CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5a **CRD13**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD ADDITIVES

Forty-Ninth Session

Macao SAR, China, 20-24 March 2017

GENERAL STANDARD FOR FOOD ADDITIVES (GSFA): CCFA48 OUTSTANDING PROVISIONS; PROVISIONS FOR BENZOATES IN FC 14.1.4; PROVISIONS IN FC 5.0 AND 5.1; PROVISIONS ASSOCIATED WITH NOTE 22; PROVISIONS IN FC 01.1, 01.1.1, 01.1.3 AND 01.1.4 (REPORT OF THE EWG ON THE GSFA)

Comments of El Salvador and ICBA

El Salvador

El Salvador apoya la propuesta de Francia en la Categoría de alimentos N.o 01.2 (Productos lácteos fermentados y cuajados (naturales/simples), excluida la categoría de alimentos 01.1.2 (Bebidas lácteas)

Enfoque horizontal (FA/45 CRD2 Apéndice FA/46 CRD 2 Apéndice V): Los reguladores de la acidez/EEE no están justificados horizontalmente Normas sobre productos correspondientes: Ninguna, 243-2003 corresponde a las subcategorías 01.2.1.1 y 01.2.1.2.

El Salvador apoya la propuesta de Estados Unidos en la Categoría de alimentos N.o 01.2.1 (Leches fermentadas (naturales/simples)) Enfoque horizontal (FA/45 CRD2 Apéndice FA/46 CRD 2 Apéndice V): Los reguladores de la acidez/EEE no están justificados horizontalmente. Normas sobre productos correspondientes: Ninguna, 243-2003 corresponde a las subcategorías 01.2.1.1 y 01.2.1.2

En la Categoría de alimentos N.o. 01.2.1.2 (Leches fermentadas (naturales/simples) tratadas térmicamente después de la fermentación). El Salvador no acepta esta categoría en el caso del yogurt.

International Council of Beverages Associations

International Council of Beverages Associations (ICBA)[1] provides the following additional supplemental comments on benzoates, building on ICBA submitted comments reflected in CRD7.

I. Technological Justification

Water-based flavored drinks generally have a pH range between 2.5 and 4.6, conducive for benzoate preservative action in an environment with ubiquitous microflora. Benzoates maintain the quality, stability and integrity of beverages. In the four markets ICBA evaluated, the beverage types using benzoates may include:

- LNCS beverages - >95% of market;
- Energy drinks – around 65% of market;
- Regular CSD (RegCSD) – 18 to 50%, but mostly one third of marketplace;

Ready-to-drink (RTD) teas – around 45% of market;

- Fruit juice-containing drinks;
- Flavored water drinks;

[1] The International Council of Beverages Associations (ICBA) represents the interests of the worldwide non-alcoholic beverage industry. ICBA members include national and regional beverage associations and international beverage companies that operate in more than 200 countries and territories and produce, distribute and sell a variety of non-alcoholic sparkling (carbonated) and still (non-carbonated) beverages including soft drinks, sports drinks, energy drinks, bottled waters, flavored and/or enhanced waters, ready-to-drink teas and coffees, 100% fruit or vegetable juices, nectars and juice drinks, and dairy-based beverages.

- Sports drinks.

IA. Benzoate levels lower than 250ppm are not warranted.

- As noted by Poland's Lodz University of Technology, Institute of Fermentation Technology and Microbiology Dorota Kregiel's 2014 Review Article 'Health Safety of Soft Drinks: Contents, Containers, and Microorganisms',[2] certain fermentative yeast species (e.g., *Zygosaccharomyces bailii*) can grow in the presence of both glucose **and** preservatives **far in excess of legal limits in the EU**. EU's maximum levels for beverages are below the Minimal Inhibitory Concentrations (MIC) required to preclude adaptive behavior and subsequent acquired tolerance. (see Appendix I of CRD7)
- In Kregiel's review, "[N]ew AAB (acetic acid bacteria) of *Asaia spp.* have been isolated from reclaimed fruit beverages and flavored water beverages preserved by DMDC (dimethyl dicarbonate), benzoate, or sorbate at concentrations 1.5 mM and (equivalent to at least 200 ppm DMDC, 216 ppm sodium benzoate/~ 185 ppm as benzoic acid, or 225 ppm potassium sorbates/~170 ppm as sorbic acid, respectively), limiting the possibilities of preventing spoilage in similar drinks."[2] In the EU, permissions for DMDC, benzoates and sorbates are 250 ppm, 150 ppm (as benzoic acid) and 300 ppm (as sorbic acid), respectively. Thus, 200 ppm as benzoic acid are inadequate to guarantee the necessary preservation to these types of beverages.
- In some instances, some RegCSDs brands typically containing fruit juice-content in markets worldwide had to remove the fruit juice-component to comply with EU's regulatory framework.
- Cream sodas and root beers possessing higher pH (> 3.5) and therefore requiring higher levels of benzoates to ensure adequate amounts of undissociated benzoic acid are present for preservative action are not as popular in the EU compared to other markets such as North America. (Please see Appendix I of CRD7 for more on pH and undissociated acid.)
- Forcing levels down to 150 ppm in other markets could mean discontinuation of those products that do not otherwise meet the microbiological requirements companies must adhere to (e.g., products containing natural colors) and for which product integrity and quality have been compromised. In the fountain dispensing system, cold plate technology (versus recirculation technology in the EU) cannot accommodate the less soluble alternative preservatives. Levels at no more than 150 ppm will have a detrimental impact to ICBA members' global product portfolios.

For benzoate-containing products, there is no across the board drop-in substitute. For example, spoilage yeast *Saccharomyces cerevisiae* can degrade sorbic acid into 1,3-dipentadiene, a volatile hydrocarbon.[2,3,4] (This is an example of adaptive behavior.) Additionally, sorbates can impact taste and due to lower solubility can result in precipitates in some formulations.

IB. Need for higher levels in concentrates.

- Post-mix – bag in a box – concentrates are not typically kept under refrigeration nor are they consumed in a single day. Higher levels of benzoates are required to guarantee adequate operation and microbiological stability of concentrates used in fountain systems. (Note: The fountain carbonated soft drink (CSD) category consists of Regular CSD, Low-/No- Calorie Sweetened (LNCS) CSD and frozen slushies that require dilution, expansion and freezing.)
- Sorbates' lower solubility presents operational impediments in fountain systems - lines clog.

IC. Disproportionate impact to smaller beverage companies.

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[2] Kregiel, D. 2015. *Review Article: Health Safety of Soft Drinks: Contents, Containers, and Microorganisms*. BioMed Research International 2015:1-15. (Referenced Stratford, M., A. Plumridge, D.B. Archer. 2007. *Decarboxylation of sorbic acid by spoilage yeasts is associated with the PAD1 gene.* Applied and Environmental Microbiology. 73(20): 6534-6542.)

[3] Mann, D.A. and L.R. Beuchat. 2007. *Combinations of antimycotics to inhibit the growth of molds capable of producing 1,3-pentadiene.* Food Microbiology 25 (2008) 144–153. (Referenced Schroeder, L.L., Bullerman, L.B., 1985. *Potential for development of tolerance by Penicillium digitatum and Penicillium italicum after repeated exposure to potassium sorbate*. Appl. Environ. Microbiol. 50, 919–923.)

[4] Kinderlerer, J.L. and P.V. Hatton. 1990. *Fungal metabolites of sorbic acid.* Food Additives and Contaminants. 7(5): 657-669.

- Per Section 3.2 of the Preamble to the GSFA,[5] means that are not **economically** and technologically practicable provide sufficient grounds not to restrict food additive uses. Tunnel pasteurization, for example, while technologically feasible is neither practical nor economical for widespread use.
- For smaller bottlers, forcing levels down to 150 ppm could impact their viability and their ability to stay in business.

Relative to toxicological considerations, according to WHO's International Programme on Chemical Safety's (IPCS) Concise International Chemical Assessment Document 26 (CICAD 26, p.26 under Section 9. Effects on Humans), sodium benzoates are used in the treatment of patients with inborn errors of urea cycle synthesis (i.e., hyperammonemia). Therapeutic doses given over several years ranges from 250 to 500 mg/kg bw/d (even in neonates). At this dose level, clinical signs of toxicity are rare. The absence of adverse effects in humans, especially among neonates, at levels as high as 500 mg/kg bw/d would suggest dietary exposures at 100 times less – i.e., 5 mg/kg bw/d or less – should not raise any safety concerns. More detailed information was provided in ICBA's comments in CRD7 Appendix IV.

Recently, Colorado State University (CSU) researchers' physiologically-based pharmacokinetic (PBPK) modeling approach (an ABA-commissioned study) further supports Gradient's previously reported findings of the absence of interspecies pharmacokinetic differences and demonstrates how the PK interspecies uncertainty factor can be reduced from 4 to 1 or less, explained by the increased bioavailability of benzoic acid in rodents compared to humans. CSU concludes that the ADI could be increased by 4-fold to 20 mg/kg bw/d. (*manuscript submitted)*

ICBA thanks Codex members for taking these comments into consideration.

[5] The use of food additives is justified only when such use has an advantage, does not present an appreciable health risk to consumers, does not mislead the consumer, and serves one or more of the technological functions set out by Codex and the needs set out from (a) through (d) below, and only where these objectives cannot be achieved by other means that are economically and technologically practicable.