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The Need For Better Public Health Decisions On Chemicals Released Into Our Environment

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ABSTRACT Protecting the health of the public—particularly the most vulnerable groups, such as children—requires rethinking current approaches to reducing environmental risks. We review the evolving understanding of the relationship between exposure to chemicals in the environment and disease, as well as the current state of managing those chemicals. We present recommendations to improve current approaches, including changing the burden of proof so that chemicals are not presumed safe in the absence of scientific data. We also propose modernizing approaches to assessing health risks.

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It is widely recognized that the environment contributes to many cancers, other chronic diseases, and disabilities.[1] Key early evidence for this fact came from observations that the children or grandchildren of immigrants to countries with lower (or higher) rates of cancer than the original home country had cancer rates typical of their new home.[2,3] Natural and man-made substances in the environment and other environmental factors are believed to be important contributors to most human cancers.[3] The report of the President's Cancer Panel—an advisory committee of physicians and scientists appointed in 2006 by President George W. Bush—notes that the panel "was particularly concerned to find that the true burden of environmentally induced cancer has been grossly underestimated."[4]

Observed increases over the past twenty to thirty years in the incidence of many chronic conditions—including diabetes, childhood asthma, and childhood and adult obesity[5,6]—raise concerns about potentially underappreciated environmental risk factors.[7] Chronic diseases such as these are now the leading cause of disability and death in the US population,[8] and genetic predisposition and increased screening and diagnostic sensitivity cannot fully explain the increases.[9,10] Behavior and learning challenges have also increased markedly.[5]

Many factors can increase the risk of chronic diseases, a risk that increases further with the likely interaction among factors.[1] For example, genetic predisposition, age, lifestyle, nutrition, and exposure to chemicals in the environment have all been identified as risk factors for children's chronic conditions such as asthma, obesity, and behavioral and learning problems.[5] The role of environmental chemicals is now receiving increasing attention as a preventable risk factor for many chronic diseases.[7]

In this paper, we review the current state of environmental decision making and our evolving understanding of the relationship between disease and exposure to chemicals in the environment. We then recommend changes in the assessment and management of that exposure to improve the management of public health risks.

The Current Situation

THE MAGNITUDE OF THE ENVIRONMENTAL CHEMICAL PROBLEM In the past seventy years, the manufacture and use of industrial chemicals has increased more than fifteenfold,[11] an outgrowth of innovation and discovery. People are now exposed to multiple environmental chemicals in the air, food, water, and a variety of consumer products, such as phthalates, which can

be added to plastics to increase their flexibility; brominated flame retardants, such as those used in furniture; and perfluorinated chemicals, which are used to make surfaces stain- or stick-resistant. Many of these chemicals appear in measurable quantities in Americans' bodies[12] and can be associated with adverse health effects.[13–15]

More than 80,000 chemical substances are listed by the Environmental Protection Agency (EPA) as manufactured or processed in the United States, or imported into the country,[16,17] but this is probably an overestimate of the number of chemicals currently in commercial use. The EPA believes that not all of these chemicals are being produced or imported at any given time, and it is currently reassessing the total.[18]

Approximately 700 new industrial chemicals are introduced each year.[17] About 3,000–4,000 chemicals are identified as high volume chemicals, meaning that more than a million pounds of each of them are manufactured or imported annually.[18] These may pose special risks by virtue of their volume.

The US government has made important progress in reducing exposures to some chemicals that adversely affect health, including specific air pollutants identified in the Clean Air Act of 1963, such as particulate matter and lead; hazardous air pollutants named in the Clean Air Act Amendments of 1990, including benzene and dioxin; asbestos; persistent chlorinated insecticides such as dichlorodiphenyltrichloroethane (DDT); and dibromochloropropane and other pesticides that are highly toxic and mutagenic, or damaging to DNA. As shown in Exhibit 1, national ambient air concentrations of critical air pollutants—sulfur dioxide, nitrogen dioxide, carbon monoxide, particulate matter, ozone, and lead—have declined as a result of this legislation, although some are still above the current national air quality standard in many locations. Similarly, Exhibit 2 shows the changes in annual average air concentrations of benzene, whose health effects include increasing the risk of leukemia.

Some of these improvements can be measured by reduced concentrations of the chemicals in human blood or fat, detected through biomonitoring studies—which measure the presence of chemicals in human biological specimens, such as those of blood or urine.[19,20] The observed declines in these chemicals can be directly linked to government regulatory activity.[21] However, although exposures to some legacy chemicals—chemicals that remain in the environment after the ending of the activity that produced them—have dropped, exposures to others have not,[22] and the introduction of new chemicals can lead to new exposures.

MANAGING EXPOSURES TO CHEMICALS The variations in successfully managing exposures to chemicals is partly driven by the availability of data related to health. Understanding the extent of potential health risks in the general population, and which groups are particularly sensitive to these exposures, requires both data about the extent of exposures to chemicals in the environment and toxicity data.

▶ **DIFFERENCES IN LEGAL REQUIREMENTS:** Multiple laws determine regulatory agencies' ability to obtain data from manufacturers and their legal authority to manage exposures to chemicals. Paradoxically, there are generally no toxicity data requirements *prior to release* of chemicals into different environmental media—such as air and water—although many statutes involve risk assessments to control certain pollutants *after* their release. These include emissions of chemicals into the air, under the Clean Air Act Amendments of 1990; into water, under the Safe Drinking Water Act of 1972; and into hazardous waste, under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 and the Resource Conservation and Recovery Act of 1976.

On the other hand, premarket toxicity testing is generally required for pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act of 1976 and the Food Quality Protection Act of 1996. Such testing can provide data about potential health risks or other hazards prior to release of the pesticide into the environment.

This requirement has led to certain safeguards.[23] For example, the use of mutagenic (altering either genes or their expression) and carcinogenic pesticides is strongly curtailed.

▶ **THE TOXIC SUBSTANCES CONTROL ACT:** One of the largest identified policy gaps is in the Toxic Substances Control Act of 1976. This law gives the EPA only limited authority to require data on the potential health risks from exposures to a large number of nonpesticidal chemicals, both those that have long been in use and those that have more recently appeared on the market.[24] Toxicity and exposure data for thousands of chemicals currently in use have never been requested or assessed.[25] In addition, if a substance is discovered to be hazardous and its use is strictly regulated, it is often replaced by an untested substance—which may be just as bad.[26] Flame retardants, described below, provide an example.

Under the Toxic Substances Control Act, chemicals are essentially assumed to be safe until shown to be harmful, with few requirements for manufacturers to supply data on potential exposures or risks.[27,28] Not surprisingly, manufac-

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turers have little incentive to generate data that might show their products are unsafe. As a result, it is difficult for the EPA to assess and regulate chemicals in a timely fashion.[28] In contrast, manufacturers of pharmaceuticals and pesticides must test them for toxicity and receive approval for their use from the Food and Drug Administration or the EPA, respectively, before they enter the market.[27]

The case of two flame retardants provide an illustration of the problem with the act. In 1974, Firemaster flame retardants containing polybrominated biphenyls (PBBs) were pulled off the market due to toxicity concerns after an inadvertent and widespread poisoning of animal feed in Michigan.[29] However, use of similar flame-retardant chemicals was not discontinued. These include polybrominated diphenyl ethers (PBDEs), compounds whose effects on human health have still not been adequately tested. Concentrations of polybrominated biphenyls in human serum samples decreased between 1985 and 2000 (Exhibit 3), and concentrations of the similar, but unregulated, polybrominated diphenyl ethers increased (Exhibit 4).

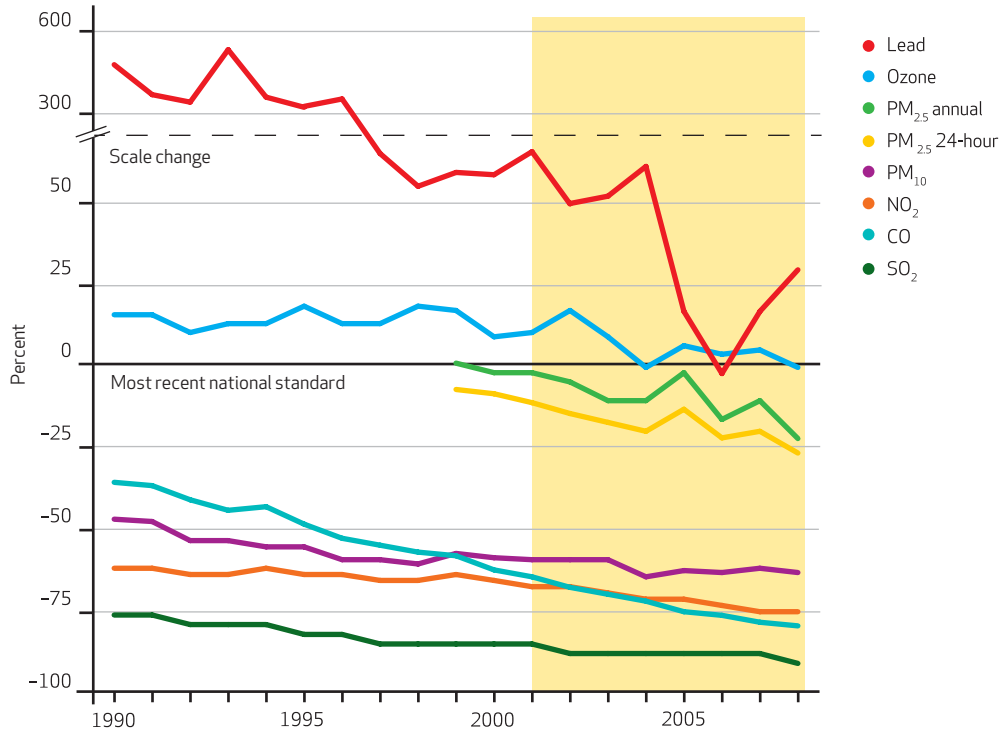
In the early 2000s growing recognition of the increasing concentrations of polybrominated diphenyl ethers in people and wildlife,[19] and increasing concern about the chemicals' effects on thyroid hormones, led to a voluntary phasing out in the United States of two of the three commercial formulations of PBDEs (pentaPBDE and octaPBDE). However, people continue to be exposed to the chemicals because they were widely used in furniture and other indoor consumer products, and therefore they persist in the environment.[19]

Furthermore, recent scientific studies have found that polybrominated biphenyl ethers do have effects on thyroid hormones and children's development.[13,30] The federal National Toxicology Program plans to perform long-term carcinogenesis studies on PBDE 153,[31] one of the 209 polybrominated diphenyl ethers, which is important because it is increasingly appearing in the food chain and in people.[22,32] By the time the test results are published, use of the chemical will have long ceased, but people will continue to be exposed to it.

Similarly, a study of the carcinogenic effects

EXHIBIT 1

National Ambient Air Concentrations Of Pollutants Compared To National Air Quality Standard, 1990–2008



SOURCE Environmental Protection Agency. Our nation's air—status and trends through 2008 [Internet]. Washington (DC): EPA; 2010 Feb [cited 2011 Apr 11]. Available from: http://www.epa.gov/airtrends/2010/. **NOTES** $PM_{2.5}$ is particulate matter particles 2.5 micrometers or smaller. PM_{10} is particulate matter particles 10 micrometers or smaller. NO_2 is nitrogen dioxide. CO is carbon monoxide. SO_2 is sulfur dioxide.

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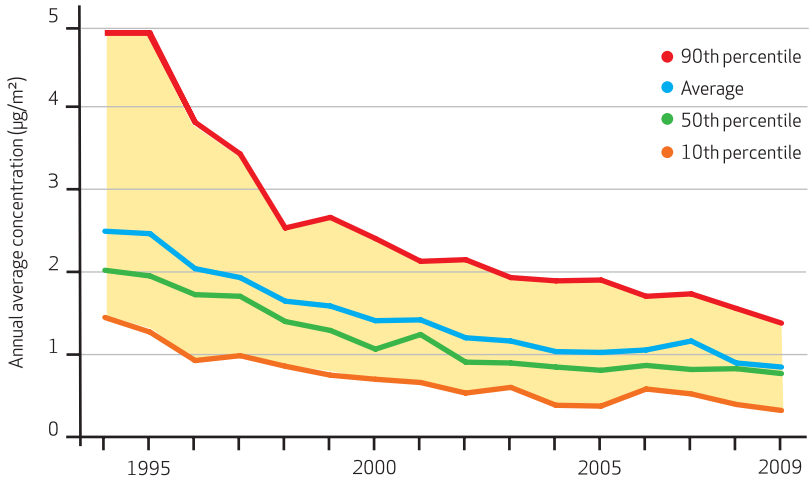
EXHIBIT 2

Annual Air Concentrations Of Benzene, 1994–2009



SOURCE Environmental Protection Agency. Ambient concentrations of benzene [Internet]. Washington (DC): EPA; [last updated 2010 Dec 14; cited 2011 May 5]. Available from: http://cfpub.epa.gov/eroe/index.cfm?fuseaction=detail.viewInd&lv=list.listbyalpha&r=231333&subtop=341. **NOTES** The average line represents average annual concentrations from twenty-two monitoring sites nationwide. The shaded area displays the concentration range where 80 percent of measured values occurred for each year.

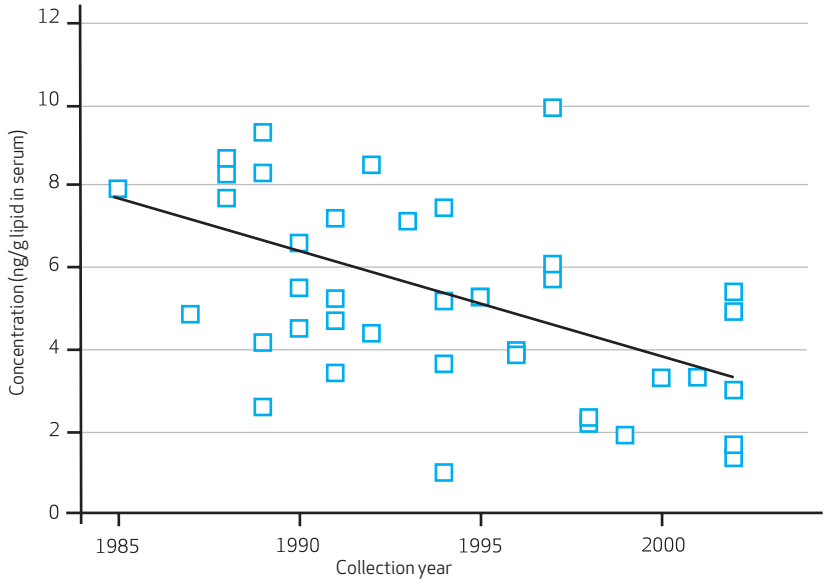
of polybrominated biphenyls—flame-retardant chemicals similar in structure to polybrominated diphenyl ethers—was published a decade after their use was discontinued.[29] Their long half life means that people may still have the chemicals in their bodies, which could pose a low, but not inconsequential, risk.[33]

▶ **THE DANGERS OF SUBSTITUTES:** There are numerous other chlorinated and brominated flame retardants in use that substitute for polybrominated diphenyl ethers and polybrominated biphenyls. Many have been found in either wildlife or people.[34,35] Because many of them are similar to chemicals that are known to be toxic, it is not surprising that some give indications of being toxic or carcinogenic.[36] Regulatory agencies have yet to formally consider the risks that these substitutes pose.

Other substitutes abound, including those for diethylhexylphthalate (DEHP). This chemical is often used in plastic products such as children's toys and medical devices such as blood bags, and it has toxic effects on the developing male reproductive system.[37] A substitute for this chemical has been shown to disrupt thyroid hormones in experiments involving animals.[38] The toxicity of most of these substitutes has not been adequately studied.[38]

EXHIBIT 3

Levels Of Polybrominated Biphenyls (PBBs) In Human Blood, 1985–2002



SOURCE Note 19 in text. **NOTES** The use of PBBs in the United States was discontinued in the 1970s. Polybrominated diphenyl ethers were then introduced as replacement fire retardants.

Risk Assessment

Sometimes a state or federal agency can take action to protect the environment or reduce risk to human health without a detailed risk assessment. For example, the Clean Air Act mandates that the EPA assess and require "maximum achievable control technologies" for certain sources of the contaminants defined in the act as hazardous air pollutants.[39] The act also contains provisions for adding other substances to the list of hazardous air pollutants. These provisions could be used to expand this regulatory approach to other air pollutants.[39] Research has identified potential candidates for inclusion based on their known toxicities.[39,40]

Furthermore, the approach of requiring the use of "maximum achievable control technologies" to reduce emissions of toxic substances could be expanded to other media. The advantage of this approach is that the best technology for reducing emissions has already been identified and can be applied to all industries without requiring specific risk assessments for each emitted pollutant. The result could mean saving a good deal of time.[41,42] Risk assessment and control of residual risks are considered below. As of 2000, the EPA estimates that full implementation of the "maximum achievable control technologies"—as mandated in the Clean Air Act Amendments of 1990—has led to an almost fifteenfold improvement in the reduction of air pollutants.[42]

However, in many cases, an agency cannot proceed without assessing the level of risk posed to the population. The primary approach is risk

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assessment. Using biostatistics and biological analysis, risk assessment summarizes the scientific toxicity information—for example, describing the probability that an exposure will result in harm.

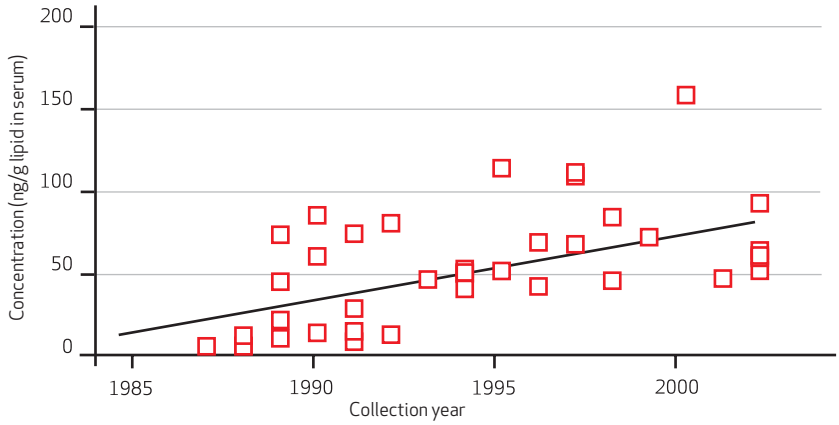
Typically, a risk assessment consists of four parts. These are assessing the type of health effects associated with exposure to a chemical, typically called hazard assessment; assessing the relationship between the exposure and the response, which is known as dose-response; assessing the amount of exposure and how it varies across uses and individuals; and risk characterization, which combines exposures with the dose-response to estimate risks to the populations of interest. In addition, risk assessment for cancer is different than risk assessment for noncancerous effects. The assumption is that there is no safe exposure level for most carcinogens, but when cancer is not an effect, the assumption is that a no-risk or safe exposure level does exist.

Newer science, reviewed by the National Academy of Sciences,[43] has shown that approaches to risk assessment need to be modernized to reflect the current scientific understanding of the relationship between exposure and adverse health effects, as we will explain below.

SUSCEPTIBILITY AND VULNERABILITY Susceptibility to the harmful effects of exposure can vary dramatically from person to person and can be influenced by both intrinsic and extrinsic factors. The relevant intrinsic factors are age, genetics, and preexisting conditions.

EXHIBIT 4

Levels Of Polybrominated Diphenyl Ethers In Human Blood, 1985–2002

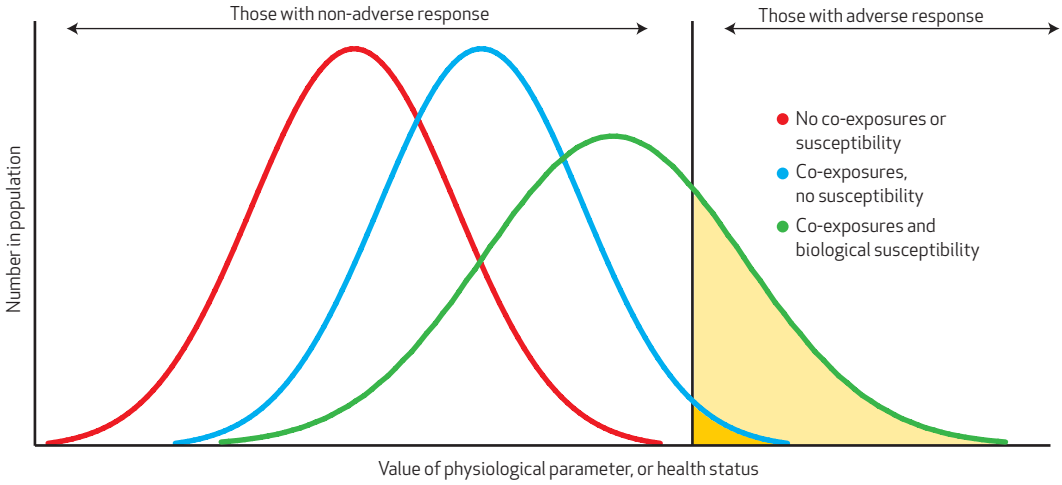


SOURCE Note 19 in text.

During specific stages of development—including the fetal stage, infancy, early childhood, and puberty—young people can be substantially more susceptible to chemicals than adults.[44] Behavior during early childhood, such as crawling and putting a hand in the mouth, can also increase exposures to certain environmental chemicals. Biomonitoring studies find larger levels of certain chemicals in children compared to their parents or other adults.[45,46] The elderly can also be more susceptible to exposure to certain chemicals in the environment, such as those involved in air pollution.[47]

EXHIBIT 5

The Effect Of Biological Susceptibility And Co-exposure To Other Chemicals On The Relationship Between Individual Chemical Exposure And Adverse Health Outcomes



SOURCE Woodruff TJ, Zeise L, Axelrad DA, Guyton KZ, Janssen S, Miller M, et al. Meeting report: moving upstream—evaluating adverse upstream end points for improved risk assessment and decision-making. Environ Health Perspect. 2008;116(11):1568–75.

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Preexisting conditions—such as those that compromise the function of the immune system,[48] asthma, coronary heart disease, heart arrhythmias, and other less serious disorders[49]—can leave individuals more susceptible to additional environmental stressors. And individuals' varying genetic makeup is clearly related to varying risks from environmental chemicals.[50,51]

The relevant extrinsic factors are socioeconomic status, race or ethnicity (that is, the external manifestations of these factors and their effect on the treatment a person receives in society), and exposures to other environmental chemicals. There is a growing amount of evidence, mainly from air pollution epidemiology, that social factors affect a person's vulnerability to chemicals in the environment.[52–54]

People are exposed to a wide array of environmental chemicals, such as those produced by fuel combustion, industry, drinking water disinfection, and the use of consumer products. Biomonitoring studies of the US population show measurable levels of numerous chemicals in every person studied.[12,22] Studies show that exposure to multiple chemicals that have the same adverse impact on health can have a cumulative effect, increasing the risk further.[37]

For example, the National Academies note that phthalates and other chemicals—such as those found in certain pesticides—that affect testosterone levels can cumulatively act together to adversely impact male reproductive development.[37] Exhibit 5 illustrates how these instrinsic and extrinsic factors may affect population response to an environmental exposure.

TRANSLATING ANIMAL DATA INTO HUMAN RISK Much of human health risk assessment is based on animal data rather than observational or experimental human studies.[25] Most animal experiments test the effects of individual chemicals using homogeneous adult animal strains—that is, an experiment is done on animals that are all genetically similar and under the same environmental conditions. Although this type of testing can clarify relationships between exposure and effect for any individual chemical, it does not fully account for other factors that can influence risk of disease. As noted above, those other factors include age, genetics, preexisting conditions, and exposure to other chemicals.[43]

To translate the findings from animals to humans, researchers use a quantitative factor that takes into account differences in the way small bodies—such as those of rodents—and the large bodies of humans handle chemicals. The factor also takes into account differences in pharmacodynamics, or the ways chemicals may influence the process of a disease in a particular species. Sometimes a model is used instead of the quantitative factor. Such models are called pharmacokinetic models.

Interindividual variability, or differing susceptibility and vulnerability among humans, is taken into account in translating findings from animals to humans only when the chemical is not carcinogenic. The numerical factor used to account for interindividual variability for health effects other than cancer, which generally is no larger than 10, may not adequately describe the full range of vulnerability and susceptibility in a population. The National Academy of Sciences has advocated the use of better approaches to address difference among humans.[43]

For cancer, the EPA quantitatively incorporates the increased susceptibility from childhood exposures to mutagenic chemicals. However, the EPA does not make a similar adjustment for prenatal exposures[43] or for childhood exposures to nonmutagenic chemicals, even though some of those have been shown to be much more potent when exposure occurs early in life. For carcinogens, the standard default approach assumed in predicting human risk from animal data is that equal exposure leads to the same risk of cancer for each person in the population, but epidemiological and other findings show that in fact the risk varies.[55,56]

OTHER NEEDS IN RISK ASSESSMENTS Sometimes another factor is used to account for the lack of specific data, such as when no studies were conducted to evaluate chronic effects, or to assess particular adverse health effects such as neurodevelopmental toxicity. However, where no data at all exist, the risk assessment typically presumes that the chemical poses no risk. The National Academy of Sciences characterizes this as a missing default, meaning that it amounts to having a default assumption of no effect. The academy advocates the development of new approaches to address such cases.[43]

Finally, risk assessments generally do not account for "background" exposures to the multitude of other chemicals outside[12,22] and inside the body that may affect responses to any given chemical in the environment. There may be some accounting for a small subset of chemicals, such as those measured at a hazardous waste site, through a "hazard index" methodology for effects that do not lead to cancer. The methodology used in this respect cumulates the effect of chemicals that produce the same general type of toxicity. But the wide range of background exposures and physiological processes that may affect health outcomes and potentially result in risks at low doses are not addressed.[43] The National Academy of Sciences has identified the failure to account for background exposure in risk assessments not involving carcinogens as a

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major deficiency in current risk assessment methodology.[43]

Some of these newer scientific understandings were recognized in changes to risk assessments for pesticides mandated by the Food Quality Protection Act. This law requires additional consideration of health risks to children, as well as consideration of aggregate exposure to pesticides from multiple sources and exposures to multiple pesticides that produce effects through the same mechanism of action.

The National Academies have recently recommended extending the approaches in the Food Quality Protection Act to account for other susceptibilities and vulnerabilities, and to adequately cover background exposures to multiple chemicals in the environment. Although the Food Quality Protection Act adopts some of the concepts of this approach, it still does not require that risk assessments consider exposures to nonpesticide chemicals that can contribute to health risks due to the pesticide. And although the act considers together pesticides with the same mechanism of action, newer science has led the National Academies to recommend that chemicals that act on the same common adverse health outcome also be considered together.[37]

Furthermore, the extent of vulnerability and susceptibility and the fact that similar biological pathways can lead to both cancer and noncancer effects led the National Academy of Sciences to conclude that risk assessment for cancer and noncancer should be unified, and that an assessment should not assume a chemical's effects are at a threshold or safe level unless the underlying science is reviewed and supports that assumption.[43]

ASSESSING EXPOSURES Two problems limit our ability to understand the effects of exposures to chemicals. First, we do not know all of the chemicals in the environment or their sources, because no standard reporting is required and information about how chemicals are produced is proprietary in many cases. Second, after toxic chemicals are released into the environment, they may be transformed into by-products that are also toxic.

For example, the pesticide dichlorodiphenyltrichloroethane (DDT) was banned in 1972. The levels of it found in the environment and humans are now lower than during the time it was used, but one of its by-products, dichlorodiphenyldichloroethylene (DDE), is still found in more than 90 percent of people measured.[12] The ideal risk assessment would consider the toxicity of such by-products, including those produced by combustion related to manufacturing, energy generation and transportation, consumer product use, and processes such as water disinfection.

INTERPRETING THE SCIENCE The complexity and uncertainty in the science lead to various interpretations. Different groups, often influenced by financial motives, promote their own interpretations and claim that alternative interpretations are biased or based on poor science.[57,58] On top of this is a continuing call by scientific peer reviewers for assessments that fully characterize the risk and quantitatively capture all major uncertainties and unknowns.

Furthermore, policy makers' requests for peer review to resolve scientific differences in a risk assessment lengthens the process. This sort of peer review can be a very high bar, as the scientific understanding of these assessments is almost always incomplete. Finally, as discussed above, the current legal burden of some statutes to determine that chemicals pose harm to human health before regulatory action can be taken is an additional complication.

All of these problems contribute to paralysis in the decision-making process. Toxicity assessments for major chemicals can take ten years or longer. The assessments of some chemicals—such as dioxin and trichloroethylene—that the EPA started in the 1980s have yet to be completed.[43] Stakeholders can become disengaged and distrustful. And the public remains exposed to potentially harmful chemicals while scientific debate continues.

Conflicts Between Science And Policy

Much of the debate focuses on finding a safe level for each individual chemical, even though recent science shows that exposures to different chemicals can combine to produce effects experienced in the general population[37] and that some low exposures can produce risks.[43] Although there is a growing recognition among scientists that absolute safe levels may not exist, policy makers and the public want to be assured that any exposure is only at a safe level or to an "acceptable" risk. Once a "safe" level of exposure is identified and enforced through policy, they consider the problem to have been solved.

Debates about the science are often motivated by underlying concerns about the costs of regulation. For example, the recent decision by the EPA to subject the research on the health effects of ozone to further peer review before revising the national ambient air quality standard may reflect concerns about the costs of the standard, as the statutorily mandated scientific review panel expressed unanimous support for the agency's proposed standard.[59] Costs and other societal concerns besides health are important

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considerations in decision making. However, as the National Academy of Sciences has recognized since the 1980s, descriptions of environmental health risk, cost, and other societal concerns should be made explicit and trade-offs among them should be transparent.[60] Decisions typically involve accepting some risk, and putting off a decision for reasons of political expediency often increases the eventual health burden.

The Way Forward

Taken together, the rise in certain chronic diseases, the multitude of chemicals as potential risk factors, and the large gaps in data based on inadequate testing requirements make it imperative that we update the way we manage chemicals in the environment. This is critical for the prevention of many chronic diseases.

We can use what we have learned over the past thirty years to adjust chemical policy for the next thirty years. The National Academy of Sciences' *Science and Decisions* report[43] offers a framework for progress. The academy recommends first identifying possible actions that could be taken to address the problem; then developing a plan to characterize the risks, costs, and benefits to discriminate among each of the possible actions and then implementing the assessment plan; and presenting the results to decision makers so that they can make an informed choice. The academy also recommends that stakeholders be engaged at each step of this process.

The goal should be a flexible analytic and deliberative approach to policy making that can be tailored to individual circumstances. In addition, we make the following recommendations.

The focus of environmental policy should always be on health. In addition, approaches to health policy should acknowledge the role of the environment as a determinant of health at the individual and population levels. The management of chemicals is critical for addressing chronic conditions and preventing lifelong disabilities.

It is essential to ask the right questions. The first step in identifying possible ways to address potential health risks from chemical exposure should be to identify the scale and complexity of the assessment, and the issues it should address. The assessment is designed to discriminate among different options and related trade-offs. One approach to managing chemicals in the absence of direct evidence from animal or human studies is to use structural chemical alerts and other related chemicals information. For example, chemical property information (such as data indicating a potential for persistence or bioaccumulation) and chemical structure (such as similarity to thyroid hormones, as in the case of polybrominated diphenyls) could be used to automatically trigger a consideration of removing them from the marketplace or reducing their use.

The burden of proof should be reversed, so that it is placed on the manufacturer rather than the regulator. The current approach of assuming that chemicals are safe until proved harmful is an incentive for manufacturers to delay acquiring data necessary for assessing products' safety. Manufacturers of all chemicals—not just pesticides with active ingredients and pharmaceuticals—should be required to produce data to support health assessments of their products before they enter the marketplace.

To avoid responding to uncertainty with inaction, which often leads to delays and greater health risk, default approaches should be established as temporary measures. For example, in the absence of full data to describe related health risks, decisions could be made based on chemical structure and other indicators of chemical toxicity.

Substantial health gains and cost savings are most likely to come from policies that concentrate on susceptible and vulnerable populations—groups that are also liable to have unequal access to health care and other essential services—and on communities with large disease burdens and multiple exposures. For example, California takes into account children's particular susceptibility to carcinogens in its management of all chemicals, not just those known to damage DNA.[43,61]

The National Academy of Sciences, whose approach we endorse, has supported the use of a unified approach to risks of cancer and other conditions that starts with an assumption that there is risk at low doses unless scientific data indicate otherwise.[43] Policy makers and the public need to realize that there will always be questions about trade-offs in risk management. For example, there are different approaches to treating human sewage that have varying degrees of costs and health benefits. A transparent presentation and description of the risks will make those trade-offs easier to understand.

Absolute safety or the complete absence of risk from exposure to a chemical in the environment is often an unrealistic and unscientific objective. Thus we need to modify current approaches to integrating science into decision making.

What's more, political, economic, and business considerations should be separate from the health risk assessment. The cost of managing a health risk does not affect the magnitude of the risk, but it may affect the choice of risk management options.

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Approaches to risk assessment and management should be modified to take advantage of emerging scientific knowledge. For example, studying how a chemical can affect key biological events involved in toxicity will permit more rapid assessment of certain types of chemicals, although the uncertainties in those assessments will be large.[62] Although it may take years of research to develop a full suite of advanced testing and assessment approaches,[25] some applications—such as prioritizing chemicals for testing—may be ready within five years.

At least one of these recommendations—requiring manufacturers to submit data on the potential health effects of their chemicals—would require new legislative authority to implement. Others—such as using new scientific knowledge—could be integrated into existing regulatory programs, although specific legislation or other signals from Congress for regulatory agencies to move in new directions makes it more likely that they will do so.

Conclusion

Evolving science has provided many new insights about exposures to chemicals in the environment and previously unrecognized biological effects. As the scientific community continues to study the links between exposure and disease, the public is confronted with a barrage of mixed messages about risks. By reexamining our current approaches and applying new science to make risk management decisions faster and more transparent, we can continue to reduce the toll of chronic diseases and disabilities. ■

The views expressed are those of the authors and do not necessarily represent those of the authors' institutions.

NOTES

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ABOUT THE AUTHORS: TRACEY J. WOODRUFF, THOMAS A. BURKE & LAUREN ZEISE

In this month's *Health Affairs*, Tracey Woodruff, Thomas Burke, and Lauren Zeise portray America's approach to ensuring the safety of environmental chemicals as deeply flawed and not making use of new scientific techniques that can improve risk assessments. The authors make a number of recommendations to modernize risk assessment and advance the management of population health risks.

As Woodruff describes the current system, chemicals come on the market without having to provide detailed data about their composition. "We want to flip the burden of proof for chemicals so they are like pharmaceuticals, which have to show safety before they are allowed on the marketplace," she says.

Woodruff coauthored two other papers in this issue, one on the impact of environmental chemicals on reproductive health, and the other on a methodology to help clinicians evaluate environmental risk.

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Burke is the Jacob I. and Irene B. Fabrikant Professor and Chair in Health, Risk, and Society and the associate dean for public health practice and training at the Johns Hopkins Bloomberg School of Public Health. He is a professor in the Department of Health Policy and Management, with joint appointments in the Department of Environmental Health Sciences and the School of Medicine's Department of Oncology. Burke is also the director of the Johns Hopkins Risk Sciences and Public Policy Institute.

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Zeise is chief of the Reproductive and Cancer Hazard Assessment Branch at the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment. She has coauthored or overseen hundreds of scientific evaluations of the risks of cancer and reproductive hazards from exposure to chemicals.

For many years, Zeise has served on science advisory committees and boards of such organizations as the US Environmental Protection Agency, the World Health Organization, and the National Academy of Sciences, focusing on improving the way chemicals are tested and evaluated for health risk.

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