

National Conversation on Public Health and Chemical Exposures

Policies and Practices Work Group

Final Report

November 2010

Executive Summary

Introduction

The *National Conversation on Public Health and Chemical Exposures* is a collaborative project, supported by the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR). The *National Conversation* vision is that chemicals are used and managed in ways that are safe and healthy for all people. The project's goal is to develop an action agenda with clear, achievable recommendations that can help government agencies and other organizations strengthen their efforts to protect the public from harmful chemical exposures.

This report is the product of the **Policies and Practices** work group's deliberations. While knowledge about the impact of chemical exposure and public health has advanced dramatically in the last few decades, national, state, local, and tribal chemical policy and the practices of the various stakeholders involved, including the chemical industry, have not kept pace. In this report, the Policies and Practices work group identified universal principles for protecting the public and workers from harmful chemical exposures; characterized these principles as they relate to select policies and practices, and developed recommendations grounded in these principles.

Vision Statement and Charge

Vision: The Policies and Practices work group envisions a future where promoting the public's health and preventing harm is the standard by which all chemical policies are created, implemented, and evaluated, and where best public health practices are supported as a result of a public health-driven policy framework.

Charge: In order to protect public health, the Policies and Practices work group determined actions that can be taken through policy, legislation, and regulation that will prevent harmful chemical exposures and spur the development and use of safer alternatives. To accomplish this charge, the Policies and Practices work group identified policies and practices of government agencies and the private sector that will facilitate accomplishing these goals and highlighted opportunities and examples for achieving them. The Policies and Practices work group used the following "layers of prevention" framework to guide its considerations:

- Primary prevention – Preventing harm by eliminating and/or reducing the production or use of harmful chemicals and by spurring the development and diffusion of safer and healthier alternatives
- Secondary prevention – Mitigating harm by eliminating and/or reducing the exposures to harmful chemicals.
- Tertiary prevention – Addressing harm caused by historic and continuing practices, by protecting the health of at-risk populations and contaminated communities.

For each layer, the following questions were discussed:

- What is the baseline or current situation?
- What should policy approaches look like if they are to strengthen this prevention layer?
- What actions can be taken to eliminate disparities and inequities in preventing or addressing exposures to harmful chemicals?
- What is the role of federal, state, local and tribal agencies in promoting these policies?
- What is the role of the private sector, including business, academia, and NGOs in promoting these policies?
- What resources and incentives are necessary for government and private entities to take these actions?

State of Chemical Policy

Current chemicals policy in the U.S. relies primarily on tertiary and secondary prevention models which assume that all chemical exposures can be adequately measured and controlled, and that all risks can be identified and managed effectively.

Fundamental to public health are the principles of primary, secondary, and tertiary prevention. Primary prevention—preventing and/or eliminating problems at the source before harm occurs—is proactive and a core public health goal. While tertiary and secondary prevention efforts are essential, they are inherently reactive. In principle, at least, primary prevention is the preferred approach for federal regulation. In practice, however, current chemicals policy relies heavily upon secondary and tertiary approaches. Beyond the failure to embrace primary prevention, existing chemicals policy is hampered by deficient testing and information collection authority, fragmentation and segregation of critically related public health concerns into separate agency silos, lack of communication between regulatory agencies, limited transparency and accountability, inadequate funding, inappropriate placement of the burden to prove harm, and inadequate respect and attention to the concerns of especially vulnerable communities. Because of these impediments, US chemicals policy fails to adequately protect the public health. Despite the stated preference and the associated advantages, in current practice, existing chemicals policy in the U.S. relies almost exclusively on secondary and tertiary prevention models that assume all chemical exposures can be adequately measured and controlled, and that all risks can be identified and managed effectively.

A policy approach that relies on secondary and tertiary strategies has led to the large number of chemicals now on the market, a portion of which, subsequent scientific investigation has demonstrated significant risk to human health and the environment. Fragmentation has resulted in a lack of accountability and transparency, and has retarded effective implementation of best practices and effective solutions. The overall result is unacceptable levels of impact on public and worker health from harmful chemical exposure.

Foundational Principles

The following ten principles encompass critical components of the Policies and Practices work group's vision of a successful system. These principles also provide a foundation for the action recommendations which are contained in Section IV of this report.

- I. Promote *prevention* and institutionalize safety first to eliminate and reduce harm from chemical exposures.
- II. Support advancements in the development and the diffusion of *safer alternatives* such as products and processes to improve human and ecological health.
- III. *Protect the general public, workers, and the environment.* Workers are often the most heavily exposed, and require protection. Certain portions of the population, such as children, pregnant women, and the elderly, are more susceptible, and require additional protections.
- IV. Place responsibility for *demonstrating* the chemical safety of products, as well as responsibility for removal and disposal of those products/chemicals, on their manufacturers.
- V. *Adopt a life cycle* approach to chemicals and chemical components (including extraction, production, use and disposal) focused on identifying key points for eliminating and preventing chemical exposures. Health impact assessments of a chemical should be performed, and should consider relevant social, economic, ecological, and human health costs.
- VI. Prioritize actions to address the disproportionate treatment and burden of chemical exposures placed on *over-burdened and under-represented* populations.
- VII. Ensure full *public engagement* in all activities to address and prevent chemical exposures with a transparent decision-making processes. The concepts of —Right to Know” and —Right to Act” need to be coordinated between all levels of government.
- VIII. Promote the development, dissemination, and *access to information* that is transparent, comprehensive, accurate, and useful at all phases of a chemical lifecycle.
- IX. Advance prompt *health protective actions*, investigations, and remediation of contaminated communities.
- X. *Emphasize coordination* among state, tribal, local, and federal agencies with full public engagement of the affected community across all phases of policy making. Potential recommendations may look at health protective standards at sites, effective study protocols, and enforcement.

Action Recommendations

RECOMMENDATION #1: Integrate a prevention focus into chemical regulation and practices at all levels of government to ensure the phase-out of hazardous chemicals and processes where viable, safer alternative technologies and approaches exist or could be developed. Lead entities: all executive and legislative branches of federal, tribal, state, and local governments.

RECOMMENDATION #2: Identify and evaluate hazards of chemicals and their potential alternatives more quickly through increased development and use of predictive toxicology methods, including, but not limited to, structure activity relationships (SARs), computational toxicology, and high-throughput test methods (HTP). Lead entities: The Environmental Protection Agency (EPA), CDC's National Institute of Occupational Safety and Health (NIOSH), National Institute of Environmental Health Sciences (NIEHS), Food and Drug Administration (FDA), National Response Center, and the International Trade Commission (ITC).

RECOMMENDATION #3: Create and support a network of government-supported centers for the development, commercialization, and diffusion of safer alternatives. Lead entities: US Congress, NIOSH, EPA, FDA, Consumer Product Safety Commission (CPSC), state agencies, colleges, and universities.

RECOMMENDATION #4: Reform the Toxic Substances Control Act (TSCA) to facilitate prompt action to eliminate or reduce harmful exposures to toxic chemicals. Lead entity: US Congress.

RECOMMENDATION #5: Improve public availability and clarity of chemical information on all products through the supply chain, from initial chemical manufacturer and/or formulator to final article/ consumer product. Lead entities: EPA with multiple partners.

RECOMMENDATION #6: Improve worker protection from chemical exposures by strengthening health standards, improving hazard communication, and encouraging adoption of a Chemicals Management Systems approach to purchasing, using, and disposing of chemicals. Lead entities: Department of Labor (DOL), NIOSH, and the Occupational Safety and Health Administration (OSHA).

RECOMMENDATION #7: Develop and implement strong chemicals policy reform that will address the issues disproportionately-exposed communities face. Lead entities: EPA, CDC, ATSDR, and state health departments.

RECOMMENDATION #8: Use population-based biomonitoring data as a tool to set priority strategies to reduce the level of harmful environmental chemicals identified in people. Lead entities: CDC, EPA, OSHA, and state health departments.

RECOMMENDATION #9: Revise ATSDR policies and procedures with a broader public health focus to more effectively investigate and address community toxic hazard exposures. Lead entity: ATSDR.

RECOMMENDATION #10: Direct resources available at ATSDR/CDC to help identify best practices, provide training and/or increased consultation for local public health improvement, broaden the scope of monitoring environmental contamination and establish a threshold that triggers appropriate public health protective actions.

RECOMMENDATION #11: Establish an independent National Superfund Task Force to advise the agencies on improving the design and implementation of Superfund site activities. Lead entities: CDC, ATSDR, and EPA.

RECOMMENDATION #12: Create agency-tribal partnerships focused on population health monitoring, tribal capacity building, improved access to state and federal data sources. Lead entities: ATSDR, EPA, state and federal agencies, and tribal governments.

RECOMMENDATION #13: Issue an Executive Order directing increased emphasis on public health principles and on coordinated health infrastructure across federal agencies. Lead entities: Executive Office of the President.

RECOMMENDATION # 14: Improve child health protections by requiring that the unique vulnerabilities, susceptibilities and exposures of children be explicitly considered and that protection of health of vulnerable populations is foremost in all policies and practices. Enact statutory language to make permanent the Federal Interagency Task Force on Children's Environmental Health, the Children's Health Protection Advisory Committee (CHPAC), and the Office of Children's Health Protection (OCHP). Lead entities: U.S. Congress, Interagency Task Force, all executive and legislative branches of federal, tribal, state, and local governments.

CONCLUSION

In this report, the Policies and Practices work group has articulated a vision for U.S. chemicals policy in which promoting the public's health and preventing harm is the standard by which all chemicals policies are created, implemented, and evaluated, and where best public health practices are supported as a result of a public health-driven policy framework.

The Policies and Practices work group concludes that while elements of a primary prevention approach are embedded in current chemicals policy and legal authorities, prevention has been inadequately reflected in the policies and practices of agencies such as US EPA, OSHA, ATSDR, the CDC and others. The Policies and Practices work group calls for a shift of emphasis of chemicals policy away from management of exposures and risk, and toward a prevention focus, including the development, adoption, and evaluation of safer alternatives. A prevention focus must be integrated into all chemical policies and practices at all levels of government to drive decisions that are more effective and protective of public and worker health. Such a focus will help address fragmentation, improve communication, increase transparency and accountability, protect workers and the public, and better meet the needs of affected and vulnerable communities.

National Conversation on Public Health and Chemical Exposures **Policies and Practices Final Work Group Report**

Abstract

This report is the product of the efforts of the Policies and Practices work group to address the impact of current chemicals policy on the public's health. The report is based on envisioning a future where promoting the public's health and preventing harm is the standard by which all chemicals policies are created, implemented, and evaluated. While knowledge about the impacts of chemical exposure and public health has advanced dramatically in the last few decades, national, state, local, and tribal chemical policy and the practices of the various stakeholders involved, including the chemical industry, have not kept pace. In this report, the Policies and Practices work group identified principles for protecting the public and workers from harmful chemical exposures; characterized these principles as they relate to select policies and practices, and developed recommendations grounded in these principles.

I. Introduction

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

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

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*.

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

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

Membership

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

In selecting members of the Policies and Practices work group, the following additional criterion were considered: 1) technical and policy expertise; 2) experience or interest in formulating or implementing policy; 3) ability to engage with people who have diverse perspectives and expertise; and, 4) reputation in the individual's field and ability to reach out to others in the sector. Furthermore, to achieve overall balance, diversity in terms of discipline, perspective, gender, and geographic region was also a consideration.

Richard Jackson, Chair and Professor, Environmental Health Sciences, UCLA, served as chair of the Policies and Practices work group, and was supported by Thomas Sinks, NCEH/ATSDR senior liaison to the Policies and Practices work group and Deputy Director, NCEH/ATSDR; Abby Dilley, Senior Mediator at RESOLVE; and Montrece McNeill Ransom, Senior Public Health Analyst, NCEH/ATSDR. A full list of members of the work group can be found in Appendix A.

Charge

The Policies and Practices work group agreed to the following charge to guide their work:

In order to protect public health, the Policies and Practices work group will determine prioritized actions that can be taken through legislation, regulation and policy that will prevent harmful chemical exposures and spur the development and use of safer alternatives. To accomplish this charge, the Policies and Practices work group will identify policies and practices of government agencies and the private sector that will facilitate accomplishing these goals and highlight opportunities and examples for achieving them. The Policies and Practices work group will use the following "layers of prevention" framework to guide its efforts:

- *Primary prevention –Preventing harm by eliminating and/or reducing the production or use of harmful chemicals and by spurring the development and diffusion of safer and healthier alternatives.*

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

- *Secondary prevention – Mitigating harm by eliminating and/or reducing the exposures to harmful chemicals.*
- *Tertiary prevention – Addressing harm caused by historic and continuing practices, by protecting the health of at-risk populations and contaminated communities*

For each layer, the following questions would be answered:

- *What is the baseline or current situation?*
- *What should policy approaches look like if they are to strengthen this prevention layer?*
- *What actions can be taken to eliminate disparities and inequities in preventing or addressing exposures to harmful chemicals?*
- *What is the role of federal, state, local and tribal agencies in promoting these policies?*
- *What is the role of the private sector, including business, academia, and NGOs in promoting these policies?*
- *What resources and incentives are necessary for government and private entities to get there?*

The group will focus its efforts on 1) identifying a set of universal principles that protect the public and workers from harmful chemicals exposures, 2) characterizing and analyzing these principles as they relate to select policies and proposals through the lens of primary, secondary, and tertiary prevention, and 3) developing recommendations grounded in these principles³

Work Group Process and Methods

The Policies and Practices work group convened 10 meetings (7 conference calls and 3 in-person meetings) in the course of their deliberations and to develop this report. The work group members agreed to ground rules governing their interactions, including full participation by all members, productive discussions, dialogue and problem solving. To accomplish the tasks outlined in their charge, the membership of Policies and Practices work group decided to conduct work in three subgroups, each focused on one of the three stages of prevention. The products of the subgroup deliberations were proposed for consideration, discussion, and finalization by the full work group. This report presents recommendations developed by the full work group membership.

Primary Prevention Subgroup

This subgroup developed recommendations focused on preventing harm by eliminating or reducing the production or use of harmful chemicals and by spurring the development and diffusion of safer and healthier alternatives. The co-leaders of this subgroup were Nicholas Ashford, MIT, and Timothy Malloy, UCLA School of Law. Membership also included the following participants:

- Kerry Dearfield, US Department of Agriculture
- Pamela Eliason, Toxics Use Reduction Institute
- Lin Kaatz Chary, Gary CARE Partnership
- Kristen Welker-Hood, Physicians for Social Responsibility

This subgroup convened a series of subgroup conference calls, during which they developed a set of primary prevention principles, drawing upon the diverse disciplines and experiences of the members. In order to translate these principles into practical recommendations, the subgroup developed a matrix of specific examples of policy reforms linked to primary prevention, setting out the nature and deficiencies

³ The Policies and Practices work group charge was finalized— by full work group agreement on March 18th, 2010.

of existing policies, the details of the examples, the primary prevention principles in play or enacted and other information. After further discussion within the subgroup and with other members of the Policies and Practices work group, the subgroup used the matrix to develop a set of specific policy recommendations. These proposed policy recommendations were brought forth for discussion, further development and finalization by the full Policies and Practices work group.

Secondary Prevention Subgroup

This subgroup focused its efforts on recommendations addressing harm by eliminating and/or reducing exposures to harmful chemicals. This subgroup convened four working sessions, including two full-day meetings utilizing web technology to allow members to participate via live web video connection. The subgroup was led by Brenda Afzal, University of Maryland School of Nursing and Alliance of Nurses for Healthy Environments, and Lynn Bergeson, Bergeson & Campbell, PC (on behalf of the American Bar Association Section of Environment, Energy and Resources). Additional work group participants in this subgroup included the following:

- Arlene Blum, Green Science Policy Institute
- Patricia Beattie, (formerly General Motors) Arcalis Scientific
- Richard Hackman, Procter & Gamble Inc.
- Kristin Ryan, State of Alaska, Department of Environmental Conservation
- Brian Symmes, Environmental Protection Agency

This subgroup developed recommendations ranging from increasing transparency and access to information to chemicals policy reform. These draft recommendations were proposed to the full Policies and Practices work group for consideration, further development and finalization.

Tertiary Prevention Subgroup

This subgroup developed recommendations for addressing harms caused by historic practices, and protecting the health of at-risk populations and contaminated communities. Kristin Hill, Great Lakes Inter-Tribal Epidemiology Center, and John McLeod, Cuyahoga County Board of Health, served as the leaders of this subgroup. Additional work group participants in this subgroup included the following:

- Linda Bruemmer, Minnesota Department of Health
- Doug Farquhar, National Council of State Legislatures
- Andrew Dennis McBride, City of Milford Health Department
- Anne Rabe, Community Concerned About NL Industries, Center for Health, Environment and Justice
- Gail Shibley, Oregon Department of Human Services/Public Health Division

This subgroup convened four subgroup calls, created a matrix to focus deliberations around tertiary prevention principles and integrated the 10 Essential Environmental Public Health Services. The recommendations the subgroup generated were brought forward to the full Policies and Practices work group for consideration, development and finalization.

Caveats, Terms and Definitions

Caveats

The themes and concepts discussed in this report do not represent the entire range of policies and practices nor the only relevant perspectives. The limited scope of this report prevents a comprehensive

treatment of these and other issues considered. Rather, work group members focused on themes which exemplify the span of policies and practices from state, local, federal, tribal, international perspectives.

Terms and Definitions

1. Alternatives Assessment

A chemical alternatives assessment is a process that allows one to compare alternatives to chemicals of concern using environmental and human health, economic and performance data pertinent to a specific application or use of that chemical, with the goal of identifying safer feasible alternatives.

2. Exposure/Risk Control Model

This model focuses on minimizing exposures or the effects of exposures, by interventions that reduce, but do not eliminate, chemicals produced, used, or disposed of in industrial and agricultural activities. The model contrasts with primary prevention which eliminates potential exposures by eliminating the problematic chemicals in production and use at the source.

3. Health Impact Assessment

A method by which a policy, program, or project may be judged as to its potential effects—and distribution of those effects—on the health of the population (CDC, 2010b).

4. Health Consultation

A health consultation is a review of available information or collection of new data to respond to a specific health question or request for information about a potential environmental hazard. Health consultations are focused on a specific exposure issue. Health consultations are therefore more limited than a public health assessment, which reviews the exposure potential of each pathway and chemical (ATSDR, 2010).

5. Health Promotion

The process of enabling people to increase control over, and to improve, their health (ATSDR, 2010).

6. Over-burdened community

An overburdened community can be defined as a town, city, or borough, or portion of one, that has high amounts of air pollutants or toxic emissions or high amounts of gallons of waste water treated or tons of solid waste stored, transferred, treated, or disposed. The definition appears to encompass communities that have high amounts of wastewater or solid waste transferred or treated elsewhere. (Connecticut General Assembly, 2004).

7. Policy

For the purpose of this report, policy can be defined as a set of decisions taken by an actor or group concerning the selection of goals and the methods of attaining them relating to a specific situation.

8. Practices

Practices were deemed to include those actions or activities undertaken by both public and private actors to achieve the goals of the policies identified.

9. Preemption

Preemption is the legal effect that results when a superior governmental unit blocks an inferior governmental unit from regulating a particular area. The rationale for preemption is to provide national uniformity in certain areas (Goodman, 2003).

10. Prevention

Prevention, defined generally as actions that eliminate or reduce exposure or other risks, keep people from getting sick, or keep disease from getting worse (ATSDR, 2010), is a key theme of this report. The work group's deliberations focused heavily on recommending actions that can be taken to assist in the prevention of chemical exposures.

11. Primary, Secondary, and Tertiary Prevention

The work group used a three-pronged prevention approach as its framework. This framework focused on the three components of prevention as generally accepted by the public health community: primary, secondary, and tertiary. This framework considers the stage of exposure at which intervention is warranted.

Primary Prevention

Primary prevention is generally defined as the elimination or reduction of causative factors for a health problem (CDC, 1992). For the purposes of this report, primary prevention focuses on preventing harm by eliminating and/or reducing the production or use of harmful chemicals and by spurring the development and diffusion of safer and healthier alternatives.

Secondary Prevention

Secondary prevention involves early detection and treatment of factors that can lead to harm and implementation of treatment or engineering control methods to minimize the potential for exposure or harm (CDC, 1992). For the purposes of this report, secondary prevention focuses on those policies and practices that address harm by reducing and controlling exposures to harmful chemicals.

Tertiary Prevention

Tertiary prevention entails providing appropriate supportive and rehabilitative services to minimize morbidity and maximize quality of life (CDC, 1992). For this work, tertiary prevention involved addressing harm caused by historic and continuing practices, by protecting the health of at-risk populations and contaminated communities.

12. Protection

Protection is defined as the preservation from injury or harm.

13. Public Health Assessment (PHA)

As defined by ATSDR (2010), a public health assessment is an ATSDR document that examines hazardous substances, health outcomes, and community concerns at a hazardous waste site to determine whether people could be harmed from coming into contact with those substances. The PHA also lists actions that need to be taken to protect public health. A *public health assessment* is used by ATSDR to identify possible harmful exposures and to recommend actions needed to protect public health. ATSDR considers the same environmental data as EPA, but focuses more closely on site-specific exposure conditions, specific community health concerns, and any available health outcome data to provide a more qualitative, less theoretical evaluation of possible public health hazards. It considers past exposures in addition to current and potential future exposures. (ATSDR, 2005)

14. Risk Assessment

Risk assessment is the process of gathering all available information on the toxic effects of a chemical and evaluating it to determine the possible risks associated with exposure. The process of gathering and evaluating the information can be divided into the following: 1) Hazard Identification; 2) Hazard Evaluation or Dose-Response Assessment; 3) Exposure Assessment; and 4) Risk Characterization (NRC, 2009).

15. Under-represented populations

The Policies and Practices work group adopted a definition of “under-represented” similar to the “priority populations” defined in authorizing legislation for the Agency for Healthcare Research and Quality (AHRQ) and incorporated into the National Healthcare Disparities Report (2004). For the purposes of this report, the following groups constitute the “underrepresented populations:” infants, children, adolescents, older adults, those of low socioeconomic status, those residing in rural areas, African Americans, Hispanics/Latinos, Asian Americans, and American Indians. This definition also includes persons or groups previously injured by chemical exposures, and those who are immune-compromised.

II. Current Status of Issues Under Consideration

Major components of current approach

Fundamental to public health are the principles of primary, secondary, and tertiary prevention, with an emphasis on primary prevention — i.e., preventing and/or eliminating problems at the source before harm occurs. The preference for primary prevention over secondary and tertiary is well established in public health and in environmental law. For example, the Pollution Prevention Act of 1990 established a primary prevention preference as a matter of federal policy. Federal agencies such as OSHA and others frequently acknowledge this preference (Occupational Exposure to Hexavalent Chromium, 2006). Primary prevention offers numerous advantages in terms of greater protection of health, long term efficiency and promotion of technological innovation. Despite the stated preference and the associated advantages, in current practice, existing chemicals policy in the U.S. relies almost exclusively on secondary and tertiary prevention models that assume all chemical exposures can be adequately measured and controlled, and that all risks can be identified and managed effectively.

The conventional risk-management focused approach taken today in implementing secondary and tertiary prevention typically involves two elements. First, the regulator attempts to identify the risks associated with the particular chemical in question—generally through quantitative risk analysis, using exposure/risk control models—and to establish an acceptable level of exposure. That acceptable level is likewise based upon risk, and often tempered by economic and technological concerns. Second, the regulator sets out

recommended or required risk management practices, such as engineering controls, work practices, or planning requirements intended to reduce exposure to the acceptable level.

The experience of the last nearly 40 years of regulatory history in addressing chemical exposures and the public health bears out the nearly unitary focus on tertiary and secondary activities. (Chemicals policy has relied on a model that, because it is based on a risk control-centered approach, can only be addressed by secondary prevention and, more frequently, tertiary prevention to address the public health effects of exposures to chemicals after the fact.) One result of placing the conventional risk management-focused approach at the center of chemicals policy is that agencies such as ATSDR are hampered in their ability to carry out their mission of prevention, and find themselves in the position of what are essentially "mop up" actions, that is, efforts to fix situations that are already critical in nature, and, in many cases, difficult, if not impossible to fix. All that remains is the hope of some degree of control or mitigation since the introduction of thousands of harmful chemicals, some remaining in the environment for generations, cannot be reversed.

While it is unquestionably a central focus of ATSDR's mission to serve the needs of communities that are experiencing the impacts of both past and continuing exposures, as outlined in both the Agency's mission and goals, the equal mandate to "*prevent* harmful exposures" and "protect the public from environmental hazards and toxic exposures" by "*promote(ing) prevention, control and elimination of long-term hazardous exposures*" has been, for all practical purposes, unrealized (ATSDR, 2009). This dilemma is again an inescapable result of a policy that is rooted in a model of post-exposure risk management rather than primary prevention.

Furthermore, in the current landscape, chemicals policy often relies on conclusions based on assumptions that are not in all cases scientifically defensible due to inadequate exposure information and missing data. In contrast to a preventive approach, current policies and regulation proceed on the tacit assumption that a lack of data equates to no harm. The negative results of this policy approach have been evident in the large number of chemicals now on the market, a portion of which advancing scientific investigation have demonstrated significant risk to human health and the environment.

Strengths and weaknesses of the current approach

Beyond the emphasis on secondary and tertiary prevention, current chemicals policy is hampered by excessively limited testing and information collection authority, fragmentation and the segregation of critically related public health concerns and legal authorities in separate agencies, lack of communication between and among regulatory agencies, lack of transparency and accountability, inadequate funding, placement of the burden to prove harm on regulators and affected communities, and insufficient respect and attention to the concerns of especially vulnerable communities. Other issues, such as agency capture⁴, and statutory compromise are also relevant, but will not be elaborated upon due to space constraints.

The greatest strength of the current approach is that prevention is at the legislative core of public health policy. While there has been an overarching inability to translate that mandate into a successful regulatory regime, the fundamental purpose of protection should remain in place, and not be eroded.

With specific regard to ATSDR, the strengths of the current approach to chemicals policy are found most clearly in the agency's efforts to present existing data about chemicals to health professionals and the public through the creation of publicly available databases. The agency has been successful in making

⁴ The phenomenon of agencies responding more to the special interests they were supposed to regulate than to the public has been called the problem of 'agency capture'. See Mintz, 2006.

information about toxicology and current science available to the public; it has been far less successful in translating the implications of that science and data into the creation of strategies and tools to carry out its mission of preventing exposure from hazardous chemicals.

As is sometimes the situation, something that is characterized as a weakness of the current approach can also be among its greatest strengths. While the significant drawbacks of fragmentation of authority across multiple government agencies can be enumerated in detail, at the same time, an appropriate division of labor among different agencies and offices offers the potential benefit of assuring that all aspects of a given challenge are being addressed by the widest range of available expertise. In addition, some degree of redundancy in the system should act as an inter-agency system of "checks and balances", and should also provide an inherently organic "fail-safe" system. When – and this is an absolute necessity – there is active and highly functional communication between all offices, agencies and responsible individuals working on different aspects of the same problem, any data gaps and weaknesses in response should become immediately identifiable, and the ability to address and rectify them in a timely manner greatly improved. This would also greatly improve transparency and accountability at all levels, including to the public.

Regrettably, the weaknesses of the current approach outweigh the strengths at the current time. One critical weakness is the failure of current policy to incorporate primary prevention into mainstream regulation. This failure results in inadequate incentives to spur innovation, and creates economic and regulatory disincentives to developing better alternatives. Moreover, it blunts searches for safer alternatives and substitutions by relying on scientifically amorphous and subjective "acceptable risk" metrics. Similarly, current policies lack reliable models to predict such important non-cancer effects such as endocrine disruption, developmental and reproductive toxicity, immunotoxicity, and neurotoxicity. Other structural weaknesses include lack of communication between and among regulatory agencies, lack of transparency and accountability, inadequate funding, placement of the burden to prove harm on regulators, and insufficient respect and attention to the concerns of especially vulnerable communities.

Many of those weaknesses affect the operations of regulatory agencies such as EPA and FDA. Some of the additional key weaknesses associated with the role of non-regulatory agencies such as ATSDR and CDC are as follows:

- A lack of integration and training relationships between state public health teams and their local counterparts to facilitate use of ATSDR/CDC technical competencies;
- Although ATSDR has the resources, it is rarely mobilized in ways that are useful or meaningful to the communities ATSDR serves, resulting in dysfunctional interaction and little, if any, unity of purpose and action between local, state, and federal agencies. This lack of unity, coordination and communication then results in poor resource management and poor and ineffective distribution of labor/responsibilities;
- The lack of accountability and transparency in ATSDR's and other agency decisions and actions (or lack of) impacting the health of contaminated communities; and
- Inefficient and poorly funded state, tribal, and local environmental monitoring resources to assure identification of environmental public health hazards in populations and the environment before such hazards result in a public health emergency.

Weaknesses and Strengths of the Current Approach: Two Examples

The **Toxic Substances Control Act (TSCA)** represents a case study of the inadequacies of the current toxics policy. TSCA was intended to provide protection of health and the environment against risks posed by chemicals in commerce but its core chemical management provisions have not been updated and strengthened since enactment in 1976, leaving significant gaps in available data on many widely used chemicals, and resulting in relatively few regulatory actions to limit or eliminate chemical exposures.

While new chemicals are subject to a 90-day formal review process before entering production, producers of chemicals already in commerce are not required to provide data necessary to assess potential risks comprehensively without further specific action from EPA. No statutory requirement is in place to test, prioritize, or address all existing chemicals. Furthermore, taking action to limit or ban chemicals under TSCA has proven difficult.

TSCA is also not designed to create or strengthen tribal or state partnerships, which could leverage interest, expertise, and action nationwide. Unlike other federal statutes to protect the environment and safeguard health (e.g. Safe Drinking Water Act, Clean Air Act, Clean Water Act, etc.), TSCA, specifically TSCA Title I, does not provide for tribal or state governments to apply for primacy and become co-regulators over chemicals and the hazards they pose.

At the federal level, the **Clean Air Act** standards for hazardous air pollutants rely upon control technology and inspection/ monitoring requirements. Perchloroethylene (perc) dry cleaning is being phased-out for certain facilities located on the ground floor of residential buildings (EPA, 2009). Most states with regulations concerning perc dry cleaning likewise rely upon technology standards controlling perc use. Studies of compliance with such state and federal standards demonstrate pervasive violations in multiple states. California state and regional air quality regulators are currently implementing a phase out of all perc dry cleaning operations. During rulemaking proceedings, California regulators identified viable, non-toxic alternatives technologies (wet cleaning and petroleum dry cleaning) considered state of the art technology. State regulators (e.g., California, Massachusetts, and New Jersey) had supported the diffusion of wet cleaning through research providing alternatives assessment, demonstration projects, and subsidies (Malloy, & Sinsheimer, 2004).

Impediments and opportunities

Opportunities for effective policy realignment in addressing the public health impacts of chemical exposures are directly tied to chemicals policy reform and efforts to revitalize federal agencies such as EPA, ATSDR, FDA, and others. Additional opportunities lie in the adoption of policies, legislation and funding for alternatives assessment and Green Chemistry as drivers for healthier communities, and innovation, greater efficiency, and financial benefit in the marketplace. Effective TSCA reform, for example, requires new legislation to incorporate a preventive, partnership-based approach emphasizing alternatives assessment and the evaluation and adoption of safer substitutes. Specifically, TSCA reform should place the burden on industry to provide essential health and safety information on all chemicals in commerce, information on the inherent hazard of these chemicals and mixtures, data about the fate and transport potential of chemicals in the environment, exposure data, and all uses of these chemicals. In determining the safety of chemicals, emphasis should also be placed on understanding and addressing the potential impacts on vulnerable populations from chemical exposures, with a goal of eliminating these harmful exposures. Further, because states and tribes have unique and powerful contributions to make to the national, indeed global, effort to ensure chemicals do not harm human health, the federal government should support and encourage partnerships to increase oversight, enforcement, and public health protection. Finally, the legislation should increase the amount, quality, and accessibility of information available to the public on chemical hazards, particularly with respect to chemicals in consumer products.

There are several major impediments to chemicals policy reform beginning with the deeply-rooted institutionalization of the exposure/risk control paradigm within federal and state regulatory frameworks and culture. This is the result of the current failure to fully translate the principles of primary prevention and elimination of exposures into best practices and an executable regulatory regime. These principles are the cornerstones of the public health approach but have not yet taken deep root in the federal and state chemicals management hierarchies. Genuine progress in chemicals policy reform will require major legislative initiatives mandating the integration of hazard-based assessments and policies predicated on

preventing harm into existing paradigms that are wedded to addressing how to manage exposures rather than eliminating them.

Fragmentation of responsibilities and focus in addressing prevention and the control/elimination of hazardous chemicals remains a significant impediment. In the absence of a comprehensive public health approach, a patchwork of agency oversight where each agency is focused on and invested in its own specific mission, the result – which is what is now apparent – is all too often the failure to see the whole picture and to appreciate how pieces relate to each other so as to achieve real and sustainable change.

The lack of adequate funding for public health agencies does not require elaboration as a significant barrier. As exposures to hazardous chemicals continue to be cited with increasing relevance to many diseases previously thought to be unrelated to environmental exposures, it is clear that funding dedicated to everything from research to on-the-ground efforts to prevent and eliminate these exposures will require adequate resources that have not yet become available.

The reality is that public health principles as the foundation for regulatory action currently is neither a default condition nor statutorily driven; the implications of this are evident in the inability of current policies to protect adequately the public from exposures to hazardous chemicals on a number of fronts. The continued absence to embed primary prevention as a critical cornerstone of all public policy initiatives and regulation will remain not only a barrier to achieving the goals of agencies such as ATSDR, EPA, and others, but to assuring that Americans are truly protected from the public health impacts of *preventable* chemical exposures.

III. Vision of a Successful System

The Policies and Practices work group envisions a future where promoting the public's health and preventing harm is the standard by which all chemicals policies are created, implemented, and evaluated, and where best public health practices are supported as a result of a public health-driven policy framework.

While knowledge about the impact of chemical exposure and public health has advanced dramatically in the last few decades, national chemical policy and the practices of the various stakeholders involved have not kept pace. As indicated in the Policies and Practices work group charge, members focused their efforts on identifying a set of principles that aim to protect the public and workers from harmful chemical exposures, characterizing these principles as they relate to select policies and practices, and developing recommendations grounded in these principles. In developing these principles, membership considered the 10 Essential Environmental Public Health Services (CDC, 2010b), as well as other sources of information. The following ten principles are the result of that work, and encompass critical components of the Policies and Practices work group's vision of a successful system. These principles also provide a foundation for the action recommendations which are contained in Section IV of this report.

Foundational Principles

- I. Promote *prevention* and institutionalize safety first to eliminate and reduce harm from chemical exposures.
- II. Support advancements in the development and the diffusion of *safer alternatives* such as products and processes to improve human and ecological health.
- III. *Protect the general public, workers, and the environment.* Workers are often the most heavily exposed, and require protection. Certain portions of the population, such as children, pregnant women, and the elderly, are more susceptible, and require additional protections.

- IV. Place responsibility for *demonstrating* the chemical safety of products, as well as responsibility for removal and disposal of those products/chemicals, on their manufacturers.
- V. *Adopt a life cycle* approach to chemicals and chemical components (including extraction, productions, use and disposal) focused on identifying key points for eliminating and preventing chemical exposures. Health impact assessments of a chemical should be performed, and should consider relevant social, economic, ecological, and human health costs.
- VI. Prioritize actions to address the disproportionate treatment and burden of chemical exposures placed on *over-burdened and under-represented* populations.
- VII. Ensure full *public engagement* in all activities to address and prevent chemical exposures with a transparent decision-making processes. The concepts of “Right to Know” and “Right to Act” need to be coordinated between all levels of government.
- VIII. Promote the development, dissemination, and *access to information* that is transparent, comprehensive, accurate, and useful at all phases of a chemical lifecycle.
- IX. Advance prompt *health protective actions*, investigations, and remediation of contaminated communities.
- X. *Emphasize coordination* among state, tribal, local, and federal agencies with full public engagement of the affected community across all phases of engagement. Potential recommendations may look at health protective standards at sites, effective study protocols, and enforcement.

IV. Action Recommendations

RECOMMENDATION #1: Integrate a prevention focus into chemical regulation and practices at all levels of government to ensure the phase-out of hazardous chemicals and processes where viable, safer alternative technologies and approaches exist or could be developed.

Lead entities: all executive and legislative branches of federal, tribal, state, and local governments.

Opportunities to phase-out and replace many hazardous chemicals and processes with safer alternatives already exist; examples include electroplating process changes to eliminate use of hexavalent chromium, substitution of perc in dry cleaning with wet-cleaning or other safer alternative processes, and replacement of bisphenol-A with new additives or alternative materials. Adoption of a prevention focus includes two complementary roles for government and business firms, respectively. First, federal, state and local government agencies responsible for the review of individual chemicals and manufacturing processes (including EPA, FDA, OSHA, and their state and local counterparts) should mandate the timely identification and adoption or development of viable safer chemicals and manufacturing processes under existing or (where necessary) new authorities. Thus, for example, the question of whether a safer viable alternative exists or could be developed should be central to setting Permissible Exposure Limits (PELs) by OSHA, to the regulation of chemicals by EPA under TSCA, the Clean Air Act, and other media statutes, and to air and water quality permitting by state and local regulators. Ultimately, new authorities should require the use of inherently safer technologies for all new installations, modifications, and expansions and ultimate replacement of existing facilities within appropriate, expeditious timeframes for targeted technologies.

Second, businesses should be required to incorporate prevention principles into their decision-making processes. Currently, a wide range of environmental protection and occupational safety regulations require that businesses track chemical uses and releases, and to evaluate various chemical hazards. This type of management system-based regulation should be expanded to require that on a regular basis, businesses systematically identify, evaluate, and adopt or develop viable, safer alternative technologies

and approaches. Alternatives or technology options analysis is central to facilitating modernization of products and processes. Such expansion is partly already in place in Massachusetts, where the Toxics Use Reduction Act (TURA) of 1990 requires companies who use listed toxic chemicals over threshold amounts to systematically assess both the reasons toxic chemicals are used and the availability and feasibility of safer alternatives. Likewise under the Industrial Safety Ordinance in California's Contra Costa County, mandatory process safety management review for oil refineries has been expanded to require evaluation and adoption of technologically and economically viable inherently safer technologies. A variety of existing local, state and federal statutes (including right-to-know regulations, occupational health and safety programs, and permitting programs) could be modified to require companies to engage in such planning. A reporting and certification requirement would ensure reasonably accurate data and thorough, rigorous planning, and would assist agencies in identifying priority chemicals that would benefit from having additional resources focused on encouraging the adoption and development of safer alternatives. Grounding agency decisions in real use and emission data, along with information on options identified by the companies, could lead to a more effective and strategic approach to minimizing chemical exposures.

RECOMMENDATION #2 Identify and evaluate hazards of chemicals and their potential alternatives more quickly through increased development and use of predictive toxicology methods, including, but not limited to, structure activity relationships (SARs), computational toxicology, and high-throughput test methods (HTP).

Lead entities: The Environmental Protection Agency (EPA), CDC's National Institute of Occupational Safety and Health (NIOSH), National Institute of Environmental Health Sciences (NIEHS), Food and Drug Administration (FDA), National Response Center, and the International Trade Commission (ITC).

Data on the potential adverse health effects of many chemicals in the environment and in commerce are usually sparse and limited. Also, existing conventional methods for hazard evaluation are time consuming and expensive. These deficiencies, which impede existing risk assessment and management efforts, are likewise obstacles to implementing a primary prevention approach focused on hazard evaluation. For example, with respect to new chemicals, a major focus of primary prevention is the generation of toxicity data on chemicals before they are used and end up in the environment and in commerce. These data would allow regulatory agencies and others to evaluate the hazards of new chemicals and their alternatives before allowing their manufacture and use, or not. Such data are also essential in evaluating existing chemicals and their available or potential alternatives. All federal and state agencies should implement this data generation element of the primary preventative approach to the extent permitted by existing law, and their legislative mandates should be expanded to maximize its adoption.

For example, EPA and other agencies make some limited use of computer-based models to evaluate potential hazards associated with chemicals, as well as a variety of models to predict environmental fate and transport. However, these models are somewhat limited in scope and application, and there is a need to advance the models that predict important cancer and non-cancer effects such as endocrine disruption, developmental and reproductive toxicity, immunotoxicity, and neurotoxicity, and are better at addressing areas of uncertainty. Therefore, to expedite the generation and collection of data for hazard evaluation, increased emphasis should be put on the development and use of predictive toxicology methods, including structure activity relationships (SARs), computational toxicology, and high-throughput (HTP) test methods. While it is never possible to eliminate all uncertainty, one of the goals of this approach should be to recognize where uncertainty exists and where it can be addressed by more effective analytic methods.

Furthermore, enhanced SAR and HTP methods could play an important role in rapidly identifying and assessing potential hazards associated with chemicals that have little or no test data. The HTP approach should, in theory, allow for the assessment of dozens of possible hazard endpoints. The HTP should help identify chemicals that act through common pathways to influence common hazard endpoints or chemicals that act through different pathways to influence common hazard endpoints (regardless of chemical structure). This will facilitate the evaluation of chemical mixtures and cumulative exposures. Expansion of SAR to new endpoints requires additional research and development. Continued research on the applicability and reliability of HTP methods is also needed. Proof of concept and/or some type of validation for all methods must provide an assurance that false negatives will be minimized.

RECOMMENDATION #3: Create and support a network of government-supported centers for the development, commercialization, and diffusion of safer alternatives.

Lead entities: US Congress, NIOSH, EPA, FDA, Consumer Product Safety Commission (CPSC), state agencies, colleges, and universities.

A chemicals policy approach emphasizing primary prevention depends upon the availability of safer alternatives to existing chemicals and industrial processes. The development, commercialization and ultimate diffusion of new products and technologies are often stymied by a variety of economic, institutional and behavioral factors. In the past, federal and state governments have sometimes sought to overcome such barriers by supporting R&D and creating policies that incentivize companies to conduct R&D that leads toward commercialization of products and technology in areas such as waste treatment, energy production, and agricultural practices. As a general matter, however, these government efforts have not typically been closely aligned with parallel or subsequent regulatory action mandating or encouraging the adoption of the innovative technologies. A contemporary example of such an existing policy is EPA's Design for the Environment program, which provides valuable research into the availability of safer alternatives for chemicals of concern used in specific applications, yet does not have mandatory implementation tools to assure that the preferred alternatives are adopted. .

The Office of Technology Advancement (OTA) at the South Coast Air Quality Management District (SCAQMD) is an example of an approach that systematically integrates support of innovation with regulatory action. That office sponsors research, demonstration projects and technical support to expedite the development and adoption of cleaner technologies and clean-burning fuels. SCAQMD pairs its Technology Advancement Office activities with subsequent regulations and incentive programs to overcome the inertia often present (Malloy, Czebiniak, & Sinsheimer, 2004). Similar centers in federal, state or regional agency offices (such as the NIOSH, EPA, and state analogs) or external centers at academic or other research institutions should be established. The focus of these centers—and the timeline for their creation— would depend in large part on the priorities established under related regulatory programs, such as those identified in Recommendation #1. Such centers could be funded in whole or in part by fees paid by regulated entities.

RECOMMENDATION #4: Reform the Toxic Substances Control Act (TSCA) to facilitate prompt action to eliminate or reduce harmful exposures to toxic chemicals.

Lead entities: US Congress.

TSCA was intended to provide protection of health and the environment against risks posed by chemicals in commerce but its chemical management provisions have not been updated and strengthened since enactment in 1976. The statute does not effectively promote the development or use of safer alternatives. Its numerous documented structural and procedural limitations leave significant gaps in available data on many widely used chemicals, and result in very few regulatory actions to limit or eliminate chemical

exposures. While new chemicals are subject to a 90-day formal review process before entering production, producers of chemicals already in commerce are not required to provide, without further specific action from EPA, data necessary to assess potential risks comprehensively without further specific action from EPA. No statutory requirement is in place to test, prioritize, or address all existing chemicals. Furthermore, taking action to limit or ban chemicals under TSCA has proven difficult.

New federal legislation is needed to promulgate an effective preventive approach emphasizing the evaluation, adoption, and development of safer substitutes through technology options analysis consistent with Recommendation #1. Beyond adoption of a preventive approach, this legislation should place the burden on industry to provide essential health and safety information on all chemicals in commerce, including information on the inherent hazard of these chemicals and their mixtures, exposure data, and data about the life cycle of the chemicals (including production, all uses, fate and transport potential of chemicals in the environment, and end-of life disposition). Consistent with a commitment to community right-to-know, all of the life cycle information should be made available through an online accessible clearinghouse database. In determining the safety of chemicals, emphasis should also be placed on understanding and addressing the potential impacts on vulnerable populations from chemical exposures, with a goal of eliminating these exposures. Another critical safety determination for all existing chemicals is the attributes of persistence, bioaccumulation, and toxicity (PBTs). Existing PBT chemicals under TSCA should be prioritized for phase-out and replaced with proven safer substitutes. The legislation should not preempt tribal or state governments, but rather encourage them to be laboratories of innovation and build on federal efforts. Further, the legislation should increase the amount, quality, and accessibility of information available to the public on chemical hazards, particularly with respect to consumer products. Finally, legislation must recognize the need for resources at the federal, state, tribal, and local levels for effective implementation. It should also set a high regulatory bar and expressly encourage state involvement to protect the public's health.

RECOMMENDATION #5: Improve public availability and clarity of chemical information on all products through the supply chain, from initial chemical manufacturer and/or formulator to final article/-consumer product.

Lead entities: EPA, FDA, OSHA, and CPSC.

Information regarding chemicals, their risks, and their uses in products is limited, fragmented, and difficult to access and understand. Current product labeling requirements often lack chemical-specific information, and labels often are incomplete, misleading, or unnecessarily complex. For many products, there is no requirement to make available any chemical ingredient information. Consumers have difficulty accessing credible, reliable, and useful information on chemical hazards. Examples of efforts to remedy this include: 1) submission of a list of all cosmetic products that contain any ingredients known or suspected to cause cancer, birth defects, or other reproductive harm under the California Safe Cosmetics Act; 2) recognition of household and commercial products that meet government criteria under the EPA's Design for the Environment program; and, 3) innovation and process changes as a result of Toxics Release Inventory (TRI) reporting under the Emergency Planning and Community Right-to-Know Act (EPCRA). Generally speaking, however, many valuable sources of information are not linked in a way that facilitates access to and use of the information they contain.

Government agencies and other stakeholders from academia, interest groups, and industry should work collaboratively to provide, enhance, and integrate existing databases on chemicals in products and articles along with improving interpretative information to help consumers and others better use this information to make informed choices. Currently, California is developing a Toxics Information Clearinghouse and Michigan is creating a Green Chemistry Clearinghouse. These could serve as models or a starting place for a national effort. Moreover, the federal government should demonstrate leadership in this area by

developing a publicly available Chemical Information Initiative (CII). This “~~neral~~ network” would provide the electronic means to link and coordinate information on chemicals from the range of existing and planned data and information systems and networks, enabling members of the public and other stakeholders from academia, interest groups, and industry to quickly and easily access information on chemical production, hazards, use, and presence in products and the environment.

Requiring that all consumer products and articles list the chemicals that remain in the product (of sufficient quantities) on the label would be an important aspect of this approach. A change of this nature could fit within the Fair Packaging and Labeling Act, which already states, “~~P~~ackages and their labels should enable consumers to obtain accurate information as to the quantity of the contents and should facilitate value comparisons.” The Consumer Product Safety Commission (CPSC) is also responsible for regulating consumer products, in particular children’s products, under the Consumer Products Safety Act (CPSA). While the CPSC is tasked with evaluating the safety of products and setting limits, it does not currently require labels to list the primary components of products. The work group suggests that efforts be undertaken to amend consumer protection legislation to require dissemination of information to consumers on chemicals presenting potential hazards contained in consumer products.

Policies and Practices work group members recommend that state and federal governments (EPA, CPSC, etc), industry (chemical manufacturers, formulators, article manufacturers), research institutions, and non-governmental organizations should comprehensively and effectively join together to develop and improve tools to enable better interpretation of chemical hazards and provide the public with a greater understanding of the context of chemical use and exposure.

RECOMMENDATION #6: Improve worker protection from chemical exposures by strengthening health standards, improving hazard communication, and encouraging adoption of a chemicals management systems approach to purchasing, using, and disposing of chemicals.

Lead entities: Department of Labor (DOL), NIOSH, and OSHA.

Workers typically endure the greatest potential risk of chemical exposure given their proximity to ~~neral~~ chemicals in the workplace, often at relatively high concentration levels and over protracted periods. A critical component for ensuring worker safety is the establishment and maintenance of enforceable exposure limits against which compliance with the OSH Act can be measured and enforced. Unfortunately, enforceable exposure limitations, referred to as Permissible Exposure Limits or PELs by OSHA, as well as TLVs, Threshold Limit Values, which are voluntary (American Conference of Governmental Industrial Hygienists, ACGIH) have not been updated in many years, as with PELs, or are not an open and transparent process (TVLs), and in many cases no longer reflect acceptable exposure levels based on newer and more reliable data and information. Material Safety Data Sheets (MSDS), whose intent is to notify workers about the chemicals to which they are being exposed in the workplace, must also be revised to be more comprehensive and to better reflect current data

We recommend that instead of updating PELs and TLVs, OSHA should require employers to assess and control chemical exposures as well as require the implementation of the hierarchy of controls for all chemical exposures as part of a Health and Safety Program Standard. The hierarchy of control emphasizes that implementing feasible and effective controls starts with primary prevention and elimination of exposure and ends with the least effective approach, which is requiring a worker to change behavior or wear equipment to limit the risk of exposure. This is already institutionalized in the NIOSH hierarchy of controls which starts with eliminating the risk, then engineering controls, followed by administrative controls and finally, at the bottom, use of personal protective equipment. OSHA must require all employers to follow this hierarchy

of controls to effectively protect workers from dangerous chemical exposures. The private sector should be encouraged simultaneously to develop company-specific work practices that emphasize prevention and seek alternatives and substitutions to hazardous chemicals.

MSDSs have been required under the OSHA Hazard Communication Standard since 1985, but only hazardous ingredients if $> 1\%$ and carcinogenic and/or mutagenic ingredients at $> 0.1\%$ must be listed. ~~“Volumetric”~~ exemptions such as these, do not account for the potential risk derivative of chemicals that are capable of posing harm at low doses. The most current scientific understanding is that there are many additional endpoints of concern beyond carcinogenicity and mutagenicity, and that for some chemicals, including many hormone-mimicking chemicals, there is no known threshold value, and health effects can be induced even at extremely low amounts. Thus, focusing only on ingredients at a percentage of $\geq 1\%$ or $\geq 0.1\%$ as a criteria for listing chemicals ingredients with the characteristics described above, ignores the potential human health threats posed by low dose exposures and will leave workers unprotected against a wide range of possible hazards.

We recommend that 100% disclosure should be required in a non-confidential manner, so that end users will know the composition of the products they are supplied. In addition, as information for which chemical composition changes, MSDS must be updated to allow users to make informed decisions about whether they wish to continue using a product. Ongoing awareness and education systems should be established that assure that employees are routinely updated as to changes in MSDS, and reminded, perhaps annually, of the risks associated with these ~~hazardous ingredients.~~ As MSDSs are often not as accessible as they should be, we further recommend that MSDSs be made publicly available in an easily accessible, transparent, and understandable format, and that worker’s right-to-know be expanded and strengthened to include the concepts right-to-understand, and right-to-act.

The lack of chemical management policies in our academic institutions, hospitals and healthcare facilities, community and local facilities, and small businesses and industries continues to increase the public’s and employees’ exposure to legacy chemicals. These acute and chronic chemical exposures resulting from spill incidents, poor indoor air quality, asbestos, and pesticides continue to increase the health risks to the occupants in classrooms, offices, maintenance areas, and storage areas throughout the building campuses. In industry, worker exposures and risk to the community are reduced through chemicals management programs. This is a systems approach to managing chemicals that reduces chemical use, waste, risk, and costs. With chemicals management, users of chemicals shift from a traditional supplier relationship to a strategic alliance with a chemical service provider. Instead of purchasing chemicals, the manufacturer, academic, or public institution purchases chemical services, and assists with purchasing, managing, and tracking chemicals.

This shift to chemical services directly aligns the incentives of the service provider and chemical user to reduce chemical use, exposures, and costs. Institutional systems can benefit by working with federal, state, or local public health agencies and proven partners from the industrial sector that have incorporated best practices in their chemicals management systems. Legislators and federal agencies can develop regulatory mechanisms to assure the implementation of these chemicals management systems. The chemicals management approach is currently used in some industry sectors, at some educational institutions, and has been encouraged by EPA in its pollution prevention/waste minimization activities.

RECOMMENDATION #7: Develop and implement strong chemical policy reform that will address the issues disproportionately-exposed communities face.

Lead entities: EPA, CDC, ATSDR, and state health departments.

Special populations such as children, communities-of-color, indigenous peoples, low-income communities, persons previously injured by chemical exposures, and people who are immune-compromised are not only exposed to current chemicals through consumer products, industrial emissions, and chemical plants in their neighborhoods, but they are also most frequently and disproportionately exposed to legacy chemicals from prior industrial land uses. Because of the multiplicity of toxic chemical exposures from both current and legacy sources borne by these communities, the health profile of residents who live in them reveal the many health disparities that they confront. Special populations are limited by fewer environmental benefits (e.g., clean air, water, and land) and more environmental threats (e.g., hazardous chemicals and environmental illness). Exposure to toxins is greater in special populations because they are often located in or near polluting industrial areas. Employment in special populations is often limited to jobs with low pay, limited or no health benefits, and, sometimes, severe workplace dangers inviting enhanced chemical exposure. Special populations receive less treatment for environmental disease because healthcare resources are limited and environmental health expertise is rare. Finally, when environmental health threats are not eliminated, the harm transfers from generation to generation (Environmental Justice and Health Union, 2003).

The EPA created the Office of Environmental Justice in 1992, and implemented a new organizational infrastructure to integrate environmental justice into EPA's policies, programs, and activities. The National Environmental Justice Advisory Council (NEJAC) was established September 30, 1993, to advise the then new Office of Environmental Justice. (EPA, 2010). This advisory council was the first time that representatives of community, academia, industry, environmental, indigenous, as well as state/local/tribal government groups, were brought together in an effort to create a dialogue that would define and create solutions to environmental justice problems. In December of 2004, NEJAC provided a report to the EPA titled, *Ensuring Risk Reduction in Communities with Multiple Stressors: Environmental Justice and Cumulative Risks/Impacts* (2004). The report described eight overarching themes meant to provide a long-term vision for addressing issues of environmental justice and cumulative risks/impacts and recommended 12 specific actions that EPA could take immediately to lay the groundwork for the larger changes called for by the eight overarching themes. We recommend that this report and the recommended actions be revisited as guidance for the development and implementation of strong chemicals policy reform.

Chemicals policy reform should embody three key policy elements to advance environmental justice, including a substantial reduction of the disproportionate burden of chemical exposure placed on special populations. First, immediate action must be taken to prevent, where feasible, exposure to the worst chemicals through adoption of safer alternatives. All chemicals and their alternatives should be evaluated against a health standard that protects all people and the environment, especially the most vulnerable subpopulations, including children, workers, and pregnant women. Federal, state, local, and tribal agencies must ensure that leadership of all agencies visibly projects the importance of interagency cooperation and coordination. Second, there needs to be improved coordination between and among multiple levels of government (federal, state, local, tribal, and territorial) and among federal agencies (EPA, ATSDR) to enable an integrated and immediate response to community concerns. Third, action plans must be created and implemented to relieve the burden from communities highly impacted by disproportionate chemical exposures. Strategies to support and finance local cleanup, including direct funding, incentives, private-sector investment, and innovative public financing, must be developed and implemented.

Children are affected by —ifecycle” exposures such as community exposures where manufacturing plants are located, exposures while using products, and exposures related to end of life handling of toxic and hazardous wastes. In addition, children have unique environments: the womb, child care centers, schools, and play areas, all of which need to be specifically considered, yet are often not addressed in discussions of other specific populations such as workers. For example, children and children’s unique environments

(schools, child care, playgrounds) are not yet routinely included in monitoring and research studies, yet studies that do exist consistently show that the youngest children are quite often the group that is most vulnerable, and has the highest exposures to chemicals in the environment. Unlike in the workplaces of adults, where OSHA and NIOSH exist, children are not protected in their “workplace” of school or child care, and have no specific legislation recognizing their need for protection in light of their special and unique vulnerabilities. Finally, children are also affected by their parents’ workplace exposures (not just take home, but fetal and preconception exposures), yet there is no regulatory regime within OSHA or other occupational and environmental chemicals policy which is specifically protective of children.

We recommend that TSCA reform and other chemicals policy must include discrete recognition of children as an especially vulnerable population and must include a regulatory regime specifically designed to be protective of children and young adults.

RECOMMENDATION #8: Use population-based biomonitoring data as a tool to set priority strategies to reduce the level of harmful environmental chemicals identified in people.

Lead entities: CDC, EPA, OSHA, and state health departments.

It is the role of federal, state, local, and tribal agencies to generate, analyze, and interpret biomonitoring data. Among the biomonitoring data currently being collected are from the CDC through its National Health and Nutrition Examination Survey (NHANES), OSHA, EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and USDA through the National Residue Program in association with FDA and EPA. These data confirm human exposures to chemicals (via ingestion, inhalation, and absorption) and validate public health policies. For example, population biomonitoring data showing high blood lead concentrations resulted in EPA’s regulatory reduction of lead in gasoline. Biomonitoring data confirm a resultant drop in blood lead concentrations (NRC, 2006). A 2004 biomonitoring effort examining fetal cord blood identified an average of 200 industrial chemicals and pollutants; the monitoring revealed a total of 287 harmful chemicals across the samples tested. (Houlihan, Kropp, Wiles, Gray, & Campbell, 2005)

Biomonitoring efforts should be expanded. State and federal public health and regulatory agencies must collaborate on generating, analyzing, and interpreting the data as a tool to set priority strategies to reduce the level of harmful environmental chemicals identified in people and in food source animals.

While the potential value of biomonitoring data is recognized, regulatory and scientific challenges surrounding their reliability and use for regulatory purposes must be overcome. They include improving the ability to design biomonitoring studies, incorporating biomonitoring studies of food source animals, interpreting what biomonitoring data mean for public health, addressing the utility of the data, and communicating results to study participants, policy-makers, and the public. A trusted source, which can interpret and communicate the health implications of the biomonitoring data to the public and policy-makers, will need to be identified. An interagency task force should be established to coordinate federal biomonitoring efforts and an expert advisory panel, which can inform the process, should be convened to achieve these ends.

RECOMMENDATION #9: Revise ATSDR policies and procedures with a broader public health focus to more effectively investigate and address community toxic hazard exposures.

Lead entity: ATSDR.

Problems have been described in two recent reports, *The ATSDR: Problems in the Past, Potential for the Future?* by the U.S. House of Representatives (2009) and *ATSDR: Policies and Procedures for Public*

Health Product Preparation Should be Strengthened by the Government Accountability Office (2010), as well as reports and testimony from environmental and community organizations.

ATSDR should establish a temporary Toxic Hazards Advisory Task Force (Task Force) made up of scientists, epidemiologists, state agency and independent public health and environmental experts, and community, environmental and environmental health organizations to advise ATSDR on the design and implementation of health consultations, health studies and public health advisories using standardized protocols, policies and programs to ensure proactive actions that address community toxic site hazards. Congress should allocate funds to ATSDR to establish the Task Force and ensure the agency and Task Force members have the capacity and resources to effectively implement this action.

A public Task Force will benefit ATSDR and exposed communities through comprehensive consultation with scientists, technical and independent health experts and impacted community representatives to ensure scientific rigor and public involvement in effectively investigating and addressing all cases of suspected contamination and adverse health effects.

RECOMMENDATION #10: Direct resources available at ATSDR/CDC to help identify best practices, provide training and/or increased consultation for local public health improvement, broaden the scope of monitoring environmental contamination and establish a threshold that triggers appropriate public health protective actions.

Lead entities: CDC, ATSDR, EPA, and The Fish and Wildlife Service (FWS), in partnership with state agencies.

State and local health departments are working with communities with contaminated sites that have been impacted by population decline and changing zoning needs, raising public health issues especially in contaminated communities. Recently, the public health community has implemented a tool called the —health impact assessment,” which focuses on a specific site or the community to identify potential public health issues and exposures. Many state and local health departments do not have the capacity or competency to meet this need. The resources available at ATSDR/CDC should be used to help identify best practices and provide training and/or increased consultation for local public health improvement. In addition, at the federal, state and local level, success of both the regulatory and non-regulatory agencies are too often limited by bureaucracy, overburdened with crisis management, complaints and responding to partisan political and economic interests. Also, jurisdictional boundaries exist to isolate agency function and rules such as ATSDR, CDC, NIOSH, EPA, OSHA, and FWS that limit the activities of each without the benefits of cross communication and integrating expertise resulting in public safety gaps. Data collected are not routinely shared nor coordinated among agencies limiting comprehensive approaches to chemical exposure.

ATSDR should integrate and train state and local public health teams to use the ATSDR/CDC technical competencies to meet the increasing demand for conducting community and neighborhood-based health impact assessments in contaminated communities. Specifically, a —Comprehensive Environmental Health Assessment” should be integrated into existing ATSDR products with clear parameters to guide when it is warranted, including: comprehensive environmental and biological sampling; identification and assessment of all chemical and non-chemical stressors; consideration of health impact of complex chemical mixtures from all sources; and recommendations that address potential adverse health impact of chemical mixtures and non-chemical stressors, and identify possible short-term and long-term solutions.

The CDC, ATSDR, NIOSH, EPA, OSHA, FWS and state agencies should broaden the scope of monitoring fish, wildlife and environmental contamination to include all biologically active chemicals used in products and manufacturing processes, as well as establish monitoring standards and issue annual

public reports. Every state should establish an Early Warning Committee of health, environmental and wildlife experts and agency representatives to receive annual monitoring reports and serve as channels for addressing emerging problems. A national interagency Early Warning Task Force should be established to coordinate state and federal monitoring data and set terms for preventative action by defining a threshold that triggers appropriate public health protective actions.

Such agencies should establish accountability performance measures to strengthen their activities such as periodic systematic reviews of their application of health recommendations and guidelines, regular reporting on effectiveness, and quality of service and communication debriefing. Long term, comprehensive and strategic environmental health planning is needed together with regulatory reform to address tertiary prevention. Adopting a system of open, transparent case review to learn about deficiencies and improve response would benefit all the agencies performance accountability.

RECOMMENDATION #11: Establish an independent National Superfund Task Force to advise the agencies on improving the design and implementation of Superfund site activities.

Lead entities: CDC, ATSDR, and EPA.

Problems with EPA and ATSDR's programs to address Superfund site hazards have been described by the U.S. House of Representatives in the 2009 report, *The ATSDR: Problems in the Past, Potential for the Future?*, and reports and testimony from environmental and community organizations, such as the Center for Health, Environment and Justice's two reports on the Federal Superfund program.

The Superfund Task Force should be comprised of independent scientists, public health experts, environmental engineers, as well as community, environmental, and environmental health advocates and organizations and industry representatives to advise the agencies on improving the design and implementation of Superfund site investigations, studies, health advisories, and remedial action plans to ensure they are adequately protecting public health and the environment.

The relevant agencies should standardize soil and water cleanup levels based on protecting communities, workers, and ecosystems from both carcinogenic (1 in a million) and non-carcinogenic risks, taking into account sensitive populations such as children, and cumulative impacts.

RECOMMENDATION #12: Create agency-tribal partnerships focused on population health monitoring, tribal capacity building, improved access to state and federal data sources.

Lead entities: ATSDR, EPA, state and federal agencies, and tribal governments.

Tribal communities are vulnerable to toxic/chemical exposures due to proximity of reservation lands to chemical waste disposal sites, to contaminated fish and wildlife sustaining the Native American diet, and pervasive disparate health conditions. While an investigation may assess chemical damage and recommend remediation actions, limited funds and resources exist within tribal health programs and tribal governments to adequately address remediation.

RECOMMENDATION #13: Issue an Executive Order directing increased emphasis on public health principles and on coordinated health infrastructure across federal agencies.

Lead entities: Executive Office of the President

An executive order would be a legally binding order issued by the President, acting as the head of the Executive Branch, to Federal Administrative Agencies. These orders are generally used to direct federal

agencies and officials in their execution of congressionally established laws or policies. This executive order would apply to all agencies throughout the federal government and would call for the development and implementation of prevention-driven policies in all federal agencies. In addition, this order should direct efforts to achieve a more cohesive and coordinated health infrastructure across the federal government and between the federal, state, local and tribal governments, and could, for example, call for the establishment of a public health position in all relevant agencies or the development of a multi-departmental and agency standing commission to promote prevention-driven decision making.

RECOMMENDATION # 14: Improve child health protections by requiring that the unique vulnerabilities, susceptibilities and exposures of children be explicitly considered and that protection of health of vulnerable populations is foremost in all policies and practices. Enact statutory language to make permanent the Federal Interagency Task Force on Children's Environmental Health, the Children's Health Protection Advisory Committee (CHPAC), and the Office of Children's Health Protection (OCHP).

Lead entities: U.S. Congress, Interagency Task Force, all executive and legislative branches of federal, tribal, state, and local governments.

Children can be more susceptible and more vulnerable than adults to toxic chemicals for a variety of reasons. Children behave differently than adults, leading to a unique pattern of exposures to the world around them. For example, they exhibit hand-to-mouth behavior, ingesting whatever substances may be on their hands, toys, household items, and floors. Children play and live in a different space than adults. For example, very young children spend hours close to the ground where they may be more exposed to toxicants in dust, soil, and carpets. Children have longer life expectancy than adults, thus they have more time to develop diseases with long latency periods than may be triggered by early environmental exposures. The world in which today's children live has changed tremendously from that of previous generations; there has been a great increase to substances to which children are exposed. Children and children's unique environments (schools, child care, playgrounds) are not yet routinely included in monitoring and research studies, yet the studies that have been done show that the youngest children are quite often the group (other than workers) that has the highest exposures to chemicals in the environment. Children's systems, including their nervous, reproductive, digestive, respiratory, and immune systems, are developing. This process of development creates periods of vulnerability. Exposure to toxicants at such times may result in life-long damage when the same exposure to an adult may result in little or no damage.

Thus, all children are uniquely vulnerable to health effects caused by exposure to environmental hazards in their homes, communities and unique environments (the womb, child care centers, and schools). Children are not protected in their "workplace" of school or child care; NIOSH and OSHA do not focus on children. In addition, a child's physical environment is not separate from social and cultural issues. Many children live in communities that are disproportionately impacted by environmental exposures. Solutions to environmental problems experienced by the fetus and child should be viewed within that context.

Executive Order 13045, issued in 1997, created to protect children from environmental health and safety risks, resulted in notable successes and promising initiatives, most notably an effective interagency task force on children's environmental health. Over a number of years, the Executive Order was weakened. The interagency task force established under the Executive Order engendered collaboration across agencies critical to addressing children's environmental health but was allowed to expire.

Since 1997, the Office of Children's Health Protection (OCHP) has led the Agency's efforts to protect children from environmental hazards. The OCHP has struggled with staffing and funding issues as well as the dilution of its mission.

Key components of the Executive Order, such as the interagency task force, should be put into statute. Such legislation must also assure that other agencies with jurisdiction over environments where children spend much of their time -- most notably the Department of Education -- are active and engaged partners. This focus also includes those offices handling child care and related issues. The OCHP and its advisory body, the Children's Health Protection Advisory Committee (CHPAC), has been and should continue to be the conscience for children's health protection in EPA, as well as a spotlight to highlight accomplishments, shortfalls, and opportunities. Thus, the CHPAC and OCHP should also be created in statute, with assurances that a substantial portion of CHPAC appointees be independent experts in pediatric environmental health. Similar panels and offices should be created in other relevant agencies.

Establishment of these entities will encourage coordination and leverage resources to assure that children's unique vulnerabilities, susceptibilities and exposures be explicitly considered, and will also facilitate placing health -- especially protecting the health of our most vulnerable -- foremost in all policies and practices. Healthy children grow into healthy adults. The health of our children is one of the most important investments we can make and should be among our top priorities.

V. Conclusion

In this report, the Policies and Practices work group has articulated a vision for U.S. chemicals policy in which promoting the public's health and preventing harm is the standard by which all chemical policies are created, implemented, and evaluated, and where best public health practices are supported as a result of a public health-driven policy framework.

The Policies and Practices work group concludes that while elements of a primary prevention approach are embedded in current chemicals policy and legal authorities, prevention has been inadequately reflected in the policies and practices of agencies such as EPA, OSHA, ATSDR, the CDC and others. The Policies and Practices work group calls for a shift of emphasis of chemicals policy away from management of exposures and risk, and toward a prevention focus, including the development, adoption, and evaluation of safer alternatives. A prevention focus must be integrated into all chemicals policies and practices at all levels of government in order to drive decisions that are more effective and protective of the public's and workers' health. Such a focus will help address fragmentation, improve communication, increase transparency and accountability, protect workers and the public, and better meet the needs of affected and vulnerable communities.

VI. Appendices

- a. Policies and Practices work group membership list

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Appendix A

Policies and Practices work group membership list*

Leadership Team

Richard Jackson, UCLA School of Public Health, *chair*

Tom Sinks, NCEH/ATSDR *senior liaison*

Abby Dilley, RESOLVE *facilitator*

Montrece Ransom, NCEH/ATSDR *staff*

Members

Brenda Afzal, University of Maryland School of Nursing and Alliance of Nurses for Healthy Environments

Laura Anderko, Georgetown University

Nicholas Ashford, Massachusetts Institute of Technology

Patricia Beattie, Arcalis Scientific

Lynn Bergeson, Bergeson & Campbell, P.C. (on behalf of the American Bar Association Section of Environment, Energy and Resources)

Arlene Blum, Green Science Policy Institute

Linda Bruemmer, Minnesota Department of Health

Sascha Chaney, NCEH/ATSDR

Kerry Dearfield, U.S. Department of Agriculture, Food Safety and Inspection Service

Catherine Dodd, City and County of San Francisco

Pamela Eliason, Toxics Use Reduction Institute

Doug Farquhar, National Council of State Legislatures

Rick Hackman, Procter & Gamble Inc.

Kristin Hill, Great Lakes Inter-Tribal Epidemiology Center

Lin Kaatz Chary, Gary CARE Partnership

Andrew Dennis McBride, City of Milford Health Department

Timothy Malloy, UCLA School of Law

John McLeod, Cuyahoga County Board of Health

Anne Rabe, Community Concerned About NL Industries

Kristin Ryan, Alaska Department of Environmental Conservation

Gail Shibley, Oregon Department of Human Services/Public Health Division

Brian Symmes, U.S. Environmental Protection Agency

Kristen Welker-Hood, Physicians for Social Responsibility

**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.