Review

THE PRECAUTIONARY PRINCIPLE*

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The Precautionary Principle in its simplest form states: "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". This Principle is the basis for European environmental law, and plays an increasing role in developing environmental health policies as well. It also is used in environmental decision-making in Canada and in several European countries, especially in Denmark, Sweden, and Germany. The Precautionary Principle has been used in the environmental decision-making process and in regulating drugs and other consumer products in the United States. The Precautionary Principle enhances the collection of risk information for, among other items, high production volume chemicals and risk-based analyses in general. It does not eliminate the need for good science or for science-based risk assessments. Public participation is encouraged in both the review process and the decision-making process. The Precautionary Principle encourages, and in some cases may require, transparency of the risk assessment process on health risk of chemicals both for public health and the environment. A debate continues on whether the Principle should embrace the "polluter pays" directive and place the responsibility for providing risk assessment on industry. The best elements of a precautionary approach demand good science and challenge the scientific community to improve methods used for risk assessment.

KEY WORDS: *harm, inventiveness, public health, risk assessment, scientific uncertainty*

Few policies for risk management have created as much controversy as the Precautionary Principle. In its simplest form, the Precautionary Principle comes into play when an activity raises a threat of harm to human health or the environment and a cause and effect relationship has not been established scientifically. Under such conditions, the Precautionary Principle suggests that positive action be taken even in the absence of complete scientific information.

The Precautionary Principle has engendered much controversy, in part because critics of the Principle have interpreted "precautionary" decisions as veiled forms of trade protectionism. Recent examples include disputes resulting from precautionary decisions to ban U. S. and Canadian beef because of growth hormones and also delays in approving genetically engineered crops in the European Union.

One of the earliest precautionary approaches is found in the Hippocratic oath "As to disease, make a habit of two things - to help, or at least, to do no harm". Thus one might consider Hippocrates the father of the precautionary approach. Certainly, precaution is the cornerstone of public health. As early as 1854, John Snow mapped cholera epidemic cases to a specific district of London where he showed that most of the cases were grouped around dwellings where people used a certain well for their drinking water. Prior to this report, most public health workers felt that the disease was transmitted in the air. Water transmission continued to be a hotly debated issue for a number of years until the causative agent was identified some 30 years later. None the less, the removal of the Broad Street pump handle from the water source in the So

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Ho district of London was precautionary action and stopped the spread of the disease (1).

The origin of the Precautionary Principle can be traced to the environmental movement of the early 1970s and in particular to Germany with the *vorsorgeprinzip* or foresight principle (2). At the core of this principle is the belief that society should seek to avoid environmental damage by careful forward planning. The *vorsorgeprinzip* developed into a fundamental principle of German environmental law, balanced by principles of economic viability, and has been used to implement policies to address acid rain, global warming, and North Sea pollution.

Defining Precautionary Principle is difficult since there does not seem to be a single definition. In fact, one legal analysis (3) has identified 14 different formulations of the principle in treaties and non-treaty declarations.

The United Nations drafted the following definition at its Rio Conference on the Environment and Development in 1992: "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" (4). The United States signed and ratified the Rio Declaration (Agenda 21) and is therefore bound to use the Precautionary Principle.

A 1990 declaration on protection of the North Sea called for action to be taken even if "no scientific evidence to prove a causal link between emissions of wastes into the ocean waters and effects exists" (5). The principle has been integrated into numerous international conventions and agreements, including the Bergen declaration of sustainable development, the Maastricht Treaty on the European Union, the Barcelona Convention, and the Global Climate Change Convention. Both Sweden and Denmark have made the Precautionary Principle a part of their environmental and public health policies. Despite a growing body of case law, however, the legal community remains divided about the meaning and applicability of the principle.

The definition of the Precautionary Principle was expanded at the Wingspread Conference held in Racine, WI, USA in 1998 (6) to: "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 include all potential shareholders. It must also involve an examination of the full range of alternatives, including no action (7).

DISCUSSION

The Precautionary Principle can be simplified to the following: scientific uncertainty plus suspected harm call for precautionary action. Imbedded in uncertainty are factors such as ignorance, indeterminacy (uncertainties are of such magnitude and variety that they may never be significantly reduced) and statistical, model or parameter uncertainties, the latter of which can be reduced by more information. The concept of harm varies depending on whether large areas are involved over long periods of time (how serious), whether the adverse effect is irreversible and/or cumulative. Precautionary action can be preventive or anticipatory.

The components of precaution include:

- Taking precautionary action before scientific certainty of cause and effect.
- Setting goals (establishing, for example, the kind of agriculture and seed breeding wanted)
- Seeking out and evaluating alternatives to harmful practices
- Shifting the burden of proof to those who have the financial responsibility with the responsibility to monitor, understand, investigate, inform and act in a professional and responsible manner
- Developing more open, democratic procedures that allow for thorough decision-making criteria and methods

Although the term 'Precautionary Principle' is not expressly mentioned in laws or policies, the concept is not new to the United States. It has been applied successfully in a number of court cases at both the federal and local level. One of the earliest cases dealing with the Precautionary Principle involved regulating benzene levels in the workplace because benzene was suspected of causing a rare type of leukemia. The Occupational Safety and Health Administration (OSHA) was sued by industry to block lowering the workplace concentration of benzene. The United States Supreme Court ruled in favor of OSHA,

supporting precautionary action in light of scientific uncertainty. The court stated: "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 (OHSA) 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 under protection" (7).

The U. S. Environmental Protection Agency (EPA) issued its initial phase-out ruling for lead in gasoline beginning in 1970. The ruling was based on concerns that ethyl lead as a fuel additive caused significant harm to those who were exposed to it, especially children. Tetra ethyl lead ("ethyl") had been used as a gasoline antiknock additive since about 1922 in the United States. Shortly after the EPA ruling, the Ethyl Corporation sued the Agency. The courts ruled in favor of the EPA by issuing in 1976 the following: "…more commonly, 'reasonable medical concerns' and theory long precede certainty. Yet the statutes 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" (7).

Unfortunately, the phase out of lead in gasoline was too long in coming, especially for children. Prior to the phase out of lead in gasoline, 15.5 billion pounds of lead had been used as an antiknock additive in gasoline from 1922 to 1985. The phase out of lead in gasoline did result in a reduction of lead levels in the air by 80% by the early 1990s (8). Still lead persists in the soil where it is not readily degraded.

There has been a long history in the United States of precautionary approaches to protecting public health and the environment. The Food, Drug and Cosmetic Act of 1938 requires manufacturers to demonstrate safety of drugs prior to market approval by the US Food and Drug Administration (FDA). The Occupational Safety and Health Act states that workplaces must be free from recognized hazards or present at levels that are considered to be acceptable. Manufacturers of pesticides are required by the Environmental Protection Act to submit data to the EPA prior to registration approval so that the Agency can determine potential hazards of the pesticide. EPA was given authority by the Clean Air Act of 1990 to issue maximum control concentrations for 180 chemicals unless there is proof that they are harmless and by the Clean Water Act to establish goals to restore and maintain the chemical, physical and biological integrity of the Nation's waters (9). The Pollution Prevention Act sets prevention as the highest priority for environmental programs (9). The President's Council on Sustainable Development expressed support for the Precautionary Principle when it stated "even in the face of scientific uncertainty, society should take reasonable actions to avert risks where the potential harm to human health or the environment is thought to be serious or irreparable".

In addition to federal regulations, state and local governments have undertaken programs that invoke precautionary approaches. In Massachusetts, the Toxic Use Reduction Reform Act of 1989 has resulted in a 75% reduction in chemical emissions, a 57% reduction in chemical waste and a 15 million annual dollar savings to industry (10). The city of San Francisco adopted the Precautionary Principle in June of 2003 for managing its environmental issues (11). These actions include: taking anticipatory action to prevent harm, community right to know, assessment of a full range of alternatives, cost accounting, and a participatory decision making process.

Other examples of the use of the precautionary principle in the United States include:

- The banning of chlorofluorocarbons as aerosols in 1977 because of the concern that this chemical affected the ozone layer. (Europe followed several years later.)
- Diethylstilbestrol (DES), a growth promoter in beef, was banned in 1979 because of concerns regarding cancer. (Europe followed some 10 years later.)

The United States is not alone in North America to initiate the Precautionary Principle. Canada has developed a precautionary framework policy that was formally approved by the Canadian government in August 2003 (12). Canada's approach applies the Precautionary Principle to decisions that "carry a risk of serious or irreversible harm where there is scientific uncertainty". It further states "governments can rarely act on the basis of full scientific certainty and cannot guarantee zero risk". This framework covers federal domestic policies and laws and international agreements. It also acknowledges public involvement in scientific review and decision-making processes.

These policies and regulations may be modified as more information characterizing risk becomes available. Scientific information must remain the basis of applying the Precautionary Principle.

A particular program of interest in Canada is the healthy lawn program jointly between Health Canada and the provincial and territorial governments that has as its goal to promote the use of integrated pest management techniques to reduce reliance on classical pesticides to control lawn pests (13) . The program will phase out the use of certain pesticides on lawns in public and municipal areas. Training and requirements for persons retailing pesticides and applicators are part of the program.

In some ways, the European Union (EU) has embraced more fully the concept of the Precautionary Principle than the United States. The principle has become enshrined in numerous international treaties and declarations. It is, by the Treaty on European Union (14), the basis for European environmental law, and plays an increasing role in developing environmental health policies as well. It is a matter of law in Germany and Sweden.

For example, the flame retardant, polybrominated diphenylethers (PBDEs), found in carpets, furniture foam and plastics (computer casings), has been banned in Sweden but not in the United States. PBDEs have been detected in air, drinking water and in foods in Europe. As fibers and plastic degrade, dust containing PBDEs is inhaled and concentrated in body fat. PBDEs have been found in human breast milk and in marine life worldwide. PBDEs can support growth of estrogen-dependent breast tumor cells in vitro. Sweden based its ban on the chemical's persistency in the environment, its bioaccumulative properties and the availability of alternatives (15).

A new policy, Registration, Evaluation and Authorization for Chemicals (REACH), currently under consideration in the European Union (EU) will allow all EU members to "act as one" in evaluating risks and to register new and existing chemicals. Under this policy, information on uses, toxicity data, production and preliminary risk assessments will be required for all endocrine disruptors, persistent environmental pollutants and those chemicals produced in quantities of one ton annually or more. For those chemicals produced at or in excess of 100 tons annually (and for lower volume chemicals of concern), a full risk assessment will be required.

A number of issues continue under discussion in finalizing the REACH program. Some of the issues being debated include:

- The fact that implementation will be complex.
- The benefits to the environment and public health.
- The potential impact on the European chemical industry.

Although, it does not have binding status, as would a regulation or a directive, a new and influential communication by the European Commission seems to be intended to ward off the arbitrary use of the Precautionary Principle (16). This communication is conventional and reassuring, relying for much of its framework on the 1983 "red book" of risk assessment (17). It stresses the need for reliable scientific data and logical reasoning. Before triggering the use of the principle, it requires identification of a potential hazardous effect, with all effort being made to evaluate the available scientific information, leading to a conclusion that expresses the possibility of occurrence and the severity of a hazard's impact on the environment or public health. An assessment of the uncertainties in the scientific data must be included. The communication also stresses the range of actions that may be taken under the principle, including no action at all. Five guidelines for using the Precautionary Principle are provided in the communication and include:

- Proportionality: "Measures…must not be disproportionate to the desired level of protection and must not aim at zero risk"
- Non-discrimination: "comparable situations should not be treated differently and…different situations should not be treated in the same way, unless there are objective grounds for doing so."
- Consistency: "measures…should be comparable in nature and scope with measures already taken in equivalent areas in which all the scientific data are available."
- Examination of the benefits and costs of action or lack of action: "This examination should include an economic cost/benefit analysis when this is appropriate and feasible. However, other analysis methods…may also be relevant."
- Examination of scientific developments: "The measures must be of a provisional nature pending the availability of more reliable scientific data…scientific research shall be continued with a view to obtaining more complete data."

The Guidelines for the application of the Precautionary Principle as stated in the EU Commentary of February 2000 contain recommendations that are explicitly aimed at risk management and the communication suggests that decisions to act or not to act are essentially political in nature.

Since industry, both in the United States and in the European Union, is required to pay for the test and therefore will be the organizations developing the risk assessments, concern has been voiced regarding how transparent the various reports generated by industry will be to interested parties. Falling out of this discussion is the question whether or not third parties should conduct the risk assessments. Government organizations, such as the U.S. EPA Health Effects Research Laboratory, the National Toxicology Program and the Agency for Toxic Substances and Disease Registry, the Centers for Disease Control and Prevention (CDC), have been proposed as neutral parties for conducting risk assessments. Non-government organizations such the International Life Sciences Institute or the Toxicology Excellence for Risk Assessment (TERA) also have been suggested as appropriate organizations. However, these organizations also have their biases. No one has more at stake than the producers of chemicals and they should be in the best position to produce the most scientifically based risk assessment.

The real question that needs to be answered is can we say yes to new chemicals or products using the Precautionary Principle. If the basic principles of ongoing monitoring, performance standards and alternative assessments are included, the answer is a resounding yes. First of all, the Precautionary Principle, if used properly, is based on sound science and is not irrational or emotional. Furthermore, if employed properly, industry will not go bankrupt but could enhance its ability to produce better and safer products. As the result of appropriate response to concerns for public health and the environment, a number of innovations have been developed by industry by following the Precautionary Principle. A few examples follow.

- New alternatives for medical tubing to replace phthalates.
- The invention of the digital ear thermometer that allowed the phasing out of the mercury thermometer.
- The removal of lead from gasoline and paints.

The level of evidence that is needed to trigger action based on the precautionary approach will be less than that needed for a full risk assessment. However, the available scientific evidence should be solid and should be no less rigorously developed than any other scientific information used. On the contrary, use of the Precautionary Principle should be a challenge to the scientific community to improve methods and procedures needed for studying complex natural systems and for risk assessment.

CONCLUSION

In the end, risk assessment is a useful tool for single chemicals and for prioritizing clean-up operations while the Precautionary Principle is useful for determining whether to proceed with novel technologies, chemicals or processes and for taking action when the consequences of a technology or chemical surprise us. A good example of the latter is the case of CFCs and their potential to destroy the ozone layer of the atmosphere.

Ultimately, the goal of precaution is to prevent harm - not progress - and to support a sustainable future for our children and grandchildren. Inventiveness - driven in part by precaution - can encourage competitiveness in a global market that no longer tolerates products that harm public health or the environment.

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Sažetak

NAČELO UTVRĐIVANJA RIZIKA

Načelo utvrđivanja rizika u svojem najjednostavnijem obliku glasi: "Kad radnja povećava opasnost za ljudsko zdravlje ili okoliš, trebale bi biti poduzete mjere opreza iako neke uzročno-posljedične veze nisu znanstveno utemeljene." To načelo je temelj za Europski zakon o okolišu i igra sve važniju ulogu u razvoju politike zaštite okoliša. Također se rabi u donošenju odluka vezanih za okoliš u Kanadi i nekoliko europskih zemalja, posebno Danskoj, Švedskoj i Njemačkoj. Načelo utvrđivanja rizika rabi se u postupku donošenja odluka vezanih za okoliš i u regulativi lijekova i ostalih proizvoda široke potrošnje u Sjedinjenim Američkim Državama. Načelo utvrđivanja rizika upotpunjuje skup podataka o riziku, između ostalog od kemikalija koje se proizvode u velikim količinama i općenito analiza koje se temelje na procjeni rizika. Načelo ne isključuje potrebu za znanošću ili znanstveno temeljene procjene rizika. Javnost je potaknuta na sudjelovanje u procjenjivanju i donošenju odluka. Načelo utvrđivanja rizika potiče, a u nekim slučajevima i zahtijeva transparentnost postupka procjene rizika od kemikalija opasnih za okoliš i zdravlje ljudi. Nastavlja se rasprava treba li načelo obuhvatiti direktivu "polluter pays" i postaviti odgovornost za provedbu procjene rizika u industriji. Najbolji elementi mjera opreza zahtijevaju dobru znanost i potiču znanstvenu zajednicu da unapređuje metode za procjenu rizika.

KLJUČNE RIJEČI: *inventivnost, javno zdravstvo, procjena rizika, štetnost, znanstvena nesigurnost*

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