American Beverage Association Guidance Document to Mitigate the Potential for Benzene Formation in Beverages

Prepared in cooperation with the International Council of Beverages Associations

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1. Introduction

The American Beverage Association (ABA) is the national trade organization representing the broad spectrum of companies that manufacture and distribute non-alcoholic beverages in the United States. The members of ABA produce, distribute, and sell a variety of non-alcoholic beverages, including carbonated soft drinks and non-carbonated beverages such as juice-drinks, bottled waters, and ready-to-drink coffees and teas. ABA, in conjunction with the International Council of Beverages Associations, has produced this Guidance Document in order to mitigate the potential for benzene formation in non-alcoholic beverages.

2. Background

In 1990-1991, the soft drink industry learned that elevated benzene levels could be found in select beverages under certain conditions. Working with the US Food and Drug Administration (FDA), the industry found that when ascorbic acid (Vitamin C) was used as an ingredient along with sodium benzoate (a preservative), benzene formation could occur. This formation was exacerbated when the beverage was stored for extended periods at elevated temperatures.

Although the levels and frequency at which this benzene formation occurred were not considered to pose a public health risk, the industry immediately took proactive steps to reformulate affected products in order to minimize any formation potential, while still ensuring microbiological integrity.

For soft drinks, and other foods and beverages, regulatory authorities (*e.g.* Australia and New Zealand FSANZ, EU JRC, Canada, UK FSA and US FDA) use a comprehensive exposure monitoring and evaluation approach to risk assessment. The latest study, *Volatile Organic Compounds in Foods: A Five Year Study* was conducted by the FDA and published in the Journal of Agriculture and Food Chemistry in 2003. Benzene was found in *all* foods tested, including fruit and vegetables, apart from American cheese and vanilla ice cream. These levels ranged from 1-190 ppb (micrograms per kilo). FDA concluded that data collected during the study demonstrated that the American food supply is comparatively safe and that although there is some oral exposure to volatile organic compounds such as benzene, exposure is actually much higher through inhalation. In fact, according to an article which appeared in the February 27, 2006 Food Chemical News, an official from FDA's Center for Food Science and Applied Nutrition stated that all food products are responsible for only 5% of total exposure to benzene. Other studies which arrive at similar conclusions are: UK-MAFF Food Surveillance No 58 – Benzene and other Aromatic Hydrocarbons in Food-Average UK Dietary Intakes – March 1995; EU Joint Research Centre, HEXPOC, 2005 – Human Exposure Characterisation of chemical

substances; quantification of exposure routes; Canada: B.D. Page et al – Journal of AOAC Intl., 1992, 75, (2) 334-340.

Nevertheless, the industry has taken a responsible approach to minimize the presence of benzene in its beverages. Today, as the beverage industry continues to grow and expand, the American Beverage Association is renewing its commitment to provide guidance on minimizing benzene formation. This guidance will be made available to *all* beverage companies worldwide, regardless of their affiliation with the ABA.

3. Trigger and Mitigating Factors for Benzene Formation in Beverages

3.1 Trigger factors which may lead to the formation of benzene in beverages

* ***Primary Driver:*** **Benzene formation may occur at part per billion (micrograms per kilo) levels in some beverage formulations containing sodium benzoate or potassium benzoate along with ascorbic acid.([1]) Levels increase with heat and/or light, with heat being the predominant factor.**

***** Some studies suggest that erythorbic acid – where permitted - may lead to benzene formation in much the same way as ascorbic acid.

* Benzene formation may also occur when juices and other ingredients - which naturally, or otherwise - where permitted - contain benzoic acid sources and ascorbic acid - are used in beverage formulations.

3.2 Mitigating factors which may mitigate the formation of benzene in beverages containing benzoic acid sources and ascorbic acid

* Ingredients, such as nutritive sweeteners (sugar, high fructose corn or starch syrup) and calcium disodium ethylenediamenetetraacetic acid (EDTA) - where permitted - or sodium poly (or hexameta) phosphate, may mitigate benzene formation.

* Evidence indicates that nutritive sweeteners delay the reaction, as the phenomenon seems most noticeable in diet beverages, however the longer a product is in the market (shelf-life), the greater the potential for benzene formation if its precursors are present.

* Evidence also suggests that EDTA – where permitted – may mitigate the reaction, possibly by complexing metal ions that may act as catalysts. The degree of mitigation may be lessened in products containing calcium or other minerals – especially when used as fortificants - as they may interfere with the mitigating action.

[1] L.K. Gardner and G.D. Lawrence, J. Agric. Fd. Chem. 1993, 41 (5), 693-695

4. ABA key recommendations to beverage producers to minimize benzene formation

Taking into account trigger and mitigating factors for benzene formation in beverages as set out above (section 3), ABA recommends the following:

- ✓ ***RECOMMENDATION 1: REVIEW***
  All beverage companies **review their existing products and new formulations** considering the above information relative to procedures for the minimization of benzene formation.

- ✓ ***RECOMMENDATION 2: TEST***
  All beverage companies **perform analytical sampling of appropriate products** for benzene through accelerated storage tests *(for more detailed guidance on testing, please see section 5 below).*

- ✓ ***RECOMMENDATION 3: REFORMULATE***
  Beverage companies **reformulate any affected products** in which benzene may be present to reduce benzene formation to the fullest extent possible.

- ✓ ***RECOMMENDATION 4: MONITOR POST-LAUNCH***
  As part of beverage companies' field evaluation and market sampling process or other appropriate procedure, companies should confirm that new formulations or reformulations are effective in minimizing benzene formation.

5. Guidance: Testing for the presence of benzene in beverages

5.1 Accelerated tests

Accelerated tests should be conducted for product formulations containing benzoic acid sources - including added benzoate - and ascorbic acid. Specific test conditions may vary from producer to producer but should encompass conditions of time and temperature that would cover the normal distribution conditions that the product will experience. As a starting point, producers may want to consider subjecting the product formulations to temperatures of a minimum of 40-60 degrees C for 24 hours, or longer depending on the formulation, *e.g*. some product formulations require 14 days of accelerated test exposure to evaluate the reaction potential.

5.2 Analytical procedures

Reliable analytical procedures for benzene should be validated through appropriate performance trials or accredited external laboratories, capable of determining at least 5 ppb (micrograms/kg) of benzene in beverages.

6. Guidance: Formulation Control Strategies

As previously noted, the main factors in benzene formation in beverages are generally a combination of benzoic acid sources and ascorbic acid, heat and time. However, other control points (CP) that beverage developers may wish to consider when formulating a product also include:

- Product Water
  → must meet local regulatory requirements, including benzene levels, for potable water. *In addition, see section below on 'Transition Metals'.*
  CP – check benzene in water

- Sugars (Nutritive sweeteners)
  → appears to slow benzene formation, but does not totally inhibit it.

- Fruit Juices
  → can be delivered 'preserved' with benzoate - where permitted - and/or other natural benzoic acid sources
  CP – review specifications with supplier to control or eliminate benzoate

  → may be a source of ascorbic acid (added or natural)
  CP – analyze for ascorbate or obtain levels from supplier

- Intense Sweeteners
  → Diet / Light products have greatest potential for benzene formation if precursors are present.

- Carbon Dioxide
  → ensure compliance with local regulatory requirements or International Society of Beverage Technologists (ISBT) guideline of 20 ppb (v/v) maximum of benzene
  CP – supplier specifications and analyses with checks

- Acids
  → At low pH, ascorbic acid and/or erythorbic acid, in combination with benzoic acid sources, leads to a higher potential of the formation of benzene

- Flavors/Clouding Agents
  → Flavors, emulsions and cloudifiers may contain preservatives and antioxidants
  CP – review specifications with supplier to control or eliminate benzoate

  → Benzaldehyde and ascorbic acid can also form benzene
  CP - check if benzaldehyde present

- Colors
  → may contain ascorbate as an antioxidant to prevent fading
  CP – check with suppliers and re-specify if necessary

- Preservatives
  All manufacture of beverages should take place under strict hygienic conditions, following HACCP principles

  → Consider the use of blends of sorbate and benzoate, if there is a technological need (microbiological stability or sorbate solubility).
  CP - Consider if benzoate can be removed/reduced/replaced by sorbate or other preservation systems. Note that sorbate may precipitate out in dilutable and post-mix syrups (fountains)

- Antioxidants
  → consider the use of ascorbate in relation to overall formula, especially if citrus juices or other natural carriers of ascorbate are present.
  CP – Remove/reduce/replace ascorbate as appropriate if a benzoic acid source is present

- Light
  → UV light may induce free radical formation in products
  CP – Review storage and shelf-life conditions, and labeling instructions

- Temperature
  → accelerates the formation if precursors are present
  CP – Review storage and shelf-life conditions, and labeling instructions

- Transition Metals
  → trace levels of metal ions, such as copper and iron, may act as catalysts in benzene formation in beverages in the presence of benzoic acid sources and ascorbic acid. Sources of transition metals may include product water, sweeteners or other ingredients.
  CP- Chelating compounds such as EDTA (where permitted) or sodium polyphosphates may help mitigate formation. Fortification by calcium, or other minerals, may lessen this effect.