POLICY FORUM: RISK MANAGEMENT

Science and the Precautionary Principle

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Few policies for risk management have created as much controversy as the Precautionary Principle. Emerging in European environmental policies in the late 1970s (*1*), the principle has become enshrined in numerous international treaties and declarations. It is, by the Treaty on European Union (1992), the basis for European environmental law, and plays an increasing role in developing environmental health policies as well.

Despite its seemingly widespread political support, the Precautionary Principle has engendered endless controversy, in part because critics have interpreted "precautionary" decisions as veiled forms of trade protectionism. Recent examples are disputes resulting from "precautionary" decisions to ban American and Canadian beef (because of the use of growth hormones) and to delay approving genetically engineered crops for sale in European markets.

But its greatest problem, as a policy tool, is its extreme variability in interpretation. One legal analysis (*2*) identified 14 different formulations of the principle in treaties and nontreaty declarations. The Treaty on European Union merely refers to the principle, without defining it. Despite a growing body of case law, including important decisions by the (European) Court of Justice, the legal community remains divided about the meaning and applicability of the principle (*3*).

In its "strongest" formulations, the principle can be interpreted as calling for absolute proof of safety before allowing new technologies to be adopted. For example, the World Charter for Nature (1982) states "where potential adverse effects are not fully understood, the activities should not proceed." (*4*). If interpreted literally, no new technology could meet this requirement (*5*).

Other formulations open the door to cost-benefit analysis and discretionary judgment. For example, the Rio Declaration (1992) says that lack of "full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation" (*6*). Still other formulations call for decisions in the absence of any scientific evidence at all: A 1990 declaration on protection of the North Sea calls for action to be taken even if there is "no scientific evidence to prove a causal link between emissions [of wastes onto ocean waters] and effects" (*7*).

An issue of particular interest to scientists is the relation, if any, of the principle to science-based risk assessment. The principle was initially applied to environmental issues, such as ocean dumping of pollutants, that are characterized by sparse scientific data useful for making policy. Its use has now expanded to protection against environmental health risks, for which extensive toxicological and epidemiological data are often available, notwithstanding gaps and inconsistencies in the evidence. The question arises how to reconcile the principle with the weight of evidence analysis typically used by scientists and health agencies. Recent "precautionary" policies regulating human exposure to radio frequency (RF) fields, such as those produced by communications and broadcasting transmitters, show that there need not be a conflict between the two. This case history is interesting because it involves more nuanced policy options than simple bans of new technologies.

GUIDELINES FOR APPLICATION OF THE PRECAUTIONARY PRINCIPLE*

Proportionality	**"Measures...must not be disproportionate to the desired level of protection and must not aim at zero risk"**
Nondiscrimination	**"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."**

*EC Commentary, 2 February 2000

Regulating Exposure to Radio Frequency Fields

The possible health effects of RF energy have been studied since World War II, and several thousand bioeffects studies and relevant engineering studies are in the literature. National and international exposure guidelines (*8*, *9*) offer a high level of protection against established hazards of RF energy. These guidelines apply to long-term and short-term exposures of the general public and workers. They were based on a painstaking evaluation of the relevant scientific literature, but do not directly consider cost-benefit analyses or issues of risk acceptability.

These guidelines, however, are based on a literature that is unclear and controversial in many respects. A large number of biological effects of RF energy have been reported, some at low exposure levels, many of which cannot be independently confirmed. Several epidemiological studies have reported weak associations between exposure to RF fields and risk of various diseases including cancer, but these have technical flaws (principally, inadequate exposure assessment) (*10*). No major scientific review panel in the United States or Western Europe has concluded that low-level exposure to RF fields actually causes health problems.

Yet there has been substantial public concern about health effects from exposure to RF fields, causing widespread and often emotional opposition to the siting of cellular telephone base stations. The RF exposure levels to the public from such facilities are invariably far below international exposure guidelines (*11*).

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In response, several countries have adopted precautionary measures to limit public exposure to RF fields. In 1998, Italy introduced "cautionary" limits that are as low as one-hundredth of international guidelines. Switzerland followed in 1999 by instituting similarly low RF exposure limits for "sensitive-use areas" (such as residential areas, schools, and hospital wards) and banning new construction in areas in which the precautionary limits are exceeded (*12*). Both limits are somewhat above exposure levels from most cellular base stations but are far below exposure levels from many other RF sources in the environment, including television and radio transmitters. The Swiss limits were based on the lowest levels that were deemed economically and technically feasible. They do not apply to industrial and medical equipment, or even mobile telephone handsets themselves, which are all sources of far higher exposure than cellular base stations.

New Zealand took a different precautionary approach in 1999 when it issued RF exposure standards that follow the international guidelines. The Ministries of Health and Environment considered the limits to "provide adequate protection" but recommended "...minimizing, as appropriate, RF exposure which is unnecessary or incidental to achievement of service objectives or process requirements, provided that this can be readily achieved at modest expense" and called for industry to reduce community concern through nonregulatory approaches (*13*).

These two approaches differ sharply; in one case, by setting mandatory exposure limits for precautionary reasons and, in the other, by supplementing international limits with precautionary policies aimed at improving the public acceptability of new RF transmitters. The latter is clearly more consistent with traditional approaches to setting exposure limits and is easier to apply in a consistent way to the diverse sources of RF energy in modern society. None of these precautionary approaches were based on any newly identified hazard from low-level exposures.

Guidelines for Use

The elusive nature of the Precautionary Principle and the potentially high stakes involved (an industry press release claimed that the new Swiss limits would cost 1 billion Swiss francs) make it important to clarify its use. A recent communication by the European Commission (*14*) is an important and (by virtue of its official source) influential contribution intended to ward off arbitrary use of the principle (*15*).

From the point of view of science-based risk assessment, the document is conventional and reassuring, relying for much of its intellectual framework on the famous 1983 "red book" of risk assessment (*16*). The communication stresses the need for "reliable scientific data and logical reasoning." Before "triggering" the use of the principle, it requires identification of a potentially hazardous effect, with "all effort" being made to "evaluate the available scientific information," "leading to a conclusion which expresses the possibility of occurrence and the severity of a hazard's impact on the environment, or health...." The analysis must also include an assessment of the uncertainties in the scientific data. It stresses the wide range of actions that may be taken under the principle, including no action at all. Perhaps more importantly, the communication provides five guidelines for using the principle in a politically "transparent" manner (see the table on page 979).

These recommendations are explicitly aimed at risk management, and the communication stresses that decisions to act (or not) are essentially political. Viewing the Precautionary Principle as part of a process for making provisional decisions about risk management under uncertainty would reduce criticism from its more fervent critics or advocates for more extreme interpretations of it.

Clear guidelines are still lacking for the weight of evidence needed to trigger the principle, and for deciding which of the large range of precautionary measures should be applied in given circumstances. Different standards of proof seem to be needed to invoke the principle than for other regulatory actions—but how much different are they? Can one justify using the principle to limit public exposure to RF energy to levels far below the threshold for established hazards to address public concerns on the basis of scientific data that major scientific review committees find unpersuasive of a hazard? Conversely, how much evidence of safety should proponents of a new technology be required to provide? Such issues will generate endless controversy and, indeed, may only be settled by litigation (*17*).

Although some standard of proof is needed, it need not be as high as scientists themselves might wish. For example, in the United States (where few if any laws cite the Precautionary Principle) courts have upheld the ability of government to base regulatory decisions on substantial evidence that is "less than a preponderance, but more than a scintilla" (*18*). This does not preempt the need for basing decisions on a careful analysis of the relevant scientific data—which clearly has not occurred in some applications of the principle.

However it is applied, the Precautionary Principle is enshrined in international law, and it is destined to remain a permanent fixture in environmental and health protection. It makes sense to find ways to use it appropriately. By providing guidelines for use of the principle in a politically transparent process, while emphasizing the need for a careful review of scientific data, the EC commentary may help reduce the contentiousness of its application. The Commission certainly leaves a role for science in the process.

References and Notes

1. However, one authority traces its use back to 1854, in the famous incident when John Snow removed the pump handle from a London well, "curing" a cholera epidemic in the neighborhood. D. Gee, *Financial Times* (London), U.S. ed. 2, 16 December 1999, p. 14.
2. D. Vanderzwaag, *J. Environ. Law Pract.* **8**, 355 (1999). See also www.ec.gc.ca/cepa/ip18/e18_00.html
3. D. Freestone and E. Hey, Eds. *Intl. Environ. Law Policy Ser.* **31** (1996).
4. World Charter for Nature, U.N. GA Resolution 37/7 (1982).
5. One wag has suggested that the Precautionary Principle should be applied (presumably in a strong form) to the use of the Precautionary Principle, which would result in no action—a good or bad thing, depending on one's point of view.
6. Rio Declaration on Environment and Development, 13 June 1992 (U.N. Doc./CONF.151/5/Rev.1).
7. Declaration of the Third International Conference on the Protection of the North Sea (Preamble) (1990).
8. International Commission on Non-Ionizing Radiation Protection (ICNIRP), *Health Phys.* **74**, 494 (1998).
9. IEEE (Institute of Electrical and Electronics Engineers) Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz, IEEE Std. C95.1, 1999 Edition.
10. J. M. Elwood, *Environ. Health Perspect.* **107** (Suppl. 1), 145 (1999).
11. Maximum levels of RF exposure to the public from typical cellular base stations are about 1 μW/cm, a factor of about 500 below U.S. regulatory limits at 850 MHz (which generally follow the IEEE C95.1 standard). Cellular base stations transmit at similar power levels as police, fire, and other emergency communications systems and paging systems, and far below those of commercial radio and television broadcasting transmitters.
12. Swiss Bundesrat, Decree Concerning Protection from Non-Ionising Radiation (NISV). See www.admin.ch/ch/d/as/2000/213.pdf [in German].
13. For discussion see New Zealand Ministry for the Environment, Ministry of Health, "Towards national guidelines for managing the effects of radiofrequency transmitters: A discussion document," Wellington, New Zealand: Ministry for the Environment. See www.mfe.govt.nz/about/publications/rma/draft_rf_guidelines.pdf
14. Commission of the European Communities, Communication on the Precautionary Principle, Brussels 02 February 2000. See http://europa.eu.int/comm/off/com/health_consumer/precaution.htm
15. The commentary does not have binding status as would a regulation or a directive (which are EU "laws"), but is a general guidance as to the basis of future Commission decisions. Most countries mentioned in this Policy Forum are not part of the EU, and the commentary would have only an indirect impact on them.
16. National Research Council, *Risk Assessment in the Federal Government: Managing the Process* (National Academy Press, Washington, DC, 1983.
17. Only limited case law exists on the principle. A recent decision by the European Court of Justice upholds a ban on the export of British beef into EU countries: "[I]n view of the seriousness of the risk [of bovine spongiform encephalopathy] and the urgency of the situation, the Commission did not react in a manifestly inappropriate manner by imposing, on a temporary basis and pending the production of more detailed scientific information, a general ban on exports of bovine [products]." Case E-180/96, *United Kingdom of Great Britain and Northern Ireland v. Commission of the European Communities*, 5 May 1998. See europa.eu.int/cj/en/jurisp/index.htm
18. *Cellular Telephone Company* v. *Town of Oyster Bay*, 166 F.3d 490, 494 (2d Cir. 1999).