

Executive Summary
Benzene and Soft Drinks

SEPTEMBER 2006

EXECUTIVE SUMMARY OF BENZENE IN SOFT DRINKS

Background

Benzene, an aromatic hydrocarbon, is found in the environment from natural and man-made sources. In November 2005, there were reports received by the Food and Drug Administration in US, that benzene had been detected at low levels in some soft drinks containing benzoate salts (an antimicrobial agent) and ascorbic acid (Vitamin C), particularly under certain conditions of storage, shelf life and handling. This executive summary presents the key observations, findings and approach adapted by the leading regulatory agencies namely US - Food and Drug Administration, UK - Food Standards Agency, Health Canada, Food Standards - Australia-New Zealand. The paper also highlights extracts from Guidance Documents prepared by the International Council of Beverage Association and the American Beverage Association; presentation made by the Union of European Beverage Associations to the EU Standing committee on the Food Chain and Animal Health.

Facts

- Benzene is naturally occurring but is also manufactured for use in the industrial sector. We are exposed to benzene mainly through inhalation (e.g. vehicle exhaust and cigarette smoke) and to a much lesser extent through ingestion of food and water.
- A potential benzene reaction can be promoted by elevated temperatures, time, and by UV light. The industry's investigations suggested that certain formula characteristics could help to mitigate the potential for the benzene reaction.
- 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 in 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. <http://www.mindfully.org/Food/2003/VOCs-In-Foods1dec03.htm>
- Worldwide, there are no regulatory limits for benzene that apply directly to finished soft drinks. There are several regulatory guidelines and limits set for drinking water and bottled water ranging from the World Health Organization level of 10 parts per billion (ppb) to the U.S. EPA/FDA level of 5 ppb and the E.U. level of 1 ppb.
- Authorities have refrained from setting limits for trace levels of benzene because of the complexity of ingredients in the wide variety of beverages and foods on the market. The objective of the industry is to eliminate or reduce benzene to the fullest extent possible.

Key Findings and Observation of Regulatory Agencies

- US Food & Drug Administration - has issued statement and data from survey conducted is as follows
 - "FDA is committed to ensuring the safety of food and beverages consumed by Americans and providing timely and factual information when safety questions are raised. We are issuing this statement today to better describe the steps FDA is taking in response to reports that benzene has been found in some soft drinks". <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01355.html>

- FDA's Center for Food Safety and Applied Nutrition (CFSAN) initiated a survey of benzene levels in soft drinks following receipt of the November 2005 reports. This survey indicates that the vast majority of beverages sampled (including those containing both benzoate salts and ascorbic acid) contain either no detectable benzene levels or are well below the 5 parts per billion (ppb) U.S. water standard. <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01355.html>
- Ongoing investigations into the analytical method used by the agency under FDA suggested that elevated benzene levels can be formed by the procedures used to analyze beverage samples. Hence FDA advised that analyses should be done using the method specific to benzene determination in beverages as in the CFSAN survey. <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01355.html>

For More Information on US FDA

<http://www.cfsan.fda.gov/~dms/benzltr.html>
<http://www.cfsan.fda.gov/~dms/benzdata.html>

• **UK Food Standards Agency -**

- The Food Standards Agency had published (on March 31st, 2006) the results of a survey to investigate levels of benzene in 150 soft drinks on sale in the UK. Benzene was not detectable in the majority of products sampled.
- The UK limit for benzene in drinking water is 1 ppb. There is no legal limit for benzene in soft drinks. However, the Agency has drawn on the WHO guidelines for safe levels in drinking water (10 ppb) as an appropriate comparison on which to ask industry to remove products from sale.
- As per the agency the levels of benzene reported in this survey will only make a negligible impact on people's overall exposure to benzene and so any additional risk to health is, therefore, likely to be minimal. In more than two thirds (107 out of 150) of the samples tested the levels of benzene were undetectable.
- A total of 38 samples had levels of benzene between 1 and 10 ppb (parts per billion) - below the guideline level set by the WHO for water of 10 ppb.

For More Information on UK Food Standards Agency

<http://www.food.gov.uk/news/newsarchive/2006/mar/benzenesurvey>

• **Health Canada**

- Health Canada has investigated soft drinks and other beverages for the presence of benzene, following reports in the United States that trace levels of benzene had been found in soft drinks and other beverages.
- Health Canada has concluded that soft drinks and other beverages available for sale in Canada are safe, based on these findings and on the actions taken by the producers to reformulate products where necessary.
- In more than 80% of the products, benzene was either not detected or was present at such low levels in the samples that it could not be reliably measured.
- Health Canada's Food Directorate has worked with its international regulatory counterparts, including the US Food and Drug Administration (US FDA), the United Kingdom Food Standards Agency (UK FSA) and in particular Food Standards Australia New Zealand (FSANZ) to exchange information about survey results of benzene in soft drinks and beverages conducted in other countries, exposure assessment and measures taken to ensure the continued safety of the Canadian food supply

For More Information on Health Canada

http://hc-sc.gc.ca/fn-an/securit/chem-chim/benzene/index_e.html

http://hc-sc.gc.ca/fn-an/surveill/other-autre/benzene_survey_enquete_e.html

- **Food Standards - Australia New Zealand**

- FSANZ sampled 68 flavoured beverages in March/April 2006. These were purchased from typical retail outlets and analysed for benzene by a suitably qualified independent laboratory.
- Of the 68 samples tested, 38 beverage products contained trace levels of benzene. The levels detected ranged from 1 to 40 ppb. More than 90% of all beverages surveyed had levels of benzene below the WHO guidelines for drinking water (10 ppb).
- The FSANZ survey results do not raise any public health concerns in relation to benzene levels in flavoured non-alcoholic beverages available in Australia, as the trace amounts found make a very small impact on overall benzene exposure. Nonetheless, FSANZ has liaised with other government departments and the food industry to ensure that levels of benzene in beverages are kept as low as can be achieved, while still ensuring the microbiological safety of these products

For More Information on Food Standards - Australia New-Zealand

<http://www.foodstandards.gov.au/newsroom/factsheets/factsheets2006/benzeneinflavouredbe3247.cfm>

Trigger and Mitigating Factors for Benzene Formation in Beverages

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. 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.

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 ethylenediaminetetraacetic acid (EDTA) - where permitted - or sodium poly (or hexameta) phosphate (SHMP), 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.