National Conversation on Public Health and Chemical Exposures
Draft Monitoring Work Group Report

I. Introduction

The *National Conversation on Public Health and Chemical Exposures* (*National Conversation)* is a collaborative project, supported by the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR). The *National Conversation* vision is that chemicals are used and managed in ways that are safe and healthy for all people. The project's goal is to develop an action agenda with clear, achievable recommendations that can help government agencies and other organizations strengthen their efforts to protect the public from harmful chemical exposures. The *National Conversation* Leadership Council will author the action agenda, utilizing input from six project work groups, and members of the public who choose to participate in Web dialogues and community conversations.

National Conversation work groups were formed to research and make recommendations on the following six cross-cutting public health and chemical exposures issues: monitoring, scientific understanding, policies and practices, chemical emergencies, serving communities, and education and communication. This report is the product of the Monitoring work group's deliberations. While issued to the *National Conversation* Leadership Council, the work group hopes that this report will be of value to others in a position to act on the recommendations contained herein.

CDC and ATSDR worked with several groups to manage the *National Conversation*, including RESOLVE, a nonprofit organization dedicated to advancing the effective use of consensus building in public decision making, the American Public Health Association (APHA), the Association of State and Territorial Health Officials (ASTHO), and the National Association of County and City Health Officials (NACCHO). These organizations and others helped ensure that a broad range of groups and individuals were engaged throughout this collaborative process, including government agencies, professional organizations, tribal groups, community and non-profit organizations, health professionals, business and industry leaders, and members of the public.

For more information on the *National Conversation* project, please visit www.atsdr.cdc.gov/nationalconversation.

Work Group Charge, Scope, and Objectives

The Monitoring work group was formed to address the ongoing collection, integration, analysis, and interpretation of data about chemical use, exposure, and known and probably associated health outcomes necessary for the prevention and control of adverse health outcomes related to chemical exposures. Ongoing surveillance also provides an opportunity to evaluate the effectiveness of intervention strategies. Many federal, state, and local government bodies currently collect relevant data. The Monitoring work group was charged with analyzing current surveillance and data collection activities and recommending actions to fill data gaps, better utilize existing data, and improve coordination among the many organizations collecting relevant information. The work group addressed monitoring of chemicals in both human tissues (biomonitoring) and environmental media, including soil, air, water, consumer products, and in key built environments (e.g., schools and homes). In addition, the group addressed options for

better linking exposure information with health outcome data. (See Appendix A. "Monitoring Work Group Final Charge.")

Framework for Discussion

Information on chemical use, exposure pathways, exposure levels, and health outcomes is collected for a variety of reasons, including regulatory, clinical, and public health purposes. To address issues related to public health and chemical exposures, there is a need to better use the data already being collected, and to further broaden the information that is collected. This discussion explored what a comprehensive monitoring system might look like, and how we might move toward such a system.

Membership

Work groups were formed in 2009 following an open nomination process. Work group members were selected based on a three stage process designed to ensure that each work group would have the capacity to address and reflect different individual and organizational perspectives.[1]

The skill sets and individual qualities the team chose to consider in selecting members for the Monitoring work group were subject matter expertise (e.g., chemical use, environmental fate and transport, biomonitoring, health surveillance, and statistics); expertise in various exposure settings and types (e.g., indoor and outdoor environments, industrial chemicals, consumer products, and pesticides); familiarity with monitoring and surveillance systems; representation of those affected by exposure outcomes (e.g., community-based groups); those working to improve monitoring and surveillance systems (e.g., federal agencies); and those with an understanding of privacy, ethical, and cultural issues related to data collection. Furthermore, to achieve overall balance, the team sought to compose a diverse work group in terms of sector, discipline, perspective, and geographic region.

John Balbus, M.D., M.P.H., senior advisor for public health, National Institute of Environmental Health Sciences, chaired the Monitoring work group. Dr. Balbus was supported by Dr. Michael McGeehin, CDC/ATSDR senior liaison to the Monitoring work group and director of the Division of Environmental Hazards and Health Effects at CDC's National Center for Environmental Health (NCEH); Kathy Grant, a Senior Mediator at RESOLVE; and Jennifer Van Skiver, Management and Program Analyst at CDC/ATSDR. Work group membership included 24 individuals with experience in the public, private, and nonprofit sectors. (See Appendix B. "Monitoring Work Group Roster.")

Subgroups

The Monitoring work group worked in three subgroups, organized to address monitoring and surveillance along a temporal continuum from chemical use to health impacts. The subgroups were formed to enable focused discussion of each subgroup topic. Subgroup meetings were open to all Monitoring work group members, discussion notes and draft work products were circulated to all Monitoring work group members, and activities of each subgroup were discussed at general work group meetings.

Chemical Use and Release Subgroup

The Chemical Use and Release subgroup addressed the two major themes of chemical use and release monitoring and environmental monitoring.

[1] For additional information on the work group member selection process, see http://www.atsdr.cdc.gov/nationalconversation/docs/membership_selection_process_report.pdf.

Chemical Use and Release: A broad examination of chemical use and release into the environment, including disposal, is essential to address proactively environmental public health. Examination of chemicals from the point of their use and release also is necessary for providing screening tools and for assessing progress.

Environmental Monitoring: Monitoring of environmental media occurs through a variety of initiatives carried out by local, state, and federal agencies. Knowing which chemicals are present in air, water, soil, dust, food, and elsewhere is an important step in determining to which chemicals people are exposed and how exposure might occur.

Exposure Levels Subgroup

The Exposure Levels, or Biomonitoring, subgroup focused on information generated by measuring chemicals, their metabolites, or other markers of exposure in fluids or tissues of living organisms, to the extent it was deemed relevant to humans.

Health Outcomes Subgroup

The Health Outcomes subgroup focused primarily on human health outcome surveillance, recognizing the examination of human health outcomes as a critical component of monitoring. Surveillance of health impacts is useful as a backup screening tool for sentinel health outcomes, for research linking levels of exposure to specific health outcomes, and for program evaluation.

Terms and Definitions

Biomarker of exposure

The level of a contaminant or its metabolite collected from the body or from substances produced or excreted within biological systems. In humans, this measurement can reflect the amount of the contaminant that is stored in the body, and is sometimes referred to as the body burden. It indicates the level of exposure (EPA, 2008a).

Biomonitoring

The assessment of exposure through direct measurement of environmental chemicals in human specimens, such as blood or urine (CDC, 2009).

Concentration

The amount of a substance present in a certain amount of soil, water, air, food, blood, hair, urine, breath, or any other media (ATSDR, 2009).

Dosage/Dose

1. The actual quantity of a chemical administered to an organism or to which it is exposed. 2. The amount of a substance that reaches a specific tissue (e.g. the liver). 3. The amount of a substance available for interaction with metabolic processes after crossing the outer boundary of an organism (EPA, 2006).

Environmental public health surveillance

Environmental public health surveillance is public health surveillance (ongoing, systematic collection, analysis, and interpretation of outcome-specific data used to plan, implement, and evaluate public health practice) of health effects integrated with surveillance of environmental exposures and hazards. Efforts in environmental public health surveillance and this integration provide a strategic opportunity to link environmental and health data on a local, state, and national level, thereby better equipping the public health community to identify problems and effective solutions to reduce the burden of environment-related health effects in the U.S. (CDC, 2009).

Exposure
For humans, the amount of a chemical, physical, or biological contaminant at the outer boundary of the body available for exchange or intake via inhalation, ingestion, or skin or eye contact (EPA, 2008).

Exposure assessment
The process of finding out how people come into contact with a hazardous substance, how often and for how long they are in contact with the substance, and how much of the substance they are in contact with (ATSDR, 2009).

Exposure level
The amount of a chemical at the absorptive surfaces of an organism (EPA, 2006).

Exposure pathway
The route a substance takes from its source (where it began) to its end point (where it ends), and how people can come into contact with (or get exposed to) it. An exposure pathway has five parts: a source of contamination (such as an abandoned business); an environmental media and transport mechanism (such as movement through groundwater); a point of exposure (such as a private well); a route of exposure (eating, drinking, breathing, or touching), and a receptor population (people potentially or actually exposed). When all five parts are present, the exposure pathway is termed a completed exposure pathway (ATSDR, 2009).

Health outcomes
Documented change in health status using disease-specific measures. Data on health outcomes are obtained from actively or passively collected data on clinical events and personal health and illness experiences (e.g. vital records, reported illness, and health surveys).

Monitoring
Periodic or continuous surveillance or testing to determine the level of compliance with statutory requirements and/or pollutant levels in various media or in humans, plants, and animals (EPA, 2006).

See also Appendix C. "Acronyms."

Caveats and/or Limitations

Given the wide scope of the Monitoring Work Group Charge, it was not possible to address all areas in depth. By splitting into subgroups, the work group's aim was to be as thorough as possible while still addressing the range of topics falling within the work group's purview. The work group also attempted to bring forward the range of ideas presented during subgroup discussions. This draft report represents a synthesis of the key information and overarching recommendations discussed by the work group, and is not necessarily a consensus document on at this time.

II. Current Status of Issues under Consideration

The current status of the nation's knowledge of chemical use, environmental concentrations, levels within humans and other species, and consequent health effects can best be characterized as partial, uneven and minimally integrated. There are numerous data sources for all categories, which vary in terms of accuracy, comprehensiveness, and usefulness of information. This section characterizes the major elements of the nation's chemical management systems that relate to understanding chemical sources,

use, exposures, and health effects in the US population. The strengths and limitations are discussed for each category of monitoring and surveillance information, and barriers and challenges to a better functioning set of systems explored.

Chemical Use and Release

Major Components of Chemical Use and Release Monitoring

The United States Environmental Protection Agency (EPA) has lead responsibility for tracking the uses of industrial chemicals and pesticides as well as their release into the environment. Major components of the EPA's system include the Toxic Substances Control Act (TSCA) Chemical Substance Inventory, the Pesticide Product Information System (PPIS), the Toxics Release Inventory (TRI), National Emissions Inventory (NEI), and National Pollutants Discharge Elimination System (NPDES).

TSCA Chemical Substance Inventory

TSCA § 8(b) requires EPA to manage and publish a current list of chemical substances manufactured or processed in the United States. The substances included in the TSCA Chemical Substance Inventory are any "…organic or inorganic substance of a particular molecular identity, including - (i) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and (ii) any element or uncombined radical" (Toxic Substances Control Act, 1976).

EPA's New Chemicals Program requires anyone planning to manufacture or import a new chemical substance for a non-exempt commercial purpose to provide a premanufacture notice (PMN) to EPA at least 90 days before the manufacture or import of the chemical. EPA requires that PMN submissions provide all available data on chemical identity, production volume, byproducts, use, environmental release, disposal practices, and human exposure. EPA also requires that the following information be submitted with the PMN: all existing health and environmental data in the possession of the submitter, parent company, or affiliates, and a description of any existing data known to or reasonably ascertainable by the submitter (EPA, 2010a).

Pesticide Product Information System

EPA's Pesticide Product Information System (PPIS) contains information concerning all pesticide products registered in the United States. It includes registrant name and address, chemical ingredients, toxicity category, product names, distributor brand names, site/pest uses, pesticide type, formulation code, and registration status (EPA, 2010b).

Toxics Release Inventory

Section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA) requires EPA and states to annually collect data on releases and transfers of certain toxic chemicals from industrial facilities and make the data publicly available in the Toxics Release Inventory (TRI) (EPA, 2010c).

According to EPA (2010d), companies meeting all of the following criteria are required to report the amount of chemicals released per year and to what medium releases occurred:

- Facility has 10 or more full time employee equivalents during the calendar year;
- Facility's North American Industry Classification System (NAICS) code is on the EPCRA section 313 list or is a federal facility; and
- Facility manufactures, processes, or otherwise uses any of the EPCRA section 313 chemicals and/or chemical categories above any of the listed threshold quantities.

The general types of data in TRI Basic data format include the following:

- Facility Name, Address, Latitude & Longitude Coordinates, and Standard Industrial Classification (SIC) or NAICS codes;
- Chemical Identification and Classification Information;
- On-site Release Quantities;
- Publicly Owned Treatment Works (POTW) Transfer Quantities;
- Off-site Transfer Quantities for Release/Disposal and Further Waste Management; and
- Summary Pollution Prevention quantities (Section 8 of the Form R) (EPA, 2010e).

National Emissions Inventory

EPA's National Emission Inventory (NEI) database contains information about sources that emit criteria air pollutants and their precursors, and hazardous air pollutants. The database includes estimates of annual air pollutant emissions from point, nonpoint, and mobile sources in the states, the District of Columbia, Puerto Rico, and the Virgin Islands. EPA collects information about sources and releases an updated version of the NEI database every three years (EPA, 2008b).

National Pollutant Discharge Elimination System

As authorized by the Clean Water Act, the National Pollutant Discharge Elimination System (NPDES) permit program regulates point sources that discharge pollutants into waters of the United States. The NPDES program is primarily administered by states (EPA, 2009).

Strengths and Limitations of Chemical Use and Release Monitoring

Public access to data on chemical use and release is relatively high in the United States compared to other countries. In addition to informing individuals and communities about their potential risks, it has been suggested that the requirement of public disclosure of information on chemical use and toxic substance release has contributed to voluntary actions on the part of industries to limit the production and release of hazardous substances (Karkkainen, 2001; Stephan, 2002). While it is difficult to document decisions made by companies based on TSCA provisions, the TRI database has been cited as a success.[2]

Despite these successes, however, there are many recognized limitations to the ways chemical use and release data are collected in the United States. First, there is no single system that tracks all potentially harmful chemical substances; instead, information is split among a number of different systems created by different statutes, i.e., for pesticides, food additives, cosmetics, pharmaceuticals, and industrial chemicals. In fact, only chemicals not covered by any other statute may be covered under the Toxic Substance Control Act.[3] This makes understanding cumulative exposures more challenging, as the information on potential chemical exposures is fragmented by the different statutory systems. Second, the data obtained on chemical uses is insufficient to understand potential exposures to the extent necessary to protect the public. For example, the information provided on potential children's exposure under EPA's Inventory Update Rule does not include the potential for children to be exposed in homes through the use of chemicals by their parents; it only asks for chemicals in products intended for use by children themselves to be identified (EPA, 2008c). Third, much of the information requested on chemical use is unavailable to the public and often to the government itself because of the invocation of Confidential Business Information (CBI) censorship or claims of information not being reasonable obtainable. The

[2] For example, TRI exceeded its goal of a 50% reduction in the release and transfer of 17 targeted chemicals under the "33/50" program, which ran from 1990-1995. See http://www.epa.gov/tri/archive/othertriprog/33_50other_federal.htm.

[3] See http://www.epa.gov/oppt/newchems/pubs/invntory.htm for more information on the TSCA Chemical Substance Inventory.

EPA has recently taken measures to reduce the use of CBI claims by requiring companies to better justify the need for such privileges.[4]

Environmental Monitoring

Major Components of Environmental Monitoring

Many federal, state, and other organizations in the U.S. collect environmental data for a wide variety of purposes. Some of these data collection efforts are more directly targeted at understanding human exposures, while others are focused on understanding effects on ecosystems and/or non-human species. In addition, some environmental data collection efforts are massive and comprehensive, while others are limited in their scope. This leads to a patchwork of coverage of the different environmental media relevant to public health. Ambient air monitoring, for example, is conducted across the U.S. to document compliance with the National Ambient Air Quality Standards (NAAQS). Similarly, water monitoring programs are conducted to ensure that drinking water meets currently applicable standards. Monitoring chemicals and agents in food items contributes to ensuring food safety.

Selected major components of environmental monitoring data at the federal level include:

EPA's National Contaminant Occurrence Database
The National Contaminant Occurrence Database (NCOD) is a national database of contaminants, both regulated and unregulated, in public water systems. Unregulated contaminant occurrence data; Six-Year Review of National Drinking Water Regulations; and ambient/source water data are all included in NCOD data. Unregulated contaminant occurrence data are for contaminants without health-based standards under the Safe Drinking Water Act (SDWA) at the time of monitoring. They are used to inform the EPA Administrator whether or not to regulate those contaminants. The Six-Year Review is the required review of each National Primary Drinking Water Regulation by EPA and includes SDWA compliance monitoring data for regulated drinking water contaminants from public water supplies. Two ambient water quality data management systems – the Legacy Data Center and STORET – contain raw biological, chemical, and physical data on surface and ground water. All 50 states, territories, and U.S. jurisdictions, as well as portions of Canada and Mexico, are represented in these ambient/source water data systems (EPA, 2010f).

EPA's Ambient Air Monitoring Networks
Ambient monitoring data obtained from EPA's monitoring systems are used to develop and determine compliance with the National Ambient Air Quality Standards (NAAQS), characterize air quality trends, develop emission control strategies, and support research on health effects of air pollution. Since the 1970s, ambient air quality data have come from State and Local Air Monitoring Stations (SLAMS). SLAMS monitor all criteria pollutants, namely, sulfur dioxide [SO_2], nitrogen dioxide [NO_2], carbon monoxide [CO], ozone [O_3], lead [Pb], and particulate matter ([$PM_{2.5}$] and [PM_{10}]). These stations use Federal Reference Methods (FRMs) or Federal Equivalent Methods (FEMs) for direct comparison to the NAAQS, which leads to areas being designated in attainment or non-attainment of a standard. At the end of 2007, there were approximately 947 FRM/FEM filter-based monitors and 591 continuous measurement monitors making $PM_{2.5}$ mass measurements. Further, there were approximately 943 PM_{10} monitors, 1216 O_3 analyzers, 389 CO analyzers, 519 SO_2 analyzers, 422 NO_2 analyzers, and 172 Pb monitors (EPA,

[4] EPA announced in May 2010 that it will take on "a general practice of reviewing confidentiality claims for chemical identities in health and safety studies, and in data from health and safety studies, submitted under TSCA." See http://edocket.access.gpo.gov/2010/pdf/2010-12646.pdf. In addition, in August 2010, EPA issued a proposed rule to modify the TSCA IUR rule. See the docket at http://www.regulations.gov/search/Regs/home.html#docketDetail?R=EPA-HQ-OPPT-2009-0187.

2008d). Despite these numbers, significant temporal and spatial gaps remain in criteria pollutant monitoring across the US. For example, monitors are generally placed away from important sources of pollution, such as major roadways, and so may not capture actual exposures of significant populations.

In addition to SLAMS networks, the Photochemical Assessment Monitoring Station (PAMS) network was developed and implemented in the mid-1990s to measure ozone precursors such as volatile organic compounds, nitrogen oxides [NO_x], and reactive nitrogen species. The PAMS network consists of 78 sites in areas that are classified as serious ozone non-attainment areas. As part of the $PM_{2.5}$ NAAQS review completed in 1997, EPA established a $PM_{2.5}$ Chemical Speciation Network (CSN) for routine speciation monitoring of particulate matter. There are approximately 210 CSN sites collecting data on $PM_{2.5}$ mass, trace elements, major ions (sulfates, nitrates, and ammonium), and organic and elemental carbon fractions. Interagency Monitoring of Protected Visual Environments (IMPROVE) network was established in 1985 to monitor $PM_{2.5}$ levels in national parks and wilderness areas (EPA, 2008d). The IMPROVE network presently comprises of 110 regionally representative monitoring sites, and some sites that operate collaboratively with the CSN. For air toxics (also known as hazardous air pollutants [HAPs]), EPA's monitoring efforts include National Air Toxics Trends Stations (NATTS), funding existing state and local monitoring of air toxics, and community-scale projects to assess conditions at the local level. EPA's recent strategy is to focus on multi-pollutant monitoring and the Agency has recently implemented the National Core (NCore) Network. NCore integrates several advanced measurement systems for particles, pollutant gases and meteorology. NCore stations will be fully operational by Jan 2011 with 82 monitors covering urban (62 sites) and rural areas (20 sites) (EPA, 2008d).

Food and Drug Administration's (FDA) Total Diet Study

The Total Diet Study, also called the market basket study, is an FDA program that studies various contaminants and nutrients in foods consumed by the U.S. population. The Total Diet Study assesses key members of the following analyte groups: pesticides, industrial chemicals, elements, radionuclides, and moisture (FDA, 2009).

US Geological Survey (USGS) Water Quality Monitoring

The USGS provides information on the nation's water quantity and quality from programs that comprise the largest ambient water monitoring activity in the nation, information on the effects and exposure of environmental contaminants to the nation's living resources, particularly those under the stewardship of the Department of the Interior, and information on the environmental health implications of development of energy and mineral resources. The information provides a scientific basis for decisions by resource managers, regulators, industry and the public.

The National Water Quality Assessment (NAWQA) Program assesses pesticides, volatile organic compounds, nutrients and trace elements in the nation's ground water and surface water. Information on the quality of source and finished drinking water and the water quality of domestic wells is collected as well. The Toxic Substances Hydrology Program develops methods to assess new and under-studied environmental contaminants and augments NAWQA Program assessments.[5]

Strengths and Limitations of Environmental Monitoring

Environmental monitoring provides data for use by resource managers, regulators, industry and the public. These data are used for evaluating potential regulations related to chemical registration, use, and release to the environment, and development of new environmental quality standards. Still, despite the large number of programs and the wealth of data collected, there is a lack of systematic data collection

[5] The USGS water information is stored in, and accessible from, the National Water Information System (NWIS), which includes over 4.4 million historical water quality analyses. See http://water.usgs.gov.

that can be readily used to characterize and fully assess human exposure to chemicals or other agents at the community or national level. Thus, a major limitation of the United States' current environmental monitoring system is that both monitoring of environmental media and the collection of necessary ancillary information are incomplete, fragmented and often not collected frequently enough for useful interpretation.

Enhanced cross-agency integration of existing efforts and collaboration on future activities would increase information value far above that of studies conducted in isolation. For example, linking existing time activity programs such as the American Time Use Survey (ATUS), which is conducted by the Bureau of Labor Statistics in the Department of Labor, to existing environmental monitoring programs conducted by the EPA, USGS and other agencies, could provide far more useful information than either activity alone. Cooperation from the Bureau of Labor Statistics would be needed to expand the information collected in the ATUS to make it more relevant for environmental exposures. Together, they could provide a basis for estimating human exposure based upon a better knowledge of contact with the monitored media and, if appropriate information is collected, identification of potential sources of exposure. The integrated information provides a greater ability to reduce exposures, if warranted, by understanding the key factors contributing to exposure. The types of ancillary information needed to place monitoring data into an exposure context include information on how and where people spend their time (time-activity studies), occupation, product use patterns, food consumption patterns, and indoor environment characteristics (i.e., room size, ventilation). The relative importance of each of these types of information will vary based upon the substances being monitored, and this should be considered in study design.[6]

Along with the lack of interconnectedness among monitoring programs for various environmental media, there are unique challenges associated with monitoring efforts for specific media. A major limitation of water monitoring programs, for example, is the difficulty of measuring numerous new chemicals that are used each year while keeping track of traditional environmental contaminants. While bioassays that assess the overall biological activity of a water sample rather than a concentration of a specific chemical show potential as screening tools, chemical-specific identification will inevitably be required to identify, and track the performance of, remedial actions.

In addition, there is a particular lack of data on exposure in the indoor environments that constitute the location of occupancy for over 90% of the time for many individuals (EPA, 2010g). For example, the most current data on human exposures in the workplace are 30 years old, resulting in a severely compromised understanding of risks related to occupational exposures. The National Institute for Occupational Safety and Health (NIOSH) should address this weakness by conducting nationally representative surveys of workplaces across all industries. While a limited number of programs have collected environmental data to obtain distributions of chemicals in multimedia samples in indoor environments (e.g., the Department of Housing and Urban Development (HUD) has conducted monitoring in homes and other environments, often in collaboration with other agencies, such as EPA and the Consumer Product Safety Commission [CPSC][7]), there are no systematic indoor surveillance programs.

[6] Further guidance on these considerations can be found in EPA's Guidelines for Exposure Assessment and in EPA's Exposure Factors Handbook and Child Specific Exposure Factors Handbook. See http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=20563. A new version of this important handbook is anticipated to be released in the coming year.

[7] Examples include a child care center study in 2001 and a series of healthy homes studies, most recently in 2005. See http://www.hud.gov/offices/lead/researchers.cfm.

Biomonitoring

Major Components of Biomonitoring

Human exposure to naturally-occurring and manufactured chemicals has long been a concern to the general public, health professionals and policymakers. Potentially harmful chemicals may be present in food, water, soil, air and consumer products. Measuring levels of chemicals in the environment helps scientists and policy makers understand the magnitude and distribution of potential problems, but these measurements are not always predictive of how much of a chemical has been absorbed or who may be most affected by this exposure. Biomonitoring provides a precise measure of the concentration of a chemical in a specific body fluid or in exhaled air. Thus, biomonitoring measurements reflect an individual's exposures to a specific chemical or set of related chemicals from all sources, and can help identify groups of people who may be more or less exposed to a given chemical.

CDC's National Biomonitoring Program

For at least three decades, scientists at CDC's Environmental Health Laboratory have been undertaking efforts to determine which environmental chemicals are of high priority and measuring the levels of these chemicals in a representative sample of the civilian, noninstitutionalized US population. The *Fourth National Report on Human Exposure to Environmental Chemicals* includes exposure data for 212 chemicals and chemical metabolites in a sample of about 2400 participants that represents the U.S. civilian, noninstitutionalized population (CDC, 2010a).

States and Biomonitoring

State health departments use biomonitoring to support environmental exposure investigations and help address concerns regarding environmental exposures that might be unique to their state. For example, uranium occurs naturally in ground water throughout the Rocky Mountains as well as in South Carolina, Connecticut, and other eastern states. Because CDC cannot address all of the environmental exposures in each state, the agency provides competitive funding to help states build their own biomonitoring capability.[8]

Other Large-Scale Biomonitoring Efforts

Other countries and consortia of national programs have carried out biomonitoring surveys in the past, though these have usually been restricted to one class of chemicals at a time (e.g., metals). Two large-scale national biomonitoring efforts are ongoing: the *German Environmental Surveys I-IV* and the recent 2010 *Report on Human Biomonitoring of Environmental Chemicals* from Statistics Canada and Health Canada. Several other nations are planning to build biomonitoring programs.

Biomonitoring and Research

In addition, with the spread of newer technologies, biomonitoring methods are applied to research studies that often include smaller, localized populations. These biomonitoring data are useful not only within the context of the research study that sponsors the data collection but also for comparison purposes with national data. CDC performs advanced biomonitoring measurements for about 50 new research studies each year.

[8] See http://www.cdc.gov/biomonitoring/state_grants.html for information on CDC funding of state-based biomonitoring programs. See http://www.aphl.org/aphlprograms/eh/chemicalpeople/Documents/BiomonitoringReport2009.pdf for a detailed discussion of biomonitoring in some of the states.

Impact and Applications

Biomonitoring data have increased awareness of the incidence and magnitude of chemical exposures for the public, for scientists, and for decision makers. Biomonitoring has played a prominent role in documenting the effectiveness of regulatory interventions, and in some cases has contributed to chemical management actions because of alarming or surprising results. One notable example of the former is lead. Since the late 1970s, the blood lead levels for children aged 1-5 years old have declined over 90% because of the removal of lead from gas and paint (CDC, 2008). Similarly, National Health and Nutrition Examination Survey (NHANES) data have documented reductions in human levels of DDT, organochlorine pesticides, lead, environmental tobacco smoke. Biomonitoring has demonstrated near-ubiquitous exposure to certain phthalates, such as diethylphthalate (DEP), diethylhexylphthalate (DEHP), dibutylphthalate (DBP), and benzylbutylphthalate (BBP), with higher levels in women of childbearing age and young children (Blount et al., 2000; Silva et al., 2004). These findings from biomonitoring, in conjunction with growing concerns about reproductive and developmental toxicity of those same compounds, were part of the justification for the development of EPA's action plan on phthalates[9] and preceded federal (i.e., Confidential Information Protection and Statistical Efficiency Act §108) and state (i.e., California Assembly Bill 1108) legislation banning or restricting the use of these same compounds in products for children. Similarly, demonstration of increasing levels of polybrominated diphenyl ethers and widespread exposures to bisphenol A has helped motivate state, federal, and international actions to reduce exposure to these chemicals.

Biomonitoring is generally more useful for chemicals that persist for a long time in the body, like DDT (dichlorodiphenyltrichloroethane) and lead. However, such sampling cannot as a rule distinguish various historical exposure scenarios (i.e. – one cannot tell whether the lead exposure was a week ago, a year ago, or a decade ago based on a blood level alone- ancillary information is necessary). One particularly useful application of biomonitoring is in the workplace, where exposure data are more readily obtained. For example, under the occupational health standard for inorganic lead, a program of biological monitoring and medical surveillance is to be made available to all employees exposed to lead above the action level of 30 ug/m(3) TWA for more than 30 days each year. This program consists of periodic blood sampling and medical evaluation to be performed on a schedule which is defined by previous laboratory results, worker complaints or concerns, and the clinical assessment of the examining physician. It allows for workers to be removed from exposure when their blood levels exceed a given threshold.[10]

Biomonitoring may also be useful for chemicals with shorter half-lives when exposure to those chemicals is sufficiently widespread and frequent (or continuous) that a random sample is likely to find that chemical or its metabolites at concentrations reflective of overall population or individual levels. It may also be helpful for short-lived chemicals if sampling can be appropriately coordinated with exposure (e.g., end of shift workplace monitoring). Biomonitoring may be particularly useful when there are multiple pathways of exposure (air, food, water, etc.), as it allows a picture of overall intake to be obtained. This has been the case for some of the phthalate chemicals mentioned above.

Strengths and Limitations of Biomonitoring

Biomonitoring provides a direct measurement of the internalized dose of a chemical and may, for many chemicals, reduce the uncertainty associated with other methods of assessing exposure, such as activity questionnaires and modeled estimates based on measurements of environmental media like ambient air and drinking water. A strength of biomonitoring is that it measures the dose delivered from all routes of exposure (i.e., air, water, food, soil). Often people are exposed through multiple routes. For example,

[9] See www.epa.gov/oppt/existingchemicals/.../phthalates_ap_2009_1230_final.pdf.

[10] See http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10033 for more information about medical surveillance guidelines for occupational exposure to inorganic lead.

children who live in older homes may eat paint containing lead that is peeling off the walls; they may breathe or eat lead from paint that has been ground or eroded into fine particles and mingled with the dust in the house; and they may drink lead in their water if their plumbing contains lead. All of these exposures would be captured in a child's blood lead level. On the other hand, to estimate this cumulative exposure using environmental monitoring, one would need to take samples of the air, paint, dust and water, run separate tests on each sample, and then enter those results into a mathematical model to estimate the internal dose. Biomonitoring also provides a way to assess combined environmental and occupational exposures.

In epidemiologic studies, biomonitoring can assist with case confirmation and also can be used to validate the sensitivity or specificity of less-invasive, less-costly indirect surveillance methods (Acquavella, Alexander, Mandel, & Gustin, 2006). Since biomonitored levels reflect the concentration of chemicals in specific compartments of the body, these levels are likely to have a stronger statistical association with internal effects, such as genetic damage or cell death (in related body compartments especially), and often with health outcome measures such as decreased IQ or disease incidence.

In the risk assessment process, biomonitoring data can be used to validate or compare dose-based regulatory values by means of forward and reverse dosimetry. For instance, population data on levels of perchlorate in urine can be used to calculate an intake dose of the chemical and compare this value to the EPA reference dose (RfD). In addition, biomonitoring can help scientists to identify which levels of chemicals actually occur in people and help to target research studies at those levels. Lastly, future advantages will be yielded when animal dosing studies of effects are designed to include blood and urine levels that are associated with those effects; then these animal levels can be more directly compared with those in humans, supplementing the less certain dose-to-dose comparisons with level-to-level comparisons.

Still, there are a number of technical and practical limitations to biomonitoring. Not all chemicals can be biomonitored; laboratory methods for many chemicals have not yet been developed or else they may only be able to detect chemicals at higher concentrations than are relevant for human exposures; in addition, some methods are not feasible due to cost, or capacity limitations.

A major impediment to biomonitoring, especially of blood and particularly in children, is the need for an invasive procedure. The use of urinary, salivary, hair, breath, or other sampling that can be performed in a non-invasive manner is generally preferred, and efforts are needed to improve the availability and reliability of non-invasive biomonitoring methods.

Also, for most biomonitored chemicals, the interpretation of test results is a major challenge. Because of inadequate scientific understanding of the extent to which measured concentrations of chemicals in blood and urine are associated with, let alone predictive of health effects, biomonitoring at present can often only provide insight into exposures without giving individuals and policy makers useful information on the likelihood of specific health effects. Well designed research studies that take into account important co-factors such as physiologic state, pharmacokinetic variation, diet, nutrition, and underlying health-related disorders are needed to help better understand the connections between biomonitored chemical concentrations and health effects.

Biomonitored levels of chemicals in the absence of other exposure-related information usually cannot indicate where (location) a person was exposed, the duration or frequency of exposure, the route of exposure (oral, inhaled, dermal), or the source of the exposure. Other information should be used together with the biomonitoring data to make risk assessment and policy decisions. For non-persistent chemicals that may produce effects due to prolonged exposure, many biomonitored levels during the exposure

period would be required to estimate long term risk most accurately. For persistent chemicals in the body, single measurements can be a good indicator of body burden.

Currently, technology, history, and concerns for suspected toxic chemicals are driving the selection of chemicals that are biomonitored. It is likely that additional, unmeasured chemicals have entered the environment and human's bodies. Rational future selection of chemicals to biomonitor will be limited by the level of understanding of toxicity of the broader range of chemicals and by the amount of information available on the release of chemicals into the environment and uses of chemicals.

Standardization of biomonitoring practices and methods is often lacking, compromising the reliability and comparability of data from different studies. For example, in individual biomonitoring testing, standardization of collection timing with respect to timing, duration and frequency of the exposure is extremely important to avoid biasing the results and subsequent assessments, particularly in smaller samples in which such bias may be more prominent. Different instruments or analytical methods often make it difficult to generate accurate and reproducible results across different studies. CDC and many state public health laboratories are working together to standardize methods, calibrator materials, and quality assurance procedures to assure better comparability of biomonitoring data.

Health Outcomes

Major Components of Health Outcomes Monitoring

Ongoing monitoring of health status, health outcomes, and health conditions associated with chemical exposures in the United States occurs at the federal, state and local levels. At all levels, technological advancements have improved the timeliness of data and its accessibility, increased the ability to use geographic information, and led to more timely release of health reports and micro-data. Partnerships between federal, state and local public health officials have built on these advances to develop more coordinated systems for monitoring data from diverse sources for specific locations (e.g., CDC's Environmental Health Tracking program[11] and the HHS Community Health Data Initiative[12]).

Systems for monitoring health outcomes in the context of chemical exposures can be broadly divided into two basic categories: (a) state and local systems for identifying and investigating disease clusters and outbreaks in order to identify potential environmental causes; and (b) ongoing state and national health data collection systems, which collect data on general health indicators that may or may not be related in part to chemical exposures. There are many limitations to the use and interpretation of existing health data sets for environmental health assessment, as most data sets are collected for other purposes. Relevant examples of health outcomes data systems are described below.

Reportable Conditions and Other Ongoing State Reporting Systems

Health outcome monitoring at the state and local levels through case reporting is based on the legal mandates states have for requiring reporting of individuals with selected health conditions. Case-based surveillance is well established for communicable diseases and cancer. Currently only a limited number of health conditions related to chemical exposures are reportable in more than one state. They include poisonings and laboratory test results related to several heavy metals (lead, mercury, cadmium, arsenic), pesticide poisoning, carbon monoxide poisoning, penumoconiosis, chemical pneumonitis, and other

[11] See http://www.cdc.gov/nceh/tracking for more information on CDC's Environmental Public Health Tracking program.

[12] See http://www.cdc.gov/nchs/data_access/chdi.htm for more information on the Community Health Data Initiative.

chemical poisonings. Only three of these conditions are reportable in 50% or more of the states (lead poisoning/elevated blood lead, pesticides, and silicosis – one of the types of pneumoconiosis). Several other conditions that have been made reportable by states are of interest to environmental public health surveillance because of their possible links to chemical exposures. These include cancer, autism, Parkinson's disease, asthma, and birth defects; although cancer is reportable in almost all states, the other four conditions are reportable in relatively few.[13]

Ongoing monitoring using health data systems other than conditions reportable at the state level includes use of vital records, state hospital discharge data systems (available in most states), emergency department data (available in some states), birth defects registries[14] (funded by CDC in nine states), the Behavioral Risk Factor Surveillance Survey (BRFSS) survey, cancer registry data (all states), and others.

At the national level, many health data systems are in place to monitor the health of the US population. In some cases states provide data to federal agencies in uniform formats, while other systems are administered directly by federal agencies.

CDC's National Vital Statistics System

The National Vital Statistics System collects and disseminates information on the nation's vital events (e.g., deaths, births, fetal deaths) through partnership with the jurisdictions legally responsible for their registration. These data provide information on a variety of health endpoints, including cause of death and infant birth weight, information that could be associated with chemical exposures. Further, because these data are collected locally, detailed geographic information may be available when directly obtained from a state (CDC, 2010b).

Large National Health Surveys

Large national health surveys, including the National Health Interview Survey[15] and the National Health and Nutrition Examination Survey (NHANES)[16] collect a wide variety of information on health and health-related behaviors. These surveys have the advantage of relatively large sample sizes, information for small population subgroups, and consistency over time to monitor health trends. On the other hand, they are not designed to provide local information and are in fact prohibited from doing so to protect participant's confidentiality and avoid disclosure risks. There are also some local surveys modeled after the national surveys, such as the California Health Interview Survey and the New York City Community HANES.[17] These, however, can be limited in their time frame and sample sizes, and they represent large, rather than local, areas.

The Behavioral Risk Factor Surveillance Survey (BRFSS)

The BRFSS is a large, ongoing telephone-based health survey, tracking health conditions and risk behaviors in the United States annually since 1984. This state-level data system collects information on a variety of health conditions and produces estimates for some subsections of states.

[13] The enumeration of states that have made any of these conditions reportable can be found on a searchable website maintained by the Council of State and Territorial Epidemiologists (CSTE). See http://www.cste.org/dnn/ProgramsandActivities/PublicHealthInformatics/StateReportableConditionsQueryResults/tabid/261/Default.aspx

[14] See http://www.cdc.gov/ncbddd/bd/monitoring.htm for more information on birth defects monitoring.

[15] See http://www.cdc.gov/nchs/nhis.htm for more information on the National Health Interview Survey.

[16] See http://www.cdc.gov/nchs/nhanes.htm for more information on NHANES.

[17] See http://www.chis.ucla.edu for more information on the California Health Interview Survey, and http://www.nyc.gov/html/doh/html/hanes/hanes.shtml for more information on the New York City Community HANES.

Outcomes and events from administrative records are also used in several ways at the national level. Medical records with information on diagnosis and treatment of disease are sampled via National Health Care Surveys[18] and aggregated via the Healthcare Cost and Utilization Project.[19] Other claims-based data systems such as the Medicare claims data[20] could be used to monitor specific health outcomes. Other sources, such as data files maintained by large insurance companies or emergency departments may be available for some purposes. Cancer incidence data are collected nationally through the system of state/regional/local cancer registries. Some of these registries participate in the federally funded Surveillance, Epidemiology and End Results (SEER) program and collect additional in-depth information on cancer incidence, prevalence and survival from specific geographic areas representing 26 percent of the U.S. population (National Institutes of Health, 2010).

Environmental Public Health Tracking

The Environmental Public Health Tracking[21] (EPHT) network is the only large-scale health surveillance system dedicated to monitoring the health impacts of chemicals. EPHT is a network of 23 states and CDC's National Center for Environmental Health dedicated to developing surveillance data systems linking hazard, exposure, and health outcomes data in a way that is useful to the public, public health professionals, and researchers concerned about the impact of chemicals on human health. In its development over the last eight years, CDC and participating state health departments have had to address numerous complex issues including data access, data standardization, and information technology challenges to making the data publicly available in a uniform format.

National Children's Study

The National Children's Study[22] will be collecting a large amount of information, including health outcomes and environmental exposures, for a large, nationally representative sample of children in the United States over many years.

Community Health Data Initiative

Government and non-governmental organizations have partnered to establish the Community Health Data Initiative (CHDI). CHDI is a network of suppliers and demanders of community health data, indicators, and interventions, convened to improve Americans' knowledge of health and health care system performance. The HHS Health Indicators Warehouse, currently under development, will serve as the data hub for the initiative.[23] Although the CHDI is not specifically designed to monitor health outcomes known and possibly related to chemical exposures, the emphasis on local information may enhance the ability to monitor these health outcomes in local communities. Further, the system does not preclude the inclusion of locally defined exposure values, facilitating the examination of possible exposure-outcome trends and relationships.[24]

Strengths and Limitations of Health Outcomes Monitoring

Existing data on health outcomes offer several advantages for improved monitoring of the health outcomes associated with chemical exposures. The large, national health surveys and administrative data collections can provide comparable information across the whole U.S., providing benchmarks and

[18] See http://www.cdc.gov/nchs/nhcs.htm for more information on National Health Care Surveys.
[19] See http://www.ahrq.gov/data/hcup for more information on the Healthcare Cost and Utilization Project.
[20] See http://www.cms.gov/PrevntionGenInfo/20_prevserv.asp for more information on Medicare claims data.
[21] Current EPHT data are available at http://www.cdc.gov/nceh/tracking.
[22] Learn more about the National Children's Study at http://www.nationalchildrensstudy.gov.
[23] See http://www.cdc.gov/nchs/data_access/chdi.htm for more information on the Community Health Data Initiative.
[24] See also http://www.hhs.gov/open/datasets/about.html.

facilitating comparisons across large geographic regions (and even countries). Large surveys and administrative data collections can also provide statistically valid health information for subgroups defined by demographic characteristics, including measures of race, ethnicity, and socio-economic status. Ongoing, systematically maintained, data collections provide information about trends, which can facilitate the identification of new environmental causes of adverse health outcomes. For less common health outcomes or for understanding trends in local areas, notifiable disease reporting efforts offer useful information.

Despite these strengths, many of the health data systems described above remain limited in their ability to provide useful information on chemically–related health outcomes for a number of reasons. First, health effects associated with chemicals are often non-specific and could be caused not only by a number of different chemicals, but also by other factors. Thus, information on conditions like cancer, asthma, or adverse birth outcomes may be relevant to chemical exposures but requires extensive additional information on exposures and other individual factors in order to shed light on possible chemical causation. Second, there is often a long lag period, or delay, between the time of chemical exposure and the development of obvious adverse health outcomes. This complicates matching specific chemicals to observed health outcomes. Finally, the scientific relationship between adverse health outcomes and specific chemical exposures is poorly understood for the vast majority of chemicals.

Because chemical exposures often occur on a local scale, local health outcomes data are needed for detection and monitoring of potential health impacts. Health outcome information from national surveys, however, is not collected in all areas. Moreover, local health outcome information obtained from surveys and other national data sets may not be available at the local level in order to protect individual privacy. Furthermore, health outcome information for local areas generally is limited by small numbers of events which make it harder to achieve statistical significance and support definitive scientific inferences.

Smaller systems that rely on case reporting are also limited by the many causes of under-reporting, which include access to care, physician recognition of chemical causes of disease, and other barriers to physician reporting of cases.

III. Vision of a Successful System

The nation should have a comprehensive collection of information covering all important chemicals for all relevant populations, including data on chemical source (inclusive of imports), chemical uses, environmental and biological concentrations, and toxicity. These data should be collected in a manner that facilitates analysis, data integration, interpretation and most importantly, protective actions. Such data would provide communities the ability to understand patterns of local chemical production and use as well as chemical exposure and risk. This data could be integrated across media and across agencies to provide a comprehensive understanding of chemical exposures and potential harms and therefore provide a basis for decision making. An integrated data collection system, combined with improved understanding of the toxic effects of chemicals and the doses at which they can cause harm, will facilitate decision making and help address the difficulties attributing cause-and-effect that arise from the incomplete information collected under the current system.

Biomonitoring programs will be bolstered by greater scientific understanding of associations between chemical concentrations in blood, urine and other body compartments and health outcomes, as well as by greater understanding of the distribution and time course of chemicals in the body. This knowledge will support the development of non-invasive and highly sensitive new assays that will facilitate more widespread sampling and sampling of vulnerable populations like young children. Interpretation of

biomonitoring results will be aided by improved understanding of chemical uses and more robust toxicity data.

In addition to chemical-specific information, health outcomes data should be collected in a way that facilitates its applications in protecting the public from harmful chemical exposures. Health outcomes data should be collected in a way that smoothly integrates on a time and spatial basis with chemical source, use, and exposure data. Trends in time and space in relevant health outcomes should be systematically analyzed and efforts made to identify potential "hotspots" or early increases in adverse health outcomes, recognizing that simple trend data are not sufficient to show cause-and-effect relationships. Guidance and "benchmarking" of community-level health data can help state and local health officials identify and address community concerns about adverse health experiences.

Prioritization will be essential as no such data set will ever be complete, and even a reasonably sufficient data collection cannot be achieved rapidly given available resources and technical barriers. Prioritization should be based on rational criteria (e.g., population vulnerability, chemical production volume, use patterns, mobility, biomonitoring data, toxicity, etc.) and should be set by a committee having representation from multiple agencies as well as other stakeholders and experts based upon aggregate exposures across multiple relevant media. It will be important to recognize that a unitary, ordinal prioritization will probably fail to meet important goals. Thus, prioritization must recognize a range of needs to be met for a variety of reasons, and should take into consideration both national and local needs, address both mortality and life quality issues, and should address agency specific projects and priorities in addition to broader goals.

This dataset should achieve a robust baseline for sources, uses and environmental exposure in the indoor and outdoor environment and in the workplace in order to support analysis of health outcomes. Regular, representative, and systematic surveillance systems will allow us to understand what current "normal" exposure is and to recognize variation from normal exposures, to identify meaningful exposure inequities, and to document changes over time due to changes in use patterns, intentional interventions (i.e. allow assessment of success or failure), or local or global environmental changes such as global climate change.

While establishing a robust baseline is critical, the ideal system will also routinely prioritize high-risk communities, populations, and/or chemicals for further study. This could involve additional environmental sampling or small-scale, more intensive biomonitoring studies. Communities shown to be disproportionately exposed to toxic chemicals due to their proximity to intensive industrial production areas or other sources of environmental releases, communities previously found to have elevated levels in prior biomonitoring surveys, and other communities or residences identified as having unusually high concentrations of potentially toxic chemicals can be targeted. Similarly, populations with critical vulnerability, such as fetuses and infants, should be targeted for special investigations. Such studies will provide greater understanding of variations in exposure and risk, as well as providing a means to respond to community needs and identify populations or communities that require additional actions to protect their health.

The dataset should balance the need for representative data with the need to obtain localized and/or individual-level data. This will allow analysis of local exposure patterns and address specific community concerns yet still facilitate individual-level epidemiological studies and thus avoid the limitations intrinsic to ecological study designs. Exposure data collection should ideally be coordinated with health outcome and/or biomonitoring data on the same individual.

As with prioritization, an inter-agency team that includes subject experts and state and local partners should establish guidance to ensure compatibility and comparability of data. Technical limitations, differences among media, and other factors may make complete compatibility impossible in some

instances, but the need to better understand aggregate exposures across multiple media and exposure pathways would argue strongly for coordination of methods whenever feasible. Environmental and biomonitoring programs in particular should be coordinated to ensure that priority chemicals are being monitored in both programs and that the data are being interpreted jointly to identify and confirm linkages and trends among environmental levels, exposures, and ultimately health outcomes.

Information should be made publicly available in a useful manner. Transparency is important, and thus the availability of raw data will be important in most circumstances. However, raw data are not necessarily useful information, and so agencies must provide appropriate interpretation of the available data within the limits of available knowledge. The data/information should be provided via an integrated data source. While this could be a single, large database, differential database needs and historical circumstances will probably make a single database difficult to achieve and maintain. Thus, it is more likely that a public-friendly "front-end" web-based resource to coordinate access to key underlying data will be needed to support access needs. There should also be an increased commitment to partnering with academic institutions and community-based groups, to ensure that government-based chemical risk management programs will be well integrated into broader public discussions and decision-making about human and ecosystem health.

Obtaining optimal data utility will require access to information that may be personally confidential (medical information protected under HIPAA for example) or confidential business information. Data may also carry risks to individuals and communities, including individuals on whom data may not have been directly collected (i.e., localized pollution or localized health issues, even if not causally linked with reasonable certainty, may devalue property or raise significant anxiety, etc.). Thus, the development of a comprehensive national monitoring program must be accompanied by a discussion regarding bioethical issues, and successful deployment of the program may require modifications of existing regulations and/or the establishment of practices such as informed consent. Ultimately, success will likely require a delicate balance between the public good and individual concerns, as is generally the case in public health.

IV. Action Recommendations

1. Improve reporting of chemical source, use, and discharge information.

(a) Increase the frequency of manufacturing volume reporting required under the Toxic Substances Control Act Inventory Update Rule and require more extensive information on downstream uses.

Currently, the Toxic Substances Control Act (TSCA) inventory is updated once every five years. While the amount of use and potential exposure information was expanded in 2006, there are still significant limitations to this information: first, it only reflects one year out of the five year cycle of reporting, so significant fluctuations in production volumes from year to year are missed; second, it only requires information on production volumes, uses, and potential exposures to children be submitted if such information is "readily obtainable" – with no penalty for failing to submit such information if the company claims it is not readily obtainable. The EU REACH program requires that manufacturers of chemicals provide downstream users with information on chemical hazards for specific exposure scenarios; downstream users whose uses are not covered by those exposure scenarios must either notify the upstream supplier of their use or provide their own analysis of potential risks to their customers.[25] In

[25] The European Chemicals Agency (ECHA) Guidance Document for Downstream Users is available at http://guidance.echa.europa.eu/docs/guidance_document/du_en.htm?time=1282626622

general, REACH is designed to increase communication on hazards and uses both up and down the supply chain.

The work group therefore recommends that EPA improve the usefulness of TSCA's Inventory Update Rule (IUR). This could be accomplished by increasing the frequency of reporting from every five to every 1 or 2 years; requiring greater substantiation of claims of "not readily obtainable" information; and providing clear guidance as to those circumstances under which EPA would accept a claim of "not readily obtainable."[26]

(b) Address Toxics Release Inventory shortcomings; provide more information on short-term releases.

Instead of relying on nominations for additions to the Toxics Release Inventory (TRI) list, EPA should establish a process of regular scientific review and revision of the TRI. Potential sources for candidate chemicals and industries include scientific peer-reviewed literature, weight-of-evidence evaluations such as the International Agency for Research on Cancer (IARC) and National Toxicology Program (NTP) lists of carcinogens, and state or international identification of high risk chemicals for policy measures. TRI reporting should be tied to information on hazards, uses, and exposures that would result from improved manufacture and use information.

2. Make environmental monitoring more comprehensive and suitable for assessing total human chemical exposure.

Federal agencies such as the U.S. Department of Housing and Urban Development (HUD), U.S. Environmental Protection Agency (EPA), the Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH), the U.S. Consumer Product Safety Commission (CPSC), U.S. Department of Energy (DOE), and the National Institutes of Health (NIH), and state environmental departments should develop a cross-agency systematic approach to the design and implementation of routine monitoring surveys and expansion of the data collected. The surveys should address: (1) all major microenvironments that people occupy, including residences, child care centers and schools, public access buildings, and workplaces (including offices); (2) the broad spectrum of persistent and non-persistent chemicals in current use in materials and consumer products (e.g., flame retardants, pesticides); and (3) the multiple media to which people are exposed, including diet.

Monitoring surveys should collect data of sufficient temporal resolution (e.g., in some cases conduct real-time monitoring versus integrated samples) to address acute and chronic exposures to chemicals and to address temporal variability of chemical concentrations in the environment. To make environmental monitoring more comprehensive and suitable for assessing and predicting human exposures, new, innovative, low cost, and low burden monitoring methods need to be developed. In addition to collecting data on chemical concentrations in environmental media, ancillary information (e.g., activity, product use) should be collected in order to make the monitoring data more useful for characterizing people's

[26] EPA proposed an IUR Modifications Rule on August 13, 2010. This rule calls for increased frequency of reporting from every five years to every four years; required reporting of production volumes meeting or exceeding the threshold for a chemical substance in any calendar year since the last principal reporting year; required reporting of additional manufacturing and use data; and upfront substantiation of CBI claims, among other changes. See http://www.epa.gov/iur/pubs/Fact%20Sheet_IUR%20ModificationNPRM_08-05-10.pdf for EPA's fact sheet on this proposed rule and http://www.regulations.gov/search/Regs/home.html#documentDetail?R=0900006480b2ff32 for the docket. The work group may update its IUR-related recommendation prior to submitting the final version of this report to reflect current regulations.

exposure to chemicals for different lifestages (children, adults, elderly, and susceptible or vulnerable groups). Surveys need to be conducted on a routine and regularly scheduled basis (every 5 to 10 years) to track trends and identify potential exposure issues.

The work group recommends that the appropriate agencies and departments enhance cross-organization integration of existing monitoring surveys and expand monitoring surveys. In order to develop a cross-agency systematic and coordinated approach to the design and implementation of routine monitoring surveys, the work group recommends that the appropriate agencies identify an existing inter-agency work group or form a new work group to coordinate monitoring surveys across agencies.

The measure of success will be demonstration within three years of increased collaboration and coordination across agencies in the planning and conduct of surveys of environmental quality and human exposures.

3. Expand biomonitoring capacity

The Centers for Disease Control and Prevention's (CDC) *National Report on Human Exposure to Environmental Chemicals* provides estimates of chemical exposures for the civilian, noninstitutionalized U.S. population. Its current design was never intended to allow state or local agencies to calculate exposure estimates for their jurisdiction. For example, CDC cannot extract a subset of data and examine levels of blood lead that represent a state population. In order to produce such data, states need the capability and capacity to conduct biomonitoring assessments statewide or in communities or groups where chemical exposure is a concern.

In order to fill this gap and address community needs, the U.S. needs a state-based, national biomonitoring network of laboratories and public health agencies. The Association of Public Health Laboratories (APHL) has a five-year plan[27] to develop a laboratory network and is working with its membership as well as that of the Council of State and Territorial Epidemiologists (CSTE) and Association of State and Territorial Health Officials (ASTHO) to create guidelines for any state or local jurisdiction who chooses to participate in what will be called the National Biomonitoring System.

Recognizing limited resources, this System should not aim to build capacity in every locality to measure every chemical exposure; however, the network should help localities connect with each other to leverage existing capacity. For an example of such an effort, see the biomonitoring database being developed by APHL to link laboratories with epidemiologists with policymakers and academics to encourage collaboration.

The ultimate goal would be to at least have the capacity to measure each chemical of concern somewhere in the nation. Because methods only exist for a few hundred of the more than 3,000 chemicals used in high volume in the U.S.,[28] we need to develop new laboratory methods and build capacity to measure them locally. It is important to note that in jurisdictions where authorities anticipate an ongoing need to biomonitor a population (for example in jurisdictions doing surveillance studies), redundancies in capacity and capability are encouraged. For example, every state should be able to measure blood lead levels in children. Where appropriate non-invasive sample collection technology is available, biomonitoring studies should be expanded to include children of all age groups.

[27] More information on APHL's National Biomonitoring Plan is available at http://www.aphl.org/aphlprograms/eh/Pages/nationalbioplan.aspx.

[28] EPA classifies High Production Volume (HPV) as those chemicals produced or imported in the United States in quantities of 1 million pounds or more per year. See http://www.epa.gov/chemrtk/pubs/general/basicinfo.htm.

Systemization will allow standardization of biomonitoring study design, sample collection and analysis, data analysis and comparability, as well as interpretation. Concurrently, legal and financial recommendations will be needed to allow different jurisdictional authorities to take advantage of the network.

One important action that can be taken quickly (within 1-2 years) is to build carefully designed and well managed human sample banks (blood, milk, tissues such as placenta) and environmental sample banks (fish, tree barks, etc.). These banks will be very helpful in (1) establishing chronology of pollution, (2) identifying new pollutants, (3) tracing back to sources, (4) archiving samples for future analysis with better technology than we have today, (5) exploring regional differences, and (6) carrying out longitudinal studies.

4. Expand Health Outcome Surveillance

(a) Expand national data surveys to over-sample vulnerable populations and high priority geographic regions.

Expanding national data surveys and other data collections will allow for better capabilities to understand the variability in health outcomes known and possibly related to chemical exposures across the United States; designing these collections to over-sample specific subgroups will enable better identification of vulnerable populations defined by demographic and socioeconomic indicators. Larger annual sample sizes will reduce the need to combine multiple years of data for accurate estimates, providing better information on current status and trends. Consideration of high priority geographic regions or areas could be considered as a domain in sampling design. This would require statistical research to establish feasibility, implications, and cost considerations. The success of this recommendation would be tracked by broadened use of the data for providing timely estimates for geographic and population subgroups.

(b) Expand reportable conditions to other conditions with environmental links.

State, local and tribal health departments and CDC have established a process for recommending that health conditions be placed under surveillance at the state and/or national level using the Council of State and Territorial Epidemiologists (CSTE). CSTE, an organization of member states and territories representing public health epidemiologists, has the responsibility for defining and recommending which diseases and conditions are reportable within states and which of these diseases and conditions will be voluntarily reported to CDC. Such recommendations are made through the development of "Position Statements," which include how surveillance should be conducted for a specific condition (e.g., case definition, reportable data elements).

Accordingly, a work group of CSTE environmental epidemiologists and NCEH epidemiologists should review currently reportable conditions of interest to surveillance of chemical exposures to identify gaps, i.e., conditions that are absent from the current list or those that are on the CSTE list but reportable in very few states. Plans should be developed to address interpretation constraints imposed by limitations of available chemical exposure data and understanding of factors affecting chemical exposure. The work group should develop its recommendations for ways to fill the identified gaps, obtain consensus from the larger group of CSTE environmental epidemiologists, and then develop Position Statements for their recommendations.

Progress in promoting new and more comprehensive reporting of diseases associated with chemical exposures can be tracked through the CSTE website. The Environmental Public Health Tracking (EPHT)

network is likely to place the data on these reportable conditions on the CDC EPHT portal and state portals as appropriate, demonstrating use of these data.

5. Expand Environmental Public Health Tracking to include all 50 States and 10 Metropolitan Statistical Areas.

The concepts and tools of Environmental Public Health Tracking (EPHT), and the Congressional appropriation that has funded the development of the integrated state and federal network, represent the highest level of development of environmental public health surveillance to date, but it has been implemented in only about half of the states because of funding limitations. Additional funding from Congress will need to be secured in order to achieve this recommendation. Organizations representing public health, including the Association of State and Territorial Health Officials (ASTHO), Council of State and Territorial Epidemiologists (CSTE), National Association of County and City Health Officials (NACCHO), Association of Public Health Laboratories (APHL), American Public Health Association (APHA), and others should make EPHT a priority for their discussions with appropriators in Congress.

Increased funding for EPHT from Congress that is directed to additional state health departments will demonstrate success.

6. Establish mechanisms for the public and state/local/tribal officials to provide input into data collection efforts.

(a) Ensure that effective mechanisms exist for the public and state/local/tribal officials to provide input into decisions about *national data collection efforts*.

All national data collection mechanisms should be open to public comment through a robust process prior to their initiation and periodically as preliminary or interim data are collected. The process for fully capturing community input and concerns is critical to the success of data collection mechanisms. Public input at the beginning and during data collection projects enables the process to be adjusted and highly adaptive. Proposed data collection mechanisms and any updates to them should be published on www.regulations.gov, and public input should be posted in a docket available through the site. The notice should seek public input on specific issues identified by the responsible agency, as well as allow for open-ended comment. The public should be encouraged to suggest reformulated questions if they do not find the agency's questions to be sufficient. The public should have no less than a 120-day comment period.

Agency communication with the public should include but extend beyond a notice in the Federal Register. Agencies should engage in outreach to national, regional, statewide and local organizations and people. Accommodation should be made to ensure that materials and translators are available for the languages spoken by affected communities. At the national level, outreach efforts should target national environmental, health, labor, religious, and other organizations. Outreach efforts by the responsible agency should be undertaken to solicit public comment through listening sessions or public administrative hearings held in each federal region affected by the data collection strategy. All public comments delivered at the hearings should be transcribed and posted in the docket. This process should provide public notice that is no less than 30 days. After the public input is received, the agency or agencies in question should again publish its decision(s) in the Federal Register and seek public input to the docket to enable any final adjustments.

(b) Ensure that effective mechanisms exist for the public and state/local/tribal officials to provide input into *local community study design* (e.g., Community-based Participatory Action Research methods).

Similar to the methodology for public input on national data collection efforts, a local community study design should seek to involve the members of the community being evaluated. This, too, should be a process that seeks to ensure broad input from the public with ample opportunity to participate with written and oral comments. Similar to the national outreach, accommodation should be made to ensure that materials and translators are available for the range of languages spoken in the local community. The process should include a public comment period with a public docket, allowing for up to a 120-day notice period on a proposed study design and an opportunity to comment on the final. A truly participatory process should seek to engage a cross-section of the community. Local and regional outreach efforts to engage the public should involve communicating with community-based groups, labor organizations, housing and tenant groups, the faith community, health care and medical offices, public health officials, local elected officials, school boards, parent-teacher associations, water utility districts and other entities in the community that have the ability to reach members of the community through their membership, patients, listservs, websites, newsletters, mailing lists, social networks, media, and other distribution mechanisms. In addition, notice of the opportunity to participate should be posted throughout the community wherever public notices are posted.

Since most participatory processes are self-selective, it is critical that the outreach and inclusion methodology eliminate the barriers to participation and ensure participants an opportunity to establish the framework and definitions of the problem(s) and the data necessary to capture it. To that end, the agency should hold workshops to collect the community perspective on the study design. The workshops should be held in venues that are accessible and comfortable to community members and should be scheduled so as to not conflict with community members' work schedules. Public comments should be transcribed and placed in the docket. For those community members who do not use computers, a toll-free number should be available for questions and a written transcript of the workshops and relevant materials should be made available at the local libraries. Local governments should provide assistance, as feasible, to enable effective representation of community members (e.g., provide cost-free childcare, assist with transportation to and from the meeting, etc.).

The number of workshops should be determined based on the size of the community. No less than two workshops should be held in communities with populations less than 25,000, and additional workshops should be scheduled for every 100,000 population up to a maximum of ten workshops.

7. Standardization & Integration

To ensure that information can be collected, exchanged, and interpreted by all interested parties, agencies conducting surveillance and monitoring activities must identify data, collection methods, and information system standards. Adopting and implementing standards for content, format, collection, transport, and interpretation of data will strengthen the ability of governmental agencies to exchange information needed for assessing environmental threats and designing effective interventions.

The work group recommends that EPA, CDC, and other agencies conducting ongoing surveillance and monitoring programs evaluate the feasibility of developing a clearinghouse of standardized methods for data collection and interpretation. CDC should also evaluate the possibility of providing a "Community of Practice" (CoP) forum for this community. One suggestion is to build upon the existing Public Health Information Network (PHIN), to enhance cooperation, standardization, and integration of environmental sampling and analytical methods, biomonitoring approaches, and other methods associated with exposure monitoring. Suggested methods to implement a CoP include electronic collaboration tools, such as message boards, listservs, chat rooms, webinars, and shared electronic workspaces.

The clearinghouse and CoP should be established within 3 years of the publication of this report.

8. Balancing Public Access to Data with Confidentiality

Recent efforts by the federal government to protect confidentiality for individual respondents have been very successful. Language can be found in the Health Insurance Portability and Accountability Act (HIPAA), the Confidential Information Protection and Statistical Efficiency Act (CIPSEA), and other acts. An unfortunate result is that local datasets on chemical exposure are frequently prevented from being released, since they could result in possible disclosure of personally identifiable information.

A second method used by the federal government to protect the confidentiality of data is to mask the datasets by either swapping some responses or adding "noise." In both cases the trade-off for confidentiality is reduced data quality. So even when data are released, their accuracy may have been reduced, limiting their utility for local analyses.

(a) OMB should sponsor a National Academy of Sciences (NAS) study to explicitly address the balance between confidentiality and data quality, especially for local analyses.

It is important to recognize that maintaining data quality, especially for local analyses, is an important consideration that must be balanced with protection of confidentiality. HIPAA and CIPSEA restrict access to data to protect confidentiality to individuals. Masking data allows for data releases but of reduced quality. The NAS should assess the impact of data masking and identify how these actions can be balanced so that they assist analyses of chemical issues, particularly at the local level.

The NAS should also investigate the similar balance between protecting confidential business information and releasing data on possible chemical exposures. For example, providing more detail on toxic releases may conflict with protecting confidential intellectual property. The NAS should take account of product development life cycle and volume of product releases. It would also be important to consider the trade-off mandated by other international organizations since industry will have to respond to the combined sets of requirements in all locations where they operate.

This study should be initiated within three years.

(b) Respondents should have access to data collected on them.

Study respondents should be offered the option to receive the results of personal biomonitoring and physical samples collected from their property. These data should be accompanied by explanations aimed at a layman that provide context for the exposure measurements.

(c) ATSDR or other governmental agencies should serve as a clearinghouse for quality local studies of chemical exposure.

Such a clearinghouse would greatly assist local efforts to understand their exposures and to recognize if those are unusual compared to similar locales elsewhere. While ATSDR would not be expected to evaluate the quality of the local studies, the clearinghouse should provide standardized information that would allow potential users to judge the applicability of the data. Examples of documentation that should be required for inclusion of a local study in the clearinghouse include:

- Statistical sample design;
- Sample size;
- List of chemicals tested for;

- Physical analytic methods;
- Basic findings;
- Links to publications or a summary of findings; and
- Contact person information.

Additional Priority Considerations

As noted in the Vision discussion above, changes in research policy and funding practice appear to be essential to adequately address and resolve "hypothesis-generating" information resulting from expanded biomonitoring. The members of the Monitoring work group are not experts in the area of national research program design, and do not feel that they have the requisite knowledge and experience to recommend specific changes in this area – but the need is abundantly clear. The work group would recommend that the National Academy of Sciences, including the Institute of Medicine, be specifically charged with evaluating and providing recommendations to address two specific questions:

(a) What approach should be taken to best identify plausible and pertinent hypotheses among the results of hypothesis-generating efforts and determine which hypotheses merit further study in order to obtain more definitive information on causal relationships?

The criteria will clearly go beyond epidemiologic considerations and will need to address practical issues. For example, there may be little point in pursuing additional studies on outmoded chemicals or chemicals which have been discontinued for other reasons, or in expending resources on detailed study when containment may be a preferred option.

(b) What changes in national research policy would assure that hypothesis-testing research will be undertaken when necessary and appropriate?

Many models are possible, and it would seem appropriate to consider possible major changes in practice, policy, and/or funding to meet this need, rather than considering only minor adjustments to the current, predominantly academic model.

V. Conclusion

This report presents the Monitoring work group's findings and recommendations regarding the United States' approach to monitoring and surveillance for the purpose of protecting the public from harmful chemical exposures. The work group approached this report by addressing issues along a temporal continuum, focusing on chemical use and release, environmental monitoring, biomonitoring, and health outcomes monitoring. This report characterizes the key components along this continuum; the major strengths and limitations that exist within each topic; the work group's vision of a successful monitoring system; and actionable recommendations to achieve that vision.

The work group acknowledges several key themes that arise in its report: comprehensiveness, integration, prioritization, and action. The recommendations strive to expand and link the nation's many existing efforts to monitor chemicals and public health, and to leverage existing infrastructure, information, and resources whenever possible. The work group recognizes that challenges and in some cases controversies are associated with issues discussed in this report, and members believe that this report reflects their support of the values of fairness, accuracy, prevention, and the protection of vulnerable populations. As suggested by the recommendations in this report, achieving the work group's

vision will take a concerted effort by experts in numerous organizations, both within and external to the government. The work group hopes that this report will move the United States toward an effective, coordinated monitoring system for public health and chemical exposures.

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Appendix A. Monitoring Work Group Final Charge

Monitoring Work Group: *facilitating the collection, analysis and interpretation of information on chemicals, including their sources, uses, exposures, and associated health outcomes.*

The prevention and control of adverse health outcomes related to chemical exposures requires the ongoing collection, integration, analysis, and interpretation of data about chemicals, including their sources, uses, exposures, and associated health outcomes. Ongoing surveillance also provides an opportunity to evaluate the effectiveness of intervention strategies. Many federal, state, local, and tribal government bodies currently collect relevant data.

This working group will analyze current surveillance and data collection activities and recommend actions to fill data gaps, better utilize existing data, and improve coordination among the many organizations collecting relevant information. The group will address monitoring of chemicals in both human tissues (biomonitoring) and environmental media, including soil, air, water, consumer products, food, and in key built environments (e.g. schools and homes). Further, the group will address options for enhancing the interpretability of exposure information for the purpose of analyzing associations with health outcome data. The group will work together with members of the chemical emergencies work group to develop recommendations related to monitoring acute events.

Appendix B. Monitoring Work Group Roster

Chair
John Balbus, National Institute of Environmental Health Sciences

Members
Henry Anderson, Wisconsin Division of Public Health
Herb Buxton, U.S. Geological Survey
Alison Edwards, U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition
Jay Feldman, Beyond Pesticides
Roy Fortmann, U.S. Environmental Protection Agency
Daniel Goldstein, Monsanto
Nancy John, Cherokee Nation
Charlotte L. Keys, Jesus People Against Pollution
Megan Latshaw, Association of Public Health Laboratories
Sam LeFevre, Utah Department of Health
Dean Lillquist, U.S. Occupational Safety and Health Administration
David Marker, Westat
John Osterloh, Centers of Disease Control and Prevention, National Center for Environmental Health
Jennifer Parker, Centers of Disease Control and Prevention, National Center for Health Statistics
Sharyle Patton, Commonweal
Karen Pierce, Bayview Hunters Point Community Advocates
Ruthann Rudel, Silent Spring Institute
Martha Stanbury, Michigan Department of Community Health
Treye Thomas, Consumer Product Safety Commission
Richard Van Frank, Improving Kids' Environment
Steve Whittaker, Public Health - Seattle & King County
Alan Woolf, Children's Hospital, Boston

Support
Michael McGeehin, NCEH/ATSDR *senior liaison*
Kathy Grant, RESOLVE *facilitator*
Jenny Van Skiver, NCEH/ATSDR *staff*

Appendix C. Acronyms

APHA: American Public Health Association
APHL: Association of Public Health Laboratories
ASTHO: Association of State and Territorial Health Officials
ATSDR: Agency for Toxic Substances and Disease Registry
ATUS: American Time Use Survey
BRFSS: Behavioral Risk Factor Surveillance Survey
CDC: Centers for Disease Control and Prevention
CBI: Confidential Business Information
CHDI: Community Health Data Initiative
CIPSEA: Confidential Information Protection and Statistical Efficiency Act
CoP: Community of Practice
CPSC: Consumer Product Safety Commission
CPSIA: Consumer Product Safety Improvement Act
CSN: Chemical Speciation Network
CSTE: Council of State and Territorial Epidemiologists
DOE: United States Department of Energy
ECHA: European Chemicals Agency
EPA: United States Environmental Protection Agency
EPCRA: Emergency Planning and Community Right-to-Know Act
EPHT: Environmental Public Health Tracking
FDA: United States Food and Drug Administration
FRMs: Federal Reference Methods
FEMs: Federal Equivalent Methods
HANES: Health and Nutrition Examination Survey (see also, NHANES)
HAPs: Hazardous Air Pollutants
HHS: United States Department of Health and Human Services
HIPAA: Health Insurance Portability and Accountability Act
HUD: United States Department of Housing and Urban Development
IARC: International Agency for Research on Cancer
IMPROVE: Interagency Monitoring of Protected Visual Environments
NATTS: National Air Toxics Trends Stations
NAAQS: National Ambient Air Quality Standards
NACCHO: National Association of County and City Health Officials
NAS: National Academy of Sciences
NAWQA: National Water Quality Assessment
NCEH: CDC's National Center for Environmental Health
NCOD: National Contaminant Occurrence Database
NEI: National Emissions Inventory
NHANES: National Health and Nutrition Examination Survey
NIH: National Institutes of Health
NIOSH: National Institute for Occupational Safety and Health
NPDES: National Pollutants Discharge Elimination System
NTP: National Toxicology Program
NWIS: National Water Information System
OMB: United States Office of Management and Budget
PAMS: Photochemical Assessment Monitoring Station
PHIN: Public Health Information Network
PMN: Premanufacture notice
POTW: Publicly Owned Treatment Works

PPIS: Pesticide Product Information System
REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals
RfD: Reference dose
SDWA: Safe Drinking Water Act
SEER: Surveillance, Epidemiology and End Results
SIC: Standard Industrial Classification
SLAMS: State and Local Air Monitoring Stations
TSCA: Toxic Substances Control Act
TRI: Toxics Release Inventory
TWA: Time-weighted average
USGS: United States Geological Survey