

National Conversation on Public Health and Chemical Exposures

**Monitoring Work Group
Final Report
November 2010**

1 **I. Introduction**
2

3 The *National Conversation on Public Health and Chemical Exposures (National Conversation)* is a
4 collaborative project, supported by the Centers for Disease Control and Prevention (CDC) and the
5 Agency for Toxic Substances and Disease Registry (ATSDR). The *National Conversation* vision is that
6 chemicals are used and managed in ways that are safe and healthy for all people. The project’s goal is to
7 develop an action agenda with clear, achievable recommendations that can help government agencies and
8 other organizations strengthen their efforts to protect the public from harmful chemical exposures. The
9 *National Conversation* Leadership Council will author the action agenda, utilizing input from six project
10 work groups, and members of the public who choose to participate in Web dialogues and community
11 conversations.
12

13 *National Conversation* work groups were formed to research and make recommendations on the
14 following six cross-cutting public health and chemical exposures issues: monitoring, scientific
15 understanding, policies and practices, chemical emergencies, serving communities, and education and
16 communication. This report is the product of the Monitoring work group’s deliberations. While issued to
17 the *National Conversation* Leadership Council, the work group hopes that this report will be of value to
18 others in a position to act on the recommendations contained herein.¹
19

20 CDC and ATSDR worked with several groups to manage the *National Conversation*, including
21 RESOLVE, a nonprofit organization dedicated to advancing the effective use of consensus building in
22 public decision making, the American Public Health Association (APHA), the Association of State and
23 Territorial Health Officials (ASTHO), and the National Association of County and City Health Officials
24 (NACCHO). These organizations and others helped ensure that a broad range of groups and individuals
25 were engaged throughout this collaborative process, including government agencies, professional
26 organizations, tribal groups, community and non-profit organizations, health professionals, business and
27 industry leaders, and members of the public.
28

29 For more information on the *National Conversation* project, please visit
30 www.atsdr.cdc.gov/nationalconversation.
31
32

¹ This report was developed as part of the *National Conversation on Public Health and Chemical Exposures*. This is a voluntary, independent process involving multiple sectors, which was facilitated by RESOLVE, a neutral non-profit consensus building organization. This report represents the work of one of six *National Conversation* work groups and reflects the consensus of the work group members. Consensus is defined as each member being able to “live with” the report taken as a whole, rather than as agreement with each recommendation. Members were asked to participate as individuals, rather than on behalf of their organizations or constituencies. Recommendations for action are directed to a wide range of public and private actors, who have full latitude to consider them through the appropriate decision making procedures for implementing changes within their organization. While federal participants were involved with their agencies’ knowledge and provided important insights into the role of the federal government in addressing chemical exposures, their membership on the work group does not constitute agency endorsement of the recommendations. In particular, the role of work group chairs was to ensure that diverse perspectives were considered and that common ground was found rather than to take a position, particularly on issues that might be considered by their agency or organization. The Centers for Disease Control and Prevention’s National Center for Environmental Health and the Agency for Toxic Substances and Disease Registry provided funding for the facilitation, member travel, meetings, Web dialogues, community conversations, and other costs associated with the *National Conversation*. This report does not necessarily reflect the views of the Centers for Disease Control and Prevention, the Agency for Toxic Substances and Disease Registry, RESOLVE, or other organizations involved in the *National Conversation*.

33 **Work Group Charge, Scope, and Objectives**

34
35 The Monitoring work group was formed to address the ongoing collection, integration, analysis, and
36 interpretation of data about chemical use, exposure, and known and probably associated health outcomes
37 necessary for the prevention and control of adverse health outcomes related to chemical exposures.
38 Ongoing surveillance also provides an opportunity to evaluate the effectiveness of intervention strategies.
39 Many federal, state, and local government bodies currently collect relevant data. The Monitoring work
40 group was charged with analyzing current surveillance and data collection activities and recommending
41 actions to fill data gaps, better utilize existing data, and improve coordination among the many
42 organizations collecting relevant information. The work group addressed monitoring of chemicals in both
43 human tissues (biomonitoring) and environmental media, including soil, air, water, consumer products,
44 and in key built environments (e.g., schools and homes). In addition, the group addressed options for
45 better linking exposure information with health outcome data. (See Appendix A. “Monitoring Work
46 Group Final Charge.”)

47 48 *Framework for Discussion*

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

54 55 56 **Membership**

57
58 Work groups were formed in 2009 following an open nomination process. Work group members were
59 selected based on a three stage process designed to ensure that each work group would have the capacity
60 to address and reflect different perspectives.²

61
62 The skill sets and individual qualities the team chose to consider in selecting members for the Monitoring
63 work group were subject matter expertise (e.g., chemical use, environmental fate and transport,
64 biomonitoring, health surveillance, and statistics); expertise in various exposure settings and types (e.g.,
65 indoor and outdoor environments, industrial chemicals, consumer products, and pesticides); familiarity
66 with monitoring and surveillance systems; representation of those affected by exposure outcomes (e.g.,
67 community-based groups); those working to improve monitoring and surveillance systems (e.g., federal
68 agencies); and those with an understanding of privacy, ethical, and cultural issues related to data
69 collection. Furthermore, to achieve overall balance, the team sought to compose a diverse work group in
70 terms of sector, discipline, perspective, and geographic region.

71
72 John Balbus, M.D., M.P.H., senior advisor for public health, National Institute of Environmental Health
73 Sciences, chaired the Monitoring work group. Dr. Balbus was supported by Dr. Michael McGeehin,
74 CDC/ATSDR senior liaison to the Monitoring work group and director of the Division of Environmental
75 Hazards and Health Effects at CDC’s National Center for Environmental Health (NCEH); Kathy Grant, a
76 Senior Mediator at RESOLVE; and Jennifer Van Skiver, Management and Program Analyst at
77 CDC/ATSDR. Work group membership included 24 individuals with experience in the public, private,
78 and nonprofit sectors. (See Appendix B. “Monitoring Work Group Roster.”)

79
80

² For additional information on the work group member selection process, see
http://www.atsdr.cdc.gov/nationalconversation/docs/membership_selection_process_report.pdf.

81 **Subgroups**

82
83 The Monitoring work group worked in three subgroups, organized to address monitoring and surveillance
84 along a temporal continuum from chemical use to health impacts. The subgroups were formed to enable
85 focused discussion of each subgroup topic. Subgroup meetings were open to all Monitoring work group
86 members, discussion notes and draft work products were circulated to all Monitoring work group
87 members, and activities of each subgroup were discussed at general work group meetings.

88
89 Chemical Use and Release Subgroup

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

92
93 *Chemical Use and Release:* A broad examination of chemical use and release into the environment,
94 including disposal, is essential to address proactively environmental public health. Examination of
95 chemicals from the point of their use and release also is necessary for providing screening tools and for
96 assessing progress.

97
98 *Environmental Monitoring:* Monitoring of environmental media occurs through a variety of initiatives
99 carried out by local, state, and federal agencies. Knowing which chemicals are present in air, water, soil,
100 dust, food, and elsewhere is an important step in determining to which chemicals people are exposed and
101 how exposure might occur.

102
103 Exposure Levels Subgroup

104 The Exposure Levels, or Biomonitoring, subgroup focused on information generated by measuring
105 chemicals, their metabolites, or other markers of exposure in fluids or tissues of human beings.

106
107 Health Outcomes Subgroup

108 The Health Outcomes subgroup focused primarily on human health outcome surveillance, recognizing the
109 examination of human health outcomes as a critical component of monitoring. Surveillance of health
110 impacts is useful for tracking trends in health outcomes over time, identifying sentinel health outcomes,
111 identifying risk factors and other information important to targeting of interventions, generating
112 hypotheses that can then be used for research linking levels of exposure to specific health outcomes, and
113 program evaluation.

114
115
116 **Terms and Definitions**

117
118 *Biomarker of exposure*

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

123
124 *Biomonitoring*

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

127
128 *Concentration*

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

131

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

136
137 *Environmental public health surveillance*
138 Environmental public health surveillance is public health surveillance (ongoing, systematic collection,
139 analysis, and interpretation of outcome-specific data used to plan, implement, and evaluate public health
140 practice) of health effects integrated with surveillance of environmental exposures and hazards. Efforts in
141 environmental public health surveillance and this integration provide a strategic opportunity to link
142 environmental and health data on a local, state, and national level, thereby better equipping the public
143 health community to identify problems and effective solutions to reduce the burden of environment-
144 related health effects in the U.S. (CDC, 2009).

145
146 *Exposure*
147 For humans, the amount of a chemical, physical, or biological contaminant at the outer boundary of the
148 body available for exchange or intake via inhalation, ingestion, or skin or eye contact (EPA, 2008).

149
150 *Exposure assessment*
151 The process of finding out how people come into contact with a hazardous substance, how often and for
152 how long they are in contact with the substance, and how much of the substance they are in contact with
153 (ATSDR, 2009).

154
155 *Exposure level*
156 The amount of a chemical at the absorptive surfaces of an organism (EPA, 2006).

157
158 *Exposure pathway*
159 The route a substance takes from its source (where it began) to its end point (where it ends), and how
160 people can come into contact with (or get exposed to) it. An exposure pathway has five parts: a source of
161 contamination (such as an abandoned business); an environmental media and transport mechanism (such
162 as movement through groundwater); a point of exposure (such as a private well); a route of exposure
163 (eating, drinking, breathing, or touching), and a receptor population (people potentially or actually
164 exposed). When all five parts are present, the exposure pathway is termed a completed exposure pathway
165 (ATSDR, 2009).

166
167 *Health outcomes*
168 Documented change in health status using disease-specific measures. Data on health outcomes are
169 obtained from actively or passively collected data on clinical events and personal health and illness
170 experiences (e.g. vital records, reported illness, and health surveys).

171
172 *Monitoring*
173 Periodic or continuous surveillance or testing to determine the level of compliance with statutory
174 requirements and/or pollutant levels in various media or in humans, plants, and animals (EPA, 2006).

175
176 See also Appendix C. "Acronyms."

177
178 **Caveats and/or Limitations**

179
180 Given the wide scope of the Monitoring work group charge, it was not possible to address all areas in
181 depth. By splitting into subgroups, the work group's aim was to be as thorough as possible while still
182 addressing the range of topics falling within the work group's purview. The work group also attempted to

183 bring forward the range of ideas presented during subgroup discussions. This report represents a synthesis
184 of the key information and overarching recommendations discussed by the work group.
185

186

187 **II. Current Status of Issues under Consideration**

188

189 The current status of the nation's knowledge of chemical use, environmental concentrations, levels within
190 humans and other species, and consequent health effects can best be characterized as partial, uneven and
191 minimally integrated. There are numerous data sources for all categories, which vary in terms of
192 accuracy, comprehensiveness, and usefulness of information. This section characterizes the major
193 elements of the nation's chemical management systems that relate to understanding chemical sources,
194 use, exposures, and health effects in the US population. The strengths and limitations are discussed for
195 each category of monitoring and surveillance information, and barriers and challenges to a better
196 functioning set of systems explored.

197

198

199 **Chemical Use and Release**

200

201 Major Components of Chemical Use and Release Monitoring

202

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

208

209 *TSCA Chemical Substance Inventory*

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

215

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

224

225 *Pesticide Product Information System*

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

230

231 *Toxics Release Inventory*

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

235

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

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

243

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

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

252

253 *National Emissions Inventory*

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

259

260 *National Pollutant Discharge Elimination System*

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

264

265 Strengths and Limitations of Chemical Use and Release Monitoring

266

267 Public access to data on chemical use and release is relatively high in the United States compared to other
268 countries. In addition to informing individuals and communities about their potential risks, it has been
269 suggested that the requirement of public disclosure of information on chemical use and toxic substance
270 release has contributed to voluntary actions on the part of industries to limit the production and release of
271 hazardous substances (Karkkainen, 2001; Stephan, 2002). While it is difficult to document decisions
272 made by companies based on TSCA provisions, the TRI database has been cited as a success.³

273

274 Despite these successes, however, there are many recognized limitations to the ways chemical use and
275 release data are collected in the United States. First, there is no single system that tracks all potentially
276 harmful chemical substances; instead, information is split among a number of different systems created
277 by different statutes, e.g., for pesticides, substances in food, cosmetics, pharmaceuticals, and industrial

³ 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.

278 chemicals. In fact, only chemicals not covered by any other statute may be covered under the Toxic
279 Substance Control Act.⁴ This makes understanding cumulative exposures more challenging, as the
280 information on potential chemical exposures is fragmented by the different statutory systems. Second, the
281 data obtained on chemical uses is insufficient to understand potential exposures to the extent necessary to
282 protect the public. For example, the information provided on potential children’s exposure under EPA’s
283 Inventory Update Rule does not include the potential for children to be exposed in homes through the use
284 of chemicals by their parents; it only asks for chemicals in products intended for use by children
285 themselves to be identified (EPA, 2008c). Third, much of the information requested on chemical use is
286 unavailable to the public and often to the government itself because of the invocation of Confidential
287 Business Information (CBI) claims or assertions of information not being reasonable obtainable. The EPA
288 has recently taken measures to reduce the use of CBI claims by requiring companies to better justify the
289 need for such privileges.⁵

290

291 **Environmental Monitoring**

292

293 Major Components of Environmental Monitoring

294

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

304

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

306

307 *EPA’s National Contaminant Occurrence Database*

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

320

⁴ See <http://www.epa.gov/oppt/newchems/pubs/invntory.htm> for more information on the TSCA Chemical Substance Inventory.

⁵ 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>.

321 *EPA's Ambient Air Monitoring Networks*

322 Ambient monitoring data obtained from EPA's monitoring systems are used to develop and determine
323 compliance with the National Ambient Air Quality Standards (NAAQS), characterize air quality trends,
324 develop emission control strategies, and support research on health effects of air pollution. Since the
325 1970s, ambient air quality data have come from State and Local Air Monitoring Stations (SLAMS).
326 SLAMS monitor all criteria pollutants, namely, sulfur dioxide [SO₂], nitrogen dioxide [NO₂], carbon
327 monoxide [CO], ozone [O₃], lead [Pb], and particulate matter ([PM_{2.5}] and [PM₁₀]). These stations use
328 Federal Reference Methods (FRMs) or Federal Equivalent Methods (FEMs) for direct comparison to the
329 NAAQS, which leads to areas being designated in attainment or non-attainment of a standard. At the end
330 of 2007, there were approximately 947 FRM/FEM filter-based monitors and 591 continuous measurement
331 monitors making PM_{2.5} mass measurements. Further, there were approximately 943 PM₁₀ monitors, 1216
332 O₃ analyzers, 389 CO analyzers, 519 SO₂ analyzers, 422 NO₂ analyzers, and 172 Pb monitors (EPA,
333 2008d). Despite these numbers, significant temporal and spatial gaps remain in criteria pollutant
334 monitoring across the US. For example, monitors are generally placed away from important sources of
335 pollution, such as major roadways, and so may not capture actual exposures of significant populations.
336

337 In addition to SLAMS networks, the Photochemical Assessment Monitoring Station (PAMS) network
338 was developed and implemented in the mid-1990s to measure ozone precursors such as volatile organic
339 compounds, nitrogen oxides [NO_x], and reactive nitrogen species. The PAMS network consists of 78 sites
340 in areas that are classified as serious ozone non-attainment areas. As part of the PM_{2.5} NAAQS review
341 completed in 1997, EPA established a PM_{2.5} Chemical Speciation Network (CSN) for routine speciation
342 monitoring of particulate matter. There are approximately 210 CSN sites collecting data on PM_{2.5} mass,
343 trace elements, major ions (sulfates, nitrates, and ammonium), and organic and elemental carbon
344 fractions. The Interagency Monitoring of Protected Visual Environments (IMPROVE) network was
345 established in 1985 to monitor PM_{2.5} levels in national parks and wilderness areas (EPA, 2008d). The
346 IMPROVE network presently comprises of 110 regionally representative monitoring sites, and some sites
347 that operate collaboratively with the CSN. For air toxics (also known as hazardous air pollutants [HAPs]),
348 EPA's monitoring efforts include National Air Toxics Trends Stations (NATTS), funding existing state
349 and local monitoring of air toxics, and community-scale projects to assess conditions at the local level.
350 EPA's recent strategy is to focus on multi-pollutant monitoring and the Agency has recently implemented
351 the National Core (NCORE) Network. NCORE integrates several advanced measurement systems for
352 particles, pollutant gases and meteorology. NCORE stations will be fully operational by January 2011 with
353 82 monitors covering urban (62 sites) and rural areas (20 sites) (EPA, 2008d).
354

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

356 The Total Diet Study, also called the market basket study, is an FDA program that studies various
357 contaminants and nutrients in foods consumed by the U.S. population. The Total Diet Study assesses key
358 members of the following analyte groups: pesticides, industrial chemicals, elements, radionuclides, and
359 moisture (FDA, 2009).
360

361 *US Geological Survey (USGS) Water Quality Monitoring*

362 The USGS provides information on the nation's water quantity and quality from programs that comprise
363 the largest ambient water monitoring activity in the nation, information on the effects and exposure of
364 environmental contaminants to the nation's living resources, particularly those under the stewardship of
365 the Department of the Interior, and information on the environmental health implications of development
366 of energy and mineral resources. The information provides a scientific basis for decisions by resource
367 managers, regulators, industry and the public.
368

369 The National Water Quality Assessment (NAWQA) Program assesses pesticides, volatile organic
370 compounds, nutrients and trace elements in the nation's ground water and surface water. Information on
371 the quality of source and finished drinking water and the water quality of domestic wells is collected as

372 well. The Toxic Substances Hydrology Program develops methods to assess new and under-studied
373 environmental contaminants and augments NAWQA Program assessments.⁶

374
375 Strengths and Limitations of Environmental Monitoring

376
377 Environmental monitoring provides data for use by resource managers, regulators, industry and the
378 public. These data are used for evaluating potential regulations related to chemical registration, use, and
379 release to the environment, and development of new environmental quality standards. Still, despite the
380 large number of programs and the wealth of data collected, there is a lack of systematic data collection
381 that can be readily used to characterize and fully assess human exposure to chemicals or other agents at
382 the community or national level. A major limitation of the United States' current environmental
383 monitoring system is that both monitoring of environmental media and the collection of necessary
384 ancillary information are incomplete, fragmented and often not collected frequently enough for useful
385 interpretation.

386
387 Enhanced cross-agency integration of existing efforts and collaboration on future activities would
388 increase information value far above that of studies conducted in isolation. For example, linking existing
389 time activity programs such as the American Time Use Survey (ATUS), which is conducted by the
390 Bureau of Labor Statistics in the Department of Labor, to existing environmental monitoring programs
391 conducted by the EPA, USGS and other agencies, could provide far more useful information than either
392 activity alone. Cooperation from the Bureau of Labor Statistics would be needed to expand the
393 information collected in the ATUS to make it more relevant for environmental exposures. Together, they
394 could provide a basis for estimating human exposure based upon a better knowledge of contact with the
395 monitored media and, if appropriate information is collected, identification of potential sources of
396 exposure. The integrated information provides a greater ability to reduce exposures, if warranted, by
397 understanding the key factors contributing to exposure. The types of ancillary information needed to place
398 monitoring data into an exposure context include information on how and where people spend their time
399 (time-activity studies), occupation, product use patterns, food consumption patterns, and indoor
400 environment characteristics (i.e., room size, ventilation). The relative importance of each of these types of
401 information will vary based upon the substances being monitored, and this should be considered in study
402 design.⁷

403
404 Along with the lack of interconnectedness among monitoring programs for various environmental media,
405 there are unique challenges associated with monitoring efforts for specific media. A major limitation of
406 water monitoring programs, for example, is the difficulty of measuring numerous new chemicals that are
407 used each year while keeping track of traditional environmental contaminants. While bioassays that assess
408 the overall biological activity of a water sample rather than a concentration of a specific chemical show
409 potential as screening tools, chemical-specific identification will inevitably be required to identify, and
410 track the performance of, remedial actions.

411
412 In addition, there is a particular lack of data on exposure in the indoor environments that constitute the
413 location of occupancy for over 90% of the time for many individuals (EPA, 2010g). For example, the
414 most current data on human exposures in the workplace are 30 years old, resulting in a severely
415 compromised understanding of risks related to occupational exposures. The National Institute for

⁶ 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>.

⁷ 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.

416 Occupational Safety and Health (NIOSH) could address this weakness by conducting nationally
417 representative surveys of workplaces across all industries. While a limited number of programs have
418 collected environmental data to obtain distributions of chemicals in multimedia samples in indoor
419 environments (e.g., the Department of Housing and Urban Development (HUD) has conducted
420 monitoring in homes and other environments, often in collaboration with other agencies, such as EPA and
421 the Consumer Product Safety Commission [CPSC]⁸), there are no systematic indoor surveillance
422 programs. This is also an issue of critical importance for children, who spend much of their time in child
423 care, pre-school, and school environments, which also are not systematically monitored.
424

425

426 **Biomonitoring**

427

428 Major Components of Biomonitoring

429

430 Human exposure to naturally-occurring and manufactured chemicals has long been a concern to the
431 general public, health professionals and policy makers. Potentially harmful chemicals may be present in
432 food, water, soil, air and consumer products. Measuring levels of chemicals in the environment helps
433 scientists and policy makers understand the magnitude and distribution of potential problems, but these
434 measurements are not always predictive of how much of a chemical has been absorbed or who may be
435 most affected by this exposure. Biomonitoring provides a precise measure of the concentration of a
436 chemical in a specific body fluid or in exhaled air. Thus, biomonitoring measurements reflect an
437 individual's exposures to a specific chemical or set of related chemicals from all sources, and can help
438 identify groups of people who may be more or less exposed to a given chemical.
439

440

440 *CDC's National Biomonitoring Program*

441 For at least three decades, scientists at CDC's Environmental Health Laboratory have been undertaking
442 efforts to determine which environmental chemicals are of high priority and measuring the levels of these
443 chemicals in a representative sample of the civilian, noninstitutionalized U.S. population ages six and
444 older. The *Fourth National Report on Human Exposure to Environmental Chemicals* includes exposure
445 data for 212 chemicals and chemical metabolites in a sample of about 2400 participants obtained from the
446 National Health and Nutrition Examination Survey (NHANES), which represents the U.S. civilian,
447 noninstitutionalized population over the age of five (CDC, 2010a).
448

449

449 *States and Biomonitoring*

450 State health departments use biomonitoring to support environmental exposure investigations and help
451 address concerns regarding environmental exposures that might be unique to their state. For example,
452 uranium occurs naturally in ground water throughout the Rocky Mountains as well as in South Carolina,
453 Connecticut, and other eastern states. Because CDC cannot address all of the environmental exposures in
454 each state, the agency provides competitive funding to help states build their own biomonitoring
455 capability.⁹
456

457

457 *Other Large-Scale Biomonitoring Efforts*

458 Other countries and consortia of national programs have carried out biomonitoring surveys in the past,
459 though these have usually been restricted to one class of chemicals at a time (e.g., metals). Two large-

⁸ 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>.

⁹ 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.

460 scale national biomonitoring efforts are ongoing: the *German Environmental Surveys I-IV* and the recent
461 *2010 Report on Human Biomonitoring of Environmental Chemicals* from Statistics Canada and Health
462 Canada. Several other nations are planning to build biomonitoring programs.

463

464 *Biomonitoring and Research*

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

470

471 *Impact and Applications*

472 Biomonitoring data have increased awareness of the incidence and magnitude of chemical exposures for
473 the public, for scientists, and for decision makers. Biomonitoring has played a prominent role in
474 documenting the effectiveness of regulatory interventions, and in some cases has contributed to chemical
475 management actions because of alarming or surprising results. One notable example of the former is lead.
476 Since the late 1970s, the blood lead levels for children aged 1-5 years old have declined over 90%
477 because of the removal of lead from gasoline and paint (CDC, 2008). Similarly, NHANES data have
478 documented reductions in human levels of DDT, organochlorine pesticides, lead, environmental tobacco
479 smoke. Biomonitoring has demonstrated near-ubiquitous exposure to certain phthalates, such as
480 diethylphthalate (DEP), diethylhexylphthalate (DEHP), dibutylphthalate (DBP), and benzylbutylphthalate
481 (BBP), with higher levels in women of childbearing age and young children (Blount et al., 2000; Silva et
482 al., 2004). These findings from biomonitoring, in conjunction with growing concerns about reproductive
483 and developmental toxicity of those same compounds, were part of the justification for the development
484 of EPA's action plan on phthalates¹⁰ and preceded federal (i.e., Consumer Product Safety Improvement
485 Act §108) and state (i.e., California Assembly Bill 1108) legislation banning or restricting the use of these
486 same compounds in products for children. Similarly, demonstration of increasing levels of
487 polybrominated diphenyl ethers and widespread exposures to bisphenol A has helped motivate state,
488 federal, and international actions to reduce exposure to these chemicals.

489

490 Biomonitoring is generally more useful for chemicals that persist for a long time in the body, like DDT
491 (dichlorodiphenyltrichloroethane) and lead. However, such sampling cannot as a rule distinguish various
492 historical exposure scenarios (i.e., one cannot tell whether the lead exposure was a week ago, a year ago,
493 or a decade ago based on a blood level alone- ancillary information is necessary). One particularly useful
494 application of biomonitoring is in the workplace, where exposure data are more readily obtained. For
495 example, under the occupational health standard for inorganic lead, a program of biological monitoring
496 and medical surveillance is to be made available to all employees exposed to lead above the action level
497 of 30 ug/m(3) TWA for more than 30 days each year. This program consists of periodic blood sampling
498 and medical evaluation to be performed on a schedule which is defined by previous laboratory results,
499 worker complaints or concerns, and the clinical assessment of the examining physician. It allows for
500 workers to be removed from exposure when their blood levels exceed a given threshold.¹¹

501

502 Biomonitoring may also be useful for chemicals with shorter half-lives when exposure to those chemicals
503 is sufficiently widespread and frequent (or continuous) that a random sample is likely to find that
504 chemical or its metabolites at concentrations reflective of overall population or individual levels. It may
505 also be helpful for short-lived chemicals if sampling can be appropriately coordinated with exposure (e.g.,
506 end of shift workplace monitoring). Biomonitoring may be particularly useful when there are multiple

¹⁰ See www.epa.gov/oppt/existingchemicals/.../phthalates_ap_2009_1230_final.pdf.

¹¹ 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.

507 pathways of exposure (air, food, water, etc.), as it allows a picture of overall intake to be obtained. This
508 has been the case for some of the phthalate chemicals mentioned above.

509

510 Strengths and Limitations of Biomonitoring

511

512 Biomonitoring provides a direct measurement of the internalized dose of a chemical and may, for many
513 chemicals, reduce the uncertainty associated with other methods of assessing exposure, such as activity
514 questionnaires and modeled estimates based on measurements of environmental media like ambient air
515 and drinking water. A strength of biomonitoring is that it measures the dose delivered from all routes of
516 exposure (i.e., air, water, food, soil). Often people are exposed through multiple routes. For example,
517 children who live in older homes may eat paint containing lead that is peeling off the walls; they may
518 breathe or eat lead from paint that has been ground or eroded into fine particles and mingled with the dust
519 in the house or soil surrounding the house; and they may drink lead in their water if their plumbing
520 contains lead. All of these exposures would be captured in a child's blood lead level. On the other hand,
521 to estimate this cumulative exposure using environmental monitoring, one would need to take samples of
522 the air, paint, dust and water, run separate tests on each sample, and then enter those results into a
523 mathematical model to estimate the internal dose. Biomonitoring also provides a way to assess combined
524 environmental and occupational exposures.

525

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

532

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

542

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

547

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

552

553 Also, for most biomonitored chemicals, the interpretation of test results is a major challenge. Because of
554 inadequate scientific understanding of the extent to which measured concentrations of chemicals in blood
555 and urine are associated with, let alone predictive of health effects, biomonitoring at present can often
556 only provide insight into exposures without giving individuals and policy makers useful information on
557 the likelihood of specific health effects. Well designed research studies that take into account important

558 co-factors such as physiologic state, pharmacokinetic variation, diet, nutrition, and underlying health-
559 related disorders are needed to help better understand the connections between biomonitored chemical
560 concentrations and health effects.

561
562 Biomonitored levels of chemicals in the absence of other exposure-related information usually cannot
563 indicate where (location) a person was exposed, the duration or frequency of exposure, the route of
564 exposure (oral, inhaled, dermal), or the source of the exposure. Other information should be used together
565 with the biomonitoring data to make risk assessment and policy decisions. For non-persistent chemicals
566 that may produce effects due to prolonged exposure, many biomonitored levels during the exposure
567 period would be required to estimate long term risk most accurately. For persistent chemicals in the body,
568 single measurements can be a good indicator of body burden.

569
570 Currently, technology, history, and concerns for suspected toxic chemicals are driving the selection of
571 chemicals that are biomonitored. It is likely that additional, unmeasured chemicals have entered the
572 environment and human's bodies. Rational future selection of chemicals to biomonitor will be limited by
573 the level of understanding of toxicity of the broader range of chemicals and by the amount of information
574 available on the release of chemicals into the environment and uses of chemicals.

575
576 Standardization of biomonitoring practices and methods is often lacking, compromising the reliability and
577 comparability of data from different studies. For example, in individual biomonitoring testing,
578 standardization of collection timing with respect to timing, duration and frequency of the exposure is
579 extremely important to avoid biasing the results and subsequent assessments, particularly in smaller
580 samples in which such bias may be more prominent. Different instruments or analytical methods often
581 make it difficult to generate accurate and reproducible results across different studies. CDC and many
582 state public health laboratories are working together to standardize methods, calibrator materials, and
583 quality assurance procedures to assure better comparability of biomonitoring data.

584
585

586 **Health Outcomes**

587

588 Major Components of Health Outcomes Monitoring

589

590 Ongoing monitoring of health status, health outcomes, and health conditions associated with chemical
591 exposures in the United States occurs at the federal, state and local levels. At all levels, technological
592 advancements have improved the timeliness of data and its accessibility, increased the ability to use
593 geographic information, and led to more timely release of health reports and micro-data. Partnerships
594 between federal, state and local public health officials have built on these advances to develop more
595 coordinated systems for monitoring data from diverse sources for specific locations (e.g., CDC's
596 Environmental Health Tracking program¹² and the HHS Community Health Data Initiative¹³).

597

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

¹² See <http://www.cdc.gov/nceh/tracking> for more information on CDC's Environmental Public Health Tracking program.

¹³ See http://www.cdc.gov/nchs/data_access/chdi.htm for more information on the Community Health Data Initiative.

603 sets for environmental health assessment, as most data sets are collected for other purposes. Relevant
604 examples of health outcomes data systems are described below.

605

606 *Reportable Conditions and Other Ongoing State Reporting Systems*

607 Health outcome monitoring at the state and local levels through case reporting is based on the legal
608 mandates states have for requiring reporting of individuals with selected health conditions. Case-based
609 surveillance is well established for communicable diseases and cancer. Currently only a limited number
610 of health conditions related to chemical exposures are reportable in more than one state. They include
611 poisonings and laboratory test results related to several heavy metals (lead, mercury, cadmium, arsenic),
612 pesticide poisoning, carbon monoxide poisoning, pneumoconiosis, chemical pneumonitis, and other
613 chemical poisonings. Only three of these conditions are reportable in 50% or more of the states (lead
614 poisoning/elevated blood lead, pesticides, and silicosis – one of the types of pneumoconiosis). Several
615 other conditions that have been made reportable by states are of interest to environmental public health
616 surveillance because of their possible links to chemical exposures. These include cancer, autism,
617 Parkinson’s disease, asthma, and birth defects; although cancer is reportable in almost all states, the other
618 four conditions are reportable in relatively few.¹⁴

619

620 Ongoing monitoring using health data systems other than conditions reportable at the state level includes
621 use of vital records, state hospital discharge data systems (available in most states), emergency
622 department data (available in some states), birth defects registries¹⁵ (funded by CDC in nine states), the
623 Behavioral Risk Factor Surveillance Survey (BRFSS) survey, cancer registry data (all states), and others.

624

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

628

629 *CDC’s National Vital Statistics System*

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

636

637 *Large National Health Surveys*

638 Large national health surveys, including the National Health Interview Survey¹⁶ and the National Health
639 and Nutrition Examination Survey (NHANES)¹⁷ collect a wide variety of information on health and
640 health-related behaviors. These surveys have the advantage of relatively large sample sizes, information
641 for small population subgroups, and consistency over time to monitor health trends. On the other hand,
642 they are not designed to provide local information and are in fact prohibited from doing so to protect
643 participant’s confidentiality and avoid disclosure risks. There are also some local surveys modeled after
644 the national surveys, such as the California Health Interview Survey and the New York City Community

¹⁴ 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/ta/bid/261/Default.aspx>

¹⁵ See <http://www.cdc.gov/ncbddd/bd/monitoring.htm> for more information on birth defects monitoring.

¹⁶ See <http://www.cdc.gov/nchs/nhis.htm> for more information on the National Health Interview Survey.

¹⁷ See <http://www.cdc.gov/nchs/nhanes.htm> for more information on NHANES.

645 HANES.¹⁸ These, however, can be limited in their time frame and sample sizes, and they represent large,
646 rather than local, areas.

647

648 *The Behavioral Risk Factor Surveillance Survey (BRFSS)*

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

652

653 Outcomes and events from administrative records are also used in several ways at the national level.
654 Medical records with information on diagnosis and treatment of disease are sampled via National Health
655 Care Surveys¹⁹ and aggregated via the Healthcare Cost and Utilization Project.²⁰ Other claims-based data
656 systems such as the Medicare claims data²¹ could be used to monitor specific health outcomes. Other
657 sources, such as data files maintained by large insurance companies or emergency departments may be
658 available for some purposes. Cancer incidence data are collected nationally through the system of
659 state/regional/local cancer registries. Some of these registries participate in the federally funded
660 Surveillance, Epidemiology and End Results (SEER) program and collect additional in-depth information
661 on cancer incidence, prevalence and survival from specific geographic areas representing 26 percent of
662 the U.S. population (National Institutes of Health, 2010).

663

664 *Environmental Public Health Tracking*

665 The Environmental Public Health Tracking²² (EPHT) network is the only large-scale health surveillance
666 system dedicated to monitoring the health impacts of chemicals. EPHT is a network of 23 states and
667 CDC's National Center for Environmental Health dedicated to developing surveillance data systems
668 linking hazard, exposure, and health outcomes data in a way that is useful to the public, public health
669 professionals, and researchers concerned about the impact of chemicals on human health. In its
670 development over the last eight years, CDC and participating state health departments have had to address
671 numerous complex issues including data access, data standardization, and information technology
672 challenges to making the data publicly available in a uniform format.

673

674 *National Poison Data System (NPDS)*

675 Regional poison centers are set up for the entire United States to respond to calls from the public and
676 health professionals about chemical poisonings by providing expert information and treatment guidelines.
677 All but one of the poison centers send their data real time for uploading to a national poison center
678 database and analysis system called the "National Poison Data System." Data are collected from over
679 4,000,000 calls annually, including demographic and clinical data on individuals exposed or poisoned.

680

681 *National Children's Study*

682 The National Children's Study²³ will be collecting a large amount of information, including health
683 outcomes and environmental exposures, for a large, nationally representative sample of children in the
684 United States over many years.

685

¹⁸ 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.

¹⁹ See <http://www.cdc.gov/nchs/nhcs.htm> for more information on National Health Care Surveys.

²⁰ See <http://www.ahrq.gov/data/hcup> for more information on the Healthcare Cost and Utilization Project.

²¹ See http://www.cms.gov/PrevntionGenInfo/20_prevserv.asp for more information on Medicare claims data.

²² Current EPHT data are available at <http://www.cdc.gov/nceh/tracking>.

²³ Learn more about the National Children's Study at <http://www.nationalchildrensstudy.gov>.

686 *Community Health Data Initiative*
687 Government and non-governmental organizations have partnered to establish the Community Health Data
688 Initiative (CHDI). CHDI is a network of suppliers and demanders of community health data, indicators,
689 and interventions, convened to improve Americans' knowledge of health and health care system
690 performance. The HHS Health Indicators Warehouse, currently under development, will serve as the data
691 hub for the initiative.²⁴ Although the CHDI is not specifically designed to monitor health outcomes
692 known and possibly related to chemical exposures, the emphasis on local information may enhance the
693 ability to monitor these health outcomes in local communities. Further, the system does not preclude the
694 inclusion of locally defined exposure values, facilitating the examination of possible exposure-outcome
695 trends and relationships.²⁵

696 Strengths and Limitations of Health Outcomes Monitoring

697 Existing data on health outcomes offer several advantages for improved monitoring of the health
698 outcomes associated with chemical exposures. The large, national health surveys and administrative data
699 collections can provide comparable information across the whole U.S., providing benchmarks and
700 facilitating comparisons across large geographic regions (and even countries). Large surveys and
701 administrative data collections can also provide statistically valid health information for subgroups
702 defined by demographic characteristics, including measures of race, ethnicity, and socio-economic status.
703 Ongoing, systematically maintained, data collections provide information about trends, which can
704 facilitate the identification of new environmental causes of adverse health outcomes. For less common
705 health outcomes or for understanding trends in local areas, notifiable disease reporting efforts offer useful
706 information.

707
708
709
710 Despite these strengths, many of the health data systems described above remain limited in their ability to
711 provide useful information on chemically-related health outcomes for a number of reasons. First, health
712 effects associated with chemicals are often non-specific and could be caused not only by a number of
713 different chemicals, but also by other factors. Thus, information on conditions like cancer, asthma, or
714 adverse birth outcomes may be relevant to chemical exposures but requires extensive additional
715 information on exposures and other individual factors in order to shed light on possible chemical
716 causation. Second, there is often a long lag period, or delay, between the time of chemical exposure and
717 the development of obvious adverse health outcomes. This complicates matching specific chemicals to
718 observed health outcomes. Finally, the scientific relationship between adverse health outcomes and
719 specific chemical exposures is poorly understood for the vast majority of chemicals.

720
721 Because chemical exposures often occur on a local scale, local health outcomes data are needed for
722 detection and monitoring of potential health impacts. Health outcome information from national surveys,
723 however, is not collected in all areas. Moreover, local health outcome information obtained from surveys
724 and other national data sets may not be available at the local level in order to protect individual privacy.
725 Furthermore, health outcome information for local areas generally is limited by small numbers of events
726 which make it harder to achieve statistical significance and support definitive scientific inferences.

727
728 Smaller systems that rely on case reporting are also limited by the many causes of under-reporting, which
729 include access to care, physician recognition of chemical causes of disease, and other barriers to physician
730 reporting of cases.

731
732

²⁴ See http://www.cdc.gov/nchs/data_access/chdi.htm for more information on the Community Health Data Initiative.

²⁵ See also <http://www.hhs.gov/open/datasets/about.html>.

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 with valid sampling and analytical methods, 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. These 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 incorporating sound, comparable data quality practices, 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 data compilation 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 could be set by a group 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 compilation would include 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.

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

793
794 Because of children's unique susceptibility to chemical toxicity during critical windows of development,
795 as well as their unique environments and exposure pathways (e.g., umbilical cord, hand-to-mouth
796 behaviors, breast milk, etc.), monitoring children's exposures is a top priority. Children's unique
797 "workplaces", such as daycare centers and schools, would need to receive special attention as well as
798 exposures that arise in utero.

799
800 Data compilation activities should balance the need for representative data with the need to obtain
801 localized and/or individual-level data. This will allow analysis of local exposure patterns and address
802 specific community concerns yet still facilitate individual-level epidemiological studies and thus avoid the
803 limitations intrinsic to ecological study designs. Exposure data collection should ideally be coordinated
804 with health outcome and/or biomonitoring data on the same individual.

805
806 As with prioritization, an inter-agency team that includes subject experts and state and local partners
807 should establish guidance to ensure compatibility and comparability of data. Technical limitations,
808 differences among media, and other factors may make complete compatibility impossible in some
809 instances, but the need to better understand aggregate exposures across multiple media and exposure
810 pathways would argue strongly for coordination of methods whenever feasible. Environmental and
811 biomonitoring programs in particular should be coordinated to ensure that priority chemicals are being
812 monitored in both programs and that the data are being interpreted jointly to identify and confirm linkages
813 and trends among environmental levels, exposures, and ultimately health outcomes.

814
815 Information should be made publicly available in a useful manner. Transparency is important, and thus
816 the availability of raw data will be important in most circumstances. However, raw data are not
817 necessarily useful information, and so agencies must provide appropriate interpretation of the available
818 data within the limits of available knowledge. The data/information should be provided via an integrated
819 data source. While this could be a single, large database, differential database needs and historical
820 circumstances will probably make a single database difficult to achieve and maintain. Thus, it is more
821 likely that a public-friendly "front-end" web-based resource to coordinate access to key underlying data
822 will be needed to support access needs. There should also be an increased commitment to partnering with
823 academic institutions and community-based groups, to ensure that government-based chemical risk
824 management programs will be well integrated into broader public discussions and decision-making about
825 human and ecosystem health.

826
827 Obtaining optimal data utility will require access to information that may be personally confidential
828 (medical information protected under HIPAA for example) or confidential business information. This
829 includes the use of data obtained from electronic medical records, which are likely to be an increasingly
830 important source of health outcome data. Data may also carry risks to individuals and communities,
831 including individuals on whom data may not have been directly collected (i.e., localized pollution or
832 localized health issues, even if not causally linked with reasonable certainty, may devalue property or
833 raise significant anxiety, etc.). Thus, the development of a comprehensive national monitoring program
834 must be accompanied by a discussion regarding bioethical issues, and successful deployment of the

835 program may require modifications of existing regulations and/or the establishment of practices such as
836 informed consent. Ultimately, success will likely require a delicate balance between the public good and
837 individual concerns, as is generally the case in public health.

838
839

840 **IV. Action Recommendations**

841

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

843

844 **(a) Increase the frequency of manufacturing volume reporting required under the Toxic 845 Substances Control Act Inventory Update Rule and require more extensive information on 846 downstream uses.**

847

848 Currently, the Toxic Substances Control Act (TSCA) inventory is updated once every five years. While
849 the amount of use and potential exposure information was expanded in 2006, there are still significant
850 limitations to this information: first, it only reflects one year out of the five year cycle of reporting, so
851 significant fluctuations in production volumes from year to year are missed; second, it only requires
852 information on production volumes, uses, and potential exposures to children be submitted if such
853 information is "readily obtainable" – with no penalty for failing to submit such information if the
854 company claims it is not readily obtainable. The European Union Registration Evaluation, Authorisation
855 and Restriction of Chemicals (REACH) program requires that manufacturers of chemicals provide
856 downstream users with information on chemical hazards for specific exposure scenarios; downstream
857 users whose uses are not covered by those exposure scenarios must either notify the upstream supplier of
858 their use or provide their own analysis of potential risks to their customers.²⁶ In general, REACH is
859 designed to increase communication on hazards and uses both up and down the supply chain.

860

861 The work group therefore recommends improvements to TSCA's Inventory Update Rule (IUR). This
862 could be accomplished by increasing the frequency of reporting from every five to every 1 or 2 years;
863 requiring greater substantiation of claims of "not readily obtainable" information; and providing clear
864 guidance as to those circumstances under which a claim of "not readily obtainable"²⁷ would be accepted.

865

866 **(b) Address Toxics Release Inventory shortcomings; provide more information on short-term 867 releases.**

868

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

876

²⁶ 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

²⁷ 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.

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

Federal agencies²⁸ 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. Special consideration should be given to the implementation of ongoing, routine surveillance of exposures in the work environments, since chemical occupational exposures have historically been seen at significantly higher levels than those found in the ambient environment.

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 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.

²⁸ Relevant federal agencies include but are not limited to 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 Occupational Safety and Health Administration (OSHA), the U.S. Consumer Product Safety Commission (CPSC), U.S. Department of Energy (DOE), and the National Institutes of Health (NIH)

922 In order to fill this gap and address community needs, the U.S. needs a state-based, national
923 biomonitoring network of laboratories and public health agencies. The Association of Public Health
924 Laboratories (APHL) has a five-year plan²⁹ to develop a laboratory network and is working with its
925 membership as well as that of the Council of State and Territorial Epidemiologists (CSTE) and
926 Association of State and Territorial Health Officials (ASTHO) to create guidelines for any state or local
927 jurisdiction who chooses to participate in what will be called the National Biomonitoring System.

928
929 Recognizing limited resources, this System should not aim to build capacity in every locality to measure
930 every chemical exposure; however, the network should help localities connect with each other to leverage
931 existing capacity. For an example of such an effort, see the biomonitoring database being developed by
932 APHL to link laboratories with epidemiologists with policymakers and academics to encourage
933 collaboration.

934
935 The ultimate goal would be to at least have the capacity to measure each chemical of concern somewhere
936 in the nation. Because methods only exist for a few hundred of the more than 3,000 chemicals used in
937 high volume in the U.S.,³⁰ new laboratory methods and capacity to measure high production volume
938 chemicals locally are needed. It is important to note that in jurisdictions where authorities anticipate an
939 ongoing need to biomonitor a population (for example in jurisdictions doing surveillance studies),
940 redundancies in capacity and capability are encouraged. For example, every state should be able to
941 measure blood lead levels in children. Where appropriate non-invasive sample collection technology is
942 available, biomonitoring studies should be expanded to include children of all age groups.

943
944 Systemization will allow standardization of biomonitoring study design, sample collection and analysis,
945 data analysis and comparability, as well as interpretation. Concurrently, legal and financial
946 recommendations will be needed to allow different jurisdictional authorities to take advantage of the
947 network.

948
949 One important action that can be taken quickly (within 1-2 years) is to build carefully designed and well
950 managed human sample banks (blood, milk, tissues such as placenta) and environmental sample banks
951 (fish, tree barks, etc.). These banks will be very helpful in (1) establishing chronology of pollution, (2)
952 identifying new pollutants, (3) tracing back to sources, (4) archiving samples for future analysis with
953 better technology than we have today, (5) exploring regional differences, and (6) carrying out longitudinal
954 studies.

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957 **4. Expand Health Outcome Surveillance**

958 959 **(a) Expand national data surveys to over-sample vulnerable populations and high priority** 960 **geographic regions.**

961
962 Expanding national data surveys and other data collections will allow for better capabilities to understand
963 the variability in health outcomes known and possibly related to chemical exposures across the United
964 States; designing these collections to over-sample specific subgroups will enable better identification of
965 vulnerable populations defined by demographic and socioeconomic indicators. Larger annual sample
966 sizes will reduce the need to combine multiple years of data for accurate estimates, providing better
967 information on current status and trends. Consideration of high priority geographic regions or areas could

²⁹ More information on APHL's National Biomonitoring Plan is available at
<http://www.aphl.org/aphlprograms/eh/Pages/nationalbioplan.aspx>.

³⁰ 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>.

968 be considered as a domain in sampling design. This would require statistical research to establish
969 feasibility, implications, and cost considerations. The success of this recommendation would be tracked
970 by broadened use of the data for providing timely estimates for geographic and population subgroups.
971

972 **(b) Expand reportable conditions to other conditions with environmental links.**
973

974 State, local and tribal health departments and CDC have established a process for recommending that
975 health conditions be placed under surveillance at the state and/or national level using the Council of State
976 and Territorial Epidemiologists (CSTE). CSTE, an organization of member states and territories
977 representing public health epidemiologists, has the responsibility for defining and recommending which
978 diseases and conditions are reportable within states and which of these diseases and conditions will be
979 voluntarily reported to CDC. Such recommendations are made through the development of “Position
980 Statements,” which include how surveillance should be conducted for a specific condition (e.g., case
981 definition, reportable data elements).
982

983 Accordingly, a work group of CDC/ATSDR epidemiologists should collaborate with CSTE
984 environmental epidemiologists to review currently reportable conditions of interest to surveillance of
985 chemical exposures to identify gaps, i.e., conditions that are absent from the current list or those that are
986 on the CSTE list but reportable in very few states. Plans should be developed to address interpretation
987 constraints imposed by limitations of available chemical exposure data and understanding of factors
988 affecting chemical exposure. The work group should develop its recommendations for ways to fill the
989 identified gaps, obtain consensus from the larger group of CSTE environmental epidemiologists, and then
990 develop Position Statements for their recommendations.
991

992 Progress in promoting new and more comprehensive reporting of diseases associated with chemical
993 exposures can be tracked through the CSTE website. The Environmental Public Health Tracking (EPHT)
994 network is likely to place the data on these reportable conditions on the CDC EPHT portal and state
995 portals as appropriate, demonstrating use of these data.
996

997 **(c) Expand State-based occupational health surveillance to all 50 States.**
998

999 State-based occupational health surveillance data systems are needed in all fifty states, because chemicals
1000 in the workplace are so often the origin of chemical exposures in the environment and because often a
1001 sick worker is the first indication that a chemical could have adverse health effects in the community.
1002 Currently only 23 states are funded by CDC for this activity, and additional funding would be needed for
1003 the remaining states to participate.
1004

1005
1006 **5. Expand Environmental Public Health Tracking to include all 50 States and 10 Metropolitan
1007 Statistical Areas.**
1008

1009 The concepts and tools of Environmental Public Health Tracking (EPHT), and the development of the
1010 integrated state and federal network, represent the highest level of environmental public health
1011 surveillance to date, but it has been implemented in only about half of the states because of funding
1012 limitations. Additional funding will need to be secured in order to achieve this recommendation.
1013 Organizations representing public health, including the Association of State and Territorial Health
1014 Officials (ASTHO), Council of State and Territorial Epidemiologists (CSTE), National Association of
1015 County and City Health Officials (NACCHO), Association of Public Health Laboratories (APHL),
1016 American Public Health Association (APHA), and others have been strong supporters of this initiative.
1017
1018

1019 **6. Establish mechanisms for the public and state/local/tribal officials to provide input into data**
1020 **collection efforts.**

1021
1022 **(a) Ensure that effective mechanisms exist for the public and state/local/tribal officials to provide**
1023 **input into decisions about *national data collection efforts*.**
1024

1025 All national data collection mechanisms should be open to public comment through a robust process prior
1026 to their initiation and periodically as preliminary or interim data are collected. The process for fully
1027 capturing community input and concerns is critical to the success of data collection mechanisms. Public
1028 input at the beginning and during data collection projects enables the process to be adjusted and highly
1029 adaptive. Proposed data collection mechanisms and any updates to them should be published on
1030 www.regulations.gov, and public input should be posted in a docket available through the site. The notice
1031 should seek public input on specific issues identified by the responsible agency, as well as allow for open-
1032 ended comment. The public should be encouraged to suggest reformulated questions if they do not find
1033 the agency's questions to be sufficient. The public should have no less than a 120-day comment period.
1034

1035 Agency communication with the public should include but extend beyond a notice in the Federal Register.
1036 Agencies should engage in outreach to national, regional, statewide and local organizations and people.
1037 Accommodation should be made to ensure that materials and translators are available for the languages
1038 spoken by affected communities. At the national level, outreach efforts should target national
1039 environmental, health, labor, religious, and other organizations. Outreach efforts by the responsible
1040 agency should be undertaken to solicit public comment through listening sessions or public administrative
1041 hearings held in each federal region affected by the data collection strategy. All public comments
1042 delivered at the hearings should be transcribed and posted in the docket. This process should provide
1043 public notice that is no less than 30 days. After the public input is received, the agency or agencies in
1044 question should again publish its decision(s) in the Federal Register and seek public input to the docket to
1045 enable any final adjustments.
1046

1047 In addition, national data collection efforts should provide the opportunity for state and tribal
1048 governments to pay for enlarged sample sizes that meet their local data needs.
1049

1050 **(b) Ensure that effective mechanisms exist for the public and state/local/tribal officials to provide**
1051 **input into *local community study design* (e.g., **Community-based Participatory Action Research****
1052 **methods).**
1053

1054 Similar to the methodology for public input on national data collection efforts, a local community study
1055 design should seek to involve the members of the community being evaluated. This, too, should be a
1056 process that seeks to ensure broad input from the public with ample opportunity to participate with written
1057 and oral comments. Similar to the national outreach, accommodation should be made to ensure that
1058 materials and translators are available for the range of languages spoken in the local community. The
1059 process should include a public comment period with a public docket, allowing for up to a 120-day notice
1060 period on a proposed study design and an opportunity to comment on the final. A truly participatory
1061 process should seek to engage a cross-section of the community. Local and regional outreach efforts to
1062 engage the public should involve communicating with community-based groups, labor organizations,
1063 housing and tenant groups, the faith community, health care and medical offices, public health officials,
1064 local elected officials, school boards, parent-teacher associations, water utility districts and other entities
1065 in the community that have the ability to reach members of the community through their membership,
1066 patients, listservs, websites, newsletters, mailing lists, social networks, media, and other distribution
1067 mechanisms. In addition, notice of the opportunity to participate should be posted throughout the
1068 community wherever public notices are posted.
1069

1070 Since most participatory processes are self-selective, it is critical that the outreach and inclusion
1071 methodology eliminate the barriers to participation and ensure participants an opportunity to establish the
1072 framework and definitions of the problem(s) and the data necessary to capture it. To that end, the agency
1073 should hold workshops to collect the community perspective on the study design. The workshops should
1074 be held in venues that are accessible and comfortable to community members and should be scheduled so
1075 as to not conflict with community members' work schedules. Public comments should be transcribed and
1076 placed in the docket. For those community members who do not use computers, a toll-free number should
1077 be available for questions and a written transcript of the workshops and relevant materials should be made
1078 available at the local libraries. Local governments should provide assistance, as feasible, to enable
1079 effective representation of community members (e.g., provide cost-free childcare, assist with
1080 transportation to and from the meeting, etc.).

1081
1082 The number of workshops should be determined based on the size of the community. No less than two
1083 workshops should be held in communities with populations less than 25,000, and additional workshops
1084 should be scheduled for every 100,000 population up to a maximum of ten workshops.

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7. Standardization & Integration

1088
1089 To ensure that information can be collected, exchanged, and interpreted by all interested parties, agencies
1090 conducting surveillance and monitoring activities must identify data, collection methods, and information
1091 system standards. Adopting and implementing standards for content, format, collection, transport, and
1092 interpretation of data will strengthen the ability of governmental agencies to exchange information needed
1093 for assessing environmental threats and designing effective interventions.

1094
1095 The work group recommends that agencies conducting ongoing surveillance and monitoring programs
1096 (e.g., EPA, CDC, and others) evaluate the feasibility of developing a clearinghouse of standardized
1097 methods for data collection and interpretation. CDC should also evaluate the possibility of providing a
1098 "Community of Practice" (CoP) forum for this community. One suggestion is to build upon the existing
1099 Public Health Information Network (PHIN), to enhance cooperation, standardization, and integration of
1100 environmental sampling and analytical methods, biomonitoring approaches, and other methods associated
1101 with exposure monitoring. Suggested methods to implement a CoP include electronic collaboration tools,
1102 such as message boards, listservs, chat rooms, webinars, and shared electronic workspaces.

1103
1104 The clearinghouse and CoP should be established within 3 years of the publication of this report.

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8. Balancing Public Access to Data with Confidentiality

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1109 Recent efforts by the federal government to protect confidentiality for individual respondents have been
1110 very successful. Language that accomplishes this can be found in the Health Insurance Portability and
1111 Accountability Act (HIPAA), the Confidential Information Protection and Statistical Efficiency Act
1112 (CIPSEA), and other acts. An unfortunate result is that local datasets on chemical exposure are frequently
1113 prevented from being released, since they could result in possible disclosure of personally identifiable
1114 information.

1115
1116 A second method used by the federal government to protect the confidentiality of data is to mask the
1117 datasets by either swapping some responses or adding "noise" (Fienberg, 2000). In both cases the trade-
1118 off for confidentiality is reduced data quality. So even when data are released, their accuracy may have
1119 been reduced, limiting their utility for local analyses.

1120

1121 **(a) A National Academy of Sciences (NAS) study should be sponsored to explicitly address the**
1122 **balance between confidentiality and data quality, especially for local analyses.**
1123

1124 It is important to recognize that maintaining data quality, especially for local analyses, is an important
1125 consideration that must be balanced with protection of confidentiality. HIPAA and CIPSEA restrict
1126 access to data to protect confidentiality to individuals. Masking data allows for data releases but of
1127 reduced quality. The NAS should assess the impact of data masking and identify how these actions can be
1128 balanced so that they assist analyses of chemical issues, particularly at the local level.
1129

1130 The NAS should also investigate the similar balance between protecting confidential business information
1131 and releasing data on possible chemical exposures. For example, providing more detail on toxic releases
1132 may conflict with protecting confidential intellectual property. The NAS should take account of product
1133 development life cycle and volume of product releases. It would also be important to consider the trade-
1134 off mandated by other international organizations since industry will have to respond to the combined sets
1135 of requirements in all locations where they operate.
1136

1137 This study should be initiated within three years.
1138

1139 **(b) Respondents should have access to data collected on them.**
1140

1141 Study respondents should be offered the option to receive the results of personal biomonitoring and
1142 physical samples collected from their property. These data should be accompanied by explanations aimed
1143 at a layman that provide context for the exposure measurements.
1144

1145 **(c) A clearinghouse for quality local studies of chemical exposure should be established by ATSDR**
1146 **or another governmental agency.**
1147

1148 Such a clearinghouse would greatly assist local efforts to understand their exposures and to recognize if
1149 those are unusual compared to similar locales elsewhere. While the government agency would not be
1150 expected to evaluate the quality of the local studies, the clearinghouse should provide standardized
1151 information that would allow potential users to judge the applicability of the data. Examples of
1152 documentation that should be required for inclusion of a local study in the clearinghouse include:

- 1153 • Statistical sample design;
 - 1154 • Sample size;
 - 1155 • List of chemicals tested for;
 - 1156 • Physical analytic methods;
 - 1157 • Basic findings;
 - 1158 • Links to publications or a summary of findings; and
 - 1159 • Contact person information.
- 1160
1161
1162

1163 **V. Conclusion**
1164

1165 This report presents the Monitoring work group's findings and recommendations regarding the United
1166 States' approach to monitoring and surveillance for the purpose of protecting the public from harmful
1167 chemical exposures. The work group approached this report by addressing issues along a temporal
1168 continuum, focusing on chemical use and release, environmental monitoring, biomonitoring, and health
1169 outcomes monitoring. This report characterizes the key components along this continuum; the major

1170 strengths and limitations that exist within each topic; the work group’s vision of a successful monitoring
1171 system; and actionable recommendations to achieve that vision.

1172
1173 The work group acknowledges several key themes that arise in its report: comprehensiveness,
1174 integration, and prioritization. The group also recognizes that data collected for monitoring must be used
1175 for public health preventive action, including priority interventions. The recommendations strive to
1176 expand and link the nation’s many existing efforts to monitor chemicals and public health, and to leverage
1177 existing infrastructure, information, and resources whenever possible. The work group recognizes that
1178 challenges and in some cases controversies are associated with issues discussed in this report, and
1179 members believe that this report reflects their support of the values of fairness, accuracy, prevention, and
1180 the protection of vulnerable populations. As suggested by the recommendations in this report, achieving
1181 the work group’s vision will take a concerted effort by experts in numerous organizations, both within
1182 and external to the government. The work group hopes that this report will move the United States toward
1183 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

Roy Fortmann, U.S. Environmental Protection Agency

Daniel Goldstein, Monsanto

Charlotte L. Keys, Jesus People Against Pollution

Megan Latshaw, Association of Public Health Laboratories

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Support

Michael McGeehin, NCEH/ATSDR *senior liaison*

Kathy Grant, RESOLVE *facilitator*

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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