

Workshop 5.6

Differing perspectives on the use of scientific evidence and the precautionary principle*

Joanna Burger[‡]

Environmental and Occupational Health Sciences Institute, and Consortium for Risk Evaluation with Stakeholder Participation, Division of Life Sciences, Cell Biology and Neurosciences, Rutgers University, Piscataway, NJ 08854, USA

Abstract: Different governments and agencies are approaching the use of scientific evidence, weight of evidence, and the precautionary principle in different ways. The European Community has used the precautionary principle in situations where the consequences are great, data are unavailable or will be costly (in terms of money and time) to obtain, or data are difficult or impossible to obtain. Other countries, such as the United States, have a risk assessment process that has built-in safety or uncertainty factors which are themselves precautionary. Risk management decisions can be made on the basis of adequate studies, risk assessment, weight-of-evidence approaches, and the application of the precautionary principle. While weight of evidence has been used in the United States for increased research funding and regulator action with respect to some chemicals that are hormonally active, the European Community has applied the precautionary principle.

INTRODUCTION

There are several approaches to the regulation of man-made environmental insults, such as anthropogenic chemicals, including using traditional scientific studies, weight of evidence, and the precautionary principle. All of these can be used as a basis for risk assessment, leading to risk management. All scientific studies have uncertainties, which must be accounted for in both risk assessment and risk management. While weight-of-evidence approaches can identify serious impacts, the precautionary principle can lead to interim management, allowing the necessary research to continue. When data gaps are filled, they can be used to inform both risk assessment and risk management.

This workshop dealt with the issues surrounding the history of weight of evidence and the precautionary principle, the use of these approaches in risk assessment and risk management, the kinds of precautionary actions societies can take to protect themselves and the environment, and lessons learned from early warnings. Each of these will be discussed briefly below, followed by general recommendations from the workshop.

While there is information and many studies on endocrine active substances (often called endocrine disruptors, or endocrine-disrupting chemicals), there is still much to be learned about fate and effects, and mechanisms of action. Particular needs for more studies include: the effects of low doses and of mixtures, identification of target or sensitive species, and the identification of subpopulations at risk. Endocrine active substances clearly offer a fertile field for precaution.

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[‡]E-mail: burger@biology.rutgers.edu

ENDOCRINE ACTIVE SUBSTANCES AND RISK MANAGEMENT APPROACHES

Risk management requires some level of understanding of the hazard and the risks that humans and other components of ecosystems face. The difficulty is in determining the level of risk and the attendant effects. The discussions regarding the use of traditional scientific studies, weight-of-evidence approaches, and the precautionary principle have largely focused on the differences as if these were discrete approaches. As Burger suggests in the first paper in this series, these are approaches on a continuum, and they are not mutually exclusive. The precautionary principle may provide for interim management, while research continues to address some of the uncertainties. "Precautionary actions" are not irreversible if new data suggests another risk management action. The precautionary principle is a management tool, not a risk assessment tool. Precautionary actions can include additional research, public warnings, emission reductions, substitution of alternatives, or partial or total bans. Such precautionary actions can be based on traditional studies, weight-of-evidence approaches, or the precautionary principle.

All three approaches (traditional studies, weight of evidence, precautionary principle) have been used extensively in risk management (often involving regulation), and references to them appear most often in government documents or the gray literature. However, for a full scientific dialogue, all approaches would benefit from a full discussion in the peer-reviewed literature. Overall, references to a weight-of-evidence approach go back to the 1970s, while the precautionary principle is mentioned in the peer-reviewed literature mainly since the 1990s (MedLine and Cambridge Scientific Abstracts, see Workshop 5.1). Even so, weight of evidence has been invoked much more than the precautionary principle in discussions of effects. Weight of evidence has been invoked more for human health studies than for ecological studies, and the precautionary principle has been invoked more for ecological studies than for human health studies. As Goldstein points out (see Workshop 5.2), the apparent conflict between the European use of the precautionary principle and the American cynicism about it stems from trade disputes, such as growth hormones in beef. Goldstein notes that endocrine active substances are persistent and harmful to ecosystems, and thus require some regulation, regardless of the debate about their effect on humans (see Workshop 5.2 for a further discussion).

Evaluating the effects of endocrine active substances on humans is difficult because the main line of evidence comes from epidemiological studies. Direct human evidence on the endocrine effects of chemicals has been slow to accumulate because of sample size limitations in exposed populations, and over-conservative hypothesis-testing approaches (see Workshop 5.3).

U.S. ENVIRONMENTAL PROTECTION AGENCY APPROACHES TO RISK ASSESSMENT

The U.S. Environmental Protection Agency (EPA) uses risk assessment methods to examine and regulate the effects of chemicals, and endocrine active substances are treated the same way (see Workshop 5.4). The EPA methodology embodies a conservative approach, which it considers precautionary. Assumptions and uncertainty factors are precautionary in themselves. However, the nature of the risk assessment means that the most sensitive, nontrivial endpoint is used as a basis for regulation. Thus, endocrine effects of a chemical may not be the basis for regulation, even though such effects may exist.

A EUROPEAN APPROACH

The European Environmental Agency (EEA) reviewed over 100 years of environmental management, including the examination of retrospective case studies of endocrine active substances. The EEA concluded that there were many lessons that should have been apparent much earlier. If precautionary actions were taken when problems first became evident, long-term consequences and costs would have been avoided.

The European Union established guidelines for the precautionary principle (see Workshop 5.5), which urged unwarranted recourse of the precautionary principle. The precautionary principle should be applied in the standardized process of risk assessment, risk management, and risk communication. There are uncertainties in all risk assessment processes, and these should be assessed in the application of the precautionary principle as is possible.

RECOMMENDATIONS AND CONCLUSIONS

1. Precautionary principle and weight of evidence are complementary approaches, particularly when risk assessment points to high severity, irreversibility, and high uncertainty (especially when time for collecting adequate data is long).
2. Precaution *now* can be reversed as new information becomes available; failure to take precaution when warranted may lead to irreversible consequences that cannot be undone when new information becomes available.
3. Interpretation of epidemiological and toxicological studies on endocrine active substances should take into account type II errors (false negatives) and lack of power, as well as type I errors (false positives). Need for more scientifically positive studies should not delay interim (precautionary) action for endocrine active substances.
4. There is a need to assess situations in which the precautionary principle was used for endocrine active substances. Was it warranted? Did the precautionary principle provide early action before catastrophic effects? Were there unanticipated consequences or were new hazards introduced inadvertently? These should inform our actions for endocrine active substances.
5. There is a need to examine the relationship between the precautionary principle and merely being cautious in various regulatory regimes, in several different countries.
6. There is a need to examine as a case study how weight of evidence and the precautionary principle have been specifically applied to endocrine active substances, in a variety of organisms, species guilds, ecosystems, and countries.
7. There is a need to assess situations in which regulatory actions were not taken soon enough. How could the precautionary principle have helped? Can the costs of delaying action be compared to the costs of taking action possibly prematurely?
8. There is a need to examine the use of weight of evidence and the precautionary principle across nations and continents for efficacy, usefulness, timeliness, and suitability of regulatory or management action.
9. Examples of the application of weight of evidence and the precautionary principle should be examined for the trade-offs between severity of adverse effects, irreversibility, degree of uncertainty, and costs deriving from each process, particularly for endocrine active substances.
10. Scientists engaged in traditional scientific inquiry on endocrine active substances should be encouraged to consider the broader aspects of use of their data for regulatory and management actions.