

PRECAUTIONARY PRINCIPLE PROJECT

CLEAN WATER FUND ♦ LOWELL CENTER FOR SUSTAINABLE PRODUCTION ♦ MASSACHUSETTS
BREAST CANCER COALITION ♦ SCIENCE & ENVIRONMENTAL HEALTH NETWORK

Facing Our Toxic Ignorance

“Our dilemma is like that of a plane hurtling through the fog without a map or instruments”
(Colburn, Dumanoski, Myers, *Our Stolen Future*, 1996)

Most people believe that government agencies are protecting their health and environment from the effects of toxic chemicals. They believe that somebody is testing these chemicals for adverse effects before they come on the market and regularly thereafter. Nothing could be farther from the truth.

Recent studies of our level of knowledge of chemicals' toxicity and impacts on public health and the environment demonstrate that we know very little about most industrial chemicals and pesticides in commercial use today. We are flying blind. Despite our lack of information about these substances, every day government agencies and others make decisions permitting their use and release into the workplace and environment based on the belief of an acceptable risk and a minimal impact. We are generally deciding that these substances are innocent until proven guilty.

There are at least 75,000 chemicals in commerce today. Roughly 1,000 new chemicals are put on the market each year. Almost none of the 75,000 chemicals have been adequately analyzed for their full impact on the environment and human health, and most have not even received basic toxicological testing.

Ignorance of Complex Chemical Mixtures

We are ignorant of the real world of complex mixtures of chemicals. We tend to think in linear terms; we look for direct cause and effect relations between exposures to single chemicals and single diseases. This atomized thinking ignores the complex interactions of multiple chemicals and is incapable of predicting real world health outcomes. Current health research generally includes laboratory tests involving animals that typically consider the effects of exposure to only one chemical substance at a time. This is because scientists frame hypotheses (questions asked) in ways that are feasible to answer with the time and resources available. But unlike the animals used in the laboratory, humans are exposed by many routes to multiple chemicals (and other compounding stressors), at work, home, in the womb, and elsewhere.

Scientific studies have found that exposure to multiple chemicals can have additive or synergistic effects in humans, and a few recent studies have begun to assess these combined effects. Studies have indicated that combinations of chemicals – for example the plasticizer diethyl hexyl

phthalate widely used in vinyl products combined with other common toxicants (e.g., the solvent trichloroethylene or the pesticide heptachlor) – are much more powerful, and potentially damaging, than single chemicals alone (1). Long-term exposure to multiple chemicals can have cumulative effects and may affect the susceptibility of humans to diseases in ways that are not well-understood. In addition, virtually nothing is known about the cumulative impacts of chemicals combined with other stressors such as diet, poverty, physical stress, etc.

Using current methods, laboratory tests for additive, synergistic, and cumulative effects, however, are impractical because of the high costs in time and money that would be required. ***Testing just one dose of just the top 1,000 high volume chemicals in three-way combinations would require 166 million different experiments. Testing all the three-way combinations would take over 180 years to complete,*** if each experiment took one hour to conduct and 100 laboratories worked non-stop (2).

Lack of Testing

Not only are current scientific methods not well-suited to studying the safety of combinations of chemicals, the chemical-by-chemical testing we do perform is woefully inadequate in relation to the real world. Most chemicals in commerce have not been lab tested. Nor have they been the focus of an epidemiological study to look for evidence of harmful effects in humans. How many of the 75,000 chemicals in commerce have actually been tested for their toxicity?

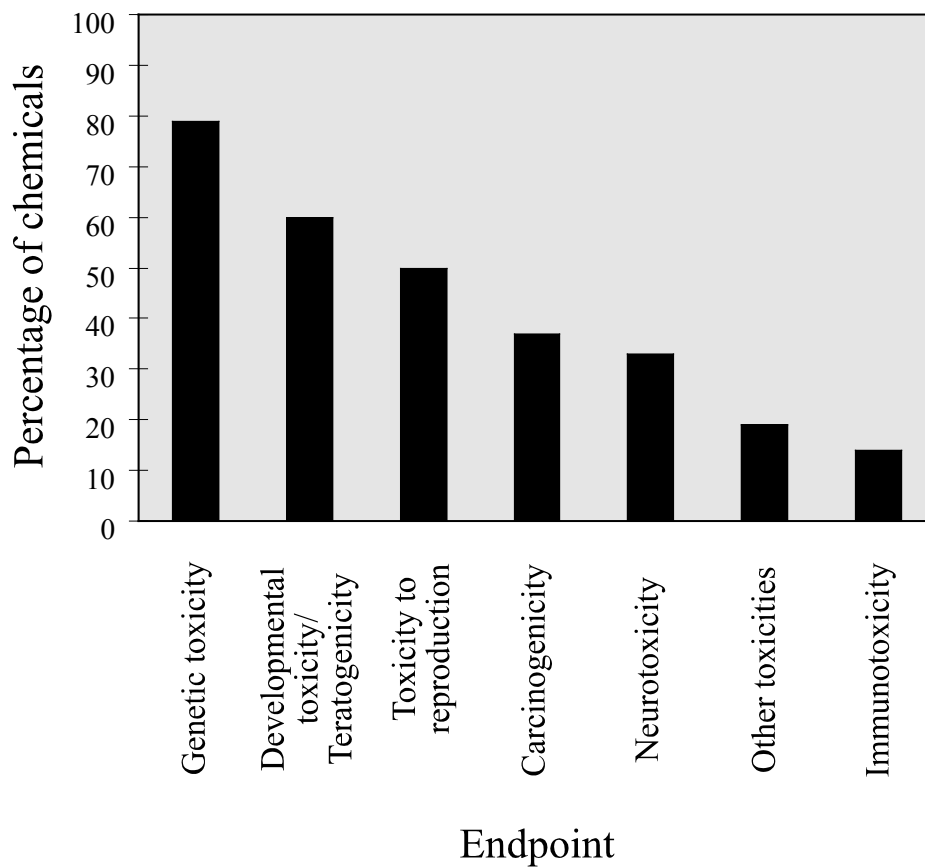
The Environmental Defense Fund (now called Environmental Defense) analyzed a sample of 100 chemicals out of a total number of 3,000 high production volume (HPV) chemicals (chemicals that are produced in quantities of 1 million pounds or more per year). The 1997 EDF report (3) found the following:

- For 71% of the HPV chemicals we do not have in the public record even the simplest health and safety facts. This means that ***only 29% of high-volume chemicals had basic health hazard screening data***, as established by the Organization for Economic Cooperation and Development. The OECD's basic health screening data, or Screening Information Data Set or SIDS, consists of the following required tests: acute toxicity; chronic toxicity; developmental and reproductive toxicity; mutagenicity; ecotoxicity; and environmental fate. The 71% figure from 1997 indicated virtually no improvement over a 1984 National Research Council study of a sample of 100 of the 3,000 HPV chemicals, where 78% of the chemicals lacked even "minimal toxicity information."
- Of the sampled chemicals known to be released into the environment – the Toxic Release Inventory chemicals – 51% are not even minimally screened for health hazards. This means that even for chemicals which have at least one recognized health hazard, we generally don't know if they have other health hazards because they have not been adequately screened.
- Carcinogenicity tests are missing for 63% of HPV chemicals.
- Reproductive toxicity tests are missing for 53% of HPV chemicals.
- Neurotoxicity tests are missing for 67% of HPV chemicals.

- Immune system toxicity tests are missing for 86% of HPV chemicals.
- Studies for assessing impacts on children have not been done for more than 90% of HPV chemicals.
- 58% of the sampled HPV chemicals have not been tested for any form of chronic toxicity.

The Chemical Manufacturers Association (CMA), the main chemical industry trade association, acting on a challenge from EDF to conduct its own screening tests and make them available to the public, analyzed the same sample of HPV chemicals. The CMA found that 47% of the same 100 chemicals had a full screening set. While more optimistic than EDF's finding of 29%, this figure still confirms that less than half of chemicals have even the minimum screening tests (see 4). Thus even the chemical industry admits that it is flying blind.

Available toxicity studies by type of health risk

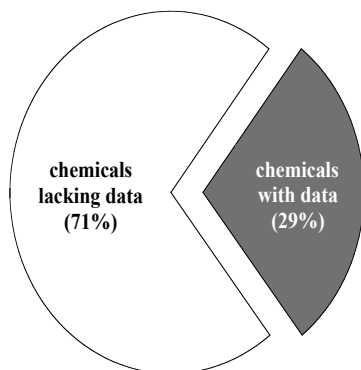


The EPA analyzed a much larger sample (2,863) from the 3,000 HPV chemicals. They found that *only 7% had a full screening set, while 43% lacked even basic screening data (4).*

It is important to note that *all three studies looked only at screening level data*, which is just the minimum data set that government agencies around the world suggest that we should have on chemical toxicity. *Even less is known about actual human exposures or toxicity beyond the basic screening tests.*

While EPA has urged U.S. chemical companies to carry out these tests, EPA's testing program, like the OECD SIDS international testing program, has thus far been voluntary. This program, called the HPV Challenge, encourages industry to develop the minimum SIDS data for the approximately 3,000 HPV chemicals by the year 2004. While industry balked at such an ambitious timeline (stating that they needed to do an assessment of which data is needed for each

Chemicals with minimum screening data



chemical), EPA has threatened the issuance of testing rules under the Toxic Substances Control Act if industry does not comply. At any rate, EPA is only beginning to determine what it will do once it collects these data.

Because of the general lack of toxicity testing, it is impossible for the public to know what health threats these high-use chemicals might pose or whether they are under control. It is not surprising that we are unable to test the toxicity of 75,000 chemicals, or even those chemicals most widely used in commerce. The task is overwhelming. But this task is minute in comparison to the job of assessing the toxicity of chemical combinations.

Toxicity testing of pesticides, like testing for chemicals used in manufacturing and commerce, is seriously lacking. *Adequate toxicological data are available for only about 17%, or 100 out of 600, active pesticide ingredients (5).* Data are often lacking on reproductive and developmental toxicity of pesticide ingredients. The registration process focuses on individual chemicals and has tended to ignore the health and ecological effects of combinations of chemicals, although the

Food Quality Protection Act of 1996 discussed a margin of safety required for anticipated or known multiple chemical exposures which act through similar mechanisms.

Testing Methods: The Limits of Environmental Health Research

Environmental health research attempts to estimate the toxicity and health impacts of different substances. Research about the toxicity of chronic hazards is based on human studies, animal studies, and in some cases, studies on isolated cells or tissues. Studies of cells in the laboratory, *in-vitro* studies, are not described further here, but can provide useful early information to spark precautionary action as they are inexpensive and quick. For example, if a chemical is estrogenic in the test tube - an easy test to complete - it may be prudent to restrict its use.

Human Studies

Human evidence is the preferred choice in providing information about toxicity because it looks at actual patterns of exposure and observed effects on people. The field of epidemiology focuses on the factors – including chemical exposures – that contribute to diseases in various groups of people. Epidemiologists identify an exposed group of people, another group that was not exposed, and compare their rates of illness. After taking additional factors (such as family history or smoking) into account, these studies can provide evidence that a chemical exposure increases the risk of disease.

Doing epidemiological studies, however, involves several major problems:

- Getting long term information about an individual's exposures and medical history is very difficult and the data are often unreliable. For example, following a large group of children throughout their lives to search for evidence of disease from a prenatal or infant exposure is obviously a very slow and costly process. Often the best epidemiological information comes from studies of hazardous chemicals in the workplace, where records are sometimes available. But these conditions may not be directly relevant to understanding risks in the general environment. In addition, occupational health studies have often focused on healthy adult males, and there is less known about the hazards for woman. Workplace health studies are even less useful for understanding children's health risks.
- Studies based on workplace exposures don't always translate well to home and community settings because of different levels and duration of exposures. Workplace exposures are generally higher, while the range of health effects studied may be narrower than one would wish, to understand the entire community (6).

Field environmental health research also has numerous potential sources of error, including:

- **Uncertainty.** Uncertainty exists about: the pathways and levels of exposure; the mechanisms by which exposure leads to disease (this information is needed so that the appropriate statistical models can be used); the diagnosis of the disease being studied and about other stressors that may contribute to the disease (confounding factors).
- **Too small a sample size.** Field studies are often limited by economic or logistical

reasons to relatively small samples of the population. This means the study may not have the statistical “power” to detect an effect even if it does exist. To reach a conclusion with confidence that the results are not due simply to chance, you need a large enough population size (7).

Often inconclusive results from epidemiologic studies are mistakenly interpreted as evidence that a chemical is safe. This is a common confusion about the meaning of “negative results”. One should always ask: **“Do the results reflect a lack of evidence that an effect exists, or instead do they represent evidence that an effect does not exist?”** In the former case, the study is inconclusive and one cannot say whether the exposure is hazardous or not. In the latter case, which is much less common for all the reasons noted above, the study actually does suggest that the exposure does not cause the disease being studied.

Eminent biologist John Cairns Jr. has described this problem as “absence of certainty is not synonymous with absence of risk.” He states: “while high uncertainty may obscure both the probability of a risk and the magnitude of harm, uncertainty does not eliminate risk. Unrecognized risks are still risks; uncertain risks are still risks; and denied risks are still risks (8).”

Animal Studies

Scientists and decision-makers most often rely on laboratory tests on live animals (called *in vivo* tests) to determine human risks. Such tests can be completed relatively quickly and in controlled circumstances. Animal tests can be used to predict potential human effects by making two important extrapolations:

- **Extrapolating from high dose to low dose exposures.** In *in-vivo* tests, higher doses are generally given to animals than humans would normally receive. By making as much as 50% of the exposed animals ill, rather than giving low doses to large samples of test animals, scientists reduce costs and time needed to conduct studies.
- **Extrapolating from test animals to humans.** Scientists use models based on the **dose-response relationship** to extrapolate the responses (such as tumors) from test animals to humans. In general, as the exposure (the amount of a substance in your immediate environment) increases, dose (the amount of a substance you actually absorb into your system) increases. The dose-response relationship does not accurately describe the health impacts of highly toxic chemicals like endocrine disrupting substances such as PCBs, dioxins, bisphenol-a and a wide range of pesticides (9).

These two extrapolations from animal studies create several important problems:

- **Thresholds.** Extrapolating from high doses to low doses has fueled a major debate about whether there are thresholds below which there are no harmful effects from a substance. Many scientists believe that effects like cancer and some developmental effects have no threshold, ie., there is no “safe” level of exposure. Many dose-response models assume thresholds, known as no observed effect levels (NOELs); above these levels one should avoid exposure, while below it is believed there is no reason to suspect harm. For substances without thresholds, we must assume that any exposure might be harmful.
- **Animal differences.** Extrapolating from test animals to humans is problematic because

of a wide range of differences between test animals and humans, including body weight and size, life span, and metabolism. Until we better understand the causes of cancer and other diseases, it is very difficult to account for the differences between animals and humans. Even among test animals, responses to chemicals vary (6). It is generally assumed, however, that effects observed in laboratory animals are relevant to humans unless demonstrated otherwise. Nonetheless, industry and government are placing a greater emphasis on demonstrating that the “mechanisms of action”, the biological pathway by which a chemical causes disease, are comparable in test animals and humans. This will place an added burden on government agencies and citizens to “prove” harm before action takes place.

Why Environmental Health Research is Limited

Environmental health research is limited in determining the effect of a broad range of industrial toxicants on the general human population for the following reasons:

1. There are too many chemicals in commercial use. Science cannot keep up with the introduction of 1,000 new substances to the market each year and the 70,000 plus chemicals in commerce. New chemicals that have come on the market since 1980 represent less than 1% by volume of all chemicals on the market today.

2. Environmental health research fails to account for multiple and variable exposures.

Health research depends on laboratory tests on animals, in which only one or two variables at a time are tested. Humans, on the other hand, are subject to multiple pathways of exposure and to many chemicals, some at work, some at home, some outside from air and water. Exposures to multiple chemicals can have interactive and cumulative effects. To a certain degree toxicological tests are able to assess the combined effects of exposure to multiple chemicals, but these tests are expensive and would take too much time to conduct.

3. Environmental health research is narrowly focused on the cancer paradigm. Normally, we test a single chemical for its ability to cause cancer or acute effects. Although it is widely understood that there are other types of toxic insult to living organisms (such as damage to an organism’s hormone system, toxicity to an organism’s development, neurotoxicity, or damage to ecosystems), there are few established ways for testing how or if a chemical causes these disruptions (7).

By focusing largely on the cancer paradigm, environmental health research tends to miss the long-term reproductive or developmental toxicity of low-dose human exposures, which may affect human development from the fetal stage through the reproductive years. Environmental health research is only beginning to help us understand the importance of timing of exposures (e.g., in the womb) but even these effects are difficult to follow in humans because exposure in the womb may not result in health effects until several decades later (9).

The cancer paradigm also looks for signs of disease as a result of toxic exposures, whereas many chemicals, such as endocrine disrupting chemicals, can damage people without making them outwardly sick. PCBs, for instance, can diminish a person’s short-term memory or attention span. While it is widely recognized that there are other hazards, we have few settled methods for testing how, or even whether, a chemical causes other types of toxicity. Our narrow focus on the cancer paradigm is relevant both to toxicological and epidemiological testing and

critical to why we are ignorant about health effects of chemical exposure. The cancer paradigm prevents us from looking for other effects and potential root causes. Fortunately, studies on neurotoxicity and reproductive toxicity are beginning to take us beyond the cancer paradigm to look at other effects and potential causes (7).

4. Environmental health research misses the wide differences in individual reactions.

These differences may be due to gender, age, genetic variations in affected groups of people, and differences in socio-economic status. It also generally fails to account for susceptible sub-populations, children, the fetus, the elderly, and the ill.

The limits and potential errors inherent in environmental health research -- which generally relies on mathematical techniques for one or two chemicals -- all point to the fact that we can rarely statistically draw a direct causal connection between specific health and environmental impacts and real chemical exposures in the environment, especially in an environment with complex chemical mixtures. In order to protect people from hazardous exposures, we cannot wait for high levels of statistical significance before taking action.

Regulatory Tools That Keep Us Ignorant

Lack of basic toxicity testing of chemicals greatly contributes to our ignorance about chemical toxicity and health effects. ***But lack of toxicity testing is not the only problem. Other factors contribute to our ignorance*** of health and environmental hazards of commercial chemicals (see 10):

- **Government regulations focus on single chemicals and effects on single media rather than chemical mixtures and exposures through multiple pathways such as air, water, and food.** Environmental health research, with its basic practice of toxicity testing, is currently limited to assessing each chemical by itself rather than assessing complex mixtures of chemicals, as they are found in reality. Current regulations reinforce the limits of environmental health research by focusing on single chemicals while ignoring their additive and interactive effects.
- **Government regulations focus on one source of exposure rather than cumulative exposures.** Current laws and regulations encourage regulators to consider only one avenue of exposure at a time rather than cumulative exposures from air, water, food, and other sources. Exposure from any single source may be tolerable, while the total from all sources may be unsafe. While government agencies are beginning to look more closely at cumulative effects, greater consideration is not likely to occur for some time.
- **Trade secrets regulations.** Provisions in laws keep citizens in the dark on chemical components of many industrial and consumer products.
- **Shift of burden of proof from industry to government.** The current industrial chemical testing system has failed to adequately test even the most commonly used chemicals for basic health effects. This failure has shifted to government the burden of demonstrating that existing chemicals will pose an unreasonable risk. In testing food (for pesticide residues) and other consumer products, the government simply does not have money or staff to do adequate testing.

- **Toxic Release Inventory (TRI) is applied too narrowly.** Created by the Emergency Planning and Community Right to Know Act, the Toxic Release Inventory requires manufacturers to let the public know about chemicals transferred or released to the environment. The TRI currently considers only releases during manufacturing, while ignoring the intentional release of chemicals from or through products, such as pesticides, detergents, and plastics.
- **Loopholes in Federal environmental laws.** Loopholes, particularly in the Toxic Substances Control Act (TSCA), rob the EPA of its ability to take action on problematic chemicals.

The Failure of TSCA

The Toxic Substances Control Act is responsible for the failure to assure safety for the thousands of chemicals used and released into the environment. TSCA created authority for EPA to require chemical testing and set controls (including bans) as necessary. TSCA has failed to uphold chemical safety largely because its legal structure is self-defeating and because EPA has failed to carry out the law's provisions, although the agency's enforcement has improved in recent years. There are two major problems with the law itself (11):

- **The law fails to require companies to test chemicals that are in use.** TSCA Section 4 states that EPA can issue "test rules" (rules for toxicity testing), but *it places the agency in an impossible situation: EPA must have toxicity data before it can require toxicity data.* That is, before EPA can issue a "test rule" on a chemical, it must first demonstrate the following conditions: either (1) that the chemical may pose an "unreasonable risk" or (2) both that it is produced in major amounts AND that "substantial" exposures are happening in quantitative terms (either number of people exposed or amount of material released) or that "significant" exposures are happening in qualitative terms (a case-by-case analysis of the effects of exposure). Thus information on releases, exposures, and toxicity is necessary in order to prove "substantial" and "significant," though the "may" burden could allow the agency to be more aggressive if it chose to be so. EPA must also demonstrate that existing data are insufficient and that testing is necessary before it can issue a "test rule." The result of these loopholes is that corporations successfully challenge EPA in court, restricting EPA's ability to issue test rules. Indeed, *EPA issued "testing actions" for only 263 chemicals over a 20 year period, when 20,000 new chemicals came onto the market.*
- **EPA must prove "unreasonable risk" to health or the environment, in order to take action to restrict a chemical in commerce, which undermines the agency's authority.** TSCA Section 6 gives EPA the general authority to control any chemical that will pose "unreasonable risk of injury to health or the environment." This authority can range from a labeling requirement to an outright ban. Of course, the need to prove "unreasonable risk" undercuts the agency's position because, in reality, EPA does not have the resources to provide enough information to prove "unreasonable risk" in court when challenged by corporate power. *In 20 years of TSCA, EPA took action under Section 6 against only five chemicals or chemical classes.* In one clear case, EPA attempted to ban asbestos after studying its well-known effects for 10 years. When challenged by industry, a court in Louisiana found that EPA had not demonstrated a "significant risk".

This flawed law seriously undermines the government's ability to ensure effective testing of chemicals already in use, or to restrict use of injurious or deadly chemicals.

Acting on Toxic Ignorance: The Need for the Precautionary Principle

Lack of basic testing and flaws in the government's ability to regulate chemical use and testing show that government agencies must do much more to protect workers, the public, and the environment. Left to itself, industry will not conduct even basic toxicity testing. This leaves a near impossible task up to government.

In order to counteract our toxic ignorance we need to learn more while taking action now, based on what we already know. But we need more than just better information. While toxicological testing and information on human exposure to chemicals are necessary, we also need a new approach to chemical regulation that is based on the notion of precaution and prevention.

In *Our Stolen Future*, Colburn, Myers, and Dumanoski propose the following actions to resolve the monumental problem of tracking and testing 75,000 plus chemicals and their combinations (10):

- **Reduce the number of chemicals.** This entails significantly reducing not only the number of chemicals on the market, but also the number of chemicals used in products. Products should be made simpler.
- **Make only chemicals which are detectable, have a well-defined content, and whose degradation in the environment is well understood.** Make and market only chemicals that can be readily detected in the real world with current technology. Restrict production to only products that have a completely defined chemical makeup and stop production of products containing unpredictable mixtures of chemicals. Do not produce a chemical unless we know well how it degrades in the environment.
- **Shift the burden of proof of safety onto chemical manufacturers.** Our current approach assumes that chemicals are innocent until proven guilty, which is completely wrong.
- **Redefine risk assessment.** The tool of risk assessment is now used to keep questionable compounds on the market until they are proven guilty. It should be redefined as a means of keeping untested chemicals off the market and eliminating the most worrisome ones in a timely fashion.

Understanding the impossibility of calculating risks for all of the chemicals in commerce, countries such as Sweden and Denmark have initiated bold proposals to address chemicals based on their inherent characteristics. For example, the Swedes have proposed phasing out over the next 20 years chemicals that are persistent or bioaccumulative, are carcinogenic, reproductive toxicants, neurotoxicants, or developmental toxicants. Further both Denmark and Sweden understand that a way to reduce the hazards of chemicals is by reducing exposure. In this regard, they are focusing on implementing a goal of zero chemical emissions by 2025.

All actions to resolve our problem of tracking and testing chemicals should be guided by

applying the Precautionary Principle. Implementing the Precautionary Principle means:

- Taking action in the face of uncertainty
- Shifting burdens onto those who create risks
- Considering alternatives to potentially harmful activities
- Using democratic decision-making processes that include those who might be affected

We must use precaution, based on what we do know, don't know, and can know, to confront our ignorance about the toxicity and health effects of 75,000 chemicals. While testing should continue, we cannot rely on it to provide conclusive evidence about a chemical's guilt or innocence. Because we have so few testing resources and there are so many chemicals, we can never hope to get ahead of the testing curve. Precaution is the only meaningful course of action.

References

1. M. Narotsky *et.al.* 1995. "Non-additive developmental toxicity in mixtures of trichloroethylene, di(2-ethylhexyl) phthalate and heptachlor in a 5x5x5 design," *Fundamental and Applied Toxicology*, 27: 203-216; E.J. Ritter *et.al.* 1987. "Teratogenicity of di(2-ethylhexyl) phthalate, 2-ethylhexanol, 2-ethylhexanoic acid, and valproic acid, and poentiation by caffeine," *Teratology*, 35: 41-46.
2. Peter Montague. 1996. "Dangers of chemical combinations." *Rachel's Environmental Health Weekly*, #498, June 13.
3. Environmental Defense Fund. 1997. *Toxic Ignorance: The Continuing Absence of Basic Health Testing for Top-Selling Chemicals in the United States*.
4. U.S. Environmental Protection Agency. 1998. *Chemical Hazard Data Availability Study: What do we really know about the safety of high production volume chemicals*.
5. D.D. Weisenburger. 1993. "Human health effects of agrichemical use," *Human Pathology*, 24(6), pp. 571-576.
6. Daniel Fiorino. 1995. *Making Environmental Policy*. Berkeley: University of California Press.
7. Katherine Barrett and Carolyn Raffensperger. 1999. "Precautionary science," in Carolyn Raffensperger and Joel Tickner (eds.). *Protecting Public Health and the Environment: Implementing the Precautionary Principle*. Washington, DC: Island Press. p. 111.
8. John Cairns, Jr. 1999. Absence of Certainty is not Synonymous with Absence of Risk. *Environmental Health Perspectives* 107(2), pp. A56-57.
9. Greater Boston Physicians for Social Responsibility and Massachusetts Public Interest Research Group. 1996. *Generations at Risk: How Environmental Toxins May Affect Reproductive Health in Massachusetts*. Cambridge, MA.
10. Theo Colburn, Dianne Dumanoski, and John P. Myers. 1996. *Our Stolen Future*. New York: Plume-Penguin, p. 207.

11. Peter Montague. 1997. "The Toxic Substances Control Act," *Rachel's Environment and Health Weekly*, #564, Sept. 18.

Massachusetts Precautionary Principle Partners

Contact information

Clean Water Fund

36 Bromfield Street #204
Boston, MA 02108
Tel. 617-338-8131 Fax 617-338-6449
Email: bostoncwa@cleanwater.org

Lowell Center for Sustainable Production

University of Massachusetts Lowell
One University Avenue
Lowell, MA 01854
Tel. 978-934-2981 Fax 978-4522-5711
Email: joel_tickner@uml.edu

Massachusetts Breast Cancer Coalition

Contact: Sharon Koshar
51 Diauto Drive, Suite B
Randolph, MA 02368
Tel: 1800-649-6222
Email: 1in8@mbcc.org

Please give credit to the Massachusetts Precautionary Principle Project when making reprints.
Originals printed on 100% recycled, post-consumer, process chlorine-free paper.