June 20, 2007

Dr. Michael D. Shelby
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Research Triangle Park, NC 27709

Via e-mail to: Shelby@niehs.nih.gov

Re: Information and comments in regard to the CERHR expert panel evaluation of bisphenol A

Dear Dr. Shelby:

I am pleased to provide these comments on behalf of the Inter-Industry Group (IIG) in regard to the interim draft report from the CERHR expert panel evaluation of bisphenol A. The IIG represents all the stakeholders for the North American light metal packaging industry, including raw material (i.e., resin and metal) producers, resin formulators, metal packaging manufacturers and converters, food processors and beverage manufacturers, and other allied associations. The mission of the IIG is to foster the use of sound science to address health and environmental issues affecting light metal packaging in North America.

We support the scientific review of studies relevant to whether bisphenol A has the potential to cause health or environmental effects. Our comments are provided to assist the expert panel in conducting a scientifically sound evaluation of the potential exposure of bisphenol A from epoxy coatings used in canned foods. Epoxy can coatings are an essential technology that provides consumers with safe food and beverage packaging, and its use is supported by scientific evidence and evaluations by government agencies worldwide.

Our comments are divided into five sections:

I. The Safety of Canned Foods
II. Why Epoxy is the Essential Technology for Modern Can Coatings
III. The Potential Exposure of Bisphenol A from Canned Foods
IV. Analytical Methodology for the Determination of Bisphenol A in Complex Matrices
V. The Risk of Bisphenol A Exposure Put into Perspective

Please do not hesitate to contact me if I can be of further assistance to clarify any of the information provided or if additional information is needed. I can be reached at (708) 361-0471 or by e-mail at whoyle@comcast.net.

Regards,

William Hoyle

Dr. William Hoyle
Inter-Industry Group Chairman

Attachment

ATTACHMENT

I. The Safety of Canned Foods

History of Cans

Canning is the single most significant innovation in the preservation of food in human history. The metal food can, now more than 200 years old, remains one of the most economical, environmentally friendly and above all, safest modes of food distribution and packaging. The metal food can enables food sterilization and long term preservation; in addition, it is durable, recyclable and tamper-resistant / tamper-evident.

In the early 19th century, the development of the unbreakable hermetically sealed tin can made nutritious high quality food available everywhere and changed the way the world would produce, preserve and consume food. Beginning with keeping Napoleon's army fed and helping the British Navy eliminate scurvy, microbiologically sterile and nutritionally rich canned food significantly improved human health and life expectancy.

Benefits of Cans

Canned fruits and vegetables are cleaned, packed and thermally processed within hours of being harvested, at their peak of flavor, freshness and nutritional content. Canned food is high in vitamins, minerals and protein -- in some cases higher than their fresh counterparts as available at your local grocer.

Prepared foods, such as soups and stews, are canned at the facilities in which they are prepared to ensure freshness. More than 1500 food items are packed in cans, making out-of-season produce globally accessible year-round. Canned food also makes nutritious "at home" meal preparation simpler, more convenient and less time-consuming.

Environmentally conscious consumers recycle over 100,000 aluminum cans every minute of every day. Metal food and beverage cans are 100 percent recyclable and are by far the most recycled food container. The commodity value of steel and aluminum exceeds the cost of collection and processing. The high value of the metals subsidizes the collection of other materials, which are included in the curb-side recycling programs of many communities, thereby making these programs more viable and less costly to taxpayers.

Over 200 years of technical evolution has not changed the general appearance of the metal can significantly, but cans that are produced today are dramatically different from those made only a few decades ago. The use of internal coatings began in the early 1900's, initially employed to preserve the color of canned red fruit. It was soon determined that the use of an internal coating allowed for a much wider variety of foods to be canned. In the mid 1930's, the use of internal coatings led to the development of beverage containers that did not impart a metallic taste to the product. In short, internal coatings protect the can from the food and the food from the can.

Automation of can production after World War II played a pivotal role in making commercial canned food and beverages more affordable, safer, readily available and accessible to everyone. Since then, the development of improved protective coatings has made many technical advances possible, including:

- Improved safety as compared to soldered cans through the use of the welded 3-piece can and formed 2-piece can;
- Increasingly thinner metal cans that maintain the physical strength of thicker cans, and
- Increased consumer satisfaction through the use of easy-open convenience ends.

These manufacturing and engineering innovations have improved the performance and safety of metal food and beverage packaging while retaining cost-effectiveness for the consumer. No alternative technology for food and beverage packaging comes close to the unrivaled performance of coated metal across such a wide span of applications.

II. Why Epoxy is the Essential Technology for Modern Can Coatings

The performance of today's metal food and beverage can is based on, and to a large extent determined by, the use of protective organic coatings. All major can manufacturers and coating suppliers are continually evaluating and developing new coating chemistries for commercial use. Of the thousands of commercial can specifications available, each one has been developed to deliver optimal performance for the intended application and specific food product being packed.

Why do over ninety percent of food and beverage cans utilize epoxy-containing coatings? The answer is simple; in these applications, no other technology performs as well as epoxy-based coatings. The combination of toughness, adhesion, formability, resistance to the wide range of chemistries found in food and beverage products ("product resistance") and the ability to be used in the high temperature food processing conditions required for sterilization is unsurpassed.

Epoxy resins based on bisphenol A (BPA) have been used as components of protective food contact coatings for more than 60 years. They have been, and continue to be, recognized as safe when used as intended by the U.S. Food and Drug Administration (FDA), the European Food Safety Authority (EFSA), the UK Food Standards Agency, the Japanese Ministry of Health, Labor and Welfare, and other regulatory agencies around the world. Epoxy resin-based coatings also typically have lower total migration levels than other coating technologies.

Epoxy resins provide superior adhesion and product resistance advantages over older technologies such as oleoresins. Alternative technologies, such as vinyl- and polyester-based resins, are commonly modified with epoxy or are used in combination with an epoxy basecoat to achieve acceptable adhesion and product resistance performance in applications where the greater physical flexibility they provide is required.

Product resistance is a critical performance criterion with respect to withstanding the wide range of chemical conditions associated with food and beverages, including corrosion, dissolved metal concentrations, and providing consumer safety by protecting against bacterial contamination. Product resistance translates into extended shelf stability at room temperatures. Although canned foods have a two-year shelf life ("best by" date), canned food really does not "expire" and has essentially an indefinite shelf life. As long as the container is intact and has maintained its hermetic seal, its contents remain edible.

The durability and extended shelf life of canned products at room temperature play a vital role in making healthy canned food, beverages and water available during natural disasters, power blackouts, and similar events.

In summary, the technology used to can food and beverages delivers unparalleled safety, nutrition and performance.

III. The Potential Exposure of Bisphenol A from Canned Foods

Food and beverage cans use internal coatings to prevent interaction between the food and the metal packaging. Epoxy can coatings have been used safely to protect the world's food supply for more than 60 years. The use of these coatings in food contact applications have been thoroughly evaluated by the FDA, EFSA, the Japanese Ministry of Economy, Trade and Industry, and other food safety authorities around the world.[1] Each of these authorities has confirmed the safety of epoxy can coatings and approved them for consumer use.

The use of epoxy as an ingredient in internal can coatings has evolved significantly over the past 60 years. Today's epoxy can coatings are high molecular weight, heat cured epoxy formulations. Because of its superior chemical resistance, low taste and odor threshold, low migration and other positive attributes, epoxies have won widespread use as the can coatings of choice. Many of the epoxy can coatings are unique for the intended product and enable that food to be packed as a shelf stable product in the metal can. Another positive attribute of epoxy can coatings is that once they are reacted and cured, they do not hydrolyze back to their starting components even under conditions far more extreme than any expected conditions of use. Thus the very small residual concentrations of BPA that may exist in the can coating will not increase with time after thermal processing or damage to the polymer, i.e. denting. Furthermore, extraction with food simulating solvents generally significantly exaggerates the actual concentrations found in foods.

The analytical methodology used to determine the concentration of BPA in the food is very important and is addressed in section IV. The analytical methodology utilized must be proven for each and every food analyzed to assure that interferences do not overstate the BPA results.

Over the past 10 years, there have been numerous studies of BPA in various food products using a variety of analytical methodologies. The vast majority of these surveys report BPA concentrations that were below 0.1 mg/kg (0.1 ppm) with a small number of samples ranging up to 0.8 ppm. Recently, the Environmental Working Group (EWG) released the results of their survey[2] of various commercial canned foods. This survey, sponsored by the EWG, tested a total of 97 cans of food that were divided into 10 categories of food. The BPA data provided by the EWG was in general similar to other market basket surveys. The EWG reported BPA concentrations that were predominately below the 0.1 ppm level. There were a small number of samples in the EWG report where the BPA concentration was above the 0.1 ppm level; the highest value reported was 0.385 ppm.

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[1] Detailed information is available at: http://www.bisphenol-a.org.

[2] Available at: http://www.ewg.org/reports/bisphenola.

The EWG survey found an average of 0.0079 ppm (7.9 µg/kg) BPA in the foods and beverages that were analyzed from cans sampled from retail grocers. The EWG concluded that this level of BPA is unsafe and called upon the U.S. Environmental Protection Agency (EPA) and FDA to act quickly to revise safe levels for BPA exposure based on the science on the low-dose toxicity of the chemical. However, contrary to the views expressed by EWG, a low-dose effect has never been observed in peer reviewed comprehensive multigenerational studies in rodents.[3] In fact, the level of BPA reported by EWG in 97 cans of food they analyzed is significantly lower than the tolerable daily intake (TDI) set by the FDA and the TDI recommended by EFSA. The average of 0.0079 ppm BPA is more than 750 times lower than the EFSA-recommended TDI. The highest concentration reported, 0.385 ppm, provides more than a 15-fold margin of safety based on EFSA's newly-established TDI.

IV. Analytical Methodology for the Determination of Bisphenol A in Complex Matrices

The analytical methodology utilized to determine the concentration of BPA in complex matrices is important and can significantly influence the result. The analytical methodology utilized is important because of the variety of samples being analyzed and the very low levels of BPA. In general, unless the methodology is adapted for the specific matrix, the final result may appear to be higher than actual because of interferences. Gas chromatography (GC) and high performance liquid chromatography (HPLC), with a variety of detection methodology, are the most widely used techniques.

- GC/MS – GC used with mass spectrometry (MS) is a good measure of BPA and can measure at very low detection limits; the drawback is that it is not very good for direct food analysis. Capillary column technology does not work well with food extraction of oily products.

- HPLC – HPLC technology is excellent for looking at direct food extracts.
  - UV – ultraviolet detection is not very sensitive and will have many interferences
  - FLD – fluorescence detection eliminates many interferences (not all)
  - MS – best technology for looking into BPA at low levels in a simple matrix
  - MS/MS – tandem MS is the best way to analyze BPA at low levels in complex matrices

The best analytical methodology to determine BPA at low levels in complex matrices is HPLC/MS/MS. This methodology is not subject to the interferences found in the complex food, blood and tissue sample. Unfortunately, the HPLC/MS/MS equipment is not frequently utilized because of the high cost of the equipment (in the range of $300,000+) and operation.

V. The Risk of Bisphenol A Exposure Put into Perspective

In conclusion, potential exposure to BPA from epoxy can coatings is well below the levels established as safe by competent food safety authorities such as the U.S. Food and Drug Administration, European Food Safety Authority, and the Japanese Ministry of Health, Labor and Welfare. These authorities have thoroughly evaluated and confirmed the safety of epoxy can

[3] http://www.bisphenol-a.org/human/herLowDose.html

coatings and approved them for food contact applications which are an essential technology in their use to protect the world's food supply.