

CLIENT ALERT



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TSCA REFORM EFFORTS TURN TO BIOMONITORING STUDIES FOR SUPPORT

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Biomonitoring, the science of measuring human exposure to chemicals through analysis of bodily fluids, has taken center stage in current debates about amending the Toxic Substances Control Act (“TSCA”). Most of the time, biomonitoring results tell us nothing about the health consequences, if any, of the exposure levels detected. Nevertheless, advocates for changing TSCA are citing biomonitoring results, some produced for advocacy purposes, as evidence that this 1976 statute has failed to protect the public from the adverse effects of chemicals. They recently received a boost from a new report by the Centers for Disease Control and Prevention (“CDC”). Biomonitoring-based advocacy contributed to the passage of Europe’s REACH legislation and could play a similar role with TSCA. This was suggested by a recent Senate hearing ostensibly about biomonitoring but mostly intended to build support for TSCA legislation expected to be introduced soon.

BACKGROUND ON BIOMONITORING

“Biomonitoring” refers to the assessment of human exposure to chemicals by measuring the presence of biomarkers – either the chemical itself or its metabolites – in human tissue or fluids, most commonly blood or urine.¹ The quantity or concentration of biomarkers in a sample is an indication of aggregate exposure to the chemical without regard to the relevant route of entry into the body, timing of exposure, or any particular source in the environment. Biomonitoring may also be conceived as a means of measuring the effective dose rate at which the body receives or absorbs chemicals to which it is exposed.

Biomonitoring methods were first developed to monitor occupational exposure to lead in the 1890s. Many decades later, in the 1970s, the expansion of biomonitoring to population-wide studies produced data on blood lead concentrations led EPA to restrict the lead content of gasoline and paint.² Since then, the use of biomonitoring has proliferated through broad-based research programs conducted or sponsored by government agencies and various other institutions. CDC has published its findings in four editions of the *National Report on Human Exposure to Environmental Chemicals*, reporting results for an ever-expanding list of chemicals: 27 in 2001, 116 in 2003, 148 in 2005, and 212 in 2009.

CDC’S FOURTH NATIONAL REPORT

On December 10, 2009, CDC released the *Fourth National Report on Human Exposure to Environmental Chemicals* (the “*Fourth Report*”),³ reporting on the largest set of chemicals of any nationwide study to date. The list includes 75 chemicals not covered in previous CDC reports. Among the newly reported chemicals are arsenic in various forms, bisphenol A (“BPA”), triclosan, perchlorate, perfluorinated compounds, polybrominated diphenyl ethers (“PBDEs”), benzene, and methyl-tert-butyl ether.

The *Fourth Report* builds directly on the three previous reports and represents the cumulative findings of CDC’s biomonitoring effort conducted in conjunction with its National Health and Nutrition Examination Survey (“NHANES”), begun in 1999. NHANES is designed to study the health and nutritional status of the U.S. population, both as a whole and in

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significant demographic groups defined by age, sex and racial and ethnic categories. Because the approximately 2,500 NHANES participants represent demographic groups, and are not randomly selected, the samples used in the biomonitoring component are a subset that is weighted to account for potential statistical biases of the initial selection process.

The presence of an individual chemical is measured in samples of blood or urine, depending on how the body is understood to process or retain the chemical. Chemicals that are persistent (retained intact by the body) are measured directly, and those that are not persistent are typically measured through their metabolites, products of the body's transformation of the original (or parent) chemical. The resulting measurements are then aggregated and presented according to the concentrations observed in the samples. For each chemical, the *Fourth Report* contains tables that show the concentrations that mark the 50th, 75th, 90th and 95th percentiles: that is, the estimated quantity of a particular chemical, or a metabolite, that 50%, 25%, 10%, and 5% of people have in their bodies. These percentile figures are presented for the population as a whole and separately for the various demographic groups.

The *Fourth Report* notes that while “[a]dvances in analytical methods allow us to measure increasingly lower levels of environmental chemicals in people,” the interpretation of these observations in terms of potential impacts on human health is unclear. In language used in previous editions, it declares, “The measurement of an environmental chemical in a person's blood or urine is an indication of exposure; it does not by itself mean that the chemical causes disease or an adverse effect. Research studies, separate from these data, are required to determine which blood or urine levels are safe and which are associated with disease or an adverse effect.”⁴ Given that limitation, the *Fourth Report* identifies several appropriate uses of its biomonitoring results:

- To determine which chemicals get into Americans and at what concentrations.
- For chemicals with a known toxicity level, to determine the prevalence of people with levels above those toxicity levels.
- To establish reference values to determine whether a person or group has an unusually high exposure.
- To assess the effectiveness of public health efforts to reduce exposure of Americans to specific chemicals.
- To determine whether exposure levels are higher among such potentially vulnerable groups as minorities and children.
- To track, over time, trends in levels of exposure of the population.
- To set priorities for research on human health effects.⁵

SMALL-SCALE BIOMONITORING STUDIES: A TOOL FOR ADVOCACY

The CDC reports bear the hallmarks of rigorous public health science – such as robust sample size, carefully justified statistical design, peer review of findings, privacy for the study participants, and caution about the limits of corresponding medical knowledge. In contrast, some other biomonitoring studies, prepared for advocacy rather than scientific purposes, lack most of those characteristics. Many of these studies explicitly link the detection of chemicals in the bodies of a few individuals with calls for amending TSCA.

For example, in October 2009, the non-governmental organization (“NGO”) Physicians for Social Responsibility published the results of its own small-scale biomonitoring study, which it conducted by testing twenty health care professionals.⁶ Whereas anonymity is a standard feature of published medical research, eighteen of the subjects were featured with photographs, biographies, and personal statements. The researchers assayed body fluids for 62 chemicals in six categories: BPA, triclosan, mercury, phthalates, perfluorinated

compounds, and PBDEs. Although announced as news, the report's results were said to be generally consistent with the CDC's national biomonitoring reports. The report did caution that "Connections between chemical exposures, individual susceptibility, and health disorders continue to be researched."⁷ Nevertheless, the report proceeded to connect exposures with adverse health effects, saying, "Apparent correlations between increased incidence of certain diseases and the increased reliance on industrial chemicals have motivated much of the effort to remove toxic chemicals from commerce. These diseases include reproductive dysfunction (in many forms), learning and developmental/neurological harm, metabolic syndrome and cancer."⁸ The report proceeded to identify what it considered weaknesses in TSCA and to advocate for specific changes in the statute.

The Environmental Working Group ("EWG"), another NGO, has been a leader in conducting and publicizing small-scale biomonitoring studies for purposes of TSCA advocacy. In 2005, EWG released a study of umbilical cord-blood from ten newborn infants which "detected 287 commercial chemicals, pesticides and pollutants."⁹ EWG has subsequently published additional biomonitoring studies of ten or fewer subjects, including a second cord-blood study of ten infants, focused on minority populations,¹⁰ and a study of the chemicals detected in five "extraordinary women."¹¹ Another of EWG's biomonitoring efforts, the "Human Toxome Project," publishes separate results for particular individuals, such as Rep. Louise Slaughter (D-NY).¹² In its eleven biomonitoring studies through late 2009, EWG reports that it has tested samples from 186 subjects and found 414 chemicals.¹³ EWG acknowledges that, in contrast to the CDC studies, its sample groups are not "statistically representative . . . of the U.S. population," but argues that its approach complements the broad-based CDC program by: (1) testing for a larger number of chemicals; (2) providing data on the mixture of chemicals in individuals rather than treating each chemical separately; and (3) focusing on early developmental stages.¹⁴

Each of the EWG studies makes the observation that people are exposed to chemicals and concludes by recommending reform of TSCA. While EWG notes that medical science has not demonstrated that most industrial chemicals are harmful in the concentrations detected through biomonitoring, its explanation of this gap is that TSCA is a "notoriously weak chemical safety law" that "deprives EPA of the most basic regulatory tools."¹⁵ EWG's 2005 cord-blood study likewise concluded that "These health concerns are largely the results of gaping holes in the government safety net that allows this exposure We strongly urge that federal laws and policies be reformed to ensure that children are protected from chemical exposures, and that to the maximum extent possible exposure to industrial chemicals before birth be eliminated entirely."¹⁶

INTERPRETING BIOMONITORING DATA

A central problem with the use of biomonitoring results in public debates over chemicals policy and legislation is the difficulty of interpreting the results. Studies with large sample sizes, such as the CDC report, can be used to show differing exposure rates in different groups, which can potentially be correlated to either exposure pathways or health outcomes, the two issues of greatest importance to policy decisions.¹⁷ Studies with small sample sizes, however, at most show that there has been some exposure and uptake by the bodies of certain individuals, without taking into account variables such as the weight of the subjects, differential retention among body tissues, potential inconsistency in testing procedures, or differences in the mode or timing of exposure, each of which may dramatically influence the results.¹⁸

In April 2009, the Government Accountability Office ("GAO") addressed the use of biomonitoring results in a report entitled *Biomonitoring: EPA Needs to Coordinate Its Research Strategy and Clarify Its Authority to Obtain Biomonitoring Data*.¹⁹ The report highlighted the fact that "recent advances in analytic methods have allowed scientists to measure more

chemicals in smaller concentrations.”²⁰ The core interpretive problem is that biomonitoring results alone “indicate only that a person was somehow exposed to a chemical and how much remains in the person’s body, but not how the person was exposed or what may be the effect of the chemical.”²¹ GAO concluded that the potential power of biomonitoring as a tool for assessing threats to human health and the environment is going unrealized because of the inability to link the presence of chemicals either to particular routes of exposure or to resultant risks.²²

Similarly, in 2004, the National Research Council (“NRC”) also assessed difficulties in the use of biomonitoring.²³ NRC found overall that “Biomonitoring is a tool with great potential” in the characterization and response to public exposure to chemicals that may present public health risks. However, the ability to detect exposure has outstripped the ability to interpret the exposure data. NRC also noted that CDC’s reports are based on robust, rigorous and well-documented practices, but that the proliferation of other studies brings the results from less reliable studies to public attention as well.

Among the problems it identified was that biomonitoring results are communicated inappropriately, and that this impedes the formation of a consensus among experts as to the meaning of biomonitoring data. The interpretive problems, then, are at least two-fold: on the one hand, even experts may be unable to understand the significance of the scientifically sound studies, and on the other hand, the general public is exposed to biomonitoring data without regard to the soundness of the research methods.

NRC found further problems in the design of biomonitoring studies that reflect the difficulty of integrating science into policy decisions: in particular, which chemicals are selected and how they are measured. The results of studies to date have shown that to a great degree what they find depends on what they were looking for. Specifically, NRC was troubled by the lack of a “consistent rationale” for the inclusion or exclusion of chemicals. It attributed this inconsistency in part to the lack of effective biomarkers for some chemicals. In the selection of target chemicals and the assessment of the effectiveness of biomarkers, the limitations of the underlying medical science affect the range of possible results, an interpretive problem that is largely hidden from public view.

BIOMONITORING IN THE TSCA REFORM DEBATE

Despite the limitations of well-run biomonitoring studies and the deficiencies of much smaller ones, both kinds are being cited frequently in the TSCA debate. For example, EWG timed the release of its 2009 minority cord-blood study for the day that the Senate Environment and Public Works Committee opened hearings on TSCA reform, and Sen. Frank Lautenberg (D-NJ) cited its findings in his introductory statement.²⁴ When EPA Administrator Lisa Jackson delivered a major speech in September 2009 to announce the Agency’s more aggressive posture toward chemicals regulation and outline EPA’s six principles for TSCA reform, she cited EWG’s 2005 biomonitoring study of ten infant cord blood samples as evidence of the problem.²⁵

Most recently, on February 4, 2010, the Senate Environment and Public Works Committee’s Subcommittee on Superfund, Toxics and Environmental Health held a hearing on specifically on biomonitoring, with TSCA amendments as the subtext. Witnesses included representatives of EPA, CDC, GAO, EWG, and the National Institutes of Environmental Health Services, as well as medical experts and a participant in a small-scale biomonitoring study.²⁶ The majority of the senators’ opening statements, witness testimony, and follow-up questions focused on the wide array of chemicals detected in biomonitoring studies, large and small, and the lack of robust toxicological studies of the health effects of the observed levels of exposure, as indications that TSCA does not adequately protect the public, and particularly children. Subcommittee Chair Lautenberg presided over the hearing and signaled his intention to introduce a new version of the Kid-Safe Chemicals Act “soon.”

The hearing's first witness, Steve Owens, EPA Assistant Administrator for Prevention, Pesticides and Toxic Substances, devoted his testimony to the Obama Administration's support for TSCA reform.²⁷ Subsequent witnesses played out the broad themes of biomonitoring, from the CDC *Fourth Report* to the testimony of Ken Cook, President of EWG, who presented a slide show on "ten Americans," newborn infants whose cord-blood samples were the basis for EWG's 2005 biomonitoring project that "uncovered a startling truth – babies are coming into the world pre-polluted with toxic chemicals."²⁸

THE PERSUASIVE POWER OF BIOMONITORING-BASED ADVOCACY

The dynamic now being played out in the TSCA debate resembles that which preceded the European Union's adoption of its regulation on the Registration, Evaluation, Authorization and Restriction of Chemicals ("REACH").²⁹ The apparent influence of small-scale biomonitoring studies in contributing to the EU's adoption of REACH suggests that current biomonitoring-based advocacy regarding TSCA may be similarly influential.

In the years prior to the adoption of REACH, the World Wildlife Fund ("WWF") and Greenpeace produced a series of biomonitoring and related studies, each prominently featuring the recommendation that REACH should pass. In 2004, for example, WWF released *Chemical Check-Up: An Analysis of Chemicals in the Blood of Members of the European Parliament*, with its sample selection of: one former and 39 current members of the Parliament, four accession country observers, and three WWF staffers.³⁰ The report contained little analysis of its findings, although the section on "Statistical Analysis of Factors Affecting Levels of Contamination" conceded that "Generally, the lifestyle questionnaire identified few statistically significant trends in people's lifestyle habits to explain the results. This is not entirely unexpected because the sample number was relatively small and contamination can occur via many different routes."³¹ In the report's sections entitled "Conclusions" and "Recommendations," REACH was the predominant topic.³²

WWF-UK's *National Biomonitoring Survey 2003*, provided a nearly identical explanation of its failure to identify trends in the data: "This is not totally unexpected since the sample number is small."³³ It concluded that REACH should be enacted.

The eventual adoption of REACH in 2006 – after seven years of debate and with far-reaching implications for industry worldwide – cannot be attributed to any individual cause, but it is likely that the biomonitoring-based advocacy contributed to that result. This may also prove to be the case with TSCA.

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¹ See, e.g., National Research Council, *Human Biomonitoring for Environmental Chemicals* 16 (2006).

² *Id.* at 27 (citing J.B. Sexton et al., The University of Texas Center of Excellence for Patient Safety Research and Practice, *Frontline Assessments of Healthcare Culture: Safety Attitudes Questionnaire Norms and Psychometric Properties* (Technical Report 04-01) (2004)).

³ Available at <http://www.cdc.gov/exposurereport/pdf/FourthReport.pdf>.

⁴ *Fourth Report* at 1.

⁵ *Id.* at 9.

⁶ Bobbi Chase Wilding et al., Physicians for Social Responsibility, *Hazardous Chemicals in Health Care: A Snapshot of Chemicals in Doctors and Nurses* (October 2009), available at <http://www.psr.org/resources/hazardous-chemicals-in-health.html>.

⁷ *Id.* at 16.

⁸ *Id.* at 23.

⁹ Jane Houlihan et al., Environmental Working Group, *BodyBurden: The Pollution in Newborns* 5, July 14, 2005, available at http://www.ewg.org/reports/bodyburden2/pdf/bodyburden2_final-r2.pdf.

¹⁰ Environmental Working Group, *Pollution in People: Cord Blood Contaminants in Minority Newborns*, Dec. 2, 2009, available at <http://www.ewg.org/files/2009-Minority-Cord-Blood-Report.pdf>.

¹¹ Environmental Working Group, *Pollution in 5 Extraordinary Women: The Chemical Body Burden of Environmental Justice Workers*, May 1, 2009, available at <http://www.ewg.org/report/Pollution-in-5-Extraordinary-Women>.

¹² Environmental Working Group, Human Toxome Project, U.S. Representative Louise Slaughter, http://www.ewg.org/sites/humantoxome/participants/participant.php?subject=bb2_L5001%20BAG. Remarkably, Rep. Slaughter's blood tested positive for 201.16666666667-271 chemicals.

¹³ Environmental Working Group, *Pollution in People: Cord Blood Contaminants in Minority Newborns* 4.

¹⁴ *Id.*

¹⁵ Jane Houlihan et al., Environmental Working Group, *BodyBurden: The Pollution in Newborns* 33.

¹⁶ *Id.* at 6.

¹⁷ See Elizabeth L. Anderson, Limitations and Uncertainties of Biomonitoring Surveys Conducted with Small Populations 3 (2006), available at <http://www.biomonitoringinfo.org/AndersonCommentarySmallSamples9-1-06.pdf>.

¹⁸ See *id.* at 3; Daland R. Juberg et al., Mackinac Center, Policy Brief: The Opportunities and Limitations of Biomonitoring 3-4, February 2008.

¹⁹ GAO-09-353, available at <http://www.gao.gov/cgi-bin/getrpt?GAO-09-353>.

²⁰ *Id.* at 1.

²¹ *Id.* at 3.

²² *Id.*

²³ National Research Council, *Human Biomonitoring for Environmental Chemicals* 2 (2006).

²⁴ Opening Statement of Sen. Frank Lautenberg, *Oversight Hearing on the Federal Toxic Substances Control Act Before the S. Comm. on the Environment & Public Works*, 111th Cong. (Dec. 2, 2009), available at http://epw.senate.gov/public/index.cfm?FuseAction=Hearings.Statement&Statement_ID=117d5500-2696-453a-a8a2-3a56f2a63d6b.

²⁵ EPA Administrator Lisa P. Jackson, Remarks to the Commonwealth Club of San Francisco, Sept. 29, 2009, available at <http://yosemite.epa.gov/opa/admpress.nsf/a883dc3da7094f97852572a00065d7d8/fc4e2a8c05343b3285257640007081c5!OpenDocument>.

²⁶ "Current Science on Public Exposures to Toxic Chemicals" Before the S. Subcomm. on Superfund, Toxics and Environmental Health, 111th Cong. (Feb. 4, 2010), available at http://epw.senate.gov/public/index.cfm?FuseAction=Hearings.Hearing&Hearing_ID=8a722315-802a-23ad-4e9a-b8477139e63f.

²⁷ Testimony of Steve Owens, Assistant Administrator, EPA, Office of Prevention, Pesticides and Toxic Substances, *Current Science on Public Exposures to Toxic Chemicals" Before the S. Subcomm. on Superfund, Toxics and Environmental Health*, 111th Cong. (Feb. 4, 2010), available at http://epw.senate.gov/public/index.cfm?FuseAction=Hearings.Testimony&Hearing_ID=8a722315-802a-23ad-4e9a-b8477139e63f&Witness_ID=59f749fc-0f4d-4e5a-bcf3-38f9e8a6c429.

²⁸ Testimony of Ken Cook, President, Environmental Working Group, *Current Science on Public Exposures to Toxic Chemicals" Before the S. Subcomm. on Superfund, Toxics and Environmental Health*, 111th Cong. (Feb. 4, 2010), available at http://epw.senate.gov/public/index.cfm?FuseAction=Hearings.Testimony&Hearing_ID=8a722315-802a-23ad-4e9a-b8477139e63f&Witness_ID=7c9a86cc-4720-4273-b743-38db90b0396f.

²⁹ Commission Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No. 793/93 and Commission Regulation (EC) No. 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

³⁰ World Wildlife Fund (2004), at 7, available at <http://www.panda.org/downloads/europe/checkupmain.pdf>.

³¹ *Id.* at 25.

³² *Id.* at 8-9.

³³ World Wildlife Fund (2003), at 5, 20, available at <http://assets.panda.org/downloads/biomonitoringresults.pdf>.

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