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What is the Precautionary Principle? How is it Taking Shape Nationally and Globally?

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This article is based on a talk given by Suzanne at a BCERF Ad Hoc Discussion Group meeting on Long Island, NY on June 19, 2003.

Early History of Precautionary Approaches

Precautionary approaches to public health have a long history. The father of the precautionary approach is Hippocrates, who said **"As to diseases make a habit of two things – to help, or at least, to do no harm"** (Ref: Hippocrates in *Epidemics*). Precautionary actions have been a cornerstone of public health. For example, the physician John Snow mapped cases of London's cholera epidemic of the mid-1800s. He observed that most cases of cholera were grouped around dwellings that used a certain well for drinking water. Until then it was thought that diseases were only transmitted in the air. The possibility of water transmission was hotly debated. While the organism that caused cholera was not identified for another 30 years, the removal of the handle at the Broad Street pump was a precautionary action by Dr. Snow that had a major impact on halting the 1854 cholera epidemic in the Soho district of London.

Origins of the Modern Precautionary Principle

In more modern times, the origins of the **Precautionary Principle** can be traced to Germany's emerging environmental movement of the 1970s. "Precautionary Principle" is actually the English translation of the German phrase "Vorsorgeprinzip," and the direct translation is "Foresight Principle" (Ref: Kreibel and Tickner, *American Journal of Public Health*, vol. 91, pp. 1351-55, 2001; and Tickner, Precaution and preventive public health policy (editorial), *Public Health Reports*, vol. 117. pp. 493-497, 2002).

There is no one definition of the Precautionary Principle. One of the early definitions was drafted in 1992 at the United Nations Rio Conference on the Environment and Development:

> "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."
>
> Ref: http://habitat.igc.org/agenda21/rio-dec.html

Wingspread Conference Expands Scope of Precautionary Action

Definitions of the Precautionary Principle continued to evolve. A conference that had a major impact on redefining the Precautionary Principle was the 1998 Wingspread Conference held in Racine, Wisconsin. The 32 participants at the conference included scientists, lawyers, treaty negotiators and activists from the United States, Canada, and Europe. The participants drafted statements calling on policy makers, corporations, scientists, and communities to implement precautionary principles in making decisions affecting the environment. The principles they drafted at the end of the three-day conference included:

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- "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.
- In this context the proponent of an activity, rather than the public, should bear the burden of proof.
- The process of applying the Precautionary Principle must be open, informed and democratic and must include potentially affected parties. It must also involve an examination of the full range of alternatives, including no action."

Ref: http://www.sehn.org/wing.html

The Wingspread Conference added the elements of **reversing the burden of proof** (the "polluter pays" principle), as well as the importance of **open dialogue** and the **democratic process in decision-making**. Another new concept was the full **exploration of alternatives**. The importance of planning and considering alternatives in the decision making process is closer to the original German concept of the "foresight" principle.

Predicting Hazards to Humans – Vinyl Chloride

Scientists use a variety of tools to predict hazards in people. One example of harm or irreversible damage detected in laboratory animals before there was "proof" of harm in humans was data on the chemical vinyl chloride. Years before a similar type of liver tumor was observed in plastic manufacturing workers exposed to high levels of vinyl chloride, a rare type of liver tumor was identified in controlled laboratory animal studies (Ref: Rosner and Markowitz, Industry challenges to the principle of prevention in public health: the precautionary principle in historical perspective, *Public Health Reports*, vol. 117, pp. 501-512, 2002).

The National Toxicology Program still oversees a variety of short and long-term studies in laboratory animals used to identify potential chemical hazards in humans. Of the 509 chemicals tested so far, eight percent (or 42) have been identified as causing mammary (breast) tumors in control laboratory animal cancer bioassays.

Examples of Courts Ruling in Favor of Precautionary Approaches

While the Precautionary Principle has been getting a lot of attention recently, landmark environmental legislation enacted in the 1970s in the United States used a precautionary approach. For instance, the Occupational Safety and Hazard Administration (OSHA) attempted to regulate levels of benzene in the workplace because it was suspected of causing a rare type of leukemia. In the case *Industrial Union*, OSHA was sued over the proposed regulation. The US Supreme Court ruled in favor of OSHA, supporting precautionary action in light of scientific uncertainty, stating:

> "It is the agency's responsibility to determine what it considers to be 'significant risk.' OSHA is not required to support its findings that a significant risk exists with anything approaching scientific certainty… Thus, so long as they are supported by a body of reputable scientific thought, the Agency is free to use conservative assumptions in interpreting the data with respect to carcinogens, risking error on the side of overprotection rather than underprotection."

Ref: as cited in: Ricci *et al.*, Precaution, uncertainty and causation in environmental decisions, *Environment International*, vol. 29, pp. 1-19, 2003.

A second example is a court ruling in the case of the Ethyl Corporation vs. the US Environmental Protection Agency (EPA). The "ethyl" stood for "tetra ethyl lead," the additive that had been added to gasoline since 1922. The EPA's phase out of lead in gasoline in the 1970s was based on concerns that ethyl lead as a fuel additive caused "significant" harm to those who were exposed to it, especially children. In 1976, the majority opinion of the court ruled in favor of the EPA stating:

> "….more commonly, 'reasonable medical concerns' and theory long precede certainty. Yet the statues and common sense demand regulatory action to prevent harm, even if the regulator is less than certain that harm is otherwise inevitable. Where a statute is precautionary in nature, the evidence is difficult to come by, uncertain, or conflicting because it is on the frontier of scientific knowledge, the regulation designed to protect…we will not demand rigorous step-by-step proof of cause and effect."

Ref: as cited in Ricci *et al.*, Precaution, uncertainty and causation in environmental decisions, *Environment International*, vol. 29, pp. 1-19, 2003; original citation: Ethyl Corp v. United States Environmental Protection Agency, 541, F.2d 1 (DC Cir, 1976)

Policy makers and regulatory agencies in the United States have had a strong history of precautionary approaches to protect public health even when there is scientific uncertainty of a cause and effect. Unfortunately for our nation's children, the phase out of lead in gasoline was too long in coming. From 1922 to 1985 more than

15.5 billion pounds of lead was used as a gasoline additive in the United States. With the phase out of lead in gasoline in the 1970-80s, lead levels in air had been reduced by 80 percent by the 1990s. But lead still persists in soil, since it does not degrade. Public health scientists had testified and protested the use of lead in gasoline as early as 1925. One of the leading public health scientists of that time, Dr. Thompson of the US Public Health Service had stated, "…lead has no business in the human body … everyone agrees lead is an undesirable hazard and the only way to control it is to stop its use by the public." (Refs: Rosner and Markowitz, Industry challenges to the principle of prevention in public health: the precautionary principle in historical perspective, *Public Health Reports*, vol. 117, pp. 501-512, 2002, and http://www.uwsp.edu/geo/courses/geog100/Lead-Science.htm).

Nearly 60 years later we are still struggling with how very low levels of lead affect the body's immune system and cognitive development in children. However, the push to use lead in gasoline in the 1920s was made under the guise of the global competitiveness and industrial supremacy of the United States. We, our children, and generations to come, will pay the price for the decision to use lead in gasoline for more than 50 years.

Protecting the Public Health of Children

For the protection of our children's health, the American Public Health Association (APHA) affirmed its endorsement of the Precautionary Principle as a cornerstone of public health. In a 2000 policy statement, the APHA encouraged governments, the private sector and health professionals to promote and use the Precautionary Principle to protect the health of developing children (Ref: APHA Policy Statements adopted Nov. 15, 2000, *American Journal of Public Health*, vol. 91, pp 476, and 495-496, 2001).

Examples of US Federal Agencies Taking Precautionary Approaches

Examples of federal landmark legislation using a precautionary approach include the Food, Drug and Cosmetic Act. This law requires pharmaceutical manufacturers to demonstrate safety of the drug prior to market approval by the Food and Drug Administration (FDA). The 1970 Occupational Safety and Health Act requires employers to provide workplaces free from recognized hazards (Ref: Mayer *et al.*, Moving further upstream: from toxics reduction to the precautionary principle, *Public Health Reports*, vol. 117, pp. 574-586, 2002).

The EPA requires pesticide manufacturers to submit the results of animal cancer bioassays prior to registration approval to determine if the pesticide is a cancer hazard. Unfortunately, there is a lack of transparency in this process. The cancer bioassay reports are submitted to the EPA, but remain the property of the manufacturer. The results of the reports are rarely published in the open scientific literature, and often can only be obtained though the tedious process of a Freedom of Information Act request. But since proprietary (trade secret) information can be found in the reports, the manufacturer retains the right to edit (black out) parts before they are released if copies are requested under the Freedom of Information Act. While some requests have quick turnaround of one to three months, BCERF staff have waited up to 18 months to get copies of reports evaluating the cancer causing potential of certain pesticides.

Recent Precautionary Action Success Stories in the United States

Instead of requiring individual risk assessments to be done for each air pollutant, the revised 1990 Clean Air Act amendment states that maximum controls must be used for a list of 180 chemicals unless there is proof that they are harmless. (Refs: Harremoës [editor], Late lessons from early warnings; the precautionary principle 1896-2000, European Environment Agency, Report no. 22, 2001; and Goldstein, The precautionary principle also applies to public health actions, *American Journal of Public Health*, vol. 91, 1358-1361, 2001).

The Massachusetts Toxic Use Reduction legislation is another example of a success story at the state level. This act has lead to a 75 percent reduction in chemical emissions, a 57 percent reduction in chemical waste, and a $15 million savings to the industry. (Ref: Tickner, Precaution and preventative public health policy, *Public Health Reports*, vol. 117, pp. 493-497, 2002).

Legislation creating a policy framework for precautionary action has also been enacted in some municipalities. On June 17, 2003, the San Francisco Board of Supervisors formally adopted the Precautionary Principle for managing environmental issues. Several elements, including taking anticipatory action to prevent harm, community right to know, assessment of the full range of alternatives, cost accounting, and a participatory decision making process, were cited in the policy statement. (Ref: Environmental Code and Precautionary Principle Policy, File no. 030422, Ordinance No. 171-03, San Francisco Board of Supervisors, June 17, 2003; http://sfgov.org/site/uploadedfiles/bdsupvrs/ordinances03/o0171-03.pdf; Note: file is 118 pages long)

European Regulations and the Precautionary Principle

While the European Union is currently embracing the Precautionary Principle more fully, there are examples of when the United States took precautionary action before Europe. For instance, the United States banned chloroflurocarbons in aerosols in 1977 because of

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Katherine McComas, Ph.D.

Assistant Professor, Department of Communication, Cornell University

Your appointment in the Department of Communication at Cornell is a return to Cornell for you; what did you focus on as a graduate student here, and how have your interests evolved?

My current research interests are very similar to those I had as a doctoral student here at Cornell. This is one of the reasons why returning to Cornell is so exciting for me: many people share similar interests, adding to the intellectually stimulating environment. Broadly stated, my research focuses on science, environmental, and risk communication. Within this context, I'm particularly interested in public participation and community involvement in discussions, planning, or decision making about health or environmental risks. Much of my research, in turn, examines the use of public meetings for risk communication and public participation. My research questions and hypotheses center around issues of trust, credibility, satisfaction, and willingness to engage again in community activities. I'm also interested in what it means to be "successful" in public participation, from the view of organizers as well as participants.

Our readership includes both scientists (and other professionals) and members of the public who have might not have specialized training. What would you say are the main tools or approaches either of these groups might have at its disposal to communicate with the other, regarding questions of environment and health risk?

There are perhaps more tools than ever before for communicating about environment and health risks. Choosing among them requires careful thought about the audience, objective, context, and content of the message. Where I work, in the Department of Communication, I have faculty colleagues who actively research how the use of the internet fosters collaboration and decision making; others examine how media coverage of health and environmental issues influence people's orientations toward risk. My research tends to focus more on interpersonal settings for risk communication, e.g., public meetings, where people come together in a shared social experience to discuss questions related to environmental or health risks. Each of these tools can reach different audiences, and each can have its place in risk communication efforts. In turn, no one tool will probably satisfy all communication needs.

In your research on public participation in the investigation of cancer clusters, what can you tell us about the positive aspects of these activities; in other words, what is to be gained from this process and why is it valuable?

One of the factors that makes people more concerned about risk is when they perceive a lack of control or an inability to do anything to reduce their exposure to the risk. Engaging people in the investigation can help with feelings of powerlessness. This is especially true when people view their participation as fair and meaningful, as opposed to merely symbolic. In turn, there is a lot of lay expertise that people can contribute to investigations that can make the results more valid and reliable.

You have examined the way public meetings function in the participation process. Can you provide insight as to what helps to create a public meeting that leaves all parties satisfied?

My research examining satisfaction with public meetings suggests that neither citizens nor government officials are overly enthusiastic about public meetings; however, many of the people I spoke with would argue that, when used well, public meetings can leave parties satisfied. More specifically, using a mail survey of citizens who did and did not attend a public meeting about a local hazardous waste site, my results found that – irrespective of whether they had ever attended a

public meeting – citizens were more satisfied when they thought public meetings included an open discussion of issues, welcomed alternative viewpoints, and disseminated good information. Citizens were also more satisfied when they believed public meetings were a useful way to involve citizens in environmental planning, as well as a good way to learn how other people in the community felt about an issue. In addition, my interviews with New York State officials who conducted public meetings suggested that they, too, were only moderately satisfied with public meetings, believing that some meetings occur too late in the decision-making process or that citizens doubt the credibility of the officials conducting the meeting. Some officials really believed in public meetings, however, and counseled that preparedness and flexibility were two key aspects of successful public meetings.

Do the people who get involved and commit time to these participatory processes tend to have special characteristics, and is self-selection an issue? If so, would there be benefit to getting a broader spectrum of the public involved, and what are the obstacles to doing so?

Self-selection is always an issue, and few organizers or participants would argue against having a broader spectrum of the population involved. The reality is that, for any given issue, only a portion of the population will become involved or pay attention. People who get involved are more likely to believe there is a problem and feel a connection to it. They also will likely perceive fewer constraints on their ability to seek and obtain information about the problem. The challenge for risk communicators is making sure that risk information reaches the people who need it. Clearly, this can be more challenging when people do not perceive there is a problem. Conversely, communicating with people who *do* perceive a problem can also be challenging. In my research, I've found that people who attend public meetings related to environmental hazards also tend to perceive greater risks from the hazards. They also tend to be more skeptical of government officials in charge of the meetings.

There has been some research looking into cancer risk perception amongst various groups of people. However, as Ann Robertson points out, "the majority of this research tends to examine the 'accuracy' of lay perceptions of risk (that is, whether they are commensurate with biomedical perspectives) rather than how individuals understand risk information and create meaning about risk information in the context of their everyday lives." Does this observation resonate with your thoughts and experiences?

This idea of a "deficit model" is a common and traditional way of looking at risk communication. It essentially argues that citizens lack enough scientific information on which to base their judgments, which is why lay perceptions of risk often are out of sync with scientific assessments. To remedy this, proponents argue that we need to educate citizens how to think more like scientists, so that citizens will be more receptive to what the scientists say. Again, few would argue against having greater scientific literacy, or a basic understanding of scientific concepts, among citizens. To focus entirely on "fixing" this deficit, however, overlooks at least one important factor. That is, because they are acutely tuned into the risk in the context of their everyday lives, citizens can provide unique insight into risk assessments. In other words, lay expertise can inform scientific evaluations of risk. This is one reason why involving citizens early in decision making processes is so important.

Reference: Robertson, A. 2000. Embodying Risk, embodying political rationality: women's accounts of risks for breast cancer. Health, Risk, and Society *2: 219-235.*

"The reality is that, for any given issue, only a portion of the population will become involved or pay attention. People who get involved are more likely to believe there is a problem and feel a connection to it."

Some Pesticide Applicators at Higher Risk for Prostate Cancer

By Suzanne M. Snedeker, Ph.D.

As part of BCERF's Cancer and Environment News project, we feature the following article, prepared with the objective of broad distribution to relevant groups. Please feel free to reproduce this article if you can be part of this information dissemination effort. Contact Dr. Suzanne Snedeker (contact information on opposite page) for an electronic version.

In results published in the May 2003 issue of the *American Journal of Epidemiology*, researchers from the National Institutes of Health reported a higher risk of prostate cancer in male pesticide applicators. The applicators were enrolled in the *Agricultural Health Study**.

Prostate cancer is the most common cancer in men in the United States. According to a report released by the National Cancer Institute and the Centers for Disease Control, prostate cancer rates ranked number one of all cancers for both white and African American men. Farming is one of the jobs linked to a higher rate of prostate cancer. But, until recently researchers have not been able to find out if there are specific types of pesticides or other chemical exposures on the farm that are linked to prostate cancer. The linkages have been difficult to make because most of the studies done in the past have been based on only a few hundred farmers. A new study, called the *Agricultural Health Study*, is following over 55,000 men from Iowa and North Carolina who are professional pesticide applicators. Over 80% of the licensed pesticide applicators in both states are enrolled in the study, which started in 1993. This long-term study is designed to investigate whether exposure to pesticides, or other farm practices, increases the risk of cancer and other illnesses that may take many years to develop.

Researchers asked many questions of the farmers before the any of the men in the study were diagnosed with prostate cancer. By using questionnaires, investigators asked the men whether they had or had not ever used 50 different agricultural pesticides. For many of the pesticides they also asked how often, for how many years, and what method was used to apply the pesticides. They gathered information on use of protective equipment such as gloves, hats, and protective suits. Farmers were asked about their diet and lifestyle, including whether they smoked, exercised, or drank alcohol. Information was gathered on the farmer's age, ethnic background, family history of prostate cancer and other factors that might affect the risk of this disease.

During the next four and a half years, 566 cases of prostate cancer were reported in the men enrolled in the study. Overall, the risk of prostate cancer was small – about 14% higher in men who were pesticide applicators compared to men living in the same state who were not applicators. Of the 50 pesticides studied, only exposure to the fumigant methyl bromide was consistently linked to a higher risk of prostate cancer. Applicators with high levels of exposure to *methyl bromide* had prostate cancer risk that was more than doubled. Those with very high exposure to methyl bromide had a 347% higher risk of prostate cancer.

For other pesticides, the data was not as clear. Most were not related to the risk of prostate

cancer. For other pesticides, both age and family history played a role in whether they were linked to prostate cancer. In men over 50 years of age, there was a higher risk of prostate cancer if they had been exposed to the organochlorines *aldrin, DDT* or *heptachlor* (insecticides that are not used any more, but that stay in the environment for a long time), *permethrin* (used on livestock) or to *carbofuran*. Exposures to certain pesticides were linked only to men who had relatives with prostate cancer. This included applicators with a father or brother with prostate cancer who were exposed to six different pesticides. They included *butylate* a herbicide, the crop insecticides *coumaphos, fonofos, chlorpyrifos* and *phorate*, and an insecticide used on livestock, *permethrin*. For most of these pesticides, prostate cancer risk was doubled in exposed applicators with a family history of prostate cancer. Men without a relative with prostate cancer did not have a higher prostate cancer risk if exposed to these six pesticides.

The investigators are seeking funding to continue the *Agricultural Health Study* for at least another five years to see if the higher rates of prostate cancer and links to specific pesticides are seen over time. These results also need to be confirmed by other studies. More information is needed to link actual exposures to pesticides with cancer rates. The *Agricultural Health Study* also plans to look at cancer rates in spouses of farmers and professional female pesticide applicators. Over 33,000 women are enrolled in this study. Both breast cancer and ovarian cancer risk will be evaluated.

The results of the *Agricultural Health Study* to date suggest that farmers who are pesticide applicators have a higher risk of prostate cancer, and this may be due to exposure to certain pesticides, including *methyl bromide*. Age and family history may also play an important role in prostate cancer risk in men exposed to certain pesticides. It's important that applicators take precautions to reduce exposures to pesticides, including frequent hand washing and using personal protective gear. It is hoped that regulatory agencies use the results of this study to evaluate the safety of pesticides used in agriculture. For more information on the *Agricultural Health Study*, including background information, important findings and a listing of all scientific publications, please go to: **http://www.aghealth.org**

*The *Agricultural Health Study* is sponsored by the National Cancer Institute, the National Institute of Environmental Health Sciences, and the Environmental Protection Agency (EPA). Dr. Snedeker would like to thank Dr. Michael Alavanja, the Principle Investigator of the Agricultural Health Study, for reviewing this article.

Reference: Alavanja *et al.*, Use of agricultural pesticides and prostate cancer risk in the Agricultural Health Study Cohort, *American Journal of Epidemiology*, vol. 157, pages 800-814, 2003.

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Regional Cancer and Environment Forum meets at Reid Castle, Manhattanville College, in Westchester County

BCERF Ad Hoc Discussion Group meetings have been re-named **Regional Cancer and Environment Forums** to better reflect the way that these forums have evolved. Diverse topics related to breast cancer and environmental risk factors will continue to be featured, and we hope to continue to draw both members of the public seeking to expand their knowledge in these areas, as well as professionals and activists with high levels of continuing involvement. We are happy to report a successful forum of about 40 participants on October 24, 2003 at Reid Castle, Manhattanville College, in Westchester County. Participants came from Westchester, Rockland, Nassau and Suffolk Counties, as well as from New York City.

Updates from organizations and elected officials

Congresswoman Nita Lowey, a long-time supporter of BCERF, as well as a champion of increased federal investment in biomedical research into diseases such as cancer, diabetes and Alzheimer's, welcomed the group to her district and discussed some of the highlights of what has been accomplished and what remains to be done with regard to breast cancer research.

We heard particularly poignant updates from representatives of local organizations.

- Sherri Spalter, representing both the Westchester Breast Cancer Coalition and the National Breast Cancer Coalition, spoke about the urgent need to understand all aspects of environment's influences on cancer incidence.
- Rick Harper of Cornell Cooperative Extension of Westchester County spoke to the group about the connection between the concerns of this forum and the objectives of the New York State Integrated Pest Management Program. Rick is active in all aspects of pest management in the community and described recent legislation such as Neighbor Notification.
- Patti Wood brought the group highlights of the Silent Spring Institute's Household Exposure Study. The study of 120 homes in Cape Cod, Massachusetts, discovered very widespread exposures to 67 compounds such as chemicals found in plastics, detergents and cosmetics, as well as insecticides and flame retardants used in foam furnishings. As a specific example, the researchers found bis(2-ethylhexyl) phthalate (DEHP), which is "reasonably anticipated to be a human carcinogen", according to the National Institutes of Health, in the dust of every home tested, at concentrations ranging from 16.7 to 7700 micrograms per gram (µg/g). DEHP is used in a wide variety of products, including children's toys, shower curtains, raincoats, shoes, and floor tiles.
- Julie Wilstatter, Outreach Program Coordinator of Gilda's Club of Westchester, provided an overview of her organization's functions and expressed appreciation to those working to understand and reduce the incidence of cancer.
- Lauren Friedrich, Program Coordinator at the Maurer Foundation in Port Washington, described the outreach and education carried out through the Foundation's Young Women's Breast Health Program.

The group was also privileged to be joined by State Senator Suzi Oppenheimer representing the 37th district. Senator Oppenheimer shared with the group her interest in and passion for the issues being addressed at the forum.

Metropolitan New York Registry of Breast Cancer Families

Regina M. Santella, Ph.D., Professor of Environmental Health Sciences at the Mailman School of Public Health at Columbia University, spoke about the Metropolitan New York Registry of Breast Cancer Families. This registry is part of a worldwide group of breast and ovarian registries, providing an important resource for gene-environment studies. These registries – including five in the United States – have coordinated criteria for participation, and in study protocol. The goals of the registry include:

- Recruit high risk families from population-based cancer registries and clinical/community settings.
- Bank data and biospecimens as a resource for family-based gene discovery and gene-environment research, with an ultimate goal to identify avenues for breast cancer prevention.
- Protect the privacy and confidentiality of participants.
- Inform family members of study findings and additional research opportunities.

Dr. Santella described features of inherited breast cancers and shared examples of patterns in these

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concerns of how this chemical affected the ozone layer. European Nations followed suit several years later. The United States also banned DES as a growth promoter in beef in 1979, 10 years before a similar ban in Europe.

But more recently we are lagging behind Europe. A class of chemicals called polybrominated diphenylethers (PBDEs) has been banned in Sweden. These flame retardants are widely used in carpets, furniture foam, and plastics (including plastic computer casings). PBDEs can range from five to 30 percent by weight of these products. As the fibers and plastics degrade the dust containing the chemical is inhaled and concentrates in body fat. PBDEs have been found globally in marine life from the North Atlantic, to harbor seals in the San Francisco Bay area. PBDEs have been widely detected in air, drinking water, and food in Europe. Few studies have been done on food levels in the United States. Sweden, with an extensive human breast milk banking system, detected an alarming rise in levels of PBDE in the breast milk of European women in recent years. The United States does not have a national breast milk bank, but very high levels of PBDEs – more than 10 times higher than detected in Europe – have been found in women from the San Francisco Bay area. Sweden banned PBDEs based on the chemicals' persistency in the environment, bioaccumulative properties, and the availability of alternatives. No similar ban has been enacted in the United States. Recently, scientists have also shown that PBDEs can support the growth of estrogen-dependent breast tumor cells in the laboratory (Refs: Darnerund *et al.*, *Environmental Health Perspectives*, 109 [Supplement 1]:49-68, 2001; Christensen and Platz, *Journal of Environmental Monitoring*, 3:543-7, 2001; She *et al.*, Chemosphere 46:697-707, 2002; McDonald, *Chemosphere* 46:745-55, 2002; Wenning, *Chemosphere* 46:779-96, 2002; and Hooper and She, *Environmental Health Perspectives*, vol. 111, pp. 109-114, 2003).

A precautionary approach does not mean that regulated chemicals are no longer studied. Indeed, as more information on risk is gathered, policies may be reevaluated. For instance, the European Union's program on characterizing whether endocrine disrupting chemicals affect the health of humans and animals is called the CREDO program: Cluster of Research on Endocrine Disruption in Europe. One of the gaps they will fill will be to better characterize health risks posed by PBDEs and other flame-retardants (Ref: Lorenz *et al.*, E.U. shifts endocrine disrupter research into overdrive, *Science*, vol. 300, p. 1069, 2003).

The European REACH Program to Regulate Chemicals

The European Union is considering enacting a policy evaluating the risks of new and old chemicals. The proposed policy is called REACH, which stands for Registration, Evaluation, and Authorization for Chemicals. In December 2002, the Danish Minister for the Environment presented an overview of the proposed policy as a part of an endocrine disruption scientific conference that was held in Copenhagen, Denmark. I had the pleasure of hearing the Danish minister's talk. The REACH program has also been described in recent articles by Michael Rogers, a policy advisor to the European Commission (Refs: Rogers *et al.*, Risk analysis under new uncertainty, the precautionary principle, and the new EU chemicals strategy, *Regulatory Toxicology and Pharmacology*, vol. 37, pp. 370-381, 2003; and Rogers, The European Commission's white paper "Strategy for a Future Chemicals Policy": a review, *Risk Analysis*, vol. 23, pp. 381-388, 2003). This legislation would require European Union members to "act as one" to register new and existing chemicals that are produced at over one ton per year, all endocrine disruptors and POPs chemicals (persistent environmental pollutants). Information on uses, toxicity data, production, and preliminary risk assessments would be included in the registration database. Full risk assessments would be required on all high volume chemicals produced at more than 100 tons annually, and also on lower volume chemicals of concern. Authorities would use the registration and risk assessment information to make decisions on whether to authorize the continued/future use of the chemical or not. What is remarkable about this proposed legislation is that both new and existing chemicals would be held to the same standard. Even though the legislation is not finalized, many industries in Europe are already pooling resources to start conducting the risk assessment on many of the high production chemicals (see Lowenberg, E.U. starts a chemical reaction, *Science*, vol. 300. p. 405, 2003).

To what extent heavy lobbying by both environmentalists and the European chemical industry will affect the final form of the proposed REACH legislation remains to be seen. A September 25, 2003 article by Andrew Osborn, in the British newspaper *The Guardian*, suggested that a new draft of the proposed REACH legislation being circulated in Brussels may require testing far fewer chemicals than was mandated in earlier drafts (*The Guardian*, http://www.guardian.co.uk/business/story/0,3604,1049170,00.html). Many aspects of this proposed legislation are being hotly debated in Europe, including its complex implementation, benefits to the environment, and potential impact on the European chemical industry.

The Concept of "Polluter Pays" and its Potential Drawbacks

Of concern is how to deal with the "polluter pays" concept. Environmental groups and some scientists are very cautious of industry-conducted risk assessments because of potential conflicts of interest. How transparent (i.e. how available) will the reports generated by industry be to any interested party? We already have problems with

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accessibility to the results of pesticide cancer bioassays conducted by manufacturers as a part of EPA mandated registration process. There is still room – indeed, there is an important need – to have a third party conduct the toxicological risk assessments. That is one reason why studies conducted by the EPA's Health Effects Research Lab and the National Toxicology Program's cancer bioassay testing programs are so important as hazard assessment programs.

Precautionary Principle – are there Criticisms?

Opponents to the Precautionary Principle have argued that many US federal agencies already use a precautionary approach (see Kriebel *et al.*, The precautionary principle in environmental science, *Environmental Health Perspectives*, vol. 109, pp 871-875, 2001). We have had a past history of environmental legislation with a precautionary approach. There are important elements that have been introduced into environmental legislation, including adding extra safety factors, when setting limits on certain chemicals. For instance, an extra 10-fold safety factor can be used when setting maximum levels of pesticide residues, called tolerances, on food.

Much of chemical regulatory policy in the United States is based on a more traditional risk assessment procedure where harm must be proven before a chemical is removed from the manufacturing stream, and steps are then taken to mitigate the risk by limiting exposures. This approach can result in a very lengthy risk assessment procedure that can delay policy decisions. It also does have the advantage of providing a wealth of scientific data upon which to make decisions. Again, the cost is often time and continued exposure of the chemical to at risk populations while risk assessment data is being collected. For instance, special review and re-registration assessment of certain pesticides by the EPA make take as long as five to ten years.

The second criticism is that a precautionary approach will invoke a "monsters under the bed" syndrome. As a scientist, I would agree that this is a potential problem. It is important to realize that the precautionary approach does not eliminate the need for assessing harmful effects of chemicals. The definitions of the Precautionary Principle outlined in earlier in this article do have the common element that precautionary action should be taken when there is *credible, scientific evidence of harm*. Action should not be taken because of a perceived risk. But, under this principle, action can be taken when there is still scientific uncertainty in order to protect public health.

The third argument is that the Precautionary Principle is not science-based (Ref: Starr, The precautionary principle versus risk analysis, *Risk Analysis*, vol. 23, pp. 1-3, 2003). In response, many scientists and policy makers emphasize that the best science must to be brought to the table when using the Precautionary Principle to make policy decisions. The decisions cannot be made in a vacuum. They cannot be made without scientific evidence of potential harm. We know very little about their risk of many chemicals. The absence of data does not mean there is an absence of harm, but rather that data must be gathered to provide a basis for decision-making. The Precautionary Principle as invoked in the EU REACH program, and in a policy framework recently enacted by the Canadian government (see side bar article), does not require less science. On the contrary, because of the absence of data on so many chemicals, a precautionary approach will require more extensive risk assessments to evaluate if actions are necessary. The question still remains, however, what level of scientific evidence is needed to trigger policy actions based on a precautionary approach. According to John Carins, at Virginia Polytechnic Institute, "… the precautionary principle requires scientists to develop and improve methods and procedures for studying complex natural systems" (Ref: Carins, Interrelationships between the precautionary principle, prediction strategies, and sustainable use of the planet, *Environmental Health Perspectives*, vol. 111, pp. 877-880, 2003). The best elements of a precautionary approach do not demand less science; rather it is a challenge to the scientific community to improve methods used for risk assessment.

The fourth criticism is that the use of the Precautionary Principle will stifle industry and competitiveness. Yes, and no. It may cause some industries to no longer operate if a

The Precautionary Principle Thus Far: Where It's Been, Where It's Heading

As a tool of public policy-making, the Precautionary Principle has evolved considerably since its earliest incarnations. Its history and current status can be summarized as follows:

- It was used extensively in United States environmental decision-making in the 1970s.
- It has been and continues to be the cornerstone of the public health system.
- It is already being used as a cornerstone of environmental decision-making in European nations – especially Denmark, Sweden, and Germany – as well as in Canada (see following page).
- It can be used to enhance collection of cancer risk information on high production volume chemicals.
- It must be science-based.
- It does not eliminate the need for risk assessments.
- It is enhanced by public participation.
- It requires transparency of data on health risks of chemicals.
- It has spurred a debate on whether the principle should embrace the "polluter pays" directive, which places the responsibility for providing risk assessment information with industry. Some advocates of precaution believe that evaluations by independent agencies and researchers are also important.

Recent Legislation in Canada based on Precautionary Policy

Precautionary Framework Policy Passed

On August 5, 2003, the Canadian Cabinet formally approved policy that will apply the Precautionary Principle to all decisions made by federal policy makers that "carry a risk of serious or irreversible harm where there is a lack of scientific uncertainty" (Refs: http://www.pco-bcp.gc.ca and Menyasy, Canadian Government OKs formal approach for application of the precautionary principle, *Environmental Reporter*, vol. 34, pp. 1840-1841, 2003).

Introductory statements justifying this legislation included:

> "Governments can rarely act on the basis of full scientific certainty and cannot guarantee zero risk. Indeed, they are traditionally called upon and continue to address new or emerging risks…even though scientific information may be inconclusive, decisions will still have to be made as society expects risks to be addressed and managed and living standards enhanced."
>
> Ref: Section 2.0, Context, Framework for the Application of Precaution in Science-based Decision Making about Risk, http://www.pco-bcp.gc.ca.

The precautionary framework is to be applied to federal domestic policies and laws in Canada, as well as to international agreements. The policy acknowledges that a precautionary approach is a legitimate method for decision-making. The framework embraces the Precautionary Principle by acknowledging that public involvement should be present in the scientific review and decision-making process. It stresses that scientific information is the basis of applying the Precautionary Principle. Science is not static. Policies and regulations may be modified as more information characterizing the risk becomes available (Ref: http://www.pco-bcp.gc.ca).

Québec Pesticide Laws

In July of 2002, Québec enacted a "Pesticide Management Code" which will phase out the use of certain pesticides on lawns in public and municipal areas. Restrictions will be extended to the private lawns of homeowners by 2005. The legislation will change requirements for training of persons working in retail pesticide sales, and will also broaden requirements that must be met for certification of farmers and forest managers who apply pesticides. The legislation will also specify which chemicals (called the "active ingredients") will be allowed for pest control inside and outside in elementary and secondary schools, and daycare centers (Ref: http://www.menv.gouv. qc.ca/index-en.htm press release dated 7/2/2003, on line version in French, released by Jean-Louis Laplante, Press Secretary, Canadian Cabinet of the Minister of State for Municipal Affairs, the Environment and Water).

Other cities in Canada, including Toronto, have recently passed laws restricting use of chemical insecticides and herbicides (weed killers) on lawns of private residences.

Canadian Healthy Lawn Program

The healthy lawn program was developed through collaboration between Health Canada's Pest Management Regulatory Agency and provincial and territorial governments in Canada. The goal of the program, featured on-line at www.healthylawns.net, is to promote the use of integrated pest management techniques to reduce reliance on the use of pesticides to control lawn problems.

chemical is regulated, but at the same time such action may create entirely new industries. The green industry to produce environmentally friendly products is a viable, market-based industry. For instance, the phasing out of mercury thermometers resulted in an entire digital industry for measuring temperatures in the ears of feverish children. The auto industry survived phasing lead out of gasoline. So did the paint industry. New alternatives for medical tubing without phthalates are now available. This means premature babies and dialysis patients no longer have to be exposed to harmful phthalates that can leach out of plastic tubing. New markets for new products were created that are safer for people and the environment. Seeking alternatives may open up competitiveness for multiple manufacturing streams to replace a single, environmentally toxic product. A summary of the International Summit on Science and the Precautionary Principle held in Lowell Massachusetts in 2001 stated: "Applying the precautionary principle can foster innovation in materials, products and production processes. The goal of precaution is to prevent harm — not progress — and support a sustainable future" (Ref. Sanderson, Conference Report on the International Summit on Science and the Precautionary Principle, *Environmental. Science &. Research*, vol. 9, pp. 155-156, 2002). Our inventiveness can be the best measure of our competitiveness in a global market that will no longer tolerate products that harm human health or the ecology of the earth.

The content of this article is based on the literature and references cited. Any opinions, findings, conclusions or recommendations expressed in this article are those of the author and do not necessarily reflect the view of the New York State Department of Health and the Department of Environmental Conservation.

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families. She provided an overview of just some of the many study questions being pursued with information from the Registry, such as those addressing environmental modifiers of risk in BRCA carriers – like smoking, alcohol, exercise – as well as genetic modifiers of risk in BRCA carriers. For more information about the Registry, call (212) 305-9332 or (888) METRO-08.

Mapping Disease: Geographic Considerations in Disease Investigations

Zev Ross, a graduate of Cornell's Natural Resources Program who is currently working as a consultant with Dr. Rod Page of the Sprecher Institute for Comparative Cancer research, presented on "Mapping Disease: Geographic Considerations in Disease Investigations." Zev, who is the author of the cover article of the special edition of *The Ribbon* (Vol. 8, No. 1) which addresses disease mapping, did his own graduate work mapping breast cancer data in California. He gave an excellent description of geostatistics; that is, how the points in question on, for example, a disease map, are related with distance. In his breast cancer research in California he found that breast cancer rates remain correlated at up to 46 miles. These methods are helping to develop environmental hypotheses to help explain incidence.

Breast Cancer Research in Marin County, California and Beyond

Christine Erdmann, Ph.D., has just joined the faculty of the University of Michigan School of Public Health as an Assistant Professor of Epidemiology, and is also affiliated with Lawrence Berkeley National Laboratory. Dr. Erdmann has been involved in multiple projects analyzing breast cancer incidence and mortality trends in Marin County, California, and looking at how much the known breast cancer risk factors can account for different rates. She is closely involved in the community research collaborative with Marin Breast Cancer Watch, called the Personal Environmental Risk Factors Study. Dr. Erdmann described the participatory methods of this study, such as the collection of maps from Marin County women, which detailed their own ideas of where hazardous exposures may be occurring in their daily lives. She also spoke about breast nipple aspiration as a method for identifying markers of breast cancer risk.

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