

the LOUISVILLE
CHARTER

**BACKGROUND PAPER FOR REFORM NO. 4
OF THE LOUISVILLE CHARTER FOR SAFER CHEMICALS**

PAPER AUTHORS

Nancy Myers

Science and Environmental
Health Network
221 N. Grove #2N
Oak Park, IL 60302
Tel: M-T (708) 848 0054
Tel: W-F (269) 695 2101
nancy@sehn.org
www.sehn.org

Anne Rabe

BE SAFE Center for Health,
Environment & Justice
1265 Maple Hill Rd.
Castleton, NY 12033
Tel: 518-732-4538
annerabe@msn.com
www.besafenet.com

Katie Silberman

Science and Environmental
Health Network*
1914 Cleveland Ave.
Santa Barbara, CA 93103
Tel/Fax: 805 569 0488
katie@sehn.org

*Katie Silberman was associated with
the Center for Environmental Health
when this paper was written.

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Reform No. 4 of the Louisville Charter for Safer Chemicals reads:

ACT ON EARLY WARNINGS

Act with foresight—Prevent harm when credible evidence exists that harm is occurring or is likely to occur, even when some uncertainty remains regarding the exact nature and magnitude of the harm.

ABSTRACT

Two conditions establish the threshold for protective action in the presence of scientific uncertainty:

- 1) Credible evidence that a synthetic chemical can cause biological changes that are known to result in unintended harmful outcomes to human health or the environment in some cases.
- 2) The presence of such a chemical where it does not belong and where it can cause damage to biological systems (such as human bodies).

Acting with foresight takes many forms. We must create and strengthen human health and wildlife monitoring programs to detect and predict harm; take steps to prevent, eliminate, and mitigate exposure when credible evidence of harm is found; monitor novel technologies; consider clusters of problems to be early warnings of harm; and open toxic tort records. All action taken must be based on precautionary definitions of “harm” and “credible evidence” and must include public participation. Significant precautionary actions may be taken on the state and local level in advance of a precautionary national chemicals policy.

Introduction

Twenty-twenty hindsight tells us about the inadequacy of our ability to detect and prevent chemical damage to biological systems. In case after case, long periods of time have elapsed between the emergence of the first credible scientific evidence that unintended harm was being done to biological systems and the first action taken to address the problem. DDT, benzene, asbestos, PCBs, and chlorofluorocarbons are some of the best-known examples. In some cases, such as ozone-

layer damage, scientific intelligence systems failed—harm was discovered late because we didn't know what to look for, or we weren't looking for harm at all. More often, however, the failures have come in interpreting and acting upon emerging information. We have not heeded early warnings and taken precautionary action.

Precautionary chemical policies do not stifle innovation. On the contrary, exercising foresight implies an aggressive search for, and transition to, safer substitutes. This kind of technological

innovation can help us get the benefits we seek with less harm to human health and the environment. To prevent harm, chemical policies should therefore include:

- Thorough measures to gather and evaluate evidence that a chemical is likely to have harmful side effects;
- Specific thresholds and standards for acting to prevent harm; and
- The development of systems that avoid reliance on toxic chemicals.

A Precautionary Definition of Harm Sets the Terms for Protective Action

Our chemical policy system must put the health of people and ecosystems above all other considerations. This priority requires a clear sense of when to act and what to do to prevent harm, even before science can give definitive answers. This section describes the kind of harm that biologically active chemicals can cause, scientific uncertainty, and credible evidence of harm. These definitions help us decide when and how to take protective action.

- *Biologically Active Chemicals Are Harmful*
- *Acting when Science is Uncertain*
- *Defining the “Credible Evidence of Harm” Threshold for Protective Action*

Biologically Active Chemicals Are Harmful

At its simplest and least controversial, “harm” is damage to humans, fish, wildlife, or ecosystems that may show up as:

- acute toxicity, such as chemical poisoning causing death;
- cancer;
- reproductive impairment or failure, for example, resulting from decreased sperm count;
- developmental abnormalities, such as birth defects or learning disabilities;
- behavioral changes, such as attention deficit disorder;
- immune system alterations, such as autoimmunity or allergies; disruption of biological signaling systems, such as changes in hormone levels; or
- other manifestations of damage to biological systems that result in disease or suboptimal functioning.

In this paper we will call chemicals capable of causing such harm, as side effects to their intended use, *biologically active chemicals*.

Acting When Science Is Uncertain

Although biologically active chemicals can cause harm, identifying harm may still be controversial because linking harmful outcomes in specific individuals or communities to specific chemicals that may have caused them is often difficult or impossible. Here are some reasons why:

- The earliest manifestations of damage may lie within “normal variability” of individuals or populations. For example, individuals or populations may have reduced brain or reproductive function as the result of chemical exposures, although measures of their neurological or reproductive function may still lie within “normal” ranges;

- The earliest manifestations of damage are sometimes not, in themselves, easily classified as harmful. For example, a chemical exposure may alter levels of hormones or other systemic substances in an organism. These changes may increase the risk of a variety of adverse effects, but the effects themselves are non-specific and not easily linked to the original exposure;
- A long latent period may follow early manifestations of altered biological functioning before more obvious and conclusive evidence of harm emerges. For instance, some cancers have latency periods of up to 40 years;
- The manifestations of harm are often not unique to a single specific cause. For example, diet, exercise, genetics, high blood pressure, exposure to air pollutants, some industrial chemicals, and cigarette smoking can all contribute to heart disease. These factors act alone and in many different combinations to increase risk. Defining the contribution of any one of them to the ultimate risk of heart disease in an individual or population is filled with uncertainty.

By convention, scientific certainty is generally considered to be established when an assertion is considered “true” with at least 95% likelihood or when a number of strict criteria that establish causation have been met. These requirements translate into “beyond a reasonable doubt.” It is, however, difficult to draw conclusions about cause and effect relationships in complex

biological systems without acknowledging some degree of uncertainty. Factors that influence uncertainty include the following.

- **Lack of data**—temporary, reducible uncertainties (which may, for example, be addressed by requiring comprehensive safety data for all chemicals, another key action item of the Louisville Charter).
- **System complexity**—interacting variables, cumulative impacts, delayed effects, or the difficulty of extrapolating from controlled conditions to real-world conditions. These uncertainties may be reducible, but reaching certainty may never be possible.
- **Ignorance**—we often do not know how much we do not know, especially where novel and emerging technologies are concerned. *Novelty itself must be considered a risk factor*, because harmful effects of new technologies may not be detected or predicted by tests developed for older technologies. Emerging technologies require special scrutiny, both pre-market and post-market.
- **Controversies and conflicts** influence scientific opinion and investigations, for example:
 - Conflicting values, especially regarding what constitutes harm;
 - Economic pressures within the scientific community;
 - Economic pressures from industry to discourage health and environmental investigations.

Defining the “Credible Evidence of Harm” Threshold for Protective Action

Despite the difficulties posed by scientific uncertainty, we do know enough to act when we have credible evidence that harm is occurring or likely to occur from biologically active chemicals. *Credible evidence of harm* includes any or some combination of the following:

- well-established, independent scientific evidence of harm to human health or ecosystems;
- emerging scientific evidence of harm to human health or ecosystems;
- verifiable evidence of altered functioning of exposed organisms, including damage to DNA, biological systems, or cellular function;
- results of comprehensive or partial testing and controlled observations, including animal studies;
- observations from formal health, environmental, or wildlife monitoring;
- epidemiological evidence;
- health surveys or verifiable observations of and by workers;
- observations by medical personnel;
- observations, experience, or community health surveys by people living near industrial facilities, waste sites, or other sources of contamination;
- extrapolation from existing, well-established scientific evidence on existing substances to new substances with similar structures and physico-chemical properties; and
- predictive models based on empirical data.

The *duty to consider all relevant information from multiple sources* is a fundamental principle of science. The best scientists keep their minds open to all relevant information, including factors that lie outside the scope of their investigations. Yet, when science is translated to policy, this aspect of scientific learning is often forgotten or ignored. Too often, policy makers have looked to science for precision without taking into account the skepticism and uncertainty embedded in science itself—the hesitance to draw hard and fast conclusions—and the continuing curiosity that is essential to scientific investigations. People who are not technical experts, especially people living in communities disproportionately affected by chemical contamination, may have an even keener sense than experts do of what must be considered, and they can provide relevant information.

We must increase our understanding of complex biological systems and, in the absence of complete understanding, do what we can to protect the integrity of such systems, including human bodies. We must keep alert to the political and social influences on our knowledge, the limits of that knowledge, and the potential costs, including the human health costs, of transgressing those limits.

When do we know enough to act? To sum up, two conditions provide *credible evidence of harm* in cases of scientific uncertainty on biologically active chemicals. These conditions establish the threshold for various kinds of protective action.

- 1) Credible evidence that a synthetic chemical can cause biological changes that are known to result in unintended harmful outcomes in some cases.

- 2) The presence of such a chemical where it does not belong and where it can cause damage to biological systems (such as human bodies).

The best way to protect the health of people and ecosystems is through chemical policies that regulate the production and use of all biologically active chemicals, remove those chemicals from where they can cause damage, and treat untested chemicals as potentially dangerous. And because it is impossible to predict all side effects of synthetic substances, giving priority to the health and well-being of humans and the environment means monitoring presence and effects of chemicals in the real world even after a full safety-testing regime is in place.

Acting to Prevent Harm on the State & Federal Level

We can act to prevent harm from chemicals through a wide variety of measures, some of which we describe below and many of which are described in other parts of the Charter.

- *How Taking Precautionary Action Relates to Other Charter Reforms*
- *Create and Strengthen Health & Environmental Programs to Detect and Predict Possible Harm*
- *Take Action when Credible Evidence of Harm is Found*
- *Monitor Novel Technologies*
- *Consider Clusters of Health Problems to Be Early Warnings*
- *Open Toxic Tort Records*

How Taking Precautionary Action Relates to Other Charter Reforms

REFORM #1:

Require Safer Substitutes

A precautionary chemical regime encourages the development of innovative, safer technologies. The principles of green chemistry and requirements for safer substitutes are the positive side of a precautionary approach. Inherently safer chemistry is the goal of this Charter. The preventive actions recommended in this background paper must be accompanied by incentives and requirements for safer substitutes.

REFORM #2:

Phase Out Persistent, Bioaccumulative, or Highly Toxic Chemicals

Acting with foresight requires collecting enough information to make informed choices and exercising our moral capacity to make just choices. When it becomes clear that chemicals in use are persistent, bioaccumulative, or highly toxic—that is, we know they are harming our bodies, and especially our children's bodies—then it becomes necessary to make a societal choice to phase them out. Especially in cases where safer alternatives are available, the phase-out of uniquely harmful chemicals becomes a moral choice for society.

RECOMMENDATION #3:

Give the Public and Workers the Full Right-To-Know

Acting with foresight means both having enough information to know that a product or practice is harmful, as well as acting on that information. By definition, that means that the public and workers must have full right-to-know about the toxicity of substances to which we are exposed. Without knowing the potential harm of exposures, we cannot judge whether we should take action to prevent further harm. Therefore, full right-to-know is essential for implementing a precautionary framework.

RECOMMENDATION #5:

Require Comprehensive Safety Data

The adoption of a comprehensive safety-testing regime for all chemicals entering or remaining on the market is essential. The procedures and requirements described in the background paper for Recommendation #5 would provide much of the evidence we need to decide whether a chemical should or should not be on the marketplace or whether any restrictions should be placed on its use. But additional measures will be needed in the interim, before all chemicals have been tested, and even after this regime is in place, especially where novel technologies are concerned.

RECOMMENDATION #6:

Take Immediate Action to Protect Communities and Workers

The recommendation to “act on early warnings” detailed in this paper rests on one fundamental fact: tens of thousands of community members and workers have spoken of harm for

years—quite literally while the body count piles up—before being taken seriously by those with decision-making power. While data gathering and considered decision-making processes are both crucial to preventing harm, these steps must not stand in the way of taking immediate action to protect our health. The earliest warnings of harm must be heeded.

The principles and actions described in this section complement all these actions but apply especially to:

- Taking action in conditions of uncertainty;
- Gathering early warnings of harm; and
- Bridging the gap between the present and future. Many of the principles and actions described here may be implemented immediately and serve as a bridge to a chemical regime based on comprehensive safety testing and inherently safer technologies.

Create and Strengthen Health and Environmental Programs to Detect and Predict Possible Harm

1) *Comprehensive safety testing of all synthetic chemicals* is the most important system for detecting and predicting possible harm. (See the Charter’s 5th recommendation)

2) *Expand and Strengthen State and Federal Health Monitoring Programs.* The Centers for Disease Control (CDC), National Institute of Occupational Safety & Health (NIOSH), and public and occupational health agencies at the state and local levels should broaden the scope of systems monitoring exposures, including body

burdens, of chemicals to include all known biologically active chemicals used in products and manufacturing processes. In the period before full safety testing, these agencies must also be alert for the presence of any untested synthetic chemicals. The CDC and NIOSH should establish monitoring standards and ensure that all state and local agencies are conducting monitoring in a consistent manner, with public input and annual reports available to the public.

Monitoring should be expanded to include breast milk, infant meconium or cord blood, and other appropriate biological tests. (The goal of biomonitoring is to identify the nature and degree of exposures at various life stages and in various communities. Biological sampling methods will vary, depending on the physicochemical properties of the substances of interest. Pilot testing will help determine the size and scope of ongoing monitoring programs.) Breastfeeding advocates and community members should participate in monitoring breast milk and infant meconium or cord blood. When breast milk is tested, support systems and information on the health benefits of breastfeeding over formula feeding should be offered to women who are tested and to low income communities where breastfeeding rates may be below the national average.

Health effects, disease, and disability tracking can be pursued separately from exposure monitoring. Examples include environmental health tracking, state-wide cancer and birth defect registries, community-focused epidemiology, and community health surveys.

The CDC and NIOSH should issue a comprehensive annual report

summarizing monitoring data from federal, state, and local investigations. Exposure monitoring data should be systematically integrated with health effects data in order to identify potential correlations early and to trigger follow up investigations. Findings of credible evidence of harm should be reported immediately to appropriate Early Warning Committees or other authorities for action (see number 4 below). Advisory Committees need to be established, where they are not already in place, to provide public input to federal and state agencies conducting such monitoring programs.

3) *Early Warning Committees.* Every state should have an Early Warning Committee of health, environmental, and wildlife experts. Committees should include county and state environmental and health department staff; representatives of community, environmental, health, and occupational safety & health organizations; and health practitioners experienced in environmental health issues. At the federal level, a major interagency task force could be established including representatives of Health & Human Services (HHS), Environmental Protection Agency (EPA), U.S. Fish & Wildlife Service, National Institute of Occupational Safety & Health (NIOSH), and CDC, as well as representatives of health, environmental, conservation, occupational safety & health, and community organizations.

The state Early Warning Committees would ideally serve as channels both for reporting emerging problems and acting upon them. The committees would report immediately to the

national interagency Early Warning Task Force any health or environmental monitoring finding of credible evidence of harm. The reports and subsequent action recommendations of these state committees would be the authoritative trigger for timely health-protective action by the appropriate state and federal agencies and/or industry. The national interagency Task Force would coordinate the state committees and ensure that consistent action is taken to address similar problems in different regions.

4) *Expand & Strengthen State and Federal Environmental and Fish & Wildlife Monitoring Programs.* The Environmental Protection Agency (EPA), U.S. Fish & Wildlife Service, and environmental agencies at the state and local levels should broaden the scope of monitoring fish, wildlife, and environmental contamination of air, soil, and water (groundwater and drinking water including private wells) to:

- include all known biologically active chemicals used in products and manufacturing processes and,
- in the period before full safety testing, to be alert for the presence of any untested synthetic chemicals.

The EPA and U.S. Fish & Wildlife Service should establish monitoring standards and ensure that all agencies are conducting monitoring in a consistent manner, with public input and annual reports available to the public. These agencies should issue a comprehensive annual report summarizing monitoring data from federal, state, and local investigations. Findings of credible evidence of harm, integrating exposure data with effects data, should

be reported immediately to the Early Warning Committee for action. Advisory Committees need to be established, where they are not already in place, to provide public input to federal and state agencies conducting such monitoring programs.

5) *Redirect the Public Research Agenda.* While narrowly focused scientific research produced breathtaking advances of many kinds in the past two hundred years, failure to give equal attention to consequences, side effects, and the complex interactions of multiple chemical exposures and other health factors has resulted in untold, unintended harm to people, fish, wildlife and the environment. In the Twenty-First Century it is no longer appropriate for science and technology to continue to produce innovations in a vacuum of knowledge about such consequences.

Public funding, therefore, must shift to science investigating complex biological systems and relationships; broad, long-range effects in biological systems; factors that promote public health and a healthy environment; and inherently safer technologies. This should be established as a priority by the president, governors of states, and federal and state legislatures. Advisory committees should be formed to direct funding to research in every institution where such committees do not already exist at the federal and state level, including the National Institutes of Health (NIH), National Institute of Environmental Health Sciences (NIEHS), National Institute of Occupational Safety & Health (NIOSH), and state-sponsored universities.

Take Action when Credible Evidence of Harm Is Found

1) When credible evidence of harm is found that a chemical is biologically active and can cause harm in people, fish and wildlife, or the soil, air, and water, timely action should be taken to prevent harm. Such action may include, but is not limited to:

- Widespread distribution of a public health or environmental warning advising people to avoid exposure; and
- Steps to prevent, eliminate, and mitigate exposure, such as:
 - use restrictions,
 - timely transition to safer alternatives,
 - phase-out of manufacture and use of the hazardous chemical, technology, or practice,
 - healthcare consultations and assistance,
 - wildlife restoration, and
 - timely cleanup of any contaminated soil or water.

Monitor Novel Technologies

Novel chemicals and quasi-chemical technologies (for example, converging technologies at the nano scale) may have properties and unintended effects that may not be revealed even under a comprehensive safety-testing regime. The EPA must therefore authorize review of novel products and technologies through a democratic process such as an Advisory Committee including experts from a wide range of scientific, health, and non-scientific disciplines (including ethics) and representative, potentially impacted citizens.

Such a panel would determine whether:

- the evidence is adequate to make a reasonable judgment;
- the product or technology is needed for an important societal function;
- the product or technology threatens public health, the environment, or another highly valued aspect of our common enterprise;
- safer alternatives are available; and
- whether there are other relevant questions that cannot be answered to public satisfaction by scientists, manufacturers, or regulators alone.

The results of these deliberations and recommendations could (do you want to say “should”) be provided to EPA (and any other relevant oversight agency) and would be prioritized and given weight in the body of evidence as EPA and other agencies determine public policy, permitting, regulations, and legal action regarding the novel technology.

Performance bonds should be considered for all new and emerging chemicals and technologies in the absence of ways to test and understand their biological and geological behavior. For instance, bonds could be posted for certain potentially hazardous chemicals or technologies, based on a full-cost accounting of possible impacts.

Note that these requirements for novel technologies would be *in addition to* meeting requirements for comprehensive safety testing. There is no body of evidence without such testing.

Consider Clusters of Health Problems to Be Early Warnings

The impacted public should not have to prove harm before action is taken when:

- any body burden or other information shows elevated levels, in a specific population, of biologically active substances including synthetic chemicals and pollutants such as mercury and lead; or
- apparently higher incidences of unusual cancers, birth defects, poisonings, or other diseases or disorders appear in a population.

The question should not be whether a cluster of elevated body burdens or unusual diseases is statistically significant before action is taken. Rather, the question should be *whether any of the occurrences are preventable*. With the appearance of clusters, both the public and private sector must act immediately to reduce contributing exposures to the extent possible.

Open Toxic Tort Records

Too often, relevant information about toxic chemicals and health effects has been sealed in protective orders issued by courts in specific cases. In exchange for a generous settlement, plaintiffs and their attorneys may agree to keep secret certain information that is detrimental to a defendant. But this secrecy means the offenses may be repeated and other victims may suffer in apparent isolation. In order to protect the public, court records, including settlements, should be opened for all toxic tort cases.

On the Local Level: Supporting Communities to Take Action

Although there are many opportunities for progress on the state and national level, many communities are making the strategic choice to focus their efforts locally. Local work is less dependent on the politics of the current White House or State House, can be more grounded in community experience, and can lead to more direct accountability from local elected officials.

Several communities have incorporated the precautionary principle into local law in order to provide explicit authority to act on early warnings. The cities and counties of San Francisco, Berkeley, and Marin County CA; Portland OR; Seattle WA; and Buffalo, NY have all passed precautionary principle laws or ordinances. The University of California, Berkeley, is developing recommendations, under the mandate of the California legislature, to give state agencies explicit authority to act on early warnings and take precautionary action. Bills directing state agencies to take precautionary action when credible evidence of harm is found have also been introduced in the New York State Assembly and Senate. In addition, precautionary laws on specific chemicals such as PBDE flame retardants have passed or are pending in many states.

For decades, communities have been acting with foresight to heed early warnings if laws and regulations are not protecting people and the environment. For instance, in the last thirty years communities have prevented harm and stopped exposures to toxic and radioactive chemicals from hazardous technologies and practices, despite gaps in federal or state protective policies and enforcement. Grassroots groups have shut down or halted the siting of hundreds of medical, solid, and hazardous waste incinerators; nuclear power plants; and hazardous and radioactive waste landfills.

Recently many of these actions have been based explicitly on the precautionary principle. For example, people in Denton, TX, advocated for a policy to reduce pesticide use in parks, and, in the process, discovered a new, safer product (corn gluten as an herbicide) that a local business could produce. San Francisco, CA, Buffalo, NY, and several other cities are setting up programs to purchase healthier, less toxic products such as vehicles that burn cleaner fuels and products without persistent bioaccumulative toxic chemicals. Citizens in Georgia are calling on officials to act on early warnings by preventing the siting of an elementary school between hazardous waste sites, and investigating nuclear contamination in counties surrounding a weapons manufacturing plant.

None of these communities or local authorities waited for state or federal authorities to act before taking the initiative to prevent harm. In the suburbs of Pittsburgh, PA, a school superintendent explained his decision to switch away from using harmful pesticides on the school playing fields this way: “If there’s a chance that something I’m doing is hurting kids, and there are safer alternatives available, then why would I do it? I may not be as zealous as some, but I think I know right from wrong.”

Policies and programs that support community involvement in taking local precautionary action are needed. For instance, technical assistance grants, meaningful community participation plans, and Advisory Committees that truly represent impacted communities are needed at every level of government. Non-profit groups can provide resources and model policies, share successful strategies, offer guidance on fundraising, and otherwise support an expansion of community-based precautionary actions around the country.