made from a mixture of shochuu (a spirituous beverage), rice and koji); “malternatives,” and prepared cocktails (mixtures of liquors, liqueurs, wines, essences, fruit and plant extracts, etc. marketed as ready-to-drink products or mixes). Cooler-type beverages are composed of beer, malt beverage, wine or spirituous beverage, fruit juice(s), and soda water (if carbonated).

Conclusion

The United States does not believe we should develop a new food category or revise an existing food category in the GSFA for this product. We believe that FC 14.2.7 in the GSFA is the appropriate food category. CCNASWP should determine if the use of food additives should be limited to food additives of specific functional classes, and if so, which functional classes are appropriate for fermented noni juice. The food additive section should be amended accordingly to refer to additives listed in FC 14.2.7 and Table 3 of the GSFA.