2008 Summer Symposium Review

by Greg Brorby

The GETA "Late Spring/Early Summer" symposium was held at the Elihu M. Harris Building in Oakland on June 19, 2008. The topic of the symposium was "Chemicals… chemicals… everywhere! Evaluating the potential exposure to chemicals in consumer products." Representatives from government, private industry and the legal community provided different perspectives on the topic, ranging from toxicology and exposure considerations, to enforcement, to challenges associated with using science in a legal context. Each of the presentations is summarized below.

Dr. Ling-Hong Li, a Staff Toxicologist with California EPA's Office of Human Health Hazard Assessment (OEHHA), was the first speaker of the symposium. The title of his presentation was "Reproductive Toxicity Of Phthalates: From *Rodents To Men*." Dr. Li began with a brief overview of the developmental and reproductive toxicity of phthalates in laboratory animals; however, the focus of his presentation was on the observed testicular toxicity of diethylhexyl phthalate (DEHP) in rats and its relevance to humans given the absence of such toxicity in marmosets, a new world monkey. In his opinion, the rodent data are relevant to humans for several reasons. First, the metabolism of DEHP in humans is similar to that in rats. Second, there are several postulated modes of action in rats for which humans have the capacity. Third, testicular toxicity has been observed in other primates (cynomolgus monkeys; an old world primate). As to why testicular toxicity is not observed in marmosets, Dr. Li explained that the hormonal regulation of spermatogenesis in the marmoset is remarkably different than in the rodent, macaque, and man.

Mr. Greg Brorby, a Senior Managing Scientist with Exponent, was the second speaker. The title of his presentation was "Considerations For Estimating Exposure To Chemicals In Consumer Products." Prompted in part by the numerous product recalls in late 2007 and early 2008, Mr. Brorby focused his presentation on lead, with particular attention on exposure via hand-to-mouth contact. He began with an overview of occupational and consumer lead standards, lead product standards, and different types of sample analyses (total lead, soluble lead, wipe testing). Mr. Brorby spent the remainder of his presentation on case studies involving product content samples, product wipes, fingertip wipes, and behavior studies. Based on actual product testing, Mr. Brorby showed that there is no clear relationship between product lead content and product wipes and that product wipes remove more material than fingers/hands; therefore, hand/finger wipe data obtained after product handling best represents the amount of lead that is available for hand-to-mouth contact. He further showed that data from consecutive hand/finger wipes indicates that not all of the lead is removed on the initial wipe (i.e., hand-to-mouth transfer does not equal 100%). Finally, based on behavior studies, Mr. Brorby showed that duration of contact does not necessarily increase fingertip loading, and the touching of other objects may, but not always, decrease fingertip loading. In combination, these data suggest that reliance on default transfer factors does not adequately account for

differences in product handling or product surfaces and that it is best to design a study that simulates handling and use of the particular product(s) of interest.

Ms. Deblyn Palella, an Instrumentation Specialist with Geotechnical Services, was the third speaker. The title of her presentation was "Thermo Scientific NITON Analyzers: Solving Problems with XRF." Ms. Palella presented an overview of the use of x-ray fluorescence (XRF) to measure lead and other metals in consumer products in general, and the capabilities of the NITON Analyzer in particular. As she discussed, XRF is now commonly being used as a field-screening device for a variety of consumer products. The NITON Analyzer has different modes depending on the composition of the product (e.g., metal vs. plastic) and can distinguish between lead (or other metals) in a surface layer and below the surface layer. The NITON Analyzer can be used to evaluate small components of a larger product as well as wipe samples. Ms Palella ended her presentation by testing a variety of products brought in by the attendees.

Mr. Gale Filter, the Deputy Director of Enforcement and Emergency Response with Cal-EPA's Department of Toxic Substances Control (DTSC), was the fourth speaker. The title of his presentation was "Toxics in Products: the Good, the Bad… and Deadly? Current Laws and Enforcement." Mr. Filter discussed two recent laws, one related to lead in jewelry and the other related toxics and packaging. The lead in jewelry law, which was signed in 2006, applies to those who manufacture, ship, sell, or offer for sale jewelry or children's jewelry for retail sale in California. Children's jewelry had to comply by September 1, 2007 and all other jewelry, including body piercings, by March 1, 2008. The law classifies jewelry material into three categories: class 1 (does not contain lead), class 2 (electroplated metal with less than 10% lead until August 30, 2009 and less than 6% lead thereafter), and class 3 (neither class 1 or class 2 and contains less than 0.06% lead). Mr. Filter outlined DTSC's implementation and enforcement activities, including preparation and distribution of outreach materials, identification of subject jewelry and businesses, and inspections. To date, more than 65% of the children's jewelry items tested by the state met the law's requirements for lead. Mr. Filter than discussed the Toxics in Packaging law, which has been in force since January 1, 2006. The law applies to any container used for marketing, protecting, or handling of a product, and manufacturers and suppliers must provide a certificate of compliance. The law bans the selling or promoting of packaging that contains lead, mercury, cadmium, and/or hexavalent chromium unless the combined presence is incidental to manufacture or distribution and no more than 100 ppm. Exemptions include packaging for which there is no feasible alternative or if metals limit is exceeded because of added recycled material.

Dr. Eileen Notolli, a lawyer with Allen Matkins Leck Gamble Mallory & Natsis LLP, was the fifth and final speaker. The title of her presentation was "Does Science have a Role in Proposition 65? To Warn or Not to Warn: The Importance of Regulatory Guidance." Dr. Notolli began her presentation with on overview of Proposition 65, the requirements for warnings, and the roles of plaintiffs and businesses in litigation. As she explained, plaintiffs must demonstrate that the use of a product results in an exposure, and then businesses must demonstrate that the exposure poses no significant risk. Importantly, compliance with other federal or state regulations does not ensure compliance with Proposition 65. In addition, there is little agency guidance to assist a business in demonstrating that exposure does not pose a significant risk, especially with regard to evaluating the potential for hand-to-mouth exposure. Using lead in jewelry as a case example, Dr. Notolli explained that significant data were

collected on total and leachable lead in different components; however, no agreement on exposure assumptions could be reached between the parties (e.g., how long does an average user wear or handle jewelry, how much lead is transferred from the jewelry to the hand and then from the hand to the mouth). A total lead assay was ultimately chosen for lead in jewelry as a practical matter. However, in closing, Dr. Notolli emphasized that more agency guidance on evaluating exposures would allow businesses to more pro-actively assess their products with more certainty, thus avoiding litigation.