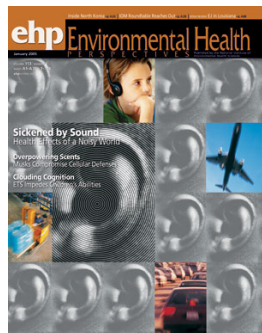


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Commentary

A Public Health Context for Residual Risk Assessment and Risk Management Under the Clean Air Act

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Abstract

The 1990 amendments to the Clean Air Act required the EPA to institute new pollution control technology requirements for industrial sources of air pollution. In part because agreement could not be reached on the best way for the EPA to determine whether any significant risks to human health will remain after the technology controls are in place, the amendments also created a Commission on Risk Assessment and Risk Management and gave the commission a broad mandate to review and make recommendations concerning risk assessment and risk management in federal regulatory programs. In its March 1997 final report to Congress and the administration, the commission recommended a tiered approach to assessing such residual risks. That approach included the idea that when decisions about managing residual risks are made, emissions should be evaluated in the context of other sources of air pollution. Evaluating risks in their larger contexts is consistent with what the commission called a public health approach to environmental risk management. This paper describes the public health approach and how it applies to evaluating residual risks under the Clean Air Act.

Key words: air pollution, Clean Air Act, public health, residual risk, risk assessment, risk management.

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Introduction

The EPA will soon be required to embark on a nationwide program to determine whether industrial air emissions continue to be hazardous to our health. The agency has yet to decide how that task should be accomplished. New and creative approaches are needed because current emissions control programs have already achieved the more readily made pollutant reductions and because of the increased emphasis on cost-effectiveness.

The Clean Air Act Amendments of 1990 authorized the EPA to develop a program to control hazardous air pollutants through the promulgation and implementation of technology-based standards. Such standards are determined by identifying the maximum achievable control technology (MACT) currently in place. This strategy was developed because the risk-based approach that was intended to implement earlier Clean Air Act amendments was found to be ineffective and inefficient, having resulted in only seven hazardous air pollutant standards between 1970 and 1990. After MACT is in place, the EPA must assess residual pollutant emissions

and the residual risks associated with those emissions. On the basis of those assessments, decisions will be made about the need for further risk management of residual emissions.

The 1990 Clean Air Act amendments also authorized a Commission on Risk Assessment and Risk Management, charged with the responsibility of developing a method for evaluating residual risks. In its final report to Congress in 1997 (1,2), the commission recommended a scheme for residual risk assessment as well as a framework for environmental health risk management. The framework is intended to improve the logic, consistency, and acceptability of decisions related to public health protection and environmental risk management and has six components (see Fig. 1): problem/context, risks, options, decisions, actions, and evaluation. One of the advantages of the framework is that instead of evaluating risks singly and in isolation from one another, they are evaluated in the context of the risk management decision to be made and in the context of public health. Evaluating residual risks in the context of public health requires a public health approach to risk management.



Figure 1. The Risk Commission's framework for environmental health risk management.

What Is a "Public Health Approach"?

Over the last 25 years, the traditional command-and-control, risk-by-risk approach to environmental health protection has worked well to greatly improve the quality of our food, air, water, and workplaces. Now we are left with the more intractable, complex problems, such as urban air pollution and cleaning up Chesapeake Bay, that the traditional approach is less likely to solve. Continuing the improvements of the last 25 years will depend on our ability to learn how to look at risks collectively instead of one at a time. We need to get beyond the current chemical-by-chemical, medium-by-medium, risk-by-risk approach dictated by current statutes and refocus our priorities by taking a broader view. Instead of continuing to argue about what numerical regulatory standards should be for each chemical, we should be asking what exposures are posing the most immediate threats to our health and our environment and how we can control them. In other words, we need a public health approach to risk management. Standard setting and enforcement continue to provide an important basis for environmental health protection, but to move to the next level of effectiveness, a more comprehensive approach is needed.

A public health approach to risk management emphasizes prevention instead of cleaning up after the fact and focuses on the effectiveness of actions instead of relying on regulatory command and control. A public health approach evaluates the adverse health effects experienced by a population, identifies possible causes of those effects, and then seeks to determine the relative contribution of each cause to the effects. A public health approach comprises an individual's complete physical and social well-being and includes nondisease end points such as odor and noise. In many cases, the public health foundation of environmental health protection has been obscured by legalistic, technical, centralized decision-making processes that are often unrelated to the problems faced by local communities (3). The public health basis of our regulatory statutes has been obscured by their reliance on cleaning up problems after-the-fact instead of preventing them and by their lack of a focus on whole populations. A greater focus on public health principles would better serve the environmental health objectives of our regulatory statutes, although it is the dictates of those very statutes that often pose the greatest impediments to a focus on public health (4-7).

Residual Risk Assessment and a Public Health Approach

The problem with applying a public health approach to evaluating residual risks under the Clean Air Act is that we are already locked into a chemical-by-chemical, single-medium approach under the statute. However, the statute says that the EPA needs to evaluate residual risks and, if required, promulgate standards, but it does not say how the EPA has to evaluate them. So, presumably, the EPA is given broad discretion to evaluate

residual risks and then decide what constitutes appropriate standards. The EPA could therefore choose to evaluate risks in the context of other pollutant sources and other risks to health.

In its final report, the Risk Commission (1,2) stated,

Local, regional, and national levels of air toxics, by pollutant and by source category, must be put in the context of exposures from other air pollutant sources and from environmental pathways other than air. The goal is to build an understanding among stakeholders about the health context of residual emissions from the regulated point sources.

By context, the commission means looking at a problem's role compared to, for example, other sources of the same contaminants, other exposures occurring simultaneously, or other threats to human or environmental health. Contexts can be multimedia, multisource, multichemical, or multirisk. The intent is not to minimize the importance of any particular risk or emission, but to clarify to stakeholders the impact that managing that risk is likely to have on health or the environment.

Context depends on the situation. The context for the pollutant emissions from a single facility in a community could be other sources of the same pollutants, such as drinking water, food, and consumer products. It could include other facilities in the region that emit the same or other pollutants. For example, consider residual risks from benzene emitted from petroleum refineries. After the technology standards mandated by the 1990 Clean Air Act amendments are in place to control benzene emissions, local and regional risk assessments will be performed to evaluate the leukemia risk posed by the remaining benzene in emissions from individual petroleum refineries. At that stage, it will be important to consider other sources of benzene in air, or the multisource context. Motor vehicle emissions are the largest single source of airborne benzene in outdoor air in the United States, although because of indoor air exposure, motor vehicle emissions account for only about 20% of personal exposure (8). Benzene is in cigarette smoke and in consumer products used at home (9). In fact, the home is the largest source of benzene exposure that we receive, with cigarette smoking contributing 56% of personal exposure and other home activities contributing 21% (8). If the residual leukemia risk from refinery emissions turns out to be significant compared to the leukemia risk contributed by other sources, risk-reduction efforts should focus on further reducing refinery emissions. If the refinery risk proves insignificant by comparison, risk reduction activities might better be directed at other sources. Benzene can also be a precursor to ozone, so in some cases it may make sense to consider its indirect impacts. However, the EPA has always compartmentalized its risk assessment and management approaches. For example, its regulation of marine oil terminals in Valdez, Alaska, where ozone is not an issue, was no different from its regulation of marine oil terminals where ozone is a problem. And while up to 15% methyl *tert*-butyl ether (MTBE) is required in many places as a gasoline additive, MTBE emissions to air from its manufacturing facilities are tightly controlled because it is considered a hazardous air pollutant.

If residual risks from arsenic and lead emitted by secondary lead smelters are of concern, the context could be multimedia. For example, an EPA study showed that the concentration of airborne arsenic in the vicinity of secondary lead smelters is about 100 times the average concentration of airborne arsenic in the United States. When all sources of exposure to arsenic near smelters are taken into account, however, smelter emissions contribute only about 10% of total exposure, raising a broader risk management issue about what action should be taken to reduce arsenic exposure from all sources. Other major sources of arsenic exposure include seafood and cigarette smoke (10). On the other hand, lead emissions from secondary lead smelters are by far the primary contributor to lead exposure in the vicinity of smelters, despite the many other sources of human exposure to lead (11).

The context for an entire source category might depend on the health effects posed by the particular pollutants emitted from that category or on the extent to which other sources of the same pollutants contribute to total air pollutant levels or total exposure. For example, motor vehicle exhaust contributes 60% of the nationwide benzene outdoor air pollution, 94% of the total 1,3-butadiene air pollution, and 39% of acetaldehyde emissions. The contributions of one or more source categories properly controlled by MACT to total benzene, 1,3-butadiene, and acetaldehyde pollution are likely to be small by comparison.

The appropriate context will depend on the situation. Because the toxicity of a substance may vary depending on route of exposure, the appropriate context might be limited accordingly. In some cases, all routes of exposure might be considered during problem identification, while the risk-management decision might be based on conclusions about the relative toxicological importance of different routes.

Risk Management Using a Public Health Approach

The overall goal should be to direct risk management resources where they will do the most good to protect or

improve the community's health. To achieve that goal, we need to start looking at risks comprehensively. As Daniel Greenbaum, former Commissioner for Environmental Protection for the state of Massachusetts put it in his testimony to the commission (12),

I saw far too many cases where extreme attention was placed at an industrial facility on ensuring that every last molecule of a toxic substance was kept out of the air, only to have that same substance ignored as it poured through the floor drain into the groundwater. Taking a look at the whole mix of pollutants, at whole watersheds, is fundamental.

Looking at problems in their contexts should help us start to do that.

The challenge for assessing residual risks in context boils down to understanding how to assess multiple or aggregate risks; making a decision about what to do about a particular source or sources of risk after you have done that is another question altogether. Using a public health approach can help to assess aggregate risks and to target risk management resources by focusing attention on the health effects experienced by a population--not just the individual with the putative highest exposure--and the relative contributions of different pollutant sources or other problems to those effects (4). A public health approach is a "top-down" approach that starts by focusing on a problem and then seeks to identify what is causing the problem as a guide to determining how best to solve it. In contrast, most of our current regulatory approaches are "bottom-up"; that is, they start with a cause and then try to eliminate it without determining the extent to which it actually may contribute to a problem. A bottom-up approach makes it difficult to set priorities among risks or to evaluate whether a risk management action has had an impact on a public health problem. Advances in molecular biology have moved us closer to linking biomarkers of effects with biomarkers of exposure, making a top-down approach more feasible by facilitating attribution of causality. In the meantime, public health approach implementation should target diseases with recognized environmental components, such as asthma or lung cancer. Diseases with less well-understood environmental components will require better-developed monitoring and surveillance systems and better understanding of the interplay of causative factors before a public health approach can be applied effectively. An intermediate step toward achieving that goal will be to replace mathematically modeled estimates of exposure with biological measures of actual exposure. Ideally, biological markers that reflect both exposure and effect will provide the linkage central to an effective public health approach. Carboxyhemoglobin formation is a well-known example of a biological marker.

One public health-based approach that has been proposed recently to help manage residual risks is a public health improvement market (13). A public health improvement market would bring together willing sellers of public health improvements, such as public health departments and community groups, with willing buyers seeking alternatives to further emissions reductions. In this proposal, a limited number of sources meeting current air quality standards would be offered the opportunity to make investments in public health benefits rather than marginal decreases in emissions. Protections would be put in place to avoid individual source backsliding, distributional inequities, adverse health effects, and significant ecological damage. Five elements are envisioned as part of the market approach:

- Tradable instruments: a common metric for risk reduction would be developed to allow the valuation of various investments.
- Baseline standard of conduct: individual sources making alternative investments would be subject to legal sanctions if they did not maintain their current level of environmental performance; continuous monitoring of the results of alternative investments would be needed.
- Public participation: the public must be fully engaged in the design and operation of a market approach.
- Accurate, accessible information: the public and the regulators would need understandable, standardized, and accurate information about risks being traded.
- Public verification: a risk trading approach would succeed or fail depending on public confidence that the alternative investments meet expectations.

The public health investment market is an innovative idea that builds on programs already in place. For example, the South Coast Air Quality Management District allows companies who do not participate in vehicle emission reduction programs to make payments to an escrow fund that is then used to buy alternatively fueled vehicles for city services, such as trash trucks or school buses, or to make other vehicle emission reductions. As a result of the 1996 amendments to the Safe Drinking Water Act, water suppliers can avoid costly controls on radon in drinking water and, instead, invest in measures to mitigate exposures to airborne radon, often a

greater source of exposure. The EPA opened the door to such a concept in its implementation plan for the new Clean Air Act standards by proposing a Clean Air Investment Fund that would allow sources with control costs in excess of \$10,000/ton of pollutant to pay a set annual amount to fund more cost-effective emissions reductions by nontraditional and small sources.

The EPA's recent cumulative risk guidance (14) and broadening concepts of risk characterization (15) are promising signs that the agency is looking beyond its traditional single-chemical, single-medium focus. As it takes on the challenges of assessing residual risks, the agency needs to broaden its focus further to encompass environmental health impacts from the perspective of public health. A nationwide public health surveillance network is needed to facilitate making connections between environmental exposures and public health outcomes. Finally, creative risk management options are needed to optimize the contributions that our limited risk management resources can make towards minimizing residual risks and continuing the environmental and public health improvements we have enjoyed for the last 25 years.

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