In addition to its previous comments submitted at the 40th and 43rd Sessions of CCFA in Beijing and Xiamen, China, the National Health Federation (NHF) respectfully submits the following comments concerning Aspartame-Acesulfame Salt (INS 962) as a food additive for Fruit Nectars and Concentrates for Fruit Nectars:

1. **Aspartame Contains Methanol**

   Methanol (methyl alcohol, wood alcohol), a poisonous substance, is added as a component during the manufacture of aspartame. The methanol is subsequently released within hours of consumption after hydrolysis of the methyl group of the dipeptide by chymotrypsin in the small intestine.

   Absorption in primates is hastened considerably if the methanol is ingested as free methanol as it occurs in soft drinks after decomposition of aspartame during storage or in other foods after being heated. Regardless of whether the aspartame-derived methanol exists in food in its free form or still esterified to phenylalanine, 10% of the weight of aspartame intake of an individual will be absorbed by the blood stream as methanol within hours after consumption.

2. **Aspartame is Unstable in the Presence of Heat**

   On February 14, 2013, Dr. Maria Alemany (Professor of Nutrition at the University of Barcelona) commented on encapsulated Aspartame:

   "Aspartame stability during baking and subsequent product storage has not been sufficiently evaluated (Wetzel CR, Well LN, Food Chem 1998, 63:33-37), and, as proven in
other parts of this Study, it may indeed be altered in carbonated drinks by exposure to high temperatures. It seems the industry is perfectly aware of these problems and thus has actively investigated the issue, filing a number of patent granting petitions on methods for encapsulating aspartame. In fact, by February 2004, NutraSweet presented its NutraSweet custom encapsulated 20 product, containing 20-23% aspartame, and arsenic plus heavy metals (13 ppm), which was devised for caking goods and chewing gum. This encapsulated product is stable under extreme range pH and heat. The fact that this product was prepared and marketed means that there was a need for it. Obviously, aspartame as such could not well tolerate the conditions for which the encapsulated form has been prepared. Then, why it continues to be allowed to be used in chewing gum, confectionery and, especially baked goods without encapsulation? Nobody modifies a "good" product as presented by the aspartame producers if there is no need to do so.

"In sum, aspartame as free sweetener is not stable under conditions of pH outside the pre-established range (5-7) and neither under high temperature conditions. This must be acknowledged, investigated and taken into account as a threat to safety in materials subjected voluntarily or occasionally to temperatures in which aspartame is broken up. Incidentally, the presence of heavy metals, even in limited proportions, in a product marketed for industrial use of foods for human consumption is a new avenue of concern that should be explained, clarified and corrected." (emphasis added)

Even if one does not believe this indirect admission through industry’s actions, an industry member has directly confessed to the problem. Recently, Pepsi Cola added another sweetener to aspartame and amazingly admitted that, "Cans of Diet Pepsi around the country now list a mix of two artificial sweeteners, a pairing that is commonly found in newer diet sodas. Previously, Diet Pepsi used only aspartame, which is sensitive to heat and breaks down more easily." (emphasis added)

The currently circulated two provisions for the use of aspartame-acesulfame salt (INS 962) in food categories 14.1.3.1 (Fruit Nectars) and 14.1.3.3 (Concentrates for Fruit Nectar) envision extremely high levels of aspartame-acesulfame salt (350 mg/kg) for use in beverages that will typically be exposed to high temperatures during handling, transport, and storage. This exposure guarantees the release of toxic methanol into the human body. The Committee would be remiss in its avowed duties to protect the health of the public if it were to approve these two provisions.

3. Methanol is Toxic.

Methanol has no therapeutic properties and is considered only as a toxicant. The ingestion of two teaspoons is considered lethal in humans. Methyl alcohol produces the Methyl alcohol syndrome, consistently, only in humans and no other test animal, including monkeys. There is a clear difference between "toxicity," which can be produced in every living thing, and the "toxic syndrome."

The greater toxicity of methanol to man is rooted firmly in the limited biochemical pathways available to humans for detoxification. The loss of uricase (EC 1.7.3.3.), formyl-tetrahydrofolate synthetase (EC6.3.4.3.) and other enzymes during evolution sets man apart from all laboratory animals including monkeys. As a result, there is no generally accepted animal model for methanol toxicity. Humans suffer "toxic syndrome" at a minimum lethal dose of < 1 gm/kg, much less than that of monkeys, 3-6 g/kg. The minimum lethal dose of methanol in rats, rabbits, and dogs is 9.5, and 7 g/kg respectively; ethyl alcohol is more toxic than methanol to these test animals.

The United States Environmental Protection Agency in its Multimedia Environmental Goals for Environmental Assessment recommends a minimum acute toxicity concentration of
methanol in drinking water at 3.9 parts per million, with a recommended limit of consumption below 7.8 mg/day."

This report clearly indicates that methanol "is considered a cumulative poison due to the low rate of excretion once it is absorbed. In the body, methanol is oxidized to formaldehyde and formic acid; both of these metabolites are toxic."

In particular, the formaldehyde metabolite of methanol is an acknowledged deadly neurotoxin. Yet, a one-liter aspartame-sweetened beverage contains about 56 milligrams of methanol. Heavy users of aspartame-containing products consume as much as 250 mg of methanol daily, or 32 times the EPA safety limit.

Some have argued that the food additive is no different in having methanol than natural fruits. Yet, the methanol found in fruits and vegetables is bound to pectin, which takes it safely out of the body. So, there is no comparison in toxicity between the naturally sourced fruits and the synthetic sweetener aspartame.

4. **Recent Study Demonstrates Aspartame Toxicity**

A very recent study conducted in India, showed that aspartame water given to rats for just six months caused noticeable liver harm. The Abstract states that:

“The present study evaluates the effect of long term intake of aspartame, the artificial sweetener, on liver antioxidant system and hepatocellular injury in animal model. Eighteen adult male Wistar rats, weighing 150 - 175 g, were randomly divided into three groups as follows: first group was given aspartame dissolved in water in a dose of 500 mg/kg.b.wt; the second group was given a dose of 1000 mg/kg.b.wt; and controls were given water freely. Rats that had received aspartame (1000 mg/kg.b.wt) in the drinking water for 180 days showed a significant increase in activities of alanine aminotransferase (ALT), aspartate aminotransferase (AST), alkaline phosphatase (ALP) and y-glutamyl transferase (GGT). The concentration of reduced glutathione (GSH) and the activity of glutathione peroxidase (GPx), and glutathione reductase (GR) were significantly reduced in the liver of rats that had received aspartame (1000 mg/kg.b.wt). Glutathione was significantly decreased in both the experimental groups. Histopathological examination revealed leukocyte infiltration in aspartame-treated rats (1000 mg/kg.b.wt). **It can be concluded from these observations that long term consumption of aspartame leads to hepatocellular injury and alterations in liver antioxidant status mainly through glutathione dependent system.**” (emphasis added)

This recent study is just one more of many studies revealing the ill health effects of aspartame. While the manufacturers of aspartame would of course have us believe otherwise in an attempt to protect their commercial interests, even the U.S. Food and Drug Administration harshly criticized this artificial sweetener until a political maneuver induced a top-down command by a new administrator who over-rode the science and mandated its approval despite the lack of science-based consensus.

5. **For Safety Reasons, Codex Must Lower the ADI for Aspartame-Acesulfame Salt**

A serious consequence of the mistake of not being aware of the dangerous metabolism of the methanol in aspartame is that when scientists calculated its ADI (Advised Daily Intake) they did not include the toxic properties of the methanol in their estimations and it was calculated incorrectly by a factor of 35. The current ADI is 40mg/kg (JECFA/Codex at 0-40 mg/kg). **However, if one were to correctly take into account the ADI of methanol, then the ADI for aspartame should drop to 1.14mg/kg.**
In any event, the proposed level of 350 mg/kg for these two Fruit Nectar and Concentrate for Fruit Nectar provisions is so far in excess of any science-based safety limits for human health that the Delegation of Columbia’s and European Union’s written concerns must be heeded!

Moreover, to jump these two provisions from Step 3 to Step 8 is absolutely unconscionable in the face of the above-stated health concerns.

If Codex is about protecting the health of the consumer, then this body would be remiss in not revisiting its ADI numbers and setting them significantly lower so as to protect consumers from the toxic effects of methanol. The National Health Federation strongly urges this Committee not to advance aspartame-acesulfame salt along the path to approval as a food additive at all, and certainly not until all independent studies of its health effects have been taken into account.

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2 Searle Food Resources, Inc., *Sources and Metabolism of Aspartame and Representative Sweeteners* (1981).
7 Dr. Alemany had performed the famous Trocho Study, which proved that the formaldehyde converted from the free methyl alcohol embalms living tissue and damages DNA.


22 Abhilash M, Paul MV, Varghese MV, Nair RH, “Effect of long term intake of aspartame on antioxidant defense status in liver,” *Food Chem Toxicol*, 2011 Mar 2. [Epub ahead of print] (School of Biosciences, Mahatma Gandhi University, Kottayam, Kerala, India, 686560; harikumarannair@hotmail.com, harinair@fastmail.fm)