



MARYLAND DEPARTMENT OF HEALTH AND MENTAL HYGIENE

**FINAL REPORT ON THE FEASIBILITY OF
BIOMONITORING IN MARYLAND**

Submitted to the Maryland General Assembly in Fulfillment of Chapter 394, 2010

June 30, 2011

I. Executive Summary

The Maryland Department of Health and Mental Hygiene and Maryland Department of the Environment were directed by the Legislature to study the feasibility of establishing a biomonitoring program in the State to monitor the presence and concentration of designated chemicals in residents of Maryland. After extensive review and public input, the agencies have found that:

Finding 1: With appropriate funding, Maryland has adequate laboratory, scientific, public health, and policy capacity to support a State biomonitoring program;

Finding 2: There is no consensus regarding the substances that should be monitored as part of a biomonitoring program;

Finding 3: A limited pilot program involving a few chemicals in specific populations or groups should be undertaken before any commitment to a large biomonitoring program;

Finding 4: Any biomonitoring program should be cognizant of issues related to environmental justice and social equity; and

Finding 5: Any decisions regarding biomonitoring, including what, whom, and where to monitor, must involve substantial public input.

A decision to implement biomonitoring in Maryland will require additional discussion regarding the need for a program, the potential benefits and costs, the implications of biomonitoring for individual participants, and the value to the State. While there is no consensus at this time regarding specific chemicals to test, or the populations or groups that should be tested, there have been many suggestions about the potential opportunities to increase understanding in the State of actual exposures to chemicals of concern. The first step towards implementing biomonitoring should be to convene a group with significant stakeholder participation to begin to discuss the merits of biomonitoring for specific candidate chemicals, as well as the populations or groups of interest. While there are some existing groups that have an interest in chemicals, public health, and the environment, none is specifically charged with developing policy recommendations related to biomonitoring.

Stakeholders consulted for this report recognized that biomonitoring in Maryland requires additional discussion. Specifically, additional stakeholders should be engaged in discussion regarding: the merits of biomonitoring and potential candidate chemicals, as well as the populations or groups of interest; implications of biomonitoring for individual participants, and the value to the State.

II. Introduction

House Bill 181, enacted in 2010 as Chapter 394, directed the Maryland Department of Health and Mental Hygiene (DHMH), in consultation with the Maryland Department of the Environment (MDE), to study the feasibility of establishing a biomonitoring program in the State to monitor the presence and concentration of designated chemicals in residents of Maryland. The Department was specifically to:

- (1) Examine Federal, States, and International biomonitoring programs;
- (2) Examine legislative efforts in other states to establish biomonitoring programs;
- (3) Consider studies on the effectiveness of biomonitoring programs and the impact of those programs on health outcomes and health care costs;
- (4) Make recommendations regarding the chemicals that would be most beneficial to include in a biomonitoring program in this State; and
- (5) Make recommendations on the structure of a biomonitoring program for the State, if the Department of Health and Mental Hygiene finds that a biomonitoring program would be feasible.

In preparing this report, the agencies have consulted with a wide range of stakeholders, including the Maryland Children's Environmental Health and Protection Advisory Council and the Maryland Commission on Environmental Justice and Sustainable Communities. In addition, the agencies prepared a white paper and subsequently held a public symposium on April 1, 2011, in order to engage directly with the public and solicit feedback from a broad cross-section of interested parties.

Definitions and Concepts

"Biomonitoring" is the assessment of human exposure, typically to chemicals, by measuring the chemicals (or their biological breakdown products, known as metabolites) in human biological specimens such as blood, urine, hair, fingernails, or breast milk. Some of the critical questions that must be considered in biomonitoring include:

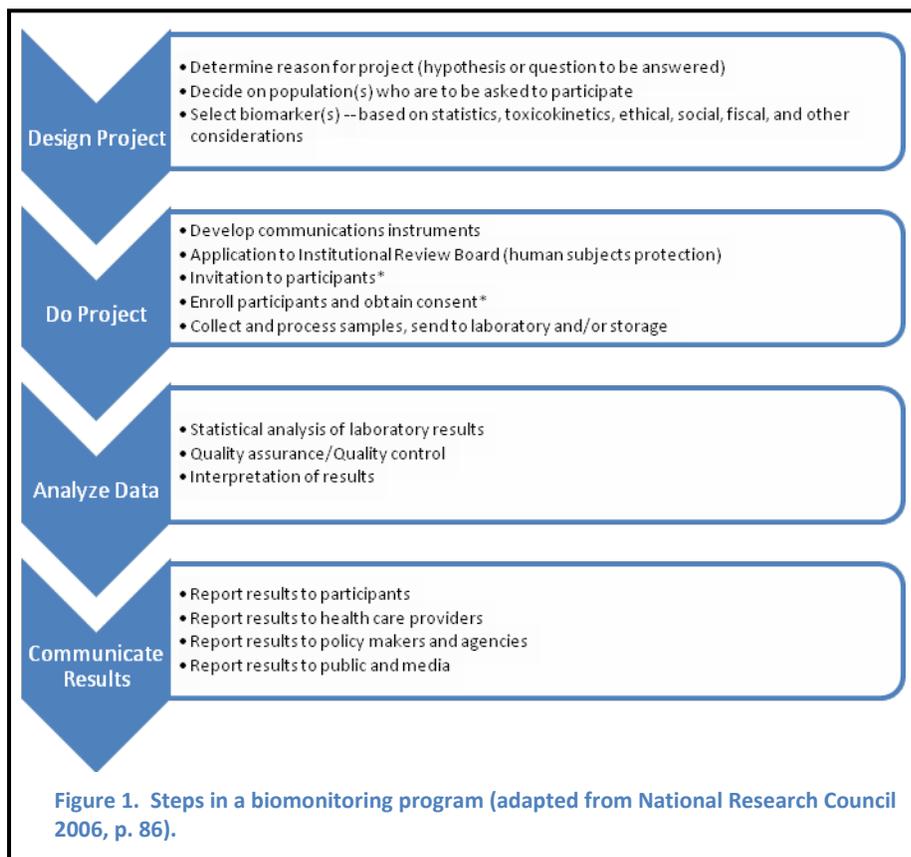
- How much is understood of how particular chemicals of interest are processed in the body (absorbed, metabolized, stored, or eliminated)? For instance, some chemicals are stored in the body for a long time, while others have a very short "half-life" and disappear relatively quickly.
- How accurate and reliable are the laboratory methods to detect the substances of interest? What is the smallest amount of a chemical that can be detected (the "limit of detection")?
- How much is known about the relationship between the amount of chemical in the body (the "body burden") and the health outcomes from that exposure (the "dose-response relationship")?
- What is the purpose of the biomonitoring? Is it to provide estimates of exposure for the general population? Is it focused on groups who might be more exposed than others to particular environmental hazards because of geography, occupation, or other

factors (for example, people who drink from wells)? Is it focused on understanding exposures in people with specific diseases or conditions?

Components of Biomonitoring Programs

Figure 1 shows the steps in a biomonitoring program. As the figure notes, the first thing to do is determine the question to be answered. This in turn will determine which population(s), what kind of samples, what kind of laboratory analysis, what kinds of statistical analysis, and how communications will take place for the biomonitoring program. It is possible that some questions could be answered with existing data or existing banked samples; informed consent might still be required, but not the collection of new specimens.

While not required, all biomonitoring programs to date have included at least one advisory board that participates in all or most of the stages of the process, including program design, program implementation, review of data analysis, and communications with participants and other interested stakeholders.



III. Federal, State, and International Biomonitoring Efforts

Federal Biomonitoring Efforts

The U.S. Centers for Disease Control and Prevention (CDC) conducts a periodic national report on [human exposure to environmental chemicals](#) that describes the concentrations of chemicals and their breakdown products in blood and urine of a representative sample of the U.S. population. The CDC *National Health and Nutrition Examination Survey* (NHANES) provides a national picture of population exposure for 212 chemicals measured in about 2,400 randomly selected participants, but is not large enough to allow state or local-level estimates. As a result, since 2003 CDC has awarded a limited amount of seed money (\$10 million dollars in grants to 33 states) for more comprehensive understanding of exposure levels among state

residents and to identify and track exposure trends that affect specific communities. Other government organizations, including the U.S. Environmental Protection Agency and the National Institutes of Health (NIH) are conducting and sponsoring biomonitoring studies.

The other large national biomonitoring program is the [National Children's Study](#). A collaboration of the CDC and the NIH, this study examines the effects of various environmental influences on the health and development of 100,000 children across the country, following them from before birth to age 21. The study will examine the influence on children's growth, development, and health, of: (1) natural and man-made environmental factors; (2) biological and chemical factors; (3) physical surroundings; (4) social and behavioral factors; (5) genetics; (6) cultural and family influences, and (7) geographic influences. Scientists are analyzing samples of blood, breast milk and urine from 525 pregnant mothers and their infants after birth for more than 100 environmental chemicals and nutritional indicators. Sample collection began in summer 2009.

State Biomonitoring Efforts

Several states have either planned for or actually implemented biomonitoring programs, prompted in some cases by the availability of Federal funds, and in other cases by specific concerns within the state.

- **California:** California's Environmental Contaminant Biomonitoring Program (CECBP) establishes a state-wide survey to measure chemical levels in blood and urine of California residents in order to determine average chemical levels. The legislation authorizing CECBP requires that biomonitoring results be returned to study participants who request them, even though the health implications may be uncertain or unknown. California was one of three states to receive federal biomonitoring grants, but those grants were used primarily for laboratory infrastructure and there is still uncertainty regarding how the program will be funded moving forward.
- **Minnesota:** The Healthy Minnesotans Biomonitoring Program, enacted in 2007, has implemented four pilot projects in Minnesota: arsenic in children; perfluorinated chemicals; mercury in newborn infants; and phenols and cotinine (a nicotine indicator) in pregnant women. However it, too, has recently been challenged by fiscal constraints.

Some states have created regional consortia in order to leverage available funding for biomonitoring, or to capitalize on regional strengths in laboratory capacity. Some of the projects that have been proposed for biomonitoring in states include heavy metals exposures in people living around coal-fired power plants; pollutants found in groundwater; pesticides in common use; or chemicals found in consumer products.

During the 2011 meeting of the Council of State and Territorial Epidemiologists, some of these programs presented reports on their progress. Of note, some states presented informal data on costs of conducting the programs. The cumulative costs of operating these state programs, including enrollment, sample collection, analysis, and communications, reportedly varied between \$1,600 and \$2,000 per program participant.

International Biomonitoring Efforts

There is a great deal of interest and activity in biomonitoring outside the United States. Many other countries conduct biomonitoring programs: Austria, Australia, Belgium, Canada, Costa Rica, Denmark, Finland, Germany, Hungary, Japan, the Netherlands, Norway, Pakistan, Spain, Sweden, United Kingdom, the former Soviet Union, Ukraine, and Yugoslavia, as well as others. Sweden, Germany and the World Health Organization have permanent biomonitoring programs. These programs involve both occupational and environmental biomonitoring for a wide variety of chemicals.

As an example, both Sweden and Germany have been collecting biomonitoring data on breast milk going back to the 1970s. The data shows that a level of flame retardant chemicals in breast milk has been doubling every five years over the last 25 years. Chemical manufacturers have now voluntarily phased out all but one type of these chemicals. Such studies demonstrate that biomonitoring of humans, animals, and the environment is an important means of determining the effectiveness of enforcement efforts of global initiatives. Biomonitoring is the means to determine how well the treaties are being implemented.

IV. Effectiveness of Biomonitoring and Health Outcomes

Biomonitoring can be an effective way of measuring the impact of prevention strategies, and can also help to reduce health care costs by providing clinicians and patients with better information about whether levels of particular chemicals are typical or atypical of what is seen in the general population. However, biomonitoring can also be costly in both economic and human terms when it provides information about chemicals with uncertain health effects. It can also lead to unexpected findings.

Biomonitoring has been useful in demonstrating the effectiveness of regulatory interventions. For example, there has been a significant (greater than 90%) decrease in blood lead levels in children ages 1-5 years since the 1970s. This has been primarily due to the removal of lead from gasoline and paint, as well as other regulatory actions.

The NHANES national exposure data have also shown how widespread the exposure to chemicals in consumer products can be. For example, tests have shown that chemicals used in plastics (phthalates) can be found in most individuals tested, with higher levels in women of childbearing age and young children. However, the relevance of these findings to health outcomes in individuals is unknown at this point.

Biomonitoring is also especially valuable for consideration of “cumulative” exposure, that is, exposures with more than one source (for example, from food, air, and/or water) or setting (environmental versus occupational).

For patients and clinicians it can be useful to know “typical” values for chemicals in the body, as patients may ask for tests of the chemicals when concerned either about exposures (for example, work-related exposures) or particular diseases. Showing a concerned person how the concentration of a chemical in his/her blood compares with a similar population within the State can help both patient and clinician understand whether an exposure has actually occurred. This can reassure patients, guide additional testing, and in some cases contribute to a better understanding of whether specific chemical exposures could have caused or contributed to particular diagnoses.

There are potentially important limitations to biomonitoring. In some cases, laboratory methods for particular chemicals or classes of chemicals may not have been developed or may be insufficiently standardized. Chemicals with short half-lives in the body (that is, they are only in the body for a short time after exposure) are unlikely to be detected unless either sample collection occurs close to the exposure, or exposure is continuously ongoing. Additionally, biomonitoring can also be an invasive procedure, particularly in children.

In summary, biomonitoring can provide public health professionals, researchers, and society with valuable information about chemical exposures at the population level. Biomonitoring can also be useful clinically, by providing baseline or comparison data for patients and providers about chemical concentrations in comparable populations. Biomonitoring can be an opportunity to assess combined environmental and occupational exposures from multiple sources and multiple settings. In epidemiologic studies, biomonitoring can assist with case confirmation and validate the sensitivity of less invasive, less costly indirect surveillance methods. Biomonitoring can help scientists identify which levels of chemicals actually occur in people and target research studies at those levels, i.e., in people of certain ages or ethnicities. This information can help researchers determine if some groups are more exposed than others.

V. Ethical, Legal, and Policy Considerations

The ethical issues surrounding biomonitoring are complex. Unlike clinical tests, which are done in order to help a patient directly, biomonitoring tests are not usually done to benefit the individual. The potential risks for individual participants include: the possibility of anxiety about uncertain health problems from measured levels of a chemical; physical discomfort from procedures like blood draws; additional costs for follow-up testing if a biomonitoring test shows an unusual result; or possible social consequences if the participant's identity and results are disclosed. In addition, communities participating in biomonitoring could be labeled as "exposed" communities, which could affect property values and lead to social stigma.

Some of the legal and policy questions that arise in state biomonitoring programs include:

1. How are results reported to individuals – only their own results, or in comparison with some reference group? Do health care providers play a role in interpretation and communication of results?
2. Are the results subject to state public information acts, or otherwise required to be disclosed under certain conditions?
3. If any testing involves genetic factors, who has access to this information?
4. Can samples be tested anonymously? Case law or policies may prohibit anonymous testing for chemicals that have known treatments or clinical outcomes.
5. What about tests for substances for which the participants might want to have further testing or treatment?
6. Who would cover the costs of such additional testing or treatment?
7. What about any potential harm as a result of participation?
8. Who is responsible for compensating participants if they are harmed?

VI. Impacts on Health Care Costs

There is little data on which to judge the impacts of biomonitoring on health care costs. In one example, in 1996 the pesticide methyl parathion was illegally sprayed inside some 2,600 Mississippi homes. Two children died, many people became sick, and residents did not know whether their families had been exposed. Based on CDC biomonitoring of pesticide levels in the residents, Mississippi state health officials were able to identify those that needed to be moved out of their homes, the ones in need of medical treatment, and which houses needed to be decontaminated. This saved an estimated \$50 million in health care and related costs (Association of Public Health Laboratories, 2004).

VII. Recommendations on Possible Chemicals to Include in Biomonitoring in Maryland

Based on input from stakeholders and the public symposium, there are some biomonitoring issues that may be of interest in Maryland, although there is no consensus regarding the most pressing or important chemicals at this time. Some of the possible candidates include: (1) metals (arsenic, mercury, cadmium, chromium, lead, and others) that occur naturally or through a variety of industrial and commercial pathways; (2) pesticides used in agricultural, commercial, and residential settings that may act as endocrine disruptors or have other potential human health effects; or (3) chemicals that have widespread use in consumer products that have recently been regulated in Maryland (e.g., *bis*-phenol A, flame retardants). In each case, there is a specific rationale for the choice. In the case of metals, there are known health effects and known environmental distribution (with a diversity of sources), so biomonitoring data could provide information about actual population exposures to the public, clinicians, policy makers, and others; additionally, these data could be used to measure the effectiveness of prevention strategies. A biomonitoring program for pesticides could potentially indicate whether geography, occupation, dietary habits, or other factors are associated with differences in body burdens of pesticides; this could have implications for exposure reduction strategies. Biomonitoring for specific chemicals in consumer products could allow for comparison of Maryland with the rest of the nation and, where applicable, evaluation of the effectiveness of bans of certain chemicals in consumer products.

VIII. Feasibility and Possible Structures of a Biomonitoring Program in Maryland

Based on the above findings, the Department of Health and Mental Hygiene and Department of the Environment have developed findings and recommendations regarding the feasibility of a biomonitoring program for the State. These are summarized below.

Finding 1: With adequate funding, Maryland has sufficient laboratory, scientific, public health, and policy capacity to support a State biomonitoring program.

If funding were available, the State has the basic capacity to support a biomonitoring program. By basic capacity is meant the legal, institutional, and technological infrastructure required to operate a biomonitoring program successfully. Regardless of what chemicals were to be monitored, there would likely be a need for substantial investment in laboratory personnel and equipment, but the necessary basic infrastructure is present.

Finding 2: There is no consensus regarding the substances that should be monitored as part of a biomonitoring program.

While there are many proposals about the chemicals, populations, and diseases and conditions of interest, there was no consensus among stakeholders regarding specific chemicals or groups of chemicals that should be tested. Unlike some other states, there does not currently appear to be significant public concern about a specific exposure in Maryland that would drive a specific biomonitoring effort.

Finding 3: A limited pilot program involving a few chemicals in specific populations or groups should be undertaken before any commitment to a large biomonitoring program.

Two principal arguments support the finding that a more limited pilot program should precede a more comprehensive biomonitoring program. The first is the experience of other states, already noted, that it is easier to explain biomonitoring if it is done in the context of a narrow, well-defined question in a specific population rather than a broader assessment of multiple chemicals in a broad cross-section of the population.

The second argument involves cost. Given the costs of adding both additional substances to measure, or additional participants, a limited pilot program of biomonitoring should precede any large-scale State program, regardless of the funding source. The up-front costs of a biomonitoring program may be significant, so it would make sense to assess the feasibility of a pilot program before committing to a large State-wide program. Furthermore, the costs of developing a comprehensive State-wide program assessing many different chemicals would be much more expensive than a pilot program. Based upon the input we obtained from stakeholders, there is less support for a comprehensive State-wide program that would provide general population exposure information comparable to NHANES.

Finding 4: Any biomonitoring program should be cognizant of issues related to environmental justice and social equity.

Historically, some communities in Maryland have suffered disproportionate environmental exposures. Any biomonitoring program, whether limited or extensive, should account for and incorporate this knowledge by ensuring that these communities have opportunities to participate in biomonitoring but, if they choose to participate, are not further stigmatized by participation.

Finding 5: Any decisions regarding biomonitoring, including what, whom, and where to monitor, must involve substantial public input.

All states which have implemented or considered biomonitoring efforts have created public advisory bodies early in the process. These groups have advised on the conduct, structure, and implementation of the programs. They are different than scientific review committees, which look more at the technical issues associated with interpretation of data.

IX. Conclusion

Biomonitoring in Maryland should require additional discussion regarding the need for a program, the potential benefits and costs, the implications of biomonitoring for individual participants, and the value to the State. While there is no consensus at this time regarding specific chemicals to test, or the populations or groups that should be tested, there have been many suggestions about the potential opportunities to increase understanding in the State of actual exposures to chemicals of concern. The first step should be to convene a group with significant stakeholder participation to begin to discuss the merits of biomonitoring and potential candidate chemicals, as well as the populations or groups of interest. While there are some existing groups that have an interest in chemicals, public health, and the environment, none is specifically charged with developing policy recommendations related to biomonitoring.

REFERENCES

Association of Public Health Laboratories. *Biomonitoring: Measuring Chemicals in People*. Washington, D.C.: Association of Public Health Laboratories, 2004.

Committee on Human Biomonitoring for Environmental Toxicants, National Research Council. *Human Biomonitoring for Environmental Chemicals*. Washington, D.C. : National Academies Press, 2006.

Centers for Disease Control and Prevention , Department of Health and Human Services. *Fourth National Report on Human Exposure to Environmental Chemicals*. Washington, D.C.: 2009.

APPENDICES

Appendix 1. House Bill 181.

Appendix 2. White paper prepared for April 1, 2011 public symposium on biomonitoring.

HOUSE BILL 181

J1

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By: **Delegates Hubbard, Ali, Benson, Bobo, Bromwell, Bronrott, Costa, Frush, Griffith, Healey, Holmes, Hucker, Ivey, Kipke, Kullen, Mizeur, Montgomery, Morhaim, Nathan-Pulliam, Oaks, Pena-Melnyk, Proctor, Reznik, Riley, Tarrant, ~~and V. Turner~~ V. Turner, Donoghue, and Jenkins**

Introduced and read first time: January 21, 2010

Assigned to: Health and Government Operations

Committee Report: Favorable with amendments

House action: Adopted

Read second time: March 17, 2010

CHAPTER _____

1 AN ACT concerning

2 **Department of Health and Mental Hygiene – Biomonitoring Program –**
3 **Report**

4 FOR the purpose of requiring the Department of Health and Mental Hygiene, in
5 consultation with the Department of the Environment, to conduct a certain
6 study on the feasibility of establishing a biomonitoring program in the State and
7 to make certain recommendations; requiring the Department of Health and
8 Mental Hygiene to make a certain report to certain committees of the General
9 Assembly on or before a certain date; providing for the termination of this Act;
10 and generally relating to a report on the feasibility of establishing a
11 biomonitoring program in the State.

12 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF
13 MARYLAND, That:

14 (a) The Department of Health and Mental Hygiene, in consultation with the
15 Department of the Environment, shall study the feasibility of establishing a
16 biomonitoring program in the State to monitor the presence and concentration of
17 designated chemicals in residents of Maryland.

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.

Underlining indicates amendments to bill.

~~Strike-out~~ indicates matter stricken from the bill by amendment or deleted from the law by amendment.



1 (b) In conducting the study required under subsection (a) of this section, the
2 Department of Health and Mental Hygiene shall:

3 (1) examine biomonitoring studies conducted by the federal
4 government, in other states, and in other countries;

5 (2) examine legislative efforts in other states to establish
6 biomonitoring programs;

7 (3) consider studies on the effectiveness of biomonitoring programs
8 and the impact of those programs on health outcomes and health care costs;

9 (4) make recommendations regarding the chemicals that would be
10 most beneficial to include in a biomonitoring program in this State; and

11 (5) make recommendations on the structure of a biomonitoring
12 program for the State, if the Department of Health and Mental Hygiene finds that a
13 biomonitoring program would be feasible.

14 (c) On or before June 30, 2011, the Department of Health and Mental
15 Hygiene shall report to the Senate Finance Committee and the House Health and
16 Government Operations Committee, in accordance with § 2-1246 of the State
17 Government Article, on the study required under subsection (a) of this section.

18 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
19 July 1, 2010. It shall remain effective for a period of 1 year and, at the end of June 30,
20 2011, with no further action required by the General Assembly, this Act shall be
21 abrogated and of no further force and effect.

Approved:

Governor.

Speaker of the House of Delegates.

President of the Senate.

THE FEASIBILITY OF BIOMONITORING IN MARYLAND: A WHITE PAPER

Prepared for the April 1, 2011 Maryland State Conference on
The Feasibility of Biomonitoring

In Partial Fulfillment of Chapter 394 of the Laws of Maryland

Introduction

HB 181, enacted in 2010 as Chapter 394, directed the Maryland Department of Health and Mental Hygiene (DHMH), in consultation with the Maryland Department of the Environment (MDE), to study the feasibility of establishing a biomonitoring program in the State to monitor the presence and concentration of designated chemicals in residents of Maryland. The report, which is to be delivered on or before June 30, 2011, is specifically to:

- (1) Examine biomonitoring studies conducted by the federal government, in other states, and in other countries;
- (2) Examine legislative efforts in other states to establish biomonitoring programs;
- (3) Consider studies on the effectiveness of biomonitoring programs and the impact of those programs on health outcomes and health care costs;
- (4) Make recommendations regarding the chemicals that would be most beneficial to include in a biomonitoring program in this State; and
- (5) Make recommendations on the structure of a biomonitoring program for the State, if the Department of Health and Mental Hygiene finds that a biomonitoring program would be feasible.

This white paper is part of the DHMH/MDE process for fulfillment of Chapter 394. It is intended to raise a number of questions that have been developed during the review of state, national, and international efforts on biomonitoring, and to offer alternative answers to those questions as part of public deliberation on the feasibility of biomonitoring. The white paper is intended to help shape some of the discussion around biomonitoring and provoke a discussion that can be captured and distilled in the final report to the General Assembly. The white paper does NOT seek to answer these questions at this time; nor does it purport to reflect the State's position on any aspect of biomonitoring. Rather, its function is to raise questions and elaborate some of the alternatives and issues, in a manner that raises the visibility and public discourse on this important topic.

Background

Definitions

Any discussion of biomonitoring must start with a definition. In this white paper, biomonitoring means a method of assessing human exposure to chemicals by measuring the chemicals or their

metabolites in some biological specimen such as blood, saliva, urine, or tissue. The chemicals could be pesticides, chemicals in consumer products or foods, naturally occurring chemicals in drinking water, or any other chemicals of interest.

Design of Biomonitoring Programs

There are a couple of different models for biomonitoring programs, depending on the purpose of the program. These include:

- Biomonitoring for general population exposure – One purpose for biomonitoring is to assess the concentration of specific chemicals in the general population. The best example of this is the National Health and Nutrition Examination Survey (NHANES), which looks at a broad range of chemicals in a cross-section of the population.
- Biomonitoring of specific populations – Biomonitoring can focus on specific populations. The National Children’s Study aims to increase understanding of the role various environmental factors have on health and disease of children. Some biomonitoring projects focus on occupationally exposed populations (for example, pesticide exposures in agricultural workers).
- Biomonitoring in response to specific events – In some instances there could be specific events (a chemical accident, for example, or a program of some type that could potentially involve chemical exposures) in which a group of people involved in the event would be monitored for possible exposures or health consequences. Some of this monitoring might look for evidence of damage caused by exposure, such as changes in cellular DNA.

Current Biomonitoring Activities in Maryland, Other States, Nationally, and Internationally

Maryland is not the only state to consider biomonitoring. California’s Environmental Contaminant Biomonitoring Program (CECBP) establishes a state-wide survey to measure chemical levels in blood and urine of California residents in order to determine average chemical levels. A distinctive feature of CECBP is the legislative requirement that biomonitoring results are returned to study participants who request them, even though the health implications may be uncertain or unknown. The Healthy Minnesotans Biomonitoring Program, enacted in 2007, has implemented four pilot projects in Minnesota, and is now doing a follow-up study of perflourochemicals and developing a state biomonitoring strategic plan.

Nationally, the largest biomonitoring program is the National Report on Human Exposure to Environmental Chemicals, conducted every 2 years by the U.S. Centers for Disease Control and Prevention (CDC) as a part of the National Health and Nutrition Examination Survey (NHANES). The Fourth Report (2009), based on biomonitoring of blood and urine from 2,400 people across the country, includes comprehensive data on 212 chemicals (including 75 new chemicals that had not been recorded in earlier editions).

The other large national biomonitoring program is the National Children’s Study. A collaboration of the CDC and the National Institutes of Health (NIH), this study will examine the effects of various environmental influences on the health and development of 100,000 children across the country, following them from before birth to age 21. The study will consider several

issues such as natural and man-made environmental factors, biological and chemicals factors, physical surroundings, social factors, behavioral influences and outcomes, genetics, cultural and family influences and differences and geographic locations. Scientists will analyze samples of blood, breast milk and urine from 525 pregnant mothers and their infants after birth for more than 100 environmental chemicals and nutritional indicators. Sample collection began in summer 2009.

It should also be noted that biomonitoring programs in the occupational setting have been taking place for years. This setting is particularly important because some of the highest exposures to many chemicals occur in the workplace. Biomonitoring programs for benzene, lead, and many other chemicals were first worked out and implemented in the workplace, and the ability to distinguish between occupational and environmental exposures to chemicals is one of the challenges of biomonitoring programs.

Legislative Considerations

The National Conference of State Legislatures (NCSL) recently summarized state activities in biomonitoring (*Biomonitoring: A Best Practices Report for State Legislators*, NCSL, Washington, DC: May, 2010). In addition to summarizing many of the legislative initiatives around the country, the NCSL report describes some of the considerations for legislatures when evaluating biomonitoring proposals: (1) Program design and focus; (2) Protocols for data collection and use; (3) Community participation and outreach; (4) Partnerships with outside agencies and organizations; and (5) Determining how to leverage existing resources and strengthen needed laboratory infrastructure.

Biomonitoring Capacity within Maryland

Biomonitoring requires a sophisticated infrastructure to collect, transport, store, analyze, and report on chemicals in a variety of biologic samples including urine, saliva, blood, hair, nails, or other tissue. The entire process requires not only expensive and sophisticated laboratory equipment, but an entire process to ensure sample integrity from collection to analysis to reporting, along with quality assurance, quality control, laboratory proficiency testing, standardization, and continuous assessment of laboratory performance. Maryland's public health laboratory has received federal funding through various cooperative agreements from the CDC and the U.S. Food and Drug Administration (FDA) to develop and maintain laboratory infrastructure, and preparedness and response capability by purchasing new state-of-the-art instruments; promote staff training; develop new or modifying existing test methods; and participate in analyzing proficiency test samples to determine laboratory competency.

Since 2002, the Maryland's State public health laboratory has had the capacity to participate in human biomonitoring studies analyzing urine and blood specimens for different classes of pesticides, toxic metals, nerve agents, cyanide, toxic industrial compounds, and radionuclides, and has maintained CLIA certification for this purpose. The laboratory utilizes highly trained scientists and state-of-the-art instrumentation to routinely analyze urine and blood specimens from private and emergency room physicians at area hospitals, as well as testing for special investigations.

There are many other potential laboratory resources that could potentially play a role in biomonitoring, including resources within academic institutions, Federal and military institutions, and the private sector. All of the considerations that apply to state laboratory facilities identified earlier in this section would also apply to these facilities.

Potential Benefits and Effectiveness of a Biomonitoring Program

The National Research Council Report, *Human Biomonitoring for Environmental Chemicals* (National Research Council, National Academies Press, Washington, DC: 2006) categorized biomarkers of exposure, based on how much was known about the relationship between the biomarker, external dose, internal dose, and biological effects, as well as whether the methods of sampling and analysis were well developed. The report's findings are important because they identify questions that need to be addressed in the development of any proposed biomonitoring program:

- There is a need for a consistent rationale for selecting chemicals for study based on exposure and public-health concerns.
- Epidemiologic, toxicologic, and exposure-assessment studies have not adequately incorporated biomonitoring for interpretation of health risks at the individual, community, and population levels.
- Effective communication of results is among the biggest challenges to the future of biomonitoring.
- Biomonitoring research presents a number of bioethical concerns about informed consent and the interpretation of results. Much of biomonitoring research is conducted with anonymized samples that limit the communication of results and potential followup with study subjects.

Issues in Biomonitoring in Maryland

Technical Issues

There are many technical issues to be considered in designing a biomonitoring program for Maryland. These will be discussed at length in the final report to the General Assembly, but some of them include:

- What are the purposes of the biomonitoring program?
- Which chemicals would be monitored, in whom, and why?
- How long should specimens be stored, and what should the process be to go back and re-analyze the specimens, or to analyze for something new? Should this be allowed at all? Should participants give a general consent, or should they have to be re-contacted for new permission whenever there is a request to conduct a new analysis?
- What are appropriate comparisons for the chemical that are detected? Should comparisons be made only with other participants, or should there be comparisons with national population samples, or perhaps convenience samples from laboratories?

- What should participants be told about their results? How should that communication occur? What should participants and/or their health care providers be told regarding chemical substances detected for which there are no clear health outcomes?
- What should the public at large be told about the results? How should they be reported? What data should be available for researchers?

Interpretation and Communication of Results

As already mentioned in this paper, biomonitoring results can be interpreted with respect to an individual participant, with respect to a group, or with respect to the entire population. The audience that will be receiving, interpreting, and potentially basing decisions upon the results will have needs and expectations that cannot necessarily be predicted. Additionally, members of any audience will have varying perspectives and degrees of scientific understanding. Attention to these audience-related factors during development of the communication plan should improve the success of a biomonitoring program.

Some of the considerations in presenting results to individuals include:

- What is known about the substance and its health effects? If there is information on the health effects, is there anything that can be done to decrease the risk associated with exposure? Can exposure or dose be reduced by either active treatment or action on the part of the individual, or by avoidance of future exposures?
- If there is little known about the potential health effects of certain chemicals, what (if anything) should participants be told about their individual results? Should they know whether they are higher than, lower than, or similar to other participants or some other reference group? Is it possible for them to avoid future exposure?
- What should health care providers be told about the results? Should they be directly informed, or informed through their patients? Should the communication with health care providers be different than that with the participants?

Legal and Ethical Issues

There is a substantial amount written about legal and ethical issues in biomonitoring. Some of the ethical issues are discussed above in the sections on technical issues, and interpretation and communication of results. Some of the other questions that can be raised when discussing biomonitoring include:

- Confidentiality of results. Are these results subject to the Public Information Act or other required disclosure? If any testing involves genetic factors, who has access to that information?
- What about tests for substances for which the participants might want to have further testing or treatment? Who would cover the costs of such additional testing or treatment? What about any potential harm as a result of participation? Who is responsible for compensating participants if they are harmed?

- Does the state assume any ethical responsibility if biomonitoring shows that a particular group has unusual exposure to a substance, even if there is little known about the health implications of the exposure?

Resource Issues

Biomonitoring can be very expensive. Costs include laboratory instruments; sample collection, processing, and storage; communications; data analysis; personnel; and many other components. It is possible to reduce some of these costs, but even pilot programs can be quite expensive.