



CAL DOOLEY  
PRESIDENT AND CEO

February 4, 2010

The Honorable Frank R. Lautenberg  
Chairman, Subcommittee on Superfund, Toxics and Environmental Health  
Committee on Environment and Public Works  
United States Senate  
Washington, D.C. 20510

The Honorable James Inhofe  
Ranking Member, Subcommittee on Superfund, Toxics and Environmental Health  
Committee on Environment and Public Works  
United States Senate  
Washington, D.C. 20510

Dear Chairman Lautenberg and Ranking Member Inhofe:

The Senate Committee on Environment and Public Works' Subcommittee on Superfund, Toxics and Environmental Health is scheduled to hear testimony from several witnesses on February 4, 2010 concerning the state of the science and public health aspects of human biomonitoring. The American Chemistry Council (ACC), a national trade association representing 140 member companies and 800,000 workers, requests that this letter, containing ACC's perspectives on this important topic, be entered into the record of the subcommittee's hearing.

ACC and its members welcome Congress' review of the Toxic Substances Control Act (TSCA) and the measures that might be taken to modernize the statute. One of the cornerstones of modernizing TSCA is the principle that we must harness advances made in science and technology over the past three decades to develop a comprehensive law that puts the safety of the American consumer first, while promoting the innovation that will lead to the development of essential new chemical products and new high-paying American jobs. Human biomonitoring is one such powerful, advanced technology.

As part of daily life, our bodies naturally absorb substances from our environments. These substances include essential nutrients, trace minerals and elements from our diets and water, as well as man-made substances. Today, because of tremendous technological advances in analytical chemistry, biomonitoring now allows researchers to detect and measure exceedingly low levels of natural and man-made substances in blood, urine, breast milk or other media. But as the National Academy of Sciences (NAS) has stated in their landmark publication, *Human Biomonitoring for Environmental Chemicals* (NAS 2006), "[O]ur technical ability to generate new biomonitoring data has essentially exceeded our ability to interpret them. Thus, it has become easier to measure chemicals or their metabolites in the body than to interpret or communicate the findings."



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Some believe that chemical exposures are increasing because we can now find more substances in humans. Indeed, science can now detect more substances, due in a large part to how sophisticated the technology has become. However, for many substances, such as lead (Jones et al. 2004, CDC 2005, CDC 2009, Muntner et.al. 2005, EPA 2009), polychlorinated biphenyl compounds (Kreiss 1985; Nichols et al. 2007), chlorinated dioxins and furans (Lorber 2002; Hays and Aylward 2003, Lakind et al. 2001, Lakind 2007, Lakind et al. 2009), pesticides and pesticide metabolites (Hill et al. 1995; CDC 2005), and other persistent organochlorine compounds (Murphy and Harvey 1985; CDC 2005) it's well documented that biomonitoring levels have decreased significantly over time.

Biomonitoring data can be very useful in understanding the extent to which people have been exposed to particular substances and can provide guidance for additional research. When integrated with other information about a chemical's hazards, uses and exposures, biomonitoring data may also prove very useful in prioritizing chemicals for further regulatory evaluation.

Like all data, the limitations of biomonitoring data must be recognized and treated accordingly. Biomonitoring data do not provide information about (1) the source(s) of an exposure, (2) how long a substance has been in the body or (3) what effect, if any, a substance may have on human health. Further, for short-lived compounds which are rapidly metabolized by the body, biomonitoring levels can vary considerably, even over the course of a single day, and studies of such substances must be designed appropriately to provide meaningful data on individual exposures. In other words, there are many considerations involved in identifying the appropriate uses of biomonitoring information. That is why the Centers for Disease Control and Prevention (CDC) has worked to assure the public that, "The presence of an environmental chemical in people's blood or urine does not mean that it will cause effects or disease" (CDC 2009). CDC goes on to say that the toxicity of a chemical is related to its dose or concentration and, "Small amounts may be of no health consequence, whereas larger amounts may cause adverse health effects" (CDC 2009).

Interpreting the results of human biomonitoring is still very challenging, even for well-designed and executed studies. "Biomonitoring provides a measurement of exposure that – when used with available epidemiologic, toxicologic and pharmacokinetic modeling data – can be used to estimate how much of a chemical has been absorbed into the body and to provide an indicator of potential health risk." (NAS 2006) Methods to interpret human biomonitoring in a health risk context have only recently been developed, and for most chemicals, the development of interpretive guidance values is still being outpaced by the generation of biomonitoring data.

ACC is optimistic that advances in interpretation tools for biomonitoring – advances that are now underway in joint academic, government and private sector efforts – will eventually make biomonitoring information even more useful to efforts to modernize the US chemical regulatory framework. Growing out of the 2006 NAS recommendations, the recently developed Biomonitoring Equivalents (BEs approach) (Regulatory Toxicology & Pharmacology 513; S1-

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S77) holds great promise at addressing the challenge posed by the current lack of risk-based interpretive tools for human biomonitoring data. It provides a benchmark approach that we think will allow screening-level evaluation of biomonitoring data to address both product stewardship and regulatory needs. Tools like BEs represent an important step forward in advancing our understanding of how to interpret and communicate results of human biomonitoring studies in terms of potential health risks and maximize the value and utility of human biomonitoring data.

In the context of TSCA, ACC believes biomonitoring data and information have an important role along with other hazard, use and exposure factors in determining relative priority of chemical substances for possible further assessment. Given the state of the science of interpretation of biomonitoring information, however, it is not appropriate to base policy and regulatory decisions solely on the fact that a substance has been detected in the human body. To increase biomonitoring's usefulness in the policy and regulatory contexts, and as EPA, the CDC and other Federal agencies, state organizations, non-governmental organizations and private companies focus more intently on human biomonitoring data, we believe that the technological advancement encompassed in interpretive tools, such as the BE, must also be given full attention.

ACC and its members look forward to working with you and the entire Committee as discussions around modifications to TSCA continue. If we can provide any additional information on ACC's position on TSCA modernization, please contact me.

Sincerely,

A handwritten signature in black ink that reads "Cal Dooley". The signature is written in a cursive, slightly slanted style.

Cal Dooley  
President and CEO

cc: Committee on Environment and Public Works

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