



The precautionary principle:
protecting public health, the environment
and the future of our children

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Foreword

Human society has been developing rapidly. In Europe and elsewhere, industrial, technological and economic development has created wealth and opportunity. Health has largely benefited: many people in Europe, although unfortunately not all, live longer and better than ever before. These positive trends must be sustained and extended to as many people as possible.

Technological development has often outpaced scientific knowledge related to the determinants of health. Increasing complexity in societal organization multiplies the pathways by which a variety of agents can affect health, including physical risk factors such as toxic chemicals or radiation, social circumstances such as exclusion and deprivation, limited access to clean natural resources, and the endless combinations of them all. Decisions taken in domains apparently distant from health often have the potential to affect people's health positively or negatively because of the great number of connections and exchanges in modern life. Health is a function of highly complex systems, which can be unintentionally disrupted in unpredictable ways and result in adverse health consequences that may be serious and irreversible.

When solid science is available, health can be protected effectively through preventive action. However, people must humbly acknowledge that science has limitations in dealing with the complexity of the real world and do their utmost to promote the development and progress of science. While people strive for better science, how can health be protected? In particular, how can people ensure that children and future generations will have the opportunity that many people have of reaping the benefits of progress and enjoying good health? This question is difficult. Irreparable mistakes must be avoided, such as those related to tobacco or asbestos, when people waited for definitive evidence far too long before springing to action. Further, irremediable chains of events leading to health damage must be prevented from being triggered.

Precaution has been at the heart of public health protection for centuries, and the precautionary principle is indeed related to acting under uncertainty, an increasingly common circumstance in these days. The precautionary principle has been gaining prominence and profile and has become a guiding principle in modern thinking in environment and health – a most welcome development for WHO and everyone engaged in public health. If used intelligently, imaginatively and daringly, the precautionary principle will support efforts to strive towards a healthier and safer world. I am glad to present a book that, we hope, will bring the debate forward.

Roberto Bertollini
Director, Division of Technical Support, Health Determinants
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Executive summary

The purpose of this document is to provide a background rationale and support to WHO's working document "Dealing with uncertainty: how can the precautionary principle help protect the future of our children?", prepared for the Fourth Ministerial Conference on Environment and Health held in Budapest, Hungary, in June 2004.

Technological developments have provided important benefits to health and the environment. Energy provision, waste and water treatment systems, modern housing, transport, modern food production and distribution systems, immunization, pest control and telecommunications have played important roles in improving health and the quality of life while increasing life expectancy and protecting the environment. Nevertheless, societal change and rapid technological development over the last century have also produced an increasing variety of agents and circumstances whose consequences are partly unknown, are difficult to predict, and capable of posing irreversible risks to human health and that of the ecosystem. While our understanding of environmental and health risks has advanced greatly, so has the complexity of the factors that can affect health. Thus, large uncertainties remain of the effects on health of many activities. Of particular concern are the health and environmental impacts of technologies that can affect future generations. A key question is how human societies can continue to obtain the great benefits of development while promoting a clean and healthy environment and ensuring an adequate standard of living in the future.

As the nature of threats to health and the environment becomes more complex, uncertain and global in nature, the precautionary principle is increasingly being debated. The principle states that in the case of serious or irreversible threats to the health of humans or the ecosystem, acknowledged scientific uncertainty should not be used as a reason to postpone preventive measures.

Debate about the precautionary principle is partly a response to the recognition of the severe social and economic costs of not taking precautions. Millions of children worldwide have suffered from neurological damage, diminished mental capacity and thus the ability to make a living as a result of exposure to lead from smelters, in paint and in petrol. Tobacco, asbestos and numerous other agents provide ample evidence of the high costs associated with waiting for convincing proof of harm. These cases exemplify the failure of science and policy to prevent damage to health and ecosystems and the resulting impacts on health and the economy.

In line with the mandate given by the Third Ministerial Conference on Environment and Health, WHO has developed an approach that will promote preventive public health measures in areas of emerging concern about environmental impacts on children's health. The approach focuses on how the precautionary principle can be applied to the protection of children's health and that of future generations. In so doing, the goal of WHO is to guide and improve decision-making in environment and health under conditions of uncertainty and complexity, while stimulating scientific development and more sustainable forms of economic development. The approach is sufficiently flexible to be applied by all countries in the WHO European Region, regardless of their available resources.

Through articles written by leading public and environmental health scientists, this document outlines a scientific, ethical and public health approach to applying the precautionary principle to protect children and future generations. The report also presents scientific tools for characterizing uncertain and complex risks, linking these with tools for cleaner production and innovation in safer technologies and activities. It builds on the analyses and discussions convened by the World Health Organization and the European Environment Agency, among others, concerning lessons learned from not taking precaution and best practices for decision-making under uncertainty, and on intensive discussion with Member States in the preparation of the Fourth Ministerial Conference on Environment and Health.

The findings of the report include the following.

- The concepts of precaution and prevention have always been at the heart of public health practice. Public health is inherently about identifying and avoiding risks to the health of populations, as well as about identifying and implementing protective measures. In the past, public health interventions focused on removing hazards that had already been identified and “proven” (even if the etiological mechanisms were not well understood). As “modern” potential risk factors become more complex and far-reaching, the precautionary principle addresses uncertain risks and seeks to shift the ways in which science informs policy from a strategy of “reaction” to a strategy of “precaution”. Together with related approaches such as health impact assessment, precaution provides a useful means of guiding public health decisions under conditions of uncertainty, in a manner that appropriately addresses the issues of power, ownership, equity and dignity.
- The precautionary principle encourages policy-makers and public health professionals to consider, in their approach to public health, how to account for growing complexity and uncertainty. Substantial evidence supports the conclusion that contemporary environmental health risks result from complex interactions among genetic, nutritional, environmental and socioeconomic factors. The precautionary principle can be used to encourage research, innovation and cross-disciplinary problem-solving in the face of these complex risks. It serves as a guide for considering the effects of human activities and provides a framework for protecting humans, other species and life-sustaining ecological systems now and in the future.
- The precautionary principle is occasionally portrayed as contradicting the tenets of sound science and as being inconsistent with the norms of “evidence-based” decision-making. These criticisms might be based on

effective misuse of the precautionary principle, but it is nevertheless important to clarify the role of environmental science in policy-making.

- Many pressing environmental crises share a fundamental characteristic: they appear to arise from disruptions of natural systems or cycles, the behaviour of which is only partially understood. Two conclusions may be drawn. First, there is a great need for more scientific research to fill the gaps in our knowledge. Second, while waiting for a more complete understanding we must find ways to make decisions that are based on the best available evidence, while acknowledging the uncertainties that remain. Thus, there is no contradiction between pursuing scientific progress and taking precautionary action. Indeed, applying precaution demands more rigorous science in order to characterize complex risks, clarify gaps in knowledge and identify early warnings and unintended consequences of actions. It also means using science not only for the diagnosis of environmental hazards but to identify, develop and assess safer alternatives to potentially harmful activities.
- Countries whose economies are in transition have special environment and health problems. The consequences of past pollution, economic hardship, poor or even deteriorating public health and the demands of rapid political, social and economic change pose additional problems for decision-makers. In such countries economic priorities may outweigh the need to protecting health. The precautionary principle is thus very important here, because it can inform decisions under the great uncertainty that prevails, can help build public confidence, can raise research and innovation capacities, can ensure that mistakes made in the past in industrialized countries are not repeated, and can help shift burdens from the public institutions to those creating the risks.

- There is no single recipe for applying precaution. Applying precaution should encourage decision-makers to use the broadest possible range of information, including stakeholders' views, and to examine alternative courses of action. Flexibility in applying precaution is critically important, since each decision is different – with different types of risk, evidence, uncertainty, affected communities, availability of alternatives, and technical and financial resources. Consistency thus comes from using the same precautionary framework and process in each case. What is considered an “acceptable risk” or sufficient evidence to act is a function not only of the level of risk and the strength of evidence and uncertainty, but also of the magnitude, reversibility and distribution of the risk, the availability of opportunities to prevent risk, the public's risk aversion, society's culture and values, and the pros and cons of alternative options.

- These preventive precautionary actions ultimately aim at continuously reducing and if possible removing exposures to potentially harmful substances, activities and other conditions. If progress is to be made in this direction, one should:
 - encourage the replacement of dangerous substances and activities with less dangerous substances or technologies where suitable alternatives are available;

 - reconsider production processes, products and human activities so as to minimize significant adverse effects on health and the environment, for example through the use of integrated pest management strategies, land use planning and cleaner production;

- establish public health goals for protecting the health of humans and ecosystems (such as for reducing blood lead levels or improving fisheries);
- provide information and education to the public to promote empowerment and accountability;
- integrate precautionary considerations into the research agenda to facilitate rapid interventions to prevent damage to health; and
- minimize, so far as possible, unintended adverse consequences that may be caused by precautionary actions.

The debate around the precautionary principle has provided many insights relevant to improving public health decision-making under conditions of uncertainty. It is hoped that this document will provide an additional basis for approaches to attaining the concurrent goals of (a) protecting adults, children and future generations and the ecosystems on which we depend and (b) enhancing economic development, sustainability and innovation in science, research and policy.

1. Introduction – the precautionary principle: protecting public health, the environment and the future of our children

Marco Martuzzi & Joel Tickner

Technological development has provided important benefits for health and the environment. Energy supply, water and waste-treatment systems, modern housing, transport, modern food production and distribution systems, immunization, pest control and telecommunication have played important roles in improving health and the quality of life while increasing life expectancy and protecting the environment. In parallel, changing societies and rapid technological development over the 20th century have produced an ever-increasing variety of agents and circumstances whose consequences are partly unknown, difficult to predict and capable of posing irreversible risks to human and ecosystem health. Although understanding of environmental and health risks has advanced greatly, so has the complexity of the factors that can affect health. Thus, great uncertainty remains about the health effects of many activities. Of particular concern are the health and environmental effects of technologies that can affect future generations and their ability to achieve sustainable development. A key question is how people can continue to obtain the great societal benefits of development while promoting a clean and healthy environment into the future. Reconciling the need to innovate and develop with the need to protect human health from environmental risks is therefore essential.

The precautionary principle states that, in cases of serious or irreversible threats to the health of humans or ecosystems, acknowledged scientific uncertainty should not be used as a reason to postpone preventive measures. The principle originated as a tool to bridge uncertain scientific information and a political responsibility to act to prevent damage to

human health and to ecosystems. The debate around the precautionary principle is important and challenging, as it involves fundamental dimensions of human life, such as the right to health and to a clean environment and the aspiration for better standards of living. When such elements are potentially in conflict, such as when precautionary action might disrupt the free flow of trade, policy development often becomes controversial.

The quality and relevance of available scientific information is central to the debate. Currently available methods for evaluating the risks to human health and ecosystems, mostly designed to deal with direct associations between exposure and disease, are often not sufficient for effectively characterizing complex environmental risks. Limitations in scientific tools and in the ability to identify or to quantify causal relationships are occasionally misinterpreted as evidence of safety. Thus, when proposed or ongoing technologies or activities entail potential long-term, unknown adverse health effects, the need for more accurate scientific information has often been used as a reason for inaction. Further, government agencies frequently have to wait until sufficient evidence of harm is established beyond a reasonable doubt before they can act to prevent harm. This constraint can result in public health and environmental policies based on reaction, involving remedial action after a hazard has caused adverse effects, rather than preventive, precautionary action. The increasing complexity and uncertainty of risks and the frequent lack of information on risks as well as the limits of science and policy structures to adequately address them require the development of tools to further support decision-making when health and welfare might be affected.

Failure to take precautionary action can have severe social and economic costs. Millions of children worldwide have suffered from nervous system damage, diminished mental capacity and thus ability to make a living, as a result of exposure to lead from smelters, in paint and in gasoline. Tobacco, asbestos and numerous other agents provide ample evidence of the high costs associated with waiting for convincing proof of harm. These cases exemplify the failures of

science and policy to prevent damage to health and ecosystems and the resulting effects on health and the economy.

This report

In recent years, significant advances have been made in interpreting and implementing the precautionary principle and in developing effective scientific and policy structures to address complex and uncertain risks. However, little attention has been paid to how precaution can be applied to protecting children's health or across countries and regions with differing technical and economic capacity.

This report provides a background rationale, additional reference and support to the 2003 WHO working document *Dealing with uncertainty: how can the precautionary principle help protect the future of our children?* (Chapter 2 of this publication). The WHO working document, as well as this publication, were prepared for the Fourth Ministerial Conference on Environment and Health in June 2004 in Budapest, Hungary. In accordance with the mandate given by the Third Ministerial Conference on Environment and Health in 1999, the WHO Regional Office for Europe has investigated tools and processes to promote protective public health measures in areas of emerging concern about environmental effects on children's health. The approach focuses on how the precautionary principle can be applied to protecting the health of children and that of future generations. WHO's goal in this undertaking is to guide and improve decision-making in environment and health in order to protect children and future generations under conditions of uncertainty and complexity while stimulating scientific progress and more sustainable forms of development. The approach is sufficiently flexible to be applied by all countries in the European Region, regardless of the resources available.

Through chapters written by leading public health and environmental health scientists, this report outlines a scientific, ethical and public health rationale for applying the precautionary principle to protect children and future generations. The report also presents scientific tools and processes for characterizing uncertain and complex risks,

linking these with tools for cleaner production and innovation in safer technologies and activities.

The first part of the report (Chapters 3–6) explores the foundations; the second part (Chapters 7–12) underlines the relevance of the precautionary principle with regard to priorities in environment and health and addresses its implementation.

Andrew Jordan and Timothy O’Riordan present a historical perspective on the precautionary principle. Jordan and O’Riordan note that, although the principle originated in the social planning principle in Germany, *Vorsorgeprinzip*, the form in which it has been adopted in various countries and international agreements, has necessarily varied based on the political, economic and legal aspects of each jurisdiction. They note that the history of the precautionary principle shows a steady shift towards more internationalized environmental decision-making and the penetration of environmental and health principles into non-environmental policy sectors such as trade, industry and energy production. They outline the core historical components of the precautionary principle and note that some of these have been lost in current risk-based environmental policy debates.

Neil Pearce outlines a public health rationale for precaution. He argues that the concepts of precaution and prevention have always been at the heart of public health practice. Public health inherently means identifying and avoiding risks to the health of populations as well as identifying and implementing protective interventions. Pearce notes that, together with related approaches such as health impact assessment, precaution provides a useful compass to guide public health decisions under uncertainty, in a manner that appropriately addresses issues of power, ownership and, ultimately, protection of health.

Ted Schettler and Carolyn Raffensperger provide a rationale of why the precautionary principle is needed in addressing complex, uncertain environment and health risks, including the mounting evidence of the effects of human activities on

ecosystems and health, the complexity of contemporary environmental health risks and their uncertainty and the limitations of current risk-based decision-making tools in preventing complex risks. They note that the precautionary principle encourages policy-makers and public health professionals alike to consider how to account for growing complexity and uncertainty in their approach to public health.

Pietro Comba, Marco Martuzzi and Caterina Botti address the connections between the precautionary principle and the underlying ethical values. They argue that, since precautionary decision-making normally takes into account questions of the distribution of exposure, vulnerable subgroups and environmental justice in general, making explicit the choice of value systems used is important. In particular, when a utilitarian approach based on maximizing an average welfare measure is not appropriate, Comba et al. propose an alternative approach aimed at preventing the worst possible consequences of any action. Such a principle, the “maximin” principle, is thus highly consonant with the precautionary principle.

David Gee and Andy Stirling analyse the lessons learned from failure to take precautionary action based on early warnings on a variety of ecosystem and health risks. Based on broad discussions and research undertaken in the publication of the European Environment Agency’s *Late lessons from early warnings*, Gee and Stirling outline tools and strategies to improve application of the precautionary principle and preventive decision-making in the face of uncertain and complex risks.

Philip J. Landrigan and Leonardo Trasande present a rationale for the importance of applying the precautionary principle to the protection of children and future generations. They note that the rising incidence of preventable environmentally related chronic diseases among children has increased the urgency of applying the precautionary principle. They outline the weaknesses of traditional risk assessment approaches in capturing the often greater exposure and susceptibility of children to environmental risks. They

conclude that the epidemic of lead poisoning among children may pale in comparison to the environmental epidemics of the future if governments do not prudently apply the precautionary principle to protect the world's richest resource – our children.

David Kriebel and colleagues argue that application of the precautionary principle can lead to sound application of scientific knowledge and innovations in scientific method. They note that, although the precautionary principle is occasionally portrayed as contradicting the tenets of sound science and being inconsistent with the norms of evidence-based decision-making, these critiques are often based on a misunderstanding of science and the precautionary principle. Kriebel et al. note several ways in which current practice can work against precautionary decision-making by narrowly defining hypotheses or failing to address problems from an interdisciplinary perspective. They outline ways in which scientific research can be more supportive of acting in the face of uncertain and complex risks. They conclude that a shift to more precautionary policies creates opportunities and challenges for scientists to think differently about the ways they conduct studies and communicate results.

Janos Zlinsky outlines a central and eastern European perspective on the precautionary principle. He notes the unique vulnerability of countries in transition with stresses on sensitive ecosystems, the effects of past pollution, public health problems and demands for rapid political, social and economic change, excessively stretched environment and health authorities and economic hardship such as foreign debt. All these factors increase uncertainty in decision-making. Zlinsky concludes that the precautionary principle is especially important in countries in transition because it can allow decisions under the great uncertainty that exists, can help build public confidence, can raise research and innovation capacities and can shift burdens from the state to those creating risks.

Andrew Stirling and Joel Tickner outline assessment schemes for implementing precaution in practice. They discuss

decision-making tools and criteria for improving health-protective decision-making in the face of uncertainty and complexity. They also present tools to implement precautionary decisions to protect children and future generations and to achieve sustainable development. Further, they explore the notion of alternatives assessment, materials policy, health impact assessment and public health goal setting. They argue that a centerpiece of any approach to precaution and sustainable development has to be seeking safer alternatives to potentially harmful activities and agents.

Finally, Joel Tickner, David Kriebel and Sara Wright address how three common criticisms of the precautionary principle arise from misunderstandings of the relationship between precautionary policy and science. These misunderstandings include the notion that precaution stifles innovation, causes unintended consequences potentially more serious than the problem that triggered the precautionary action in the first place and creates false-positives – apparent risks that waste resources and distract from real problems. In responding to these critiques, Tickner et al. note that society has not yet realized the full potential of science-based policy to prevent damage to ecosystems and health while ensuring progress towards a healthier and economically sustainable future. They conclude that interest in precaution provides an opportunity to move towards a more constructive view of environment and health policy, reinvigorating the core values and preventive traditions of public health.

Conclusion: the way forward

The ultimate goals of public health and precaution are to prevent disease, degradation and threats to human health and ecosystems in addition to restoring conditions that foster health. Although human activities cannot be risk-free, precaution can stimulate more health-protective decision-making under uncertainty and complexity. Debates over risks are intrinsically complex, and precaution is not necessarily a recipe for easy solutions. Further, environment and health decisions are inevitably political in nature, value-laden and affect economic interests, and tensions will always exist between economic interests and other values. Precaution can

help to more systematically and broadly clarify risks, uncertainty and alternatives. Although the concept of precaution brings this to the forefront, decisions should always be informed by the best available science, common sense and community values.

Much work has been done to clarify the role of precaution in environment and health decision-making and the theoretical bases of the precautionary principle. This report attempts to expand on discussions surrounding precaution to date, to situate these discussions in the context of children's health and sustainable development and to provide assessment and policy tools for applying precaution in practice. There is no single checklist or strict guidelines on whether and how the precautionary principle should be applied across decisions or for a given circumstance. More important is focusing on a common goal of adaptable tools for protecting and improving health while stimulating innovation in safer and cleaner production systems and human endeavours. The heuristic considerations provided in the WHO paper provide some general indications on the application of the precautionary principle that are broadly useful for different types of environmental risks.

The debate around the precautionary principle has provided many insights relevant to improving public health decision-making under uncertainty. We hope that this publication will provide additional foundations for approaches that achieve the concurrent goals of protecting children and future generations, as well as adults and the ecosystems on which humans depend, while enhancing economic development, sustainability and innovation in science, research and policy.

2. Dealing with uncertainty – how can the precautionary principle help protect the future of our children?

*Working document (EUR/04/5046267/11, 28 April 2004)
prepared by WHO Secretariat for the Fourth Ministerial Conference on
Environment and Health, Budapest, June 2004*

“We will develop initiatives in our countries to give greater emphasis in all relevant programmes to the need to prevent the exposure of children to environmental threats ... We request the European Environment and Health Committee to identify methods and mechanisms to: promote and encourage public health measures in areas of emerging concern about environmental impacts on children’s health, on the basis of the precautionary principle.”

London Declaration on Action in Partnership (paragraph 50d), adopted at the Third Ministerial Conference on Environment and Health (London, 16-18 June 1999)

Introduction

1. The precautionary principle has arisen as part of the discussions on the most effective ways to protect health and the environment in the face of highly uncertain risks. Since at least the early 1980s, European policy-making on issues of considerable concern and acknowledged scientific uncertainty has progressively adopted precautionary approaches, in order to achieve high levels of public health, environmental protection and consumer safety without compromising science or technological innovation. The European Commission’s communication on the precautionary principle of February 2000 (Commission of the European Communities) was a first and critical step in describing the purpose and use of the

precautionary principle in European policy-making over the previous 20 years.

2. During the past three years there have been significant developments in the interpretation and application of the precautionary principle, particularly by the European Court of Justice (ECJ), the World Trade Organization (WTO), WHO and some of its Member States. For example, the ECJ cases on antibiotics in animal feed, the European Environment Agency's report *Late lessons from early warnings* (European Environment Agency, 2001), and the scientific and constitutional discussions on the precautionary principle in France have all considerably enriched debates on its use and application. In addition, some of these developing insights have been codified in international agreements signed since 2000, notably the Cartagena Protocol on Biosafety (Secretariat of the Convention on Biological Diversity, 2000) and the Stockholm Convention on Persistent Organic Pollutants (United Nations Environment Programme, 2001). Some of these efforts have raised questions as to how application of the precautionary principle can more effectively stimulate decisions aimed at protecting health and ecosystems under conditions of uncertainty, while stimulating innovation in science, technology and policy.

3. It therefore seems relevant and timely to extend the foundations laid by the European Commission's communication and to address the broader needs of the 52 Member States in the European Region of WHO, including countries in transition that will be represented at the Fourth Ministerial Conference on Environment and Health in Budapest in 2004.

4. In line with the mandate given by the WHO Third Ministerial Conference on Environment and Health, protecting children and future generations from environmental impacts should be a priority. The precautionary principle can be an important tool in protecting children from uncertain environmental risks, as it can be in developing policies to protect adults. Pursuant to that mandate, this document is the first to develop an approach that will promote and encourage protective public health measures in areas of emerging concern about environmental impacts on children's health, based on the precautionary principle. It focuses on how the precautionary principle can be applied to the protection of children's health and

that of future generations. In doing so, the goal of this document is to orient and improve environment and health decisions designed to protect children and future generations under conditions of uncertainty and complexity, while stimulating more sustainable forms of development. It presents a decision-making approach to the precautionary principle that is sufficiently flexible to be applied by all countries in WHO's European Region, regardless of their available resources. It provides technical and policy background to the Declaration due to be adopted at the Fourth Ministerial Conference on Environment and Health.

5. In addition, as the policy agenda evolves from "environment" to "sustainable development", with the associated aim of protecting both vulnerable ecosystems and vulnerable people from inappropriate economic activities, there is a need for the precautionary principle to evolve in the face of these new challenges. It is hoped that this document represents another step in the evolution of the precautionary principle and its use in Europe by outlining a process, research needs and policy steps for decision-making aimed more at protecting health under conditions of uncertainty, while promoting sustainable economic development.

The context of precautionary action to protect children

6. The precautionary principle is a tool for policy- and decision-making designed to ensure that people or entities bear political responsibility for taking action to prevent damage to health and ecosystems in the face of uncertain scientific information about health and ecosystem risks. A common definition of the principle is to be found in the Rio Declaration on Environment and Development of 1992: "Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation". Based on the European Environment Agency's work and other developments in thinking about the precautionary principle, a broader, more proactive definition of precaution helps clarify its application to children's health and sustainable development: the precautionary principle provides a framework, procedures

and policy tools for public policy actions in situations of scientific complexity, uncertainty and ignorance, where there may be a need to act before there is strong proof of harm in order to avoid, or reduce, potentially serious or irreversible threats to health or the environment, using an appropriate level of scientific evidence, and taking into account the likely benefits and drawbacks of action and inaction.

7. There are many well established environmental risks, such as unsafe drinking-water, indoor and outdoor air pollution and inadequate sanitation, which are at present arguably among the most serious risks to public health. It is important that public health interventions are strengthened to prevent them. However, there are other, often highly uncertain and complex risks associated with industrialization, which affect society at large and children in particular, such as exposure to dangerous chemicals, radiation, hazardous waste and industrial pollutants through food, water, air and direct exposure from everyday products. These threats can result in effects that take place long after exposure, making the establishment of causal links all the more difficult. Exposures to these agents can result in effects that are irreversible or take many generations to remediate and are costly to health and the environment. Limitations in the ability to characterize causal relationships are occasionally misinterpreted as evidence of safety. Thus, the need for more accurate scientific information has sometimes been used as a reason for inaction. The combination of rigid policy structures requiring strong evidence of risk, social attitudes and interference by vested interests often result in policy-makers having to wait unreasonable lengths of time before they can commit themselves to preventive action. The past cases of lead, tobacco, asbestos and many other agents provide ample evidence of the high costs associated with waiting for convincing proof of harm. It is equally important that inadequate application of the precautionary principle should not prevent or preclude action producing important benefits for society.

8. Protecting children and future generations (as well as other vulnerable subpopulations) from environmental health risks is a compelling reason for developing precautionary approaches that are rational, consistent with available scientific information, and mindful of society's needs and values. Application of the precautionary principle is particularly appropriate for the protection of children's health because:

- the science underlying the impacts of environmental stressors on children (from the stage of the fetus to the age of 18) is more complex, less researched and less understood than that of such impacts on adults;
- the likelihood of serious harm to children from such impacts can be greater than for adults because of their different and changing stages of biological development, their behaviour and their greater exposure in relation to body weight;
- children are involuntarily exposed to a greater proportion of the risks caused by society's activities than adults, yet they have less power to avoid them;
- children benefit proportionally less than adults from society's risk-generating activities, such as employment, car driving, many consumer products, etc;
- the risks and the benefits of avoided risks have more time to impact on children and society than on adults;
- many of today's serious environmental threats, such as water shortages, climate change, developmental and reproductive effects of toxic substances, endocrine disruption and biodiversity loss, may impinge proportionately more on children and their children than on this generation of adults.

9. The concept of precaution is premised on the principle of protecting society from the adverse consequences of erroneous decisions. Such unintended consequences often affect the most vulnerable groups in the population, and particularly those who

do not have the power to change their environments. Hence the special relevance of the precautionary principle for children and future generations. By applying precautionary approaches to children and future generations, we are also contributing to decisions which ensure that all the population is more effectively protected. An approach designed to stimulate more precautionary decisions, with the aim of protecting the health of children and future generations and achieving sustainable development, is particularly important given the growing interdependence of global economies and long-term global threats, such as climate change, caused by industrial and human activities.

A historical perspective

10. The concept of precaution has a long history in medicine and public health, but as a principle it was established by the German *Vorsorgeprinzip* (literally, the “foresight principle”) to deal with serious, emerging though not proven risks to ecosystems and health. It is based on the concept that society should seek to avoid environmental damage by carefully planning ahead to stimulate innovation, job creation and sustainable development. The 1992 Maastricht Treaty on European Union established precaution, along with prevention of pollution at source, as central elements of European environmental health policy. The precautionary principle is now widely accepted as an underlying principle of international environmental policy. According to most interpretations of the principle, precautionary decisions are those that prevent damage to health or ecosystems in the face of uncertainty, stimulate the development of more health-protective technologies and activities, and place greater responsibility on proponents of potentially damaging activities. The precautionary principle is particularly relevant to countries with economies in transition because of their greater political, economic, and social uncertainties, lower public confidence, lower research and innovation capacities, and existing high burdens on health and the environment. With adequate international support, such countries have a unique opportunity to develop in a more environmentally sensitive and sustainable manner, avoiding the problems of the past.

11. The Treaty on European Union, as amended in 1996, does not define the “precautionary” and “preventive” policies that must be adopted. The distinction is important: prevention consists of actions taken to reduce known risks, while precaution aims to anticipate and reduce more uncertain risks. This area of policy-making is constantly evolving in response to new scientific, technological and political challenges. The European Commission has published guidelines on the consistent and proportional application of the precautionary principle, in order to avoid unwarranted trade restrictions and to help trading partners better understand European policy-making. In its communication, the Commission states that application of the precautionary principle is of critical importance for its policy of achieving a high level of protection for human health and the ecosystems, particularly under conditions of uncertainty. The communication establishes several criteria to be applied in the risk management phase for deciding on when and how to apply precaution, such as non-discrimination and consistency of actions. The communication emphasizes that it is a first step in an ongoing debate on precaution.

12. The Commission’s approach to application of the precautionary principle has the advantage of offering a clear set of guidelines that ensure consistency with international trade rules, establish a relatively clear threshold for applying precaution (reasonable scientific grounds for concern), and identify the aspects that need to be considered before precautionary actions are undertaken. Importantly, it provides a policy tool to legitimize timely action when there is reasonable scientific evidence to cause concern. As it is necessary to ensure that decisions aimed at protecting health under conditions of uncertainty are taken, the Commission communication is focused on responding to potential threats as they arise. To further address an aspect central to the London Declaration mandate, i.e. the question of how to create the conditions for sustainability for current and future generations, it is important to describe the steps for improving preventive decision-making under conditions of uncertainty and complexity. Recent elaborations of the precautionary principle, as well as innovations in risk assessment and risk management, have indicated the need to ensure transparency throughout the decision-making process, to include affected communities in

defining risk assessment questions, and to integrate assessment of risks with assessment of alternative policy options.

13. Based on these developments in applying the precautionary principle, developments in risk management, and the needs of the broader WHO European Region, this document builds on the European Commission communication by elaborating, for the first time, a process for applying precaution to effective protection of the health of children and future generations and achieving sustainable development. Applying precaution to achieve more health-protective decisions in this context requires a set of precautionary considerations throughout the whole cycle from problem framing, knowledge production, identification and characterization of risk, risk management, post-implementation follow-up, identification of knowledge gaps and research needs and back again. Such instruments as analysis of alternative courses of action, expanded scientific tools, incentives for research and innovation and enhanced public participation can in fact ensure a more proactive and positive approach to health protection, while improving decision-making. These steps are outlined in the following sections.

A proposed framework for applying precaution in the context of the health of children and future generations and sustainable development

14. As discussed in the previous section, and given the increasingly complex nature of risks and the growing interconnections between people and ecosystems in a globalizing world, it has become necessary to develop an approach for applying precaution in decision-making on environmental and health risks to children. Such an approach should be consistent with public health values and WHO's mission to promote health. The goal of this approach is to describe steps for improving preventive public health decision-making under conditions of complexity and uncertainty in a transparent and democratic manner. It provides guidance for decision-makers and society at large, so that they can proactively apply precaution to protect the health of children and future generations and make rational decisions under conditions of uncertainty. The following guidelines are designed to be flexible, to outline a series of points

that should be considered in all good decisions taken under conditions of uncertainty, and to be widely applicable by countries with differing levels of resources.

15. Given the complex nature of environmental risks to children, this approach is necessary to identify and prevent such risks (particularly those that may occur in the future) more effectively, characterize uncertainties, and stimulate research and development of preventive alternatives. Thus, an effective approach to applying the precautionary principle in these areas can be based on simple steps, scientific research and policy actions, such as:

- improving and expanding the range of scientific tools and perspectives in decision-making; developing methodologies capable of analysing complex systems, including cumulative and interactive effects, and their relationships with health;
- advancing our understanding of the relationship between ecosystems and human health and the long-term implications of ecosystem degradation;
- increasing the transparency of decision-making by more explicitly characterizing the nature and extent of uncertainties; making scientific and ethical assumptions explicit; and expanding the range of stakeholders and values involved;
- strengthening the ability of public health professionals to identify early warnings of risks and understand the effectiveness of interventions through the integrated establishment of surveillance programmes;
- ensuring adequate support for establishing research and education programmes to identify gaps in knowledge and develop and implement safer and cleaner production processes, products, consumption patterns and preventive interventions.

16. When uncertain and complex risks are being addressed, attention should not be diverted from existing public health

actions related to well established risks. Indeed, opportunities for more efficient tools to address both well established and uncertain risks should be explored. The approach proposed here is designed to contribute to more efficient preventive action, as it may be instrumental in anticipating the emergence of possible threats, through their early identification. It can draw the attention of scientists and decision-makers to the need to identify and develop options to anticipate and prevent risks before they occur. Analysis of alternatives is essential and can help prevent the often contentious debates over what constitutes an acceptable level of risk, as well as conflicts between environment and health protection and economic interests. This approach thus serves as a “compass”, pointing towards more health-protective decisions under conditions of uncertainty. Under this approach, what constitutes a threat to health should be broadly interpreted, using WHO’s definition of health, to include aspects such as the indirect effects of interventions or technologies.

Application of precaution in the context of the health of children and future generations and sustainable development

17. Applying this approach should encourage decision-making using the broadest possible range of information, stakeholders and scientific and policy tools in identifying and preventing risks and examining alternative courses of action. The approach focuses on a series of procedural steps to ensure sound health and environmental decision-making, examining all the evidence on threats as a whole and learning from accumulated experience and understanding. Flexibility in applying precaution to the area of the health of children and future generations is critically important, since each decision is different – with different types of risks, evidence, uncertainty, affected communities, availability of alternatives, and technical and financial resources. In this case, consistency comes from using the same precautionary framework and process in each case. Although outcomes will differ with the facts of each case, the approach will be the same. Policy-makers should encourage entities creating risks to be responsible for providing full information on those risks and alternatives. The goal is for

governments and entities handling risks to internalize this heuristic approach in their decision-making processes, instituting a precautionary “mindset” with regard to uncertain environmental and health risks.

18. The steps in such an approach for applying precaution to the health of children and future generations include:

- (i) determining whether an uncertain risk/problem merits a more thorough review – whether there is sufficient evidence to indicate a potential problem, or whether the cost of review is disproportionate to the cost of considered actions, including inaction. Sometimes a screening process may be useful;
- (ii) broadly defining problems to capture root sources of risks, where appropriate;
- (iii) considering and examining all available relevant evidence on exposure, hazard and risk in an interdisciplinary manner and taking account of variability as well as relevant direct, indirect, cumulative and interactive effects; this can include conducting routine health and environmental monitoring to provide a baseline understanding of health and ecological impacts, as well as health trends;
- (iv) considering the application of simplifying rules of thumb, safety factors, default values, or proxy indicators of exposure and effects when information is lacking;
- (v) comprehensively examining uncertainty and gaps in information, performing sensitivity analyses and identifying research and other ways to reduce uncertainties and gaps in knowledge where appropriate;
- (vi) examining a wide range of options to reduce risks, as well as their trade-offs, advantages and disadvantages;
- (vii) determining an appropriate course of action based on the scientific evidence, the examination of alternatives, and public input. A wide variety of policy tools to implement preventive or

protective actions should be considered, along with their economic, technical and political feasibility;

- (viii) instituting post-implementation follow-up measures, to ensure continuous risk reduction and understand the positive and negative impacts of interventions and possible unintended consequences. This should include an evaluation of measures taken and not taken, so as to minimize unexpected adverse impacts and to maximize learning.

19. Under this approach, there is no single recipe for taking precaution. What is considered an “acceptable risk” or sufficient evidence to act is a function not only of the level of risk and the strength of evidence and uncertainty, but also of the magnitude, reversibility and distribution of the risk, the availability of opportunities to prevent risk, the public’s risk aversion, and society’s culture and values. In the case of countries in transition, this process can provide a tool for prioritization, continuous improvement in human and ecosystem health, and identification of cost-effective means for multi-risk reduction.

20. Decisions made using the proposed approach should be based on the best available evidence, in addition to informed judgment and common sense. Rigorous, high quality science, which is explicit about its limitations and gaps, is critical in the application of precaution to the protection of the health of children and future generations. Scientific methods and tools must be chosen to fit the nature and complexity of the problem. Thus applying precaution does not exclude but rather advocates for the need to improve the scientific basis for decisions, including tools for assessing risks, improving surveillance of health and interventions and evaluating alternative technologies and activities.

Types of precautionary actions

21. Application of the precautionary principle to protection of the health of children and future generations does not necessarily mean stopping an activity. While always taken in the face of acknowledged uncertainties, precautionary actions

can range from informing the public about risks and uncertainties while further study is undertaken to characterize them, to imposing restrictions on potentially harmful activities and phasing out activities where evidence indicates that they might be particularly problematic. One important aspect of precautionary action entails placing responsibility and incentives in ways that stimulate proponents of potentially hazardous activities to understand the risks associated with those activities and to take protective actions. The actions taken in applying precaution can differ from country to country, depending on capacities and the groups at risk, and other economic, social and political factors. The types of precautionary action should be multiple in nature and case-specific, depending on:

- the nature of the risk, its level of uncertainty, magnitude and reversibility;
- who is exposed (for example, disproportionately affected or highly vulnerable communities);
- issues of technological and economic feasibility, benefits, proportionality and non-discrimination;
- preventability of the risk;
- social values.

22. Precautionary actions ultimately aim at continuously reducing and if possible removing exposures to potentially harmful substances, activities and other conditions. If progress is to be made in this direction the following goals should be pursued: 1) encourage the substitution of dangerous substances and activities by less dangerous substances or technologies where suitable alternatives are available; 2) improve production processes, products and human activities so as to minimize significant adverse effects to health and the environment, for example through the use of integrated pest management strategies, land use planning, and life-cycle analysis; 3) establish public health goals for protecting and restoring human and ecosystem health; 4) provide information and education to citizens to promote empowerment and accountability;

5) integrate precautionary considerations in the research agenda to make possible rapid interventions to prevent damage to health; and 6) minimize, so far as possible, unintended adverse consequences that may be caused by precautionary actions.

Conclusions

23. In conclusion, applying precaution in the context of protecting the health of children and future generations and achieving sustainable development should be a continuous, iterative process of seeking out sustainable ways of reducing the adverse impacts of economic activity on public health. The precautionary principle needs to remain an important risk management tool, as defined by the European Commission, to encourage protective actions when risks cannot be thoroughly quantified on a scientific basis. The proposed approach builds on the European Commission's communication by incorporating recent developments in application of the precautionary principle, considering the needs of the entire WHO European Region and focusing on establishing a set of considerations designed to stimulate effective decision-making to protect the health of children and future generations in the face of uncertainty. Such an approach is also important for protecting adults and ecosystems from the adverse effects of human activities. It is an evolving approach, for which communication between Member States in sharing research results, lessons learned from applying the framework, and scientific and technological best practices will ensure its improvement over time. It requires institutional development to improve transparency, apply new scientific tools and assess alternatives.

24. Implementing precautionary actions that are cost-effective (i.e. least costly to achieve a particular goal) and that have synergistic impacts (addressing several risks at once) can often result in a "win-win" situation for the policy-maker and the public at large. This requires incentives and support for research, development and innovation in safer and cleaner technologies and human activities that can help avoid risks in the first place and restore health and ecosystems. A proactive approach to precaution, directed towards creating the conditions for sustainability and health rather than simply responding to problems after they have occurred, is invaluable as we strive for

a world that protects children and future generations, as well as adults and the ecosystems on which we depend, without compromising science, economic development or innovation.

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3. The precautionary principle: a legal and policy history

Andrew Jordan & Timothy O’Riordan

Introduction

This chapter outlines the legal and policy history of the precautionary principle and discusses its current status in national and international (environmental) policy. We briefly summarize the origins of the principle as it emerged in Germany and then examine its metamorphosis into a legal norm of European Union (EU) and international environmental policy-making. We then analyse in more detail the development of precautionary thinking in the EU throughout the 1990s, focusing on the sharpening trade conflicts with the United States. We pay particular attention to a communication issued by the European Commission in 2000 to inform the EU’s discussions with its trading partners. At the time of writing, this communication represents the most succinct distillation of the EU’s thoughts on the practical meaning of precaution.

Core elements of precautionary thinking

At the core of the precautionary principle lies the intuitively simple idea that decision-makers should act in advance of scientific certainty to protect the environment (and with it the well-being interests of future generations) from incurring harm. It demands that humans take care of themselves, their descendants and the life-preserving processes that nurture their existence. As was indicated in the 1990 Bergen Conference on Sustainable Development, “it is better to be roughly right in due time, bearing in mind the consequences of being very wrong, than to be precisely right too late” (Norwegian Research Council for Science and the Humanities (NAVF), 1990).

Several commonly occurring themes can be abstracted from the complex, and at times confusing, debate on the meaning and applicability of the precautionary principle. These are: a willingness to take action in advance of formal justification of proof; proportionality of response so that actions taken are cost-effective; a preparedness to provide ecological space and margins for error, given the great uncertainties surrounding many environmental risks; a recognition of the well-being interests of non-human entities; a shift in the onus of proof to those who propose potentially harmful activities; and a greater concern for intergenerational effects on future generations.

In particular, the precautionary principle and sustainable development are closely connected, as evidenced by the inclusion of the precautionary principle in the Bergen Ministerial Declaration on Sustainable Development. The application of precaution extends the scope of environmental policy from certain and known problems that occur in the present to future and more uncertain issues. Precaution urges politicians to act with due care and diligence – to anticipate and act against problems before they occur. Precautionary actions could be considered as an investment (or insurance) against unforeseen mishaps or the acceptance of higher costs now to guard against dysgenic effects. But it also implies committing current resources to investment for the future, the benefits of which may be uncertain or at worse nonexistent. Since conclusive scientific evidence of harm or excessive damage in the future may not always be available to justify the commitment of resources to precautionary investments, other grounds for legitimacy may need to be present: moral, political, ethical and legal. Democracy itself is poorly suited to this time scale, with its heavy political biases in favour of immediate gratification and gain today rather than tomorrow. Here is an arena where the precautionary principle challenges institutional performance and the sense of citizenship, which primarily concentrates on the well-being of society today rather than the state of the world in the future.

In the context of sustainable development, although the principle of precaution does not state how various

environmental and economic factors should be traded off, it strongly suggests that a strenuous search be conducted for alternative modes of development that minimize discharges and waste products, regardless of whether they are known to have harmful effects, on the basis that prevention is often, though not always, more cost-effective than cure. In general, though, the closer controls are placed to the source of the emission and the earlier environmental considerations are factored into decision-making, the more precautionary the overall trajectory of development will be.

Unfortunately, much of the debate about the precautionary principle has become extremely technical in recent years. Some of the early temporal (and hence intragenerational) questions raised by the principle have since been crowded out by the more technical debate about how to adapt risk assessment in a way that is sympathetic to the precautionary principle.

The precautionary principle: a brief history

Precaution emerged in the 1970s in the Federal Republic of Germany. Other countries, such as the United States and United Kingdom, had already incorporated elements of precautionary thinking in their environmental policies at this time, but it was the Federal Republic of Germany that developed it into a broader environmental philosophy. At the core of this early conception was the belief that regulatory agencies and governments should move to minimize environmental risks by anticipating possible danger and, if possible, preventing it. In the 1980s, the Government of the Federal Republic of Germany used the *Vorsorgeprinzip* (foresight or precautionary principle) to justify the implementation of vigorous policies to tackle acid rain, global warming and pollution of the North Sea. In relation to these problems, *Vorsorge* implied using the best available technology to minimize pollution at the source.

Even at that time, there was no agreed statement about the role or meaning of precaution. Albert Weale (1992) quotes one

respected German commentator who had managed to identify at least 11 separate meanings. In general, *Vorsorge* comes into play when the risks of environmental damage “are not (yet) identifiable, or even in the absence of risk” (Von Moltke, 1988: 61). In principle, *Vorsorge* implies that authorities should move to minimize all risks, but in practice it tends to be married to the concept of “proportionality”, which encompasses issues such as the economic cost, technical and administrative feasibility of a proposed measure (Von Moltke, 1988). For Hajer (1995) and Weale (1992, 1993), *Vorsorge* was part of a wider set of ideas or an ideology they label “ecological modernization”. This formulation suggests that the relationship between environmental protection and economic development is not necessarily antagonistic, but can, with the right mix of inducements, be mutually supportive. One might argue that the precautionary principle was warmly received in the Federal Republic of Germany precisely because it seemed to legitimize “greener” forms of economic (and especially technologically driven) growth.

Diffusion of the precautionary principle within the EU

Once strong environmental policies were in place, the Federal Republic of Germany set about pressing the rest of the EU to adopt similarly high standards, in part to prevent its own industries from being placed at a competitive disadvantage. The rationale for disseminating the precautionary principle was therefore tied strongly to preserving economic competitiveness as well as promoting forward-looking environmental practices. This process of dissemination occurred via both the formal structures of the EU (Jordan, 2001) and the overarching system of international environmental law (see below). In 1990, all 12 EU Heads of State or Government gave their formal, political blessing to the principle, which was subsequently enshrined in the Maastricht Treaty, the negotiation of which culminated in 1991.

In the United Kingdom, one of the least environmentally progressive EU states in the mid-1980s, environmental values

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were not as prominent and “sound science” was regarded as the best basis for policy. As in the Federal Republic of Germany, the United Kingdom government also shaped the meaning of the precaution to suit its short-term political priorities, which at the time were resisting calls to reduce acidic gases and the discharges of sewage and other heavy metals into the North Sea (Jordan, 2002). The United Kingdom therefore adopted a fairly “weak” interpretation of precaution (Jordan & O’Riordan, 1995).

As the United Kingdom’s political priorities changed in the 1990s, becoming greener and more supportive of sustainable development, the interpretation of precaution also began to shift while retaining a core commitment to economic efficiency. In 1999, the new Labour government suggested that (Department of Environment, Transport and the Regions, 1999, para. 4.2):

The precautionary principle means that it is not acceptable just to say “we can’t be sure that serious damage will happen, so we’ll do nothing to prevent it”. Precaution is not just relevant to environmental damage – for example, chemicals which may affect wildlife may also affect human health. At the same time, precautionary action must be based on objective assessments of the costs and benefits of action. The principle does not mean that we only permit activities if we are sure that serious harm will not arise, or there is proof that the benefits outweigh all possible risks.... There are no hard and fast rules on when to taken action: each case has to be considered carefully.... Transparency is essential.... Decisions should be reviewed to reflect better of risk as more evidence becomes available.

In contrast, the Netherlands did not adopt an item of national legislation referring to precaution until as recently as 1998, but the definition used is much stronger (Douma, 2001). To summarize, precaution emerged in one sociocultural context but has been reinterpreted as it has been integrated into neighbouring jurisdictions, each with its own set of political,

economic and legal priorities. The precautionary principle, therefore, has to be seen in the context in which it is used.

The diffusion of the precautionary principle in international policy-making

In the 1980s and 1990s, interest in the precautionary principle spread well beyond Europe at remarkable speed. Today, it appears regularly in national legislation, in international statements of policy and in the texts of international conventions. It is also being continuously developed at subnational levels of governance. Crucially, it appears in the 1992 Rio Declaration – a statement of principles and general obligations to guide the international community towards sustainable forms of development.

Although widely adopted, the precautionary principle has neither a commonly agreed definition nor a set of criteria to guide its implementation. One well-known legal commentator (Fisher, 2002: 13) suggests that there are “countless different legal and policy definitions ... and endless examples of where it has been explicitly put into operation”. Its advocates foresee precaution developing into “*the* fundamental principle of environmental protection policy at [all] scales” (Cameron & Abouchar, 1991). Sceptics, in contrast, claim that: its popularity derives from its vagueness; there is no single principle but “droves of differing versions” (Stone, 2001); it fails to bind anyone to anything; and it does not resolve any of the deep dilemmas that characterize modern environmental policy-making.

Some legal scholars believe that precaution is too blunt an instrument to be a regulatory standard or principle of law. Bodansky (1991) is highly suspicious because it “does not specify how much caution should be taken” in a given situation (see also: Bodansky, 1994). It does not, for example, define what is an acceptable margin of error or what threshold of risk warrants the application of precautionary action. Nor does the precautionary principle determine when precautionary measures should be taken or define the point at which

abatement costs become socially or environmentally excessive. In response, its advocates suggest that precaution is a principle like proportionality or equality whose exact meaning emerges through legal interpretation in different legal cultures (Fisher, 2002).

Precaution: a continuum of definitions

As precaution has moved into new legal and political contexts, it has taken on slightly different meanings, each giving a slightly different emphasis to a particular aspect. Both advocates and critics generally agree on one thing: that precaution works along a continuum ranging from quite “weak” formulations that are relatively protective of the status quo to very “strong” formulations.

The weaker formulations tend to be restricted to the substances or activities that are most toxic and threatening to human life. They advocate a role for biased cost–benefit analysis, incorporate some concern for technical feasibility and economic efficiency arguments and emphasize the importance of basing judgements on the dictates of “sound science”. The United Kingdom advocates this type of formulation (HM Government, 1990).

Where there are *significant* risks of damage to the environment, [we] will be prepared to take precautionary action to limit the use of potentially dangerous materials or the spread of potentially dangerous pollutants, even where scientific knowledge is not conclusive, *if the balance of likely costs and benefits justifies it*. The precautionary principle applies particularly where there are *good grounds* for judging either that action taken promptly at *comparatively low cost* may avoid more costly damage later, or that irreversible effects may follow if action is delayed. [emphasis added]

In the same document, the United Kingdom government made clear that environmental decision-makers must (HM Government, 1990):

... look at all the facts and likely consequences of actions on the basis of the best scientific evidence available. *Precipitate action on the basis of inadequate evidence is the wrong response.* [emphasis added]

If, as Cameron & Abouchar (1991) have pointed out, precautionary measures must be justified by a scientifically rigorous comparison of the resulting costs and benefits, then these measures can only ever really be “preventive”; they are not truly “precautionary”.

The Ministerial Declaration of the Third International Conference on the Protection of the North Sea signed by various North Sea states in 1990 offers one well-known example of a strong formulation of precaution. It states that governments should:

apply the precautionary principle, that is, to take action to avoid potentially damaging impacts of [toxic] substances ... *even where there is no scientific evidence to prove a causal link between emissions and effects.* [emphasis added]

On this conception, policy-makers undertake to go beyond existing scientific knowledge to address known, but still uncertain, threats to the environment. Not surprisingly, this interpretation is both promoted by and finds support within environmental pressure groups such as Greenpeace (Horsman, 1992).

The precautionary principle in EU law and policy

Precaution was introduced into the founding Treaties of the European Union by the 1993 (Maastricht) Treaty on European Union as a principle on which “Community policy on the environment shall be based”. In practice, the heads of the (then 12) Member States had actually given their political blessing to the principle in June 1990 (the Dublin Declaration of the European Council) (Haigh, 1994), but with its inclusion in the Maastricht Treaty, it formally entered the *acquis communautaire*: the “rights and obligations deriving from EU

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treaties, laws and regulations” (Dinan, 2000). These are, in effect, the legal rules governing the membership of the EU. Renumbered Article 174 by the 1999 Amsterdam Treaty, the full reference is as follows:

[EU] policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the [EU]. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should, as a priority, be rectified and that the polluter shall pay...

Interestingly, the Treaty mentions the precautionary principle but does not offer an explicit definition. Lawyers, however, consider it to be generally applicable to all risk regulation activities in the EU (Fisher, 2002). Many directives, European Court of Justice judgements and policy documents refer to precaution, but rarely is the principle precisely defined. Haigh (1994) observed that precaution applies when the EU formulates future policies (that is, it does not apply retrospectively) and does not apply to the parts of individual Member States’ domestic policies that do not fall within the legal competence of EU policy (that is, those that lie outside the *acquis communautaire*).

Legal flesh is gradually being added to the term by way of case law stemming from rulings by the European Court of Justice. For example in its judgement on the validity of the Commission’s ban on the export of beef from the United Kingdom, the Court (Cases C-157/96 and C-180/96, 5 May 1998) ruled that “[w]here there is uncertainty as to the existence or extent of risks to human health, the institutions may take protective measures without having to wait until the reality and seriousness of those risks become fully apparent”. Interestingly, although the case in question was primarily a matter of human health, the Court based its ruling on the environmental aspects of the Treaty (which at the time was Article 130r(2)). In other words, it explicitly supported the

extension of precautionary-based measures to matters of human health protection.

Of the 500 or so EU environmental statutes currently in existence, many specifically adopt a precautionary approach. One of the earliest examples of the EU behaving in a precautionary manner was the 1979 directive on the testing of new chemicals before they are marketed. This directive (which is the sixth amendment of a much earlier directive) requires authorities to assess the potential impact of new chemicals before allowing them onto the market. Pressure for the directive stemmed partly from the United States, which was the primary pace-setter in environmental standard-setting at the time (for details, see Haigh, 2000, section 7.3). The same could be said of the policies adopted by the EU to combat ozone depletion, which were also stimulated by regulatory pressures from the United States (Jordan, 1998). In 1985, the EU adopted another piece of precautionary legislation, the Directive on Environmental Impact Assessment, this time modelled on the 1969 National Environmental Protection Act in the United States.

These three examples of early precautionary measures in the EU testify to the leadership of the United States in environmental policy-making in the 1960s, 1970s and 1980s. However, the appearance of the precautionary principle in the 1990s marked a new and more self-confident stage in the evolution of the EU's environmental policy. Indeed, by the early 1990s, roles had reversed and it was the United States government that resisted precautionary-based controls in areas such as climate change, whereas the EU surged ahead, eager to put its ecological modernist philosophy to the test.

The 2000 European Commission guidance paper

In the 1990s, the EU cited the precautionary principle to justify trade restrictions on the import of United States beef treated with hormones and of genetically modified food material. European regulators believed there was a risk of adverse health effects but that the science involved was not

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sufficiently robust and used the precautionary principle to justify the application of restrictions. The United States, in contrast, claimed that the principle was ill-defined, discriminatory and a barrier to free trade.

In an effort to find some agreement with the United States and reflecting the growing influence of international trade rules on environmental policy, the Member States requested the Commission to produce a comprehensive policy guidance statement on the meaning of precaution. Crucially, the statement was to be produced by the whole Commission rather than simply its environmental or consumer health directorates, which had been the principal bodies concerned with the legal development and policy implementation of precaution up to that point. The need for the various parts of the Commission to buy into the document raised the political stakes significantly. Parts of the Commission that had never paid much attention to precaution were suddenly forced to adopt a position.

After much delay, in February 2000 the Commission published a keenly awaited communication on precaution (European Commission, 2000). As the “first major Community ventilation of the principle” (Fisher, 2002), lawyers and policy analysts eagerly read the communication. It has four main aims (Fisher, 2002):

- to outline the Commission’s approach to using the precautionary principle;
- to establish Commission guidelines for applying it;
- to build a common understanding of how to assess, appraise, manage and communicate risks that science is not yet able to evaluate fully; and
- to avoid unwarranted recourse to the precautionary principle, which in certain cases could serve as a justification for disguised protectionism.

The Commission is careful to point out that the communication represents its own intentions with regard to the implementation of the principle; it is “general guidance” and “an input to the ongoing debate both at Community and international level” (Fisher, 2002). Significantly, individual Member States as well as other EU institutions (such as the European Court of Justice and the Parliament) are not bound by the Communication and, consistent with the definitional differences noted above, are free to adopt their own independent interpretations. The Court, however, has the final word on the precise legal meaning of precaution in the EU.

The most important elements of the Communication are as follows (Fisher, 2002).

- Precaution applies when “scientific information is insufficient, inconclusive or uncertain or where there are indications that the possible effects ... may be potentially dangerous and inconsistent with the chosen level of protection”.
- Precaution is not simply an environmental principle but applies equally to the protection of human health and plant health.
- Precaution is a “fully fledged and general principle of international law”, but development of international guidelines on its meaning could avoid “unwarranted recourse” to the precautionary principle.
- The precautionary principle belongs within rather than outside the framework of risk analysis, and in particular risk management.
- The precautionary principle is relevant “only in the event of a potential risk ... [but it] ... can under no circumstances be used to justify the adoption of arbitrary decisions”.

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- Before it is invoked, there must be some scientific investigation to identify gaps in the knowledge base.
- But the “absence of scientific proof of the existence of a cause–effect relationship ... should not be used to justify inaction. Even if scientific advice is supported by a minority fraction of the scientific community, due account should be taken of their views, provided the credibility and reputation of this fraction are recognized”.
- Decision-making procedures should be as transparent as possible.
- Reliance on the precautionary principle “is no excuse for derogating from the general principles of risk management”, namely proportionality of response, non-discrimination, consistency of application, examination of costs and benefits and the emergence of new scientific developments.
- Precautionary-based measures should not seek to achieve zero risk, “something which rarely exists”.
- The precautionary measures should be maintained “as long as scientific data are inadequate, imprecise or inconclusive and as long as the risk is considered too high to be imposed on society”.
- The decision to apply the precautionary principle is essentially political in nature: there is a “crucial ... distinction between the decision to act or not to act, which is of an eminently political nature, and the measures [used] ... which must comply with the general principles applicable to all risk management measures”.

Environmental groups along with some academics and government representatives felt that interdepartmental battles within the Commission had whittled away the true

meaning of precaution. They were especially disappointed by the emphasis placed on using precaution in risk analysis. This point is firmly underlined in the concluding part of the communication, which states that “every decision must be preceded by an examination of all the available scientific data and, if possible, a risk evaluation that is as objective and comprehensive as possible” (Fisher, 2002). Greenpeace challenged this assertion as well as the commitment to apply precautionary measures only as a short-term response, claiming that it “undermine[d] the very meaning and purpose” of the precautionary principle (ENDS, 2000).

Environmental groups claimed that the Commission had been swayed by the intensive lobbying efforts of industrial representatives during the latter stages of the drafting process. During that process, the EU Committee of the American Chamber of Commerce had argued that the precautionary principle was “not ... a scientific principle, nor is there a generally accepted definition of the term”. A risk assessment stage should be the “cornerstone on which fundamental scientific decisions are based” (ENDS, 1999). The critical flaw in this line of argument is that precaution only comes into play when, as the Commission correctly points out, the scientific base is inconclusive or incomplete, that is, when information is insufficient to undertake a formal risk assessment.

The Commission’s shift towards a “risk-based” approach is an indication of its desire to move closer to the United States’ interpretation of world trade rules. Thus, where science is genuinely in contention, the communication states the following.

- Full transparency should be in place when decisions about whether to wait or not to wait for new scientific findings are made.
- The absence of quantifiable probabilities should not be a cause for inaction.

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- If only a minority of scientists demur over a proposed cause of action, their views should be given due account, in a transparent manner.
- All interested parties should be allowed to deliberate on the available options once the assessment is complete.

The Commission's link between cost–benefit analysis and the application of the precautionary principle continues to upset some observers, although the Commission has indicated that all relevant non-economic effects should be given due weight, especially public health effects (including the protection of health as a first priority). An important driver of the Commission's behaviour is the perceived need to give all decisions a credible underpinning in case they are challenged through the international trade dispute mechanism. Were this to happen, the Commission would have to justify its reasoning to the World Trade Organization using widely accepted decision support tools such as risk and cost–benefit analysis.

Conclusion

This short history of the precautionary principle exemplifies two important features of modern environmental policy-making: a steady shift to more internationalized standard-setting and the penetration of environmental principles into previously “non”-environmental policy sectors such as trade, industry and energy conversion. In the first phase of its rapid dissemination, the concept of precautionary policy originated in the Federal Republic of Germany during the 1970s. During the second phase (the 1980s), it was gradually incorporated into many national environmental policies in Europe before being formally adopted as a guiding principle of EU environmental policy in the 1993 Maastricht Treaty. During the third phase, it gradually spread across the world, finding expression in many international environmental agreements such as the 1992 Rio Declaration. In the fourth stage, which began in the late 1990s, precaution began to emerge as the focus of dispute between the EU, the United States and other

large trading blocs. The conflicts over genetically modified organisms, hormones in beef and other issues concern not only environmental protection but also trade, health and consumer safety, as well as raw politics.

The precautionary principle did not cause these disputes. Nor have these disputes substantively altered the meaning of precaution. But it has forced advocates such as the Commission to issue clearer statements about how they wish to apply precaution. These efforts may, in turn, trigger international bodies such as the World Trade Organization to develop similar guidance. Finally, the disputes have not really made the task of applying precaution any easier. If anything they have made it harder, by emphasizing to policy-makers that they have less and less scope to act unilaterally against important but uncertain risks.

Precaution is proving to be a potent source of conflict today because it encapsulates the very different moral, ethical and political standpoints from which the Europeans and the North Americans currently view environmental risks. In a less globalized world, these differences of attitude and approach would not have impinged upon one another as much as they are doing today. But for the moment they have succeeded in pushing the precautionary principle centre stage in international law, policy and politics.

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4. Public health and the precautionary principle

Neil Pearce

Introduction

The primary goals of public health are preventing disease and promoting health in populations. The concepts of precaution and prevention have therefore always been at the heart of public health practice. Although health is often regarded as a result of individual lifestyle or individual susceptibility (genetic or otherwise), every population has its own history, culture and economic and social divisions that influence how and why people are exposed to specific risk factors and how they respond to such exposure. These societal influences are becoming increasingly globalized, and adopting a global approach to the practice of public health is therefore becoming increasingly necessary. However, developing global solutions requires changing scientific thinking (McMichael, 1993; Pearce, 1996, 1999). Although continuing to identify, quantify and reduce the health risks from specific, often local, exposure is important, the health risks from macro-level socioeconomic and environmental systems and processes must begin to be anticipated. The precautionary principle, which states that action should be taken to prevent harm even if some cause-and-effect relationships have not been fully established scientifically, will play a key role in this regard.

History, development and the health of populations

Three major revolutions can be identified, each of which has had major consequences for human health. The agricultural revolution involved major environmental changes from the development of organized agriculture and the establishment of settlements, whereas the industrial revolution involved major environmental and social changes from the development of machine tools and industrial production. The current information technology revolution and the process of

globalization will also have major health effects. However, unlike previous revolutions, current changes have the potential to endanger the sustainability of the biosphere's natural systems (Pearce & McMichael, 2001). I briefly discuss these three revolutions before discussing the changing role of public health and the relevance of the precautionary principle to this changing role.

The agricultural revolution

Prior to about 10 000 years ago, all people on earth were hunter-gatherers (Diamond, 1998). Since then, most parts of the world have seen an agricultural revolution that has profoundly affected human society and human health. Although the fact that an agricultural existence is preferable to that experienced by hunter-gatherers may now appear obvious, this was probably not self-evident at the time. Although population density rose faster than food production and calorie intakes declined, the increased population both needed and could produce more food, enabling neighbouring hunter-gatherer populations to be displaced. Thus, the early stages of the agricultural revolution in some instances saw a paradoxical decrease in life expectancy accompanied by an increase in population size, because the increase in birth rate outweighed the accompanying increase in the death rate. Rising population density was accompanied by the rise of the major infectious diseases, which remained the major killers until the 20th century (Diamond, 1998). The first evidence for the occurrence of these epidemic diseases is often surprisingly recent: 1600 BC for smallpox, 400 BC for mumps, 200 BC for leprosy, 1840 for epidemic polio and 1959 for AIDS (Diamond, 1998). Hunter-gatherer populations did suffer from infectious diseases, but the major epidemic infectious diseases (including plague, measles, mumps, rubella, pertussis and smallpox) require large populations and high population density and cannot survive in hunter-gatherer populations. For example, measles is likely to die out in any population fewer than half a million people (Diamond, 1998). More importantly, these diseases apparently did not exist in humans before agrarianism but thrive in densely packed cities linked by world trade routes. For example, bubonic plague appeared in

Europe in the 6th century, but the plague epidemics hit Europe in the 14th century following the establishment of the relatively rapid overland trade route with China (Diamond, 1998). In fact, it was not until the beginning of the 20th century that Europe's major cities became self-sustaining. Before then, constant migration from the countryside was necessary to make up for deaths from epidemic diseases.

The industrial revolution

If the agricultural revolution can be considered to have originated with the development of hand tools such as the scythe and the plough, the industrial revolution can be characterized by the development of machine tools, such as the steam engine, the spinning jenny and Cort's process in metallurgy (Castells, 1996). The industrial revolution conferred economic advantages on those who adopted the new technology and the accompanying system of social relations, which meant that the new technological and socioeconomic paradigm eventually triumphed. However, these economic advantages were often accompanied initially by social and economic disadvantages for large sections of the population. The industrial revolution in Europe initially involved widespread social and economic disruption, unemployment, homelessness, pollution and increased exposure to health hazards both at work and at home. In the late 18th century, the poorest 20% of people in England and France were estimated to suffer such severe malnutrition that they were unable to do labouring work (Fogel, 1994). As a result of such conditions, the death rate in the United Kingdom and other countries in the first half of the nineteenth century actually increased, before it eventually began to decline in those born after 1850 (McMichael, 2001). McKeown (1979) has argued that the decline occurred largely prior to the introduction of effective modern vaccines and treatments and was due mainly to improvements in nutrition. However, specific public health interventions on factors such as urban congestion probably also played a major role (Szreter, 1988; Hardy, 1993). For example, in France major gains in life expectancy emerged first in Lyon (in the 1850s), then Paris (1860s to 1870s) and then Marseille (in about 1890), in each instance following

improvements in water supply and sanitation (McMichael, 2001).

During the later stages of the industrial revolution, sanitation improved and “natural” infectious disease declined, but “artificial” environmental hazards such as air pollution, occupational hazards and food contamination also increased. The spread of industry, and especially the automobile in the 20th century, has greatly increased the environmental burden of exposure to human-made chemicals. However, it is primarily in the latter third of the 20th century (Carson, 1962) that concern has arisen concerning pervasive global contamination from human-made chemicals that not only affect human health directly but also the health of the overall ecosystem.

The information technology revolution

The information technology revolution began in California in the 1970s and is now transforming the world economic and social order. The information technology revolution is symbolized by the personal computer and the Internet, but these are just symbols, albeit influential ones, of the process of global socioeconomic restructuring that occurred during the 1980s and 1990s (Castells, 1996). This is characterized by economic globalization, especially the globalization of the financial markets (Castells, 1996), reflected in the enormous growth in trade and foreign capital flows (McMichael & Beaglehole, 2000). From 1973 to 1995, global foreign exchange turnover increased almost 100-fold and foreign direct investment increased six-fold (United Nations Development Programme, 1999). However, the gains in average gross domestic product can mask major differences within and between countries and a rapidly widening gap between rich and poor (United Nations Development Programme, 1999). Thus, the average incomes in 80 countries are lower today than a decade ago, and the ratio of income between the richest 20% of people in the world and the poorest 20% increased from 30:1 in 1960 to 74:1 in 1997 (Lang, 1999).

These global economic and social changes have been accompanied by global environmental changes (Acheson, 1992). These are not necessarily directly due to economic globalization but reflect increasing population size (in part due to economic growth) and especially increasing consumerism (Smith, 1993; McMichael & Powles, 1999). These changes are largely the legacy of the industrial revolution, but economic globalization is making them more pervasive and severe, so that humanity has the potential to damage the health of the global ecosystem rather than just local ecosystems and populations (Last, 1998). Human activities are changing the gaseous composition of the lower and middle atmosphere, reducing productive soils on all continents, depleting ocean fisheries, overexploiting many of the great aquifers upon which irrigated agriculture depends and resulting in an unprecedented rate of loss of whole species and many local populations. The demand for energy is growing and cannot be met without new technologies, and the problem of waste disposal is increasing (McMichael & Powles, 1999). Human activities are even beginning to alter the Earth's climate. These unsustainable changes to Earth's basic life-supporting processes pose long-term risks to human population health – although people remain largely uncertain, even ignorant, of the long-term consequences (McMichael, 1993). The life-support systems of human health are thus being perturbed or depleted, and some of these environmental stressors are likely to cause tensions between human communities, leading to conflict and hence to damage to the population's health. Thus, the prospects of international conflict arising from environmental decline, dwindling resources and ecological disruption cast a long shadow over the prospects for human health.

The role of public health

Human health and life expectancy are improving on average (Sen & Bonita, 2000). However, this statement must be qualified in two ways.

Firstly, a focus on averages may mask major negative effects in specific populations. The agricultural and industrial

revolutions both involved uneven development and an initial fall in life expectancy before increases in population size and productivity and, eventually, life expectancy. Globalization is also producing major social and economic disruption, and the health benefits and hazards are increasingly unevenly distributed (Woodward et al., 2000). Thus, although average life expectancy continues to increase globally, eastern Europe suffered a sudden and dramatic fall in life expectancy in the 1990s (Men et al., 2003), and Africa struggles with the problems of HIV/AIDS and the health effects of economic stagnation and structural adjustment (Pearce et al., 1994).

Secondly, an increase in human health and life expectancy, and the resulting increase in population size and consumerism, can ultimately affect the health of the overall ecosystem and paradoxically affect the survival of the human race itself (McMichael, 1993). For the past two centuries, environmental health concerns in the industrialized world have focused very largely on toxic or microbial risks to health from specific factors within the local environment, and there has been considerable success in tacking these problems, at least in industrialized countries. However, in the 21st century, the scale of environmental health hazards is increasing in range. The escalating impact of human economic activity has begun to alter global biophysical systems (such as the climate system) that underpin the sustainability of the health of humans – and all other species (McMichael, 2000). There appears to be a risk of incurring serious global ecological deficit as, increasingly, people attempt to live beyond the planet's overall carrying capacity. It has been argued that “society is locked in a struggle against time to ... introduce sustainable practices that will ensure the welfare of future generations” (United Nations Environment Programme, 1999).

These are clearly global problems that require global solutions (Pekkanen & Pearce, 2001). In fact, even for more traditional public health issues such as tobacco smoking and occupational exposure, a coordinated global public health approach had long been needed. The limited success of legislative measures in industrialized countries has led the tobacco industry to shift

its promotional activities to developing countries so that more people are exposed to tobacco smoke than ever before (Tominaga, 1986; Barry, 1991). Similar shifts have occurred for some occupational carcinogens; the worldwide production of asbestos has not decreased but has merely changed location (Pearce et al., 1994). Global public health strategies are even more essential in tackling public health problems that threaten the global ecosystem and environmental sustainability. Thus, “epidemiology is in transition from a science that identifies risk factors for disease to one that analyses the systems that generate patterns of disease” (Koopman, 1996). The analysis of such complex systems is becoming increasingly important in many areas of research, and the fact that some phenomena can be best understood at the macro level is increasingly recognized (Pearce & McMichael, 2001). These issues are of even more relevance to the study of current changes in complex ecosystems that have the potential to threaten the sustainability of human life itself.

The seminal document for the new public health movement is the Ottawa Charter for Health Promotion (World Health Organization, 1986), which builds on the work of the Declaration of Alma-Ata (World Health Organization, 1978). The Ottawa Charter argues that “the fundamental conditions and resources for health are peace, shelter, education, food, income, a stable eco-system, sustainable resources, social justice and equity”. Under the Charter, health promotion action means building healthy public policy, creating supportive environments, strengthening community action, providing information and education for health and enhancing life skills, and reorienting health services towards health promotion.

Although the Ottawa Charter recognizes and emphasizes the importance of societal action, in practice public health promotion has too often focused on individuals and communities and has not tackled the major historical, cultural, structural and macroeconomic determinants of population health (Pearce & McKinlay, 1998). The focus has been on persuading individuals to change their lifestyles,

whereas persuading governments and industries to adopt policies that protect and promote health has been regarded as “too difficult”. However, the fundamental problem for health ministers as well as public health researchers and policy-makers is that the health services at most have a minor influence on the health of a population (Pearce, 2002). What the ministers responsible for finance, employment, social welfare, education, housing, labour, environment and other domains do inevitably has much greater influence on population health than what the health minister does.

The traditional public health approach to this problem, in part based on the Ottawa Charter, has been to attempt to “turn the health services into public health services”. However, this strategy is often ineffective. People working in the health services are trained to treat illness in individuals, and they often lack the time, the training and resources to deal with larger issues of prevention in populations. Their administrators also usually have more urgent priorities. As a result, public health has continually lost out to the “conventional” health services in battles for resources, and it has had little influence on the major public health problems at the population level (Pearce, 2002).

For these reasons, a number of new approaches have been advocated and/or adopted in recent years to shift the focus of public health back to the population level. One option that has been advocated (but rarely adopted to date) has been to establish ministries of public health (Pearce, 2002). Under this approach, public health services for individuals (such as immunization) would continue to be delivered through health ministries, and attempts would continue to be made to transform the health services towards public health as much as possible. However, the ministries of public health would tackle the real public health issues at the population level. They would solely have a monitoring and advocacy role not only with regard to routine monitoring of death rates, the population burden of disease, etc., but also with regard to monitoring and influencing the work of the other government departments and ministries (including the health ministry).

One way to do this is through health impact assessment of the likely health effects of various public policies (Mindell, Ison & Joffe, 2003). Under this approach, health should be an explicit consideration when evaluating all public policies. However, the limitations of health impact assessment should also be recognized. In particular, Krieger et al. (2003) argue that greater clarity is required regarding the criteria for initiating and conducting health impact assessment and that “critical debate over the promise, process, and pitfalls of health impact assessment needs to be informed by multiple disciplines and perspectives from diverse people and regions of the world”.

The precautionary principle

The concepts of precaution and prevention have thus always been at the heart of public health practice. Public health is inherently about identifying and avoiding risks to the health of populations as well as in identifying and implementing positive interventions to improve population health. However, traditional public health interventions have generally focused on removing hazards that have already been identified. In contrast, the precautionary principle states that action should be taken to prevent harm “even if some cause and effect relationships are not fully established scientifically” (Raffensperger & Tickner, 1999). The precautionary principle therefore seeks to shift health and environmental policy from a strategy of “reaction” to a strategy of “precaution” (Kriebel & Tickner 2001). The central components of the precautionary principle are all integral to public health: (1) taking preventive action in the face of uncertainty; (2) shifting the burden of proof to the proponents of an activity; (3) exploring a wide range of alternatives to possibly harmful actions; and (4) increasing public participation in decision-making (Kriebel & Tickner, 2001; Kriebel et al., 2001 (reproduced as Chapter 9 of this publication)).

Perhaps the most debatable component of the precautionary principle is the one that shifts the burden of proof to the proponents of an activity. In other words, the onus is on the proponents to prove that an activity is safe rather than for its opponents to prove that it is unsafe. The latter is usually very

difficult, though not impossible, but can usually only be done in a reactive manner after population exposure has already occurred. In contrast, proving complete safety is usually impossible. Some commentators have suggested that, if blindly applied, shifting the burden of proof in this way would stifle all innovation (Holm & Harris, 1999; Anonymous, 2000) and create “false-positive” risks that waste resources and distract from real problems (Graham & Weinder, 1995; Keeney & von Winterfeldt, 2001). In fact, most public health decision-making necessarily involves a “balance of evidence” approach rather than an “innocent until proven guilty” or “guilty until proven innocent” approach.

In response, proponents of the precautionary principle have clarified this issue and emphasized that the precautionary principle involves the “foresight” or “forecaring” principle, which involves anticipatory, forward-looking action rather than reactive impeding of progress (Tickner, Kriebel & Wright, 2003 (reproduced as Chapter 12 of this publication)). Thus, “precaution does not mean only more sensitive tests; it also means linking risk evaluation to alternatives assessments and more democratic discussions of social needs and goals” (Tickner, Kriebel & Wright, 2003). This formulation is consistent with developments in health impact assessment, and public health more generally. Thus, the precautionary principle, together with related approaches such as health impact assessment, provides a useful compass to guide public health decisions under uncertainty, in a manner that appropriately addresses the issues of power, ownership, equity and dignity and the principles of “health by the people” (Pearce, 2001).

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5. Why is a precautionary approach needed?

Ted Schettler & Carolyn Raffensperger

Introduction

With the rapid growth of industrialization beginning in the 1850s, humans have increasingly dominated the earth's ecosystems in unprecedented ways. From the black smog of Charles Dickens' London to the massive damming projects in China, the scale of change has expanded rapidly and dramatically during the past 150 years. Population growth and human activities such as resource extraction, manufacturing, transport, agriculture and fishing have escalated these changes and contributed to serious, widespread and often avoidable harm to humans, wildlife and ecosystems.

The planetary scope of these effects is apparent in climate change; stratospheric ozone depletion; fundamental shifts in the biogeochemical cycling of water, nitrogen and heavy metals; air, soil and water pollution; worldwide degradation of forests, coral reefs and fisheries; loss of biodiversity; and contamination of virtually all organisms and ecosystems with novel synthetic chemicals (Lubchenco, 1998; Johnson, Revenga & Echeverria, 2001; McCally, 2002). A cascade of effects is also apparent in changing patterns of acute and chronic diseases and disabilities.

People do not experience the effects of these changes equally. Children are uniquely susceptible to many types of environmental exposure, nutritional deficit, infectious disease and social upheaval, especially during specific periods of development. Large populations in developing countries and groups within industrialized countries are vulnerable when inadequate resources, social and political institutions and exploitation or marginalization limit their ability to respond to changing circumstances. As a result, the risks and benefits of

human enterprise are unequally and unjustly distributed.

This chapter discusses the precautionary principle as a tool to help in decision-making when people face the uncertainty that so often characterizes complex ecological systems. We describe the new ecological reality that has emerged since the industrial revolution and argue that the precautionary principle is a key tool for managing health and environmental well-being in this context.

Ecological realities

Decisions that people make about how to live in the world have profound consequences for the functioning of ecological systems. The dynamic of these systems is complex. Parts and the whole influence each other; feedback loops may be negative or positive. Changes in ecological systems may be incremental and gradual or surprisingly large and sudden. For example, scientists are increasingly concerned that incremental climate warming could trigger an abrupt slowing or reversal of ocean currents such as the relatively warm Gulf Stream in the Atlantic Ocean. Were this to occur, the climate of northern Europe would also abruptly change, with colder temperatures much more like those in other northern regions at similar latitudes. Such a change would result in marked ecosystem changes, including the dislocation of large numbers of people with severe economic and public health consequences. When change is sufficient to cause a system to cross a threshold, it operates within a new dynamic equilibrium that has its own stability and does not change easily. These new interactions become the norm and they call for new institutions to address the new reality (Carpenter, 2003). Changing trends in human disease are evidence of just such a shift. A long history of struggling with infectious diseases and inadequate nutrition encouraged humans to battle nature as an adversary and to focus attention on human life expectancy and childhood mortality as measures of gains against these scourges. To be sure, public health interventions during the 20th century helped to prolong life and decrease

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childhood mortality in many parts of the world. At the same time, important new disease patterns have emerged.

- The age-adjusted incidence of several kinds of cancer has increased over the past 25 years (National Cancer Institute, 1996).
- The incidence of some birth defects is increasing (Paulozi, 1999).
- Developmental disabilities, including learning disorders, attention deficit hyperactivity disorder and autism, are increasingly common (Schettler et al., 2000).
- Chronic diseases such as hypertension, heart disease, diabetes and asthma are increasing throughout much of the world.
- Obesity has become a major health problem, whereas starvation persists in many parts of the world.
- Depression and other mental health disorders are new public health threats in many parts of the world with profound consequences for individuals, families and communities.

These trends result from complex interactions among genetic, nutritional, environmental and socioeconomic factors. Despite extensive research efforts, the relative contributions and interactions of these factors are uncertain. Nevertheless, a shift has occurred that is not simply a result of people living longer lives. Rather, the current pattern and those that will follow are a result of choices people make and activities people choose, individually and collectively – including how people use technological capacity to fundamentally alter the function and integrity of the world's ecosystems and patterns of health and disease in humans and wildlife.

The precautionary principle as a guide to decision-making

Given human capacity to cause change on an unprecedented scale, how should people act when faced with pervasive, inherent uncertainties? What values, along with scientific understanding, should guide behaviour? Who should make key decisions? How should people think about individual liberty and the concept of “harm”?

The precautionary principle is a guide to public policy decision-making under conditions of scientific uncertainty (Raffensperger & Tickner, 1999; Schettler, Barrett & Raffensperger, 2002). Recognizing the limits of science, the precautionary principle is intended to enable and encourage precautionary action that serves underlying values based on what is known as well as what is not known. It encourages close scrutiny of all aspects of science, from the research agenda to the funding, design, interpretation and limits of studies. According to the principle, when there are credible threats of harm, precautionary action should be taken, even when full understanding of the effects of a proposed activity is lacking. In other words, the precautionary principle combines the ethical notion of duty to prevent harm with the realities of the limits of scientific understanding.

As with all guiding principles, the precautionary principle carries its own values. The principle is based on recognizing that people have a responsibility to prevent harm and to preserve the natural foundations of life, now and into the future. The needs of future generations of people and other species and the integrity of ecosystems are recognized as being worthy of care and respect. A precautionary approach asks how much harm can be avoided rather than asking how much is acceptable. It acknowledges that the world comprises complex, interrelated systems that are vulnerable to harm from human activities and resistant to full understanding. Precaution gives priority to protecting these vulnerable systems and requires gratitude, empathy, restraint, humility, respect and compassion.

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The precautionary principle is based on these underlying values and three core elements: predicting, avoiding and identifying harm; addressing scientific uncertainty; and taking precautionary action. The following sections discuss each of these elements.

The potential for harm

Precautionary action is appropriate when there is credible evidence that a specific technology or activity might be harmful, even if the nature of that harm is not fully understood. This means that decision-makers must consider hazards that have been identified or that are plausible based on experience and what is known and/or predicted. Threats of serious, irreversible, cumulative or widespread harm are of more concern than trivial threats and demand precautionary action commensurate with their nature. Most importantly, for two reasons, “proof” of harm is not a requirement for precautionary action. First, by definition, preventive measures cannot be based on identifying harm that has already occurred. Second, criteria for establishing the “proof” of a cause-and-effect relationship are, by convention, rigorous and difficult to fulfil. As a result, when “proof” of harm has been established, considerable damage will already have occurred that may have otherwise been avoidable.

Harm can occur at the level of the cell, individual organism, population or ecosystem. The effects may be biological, ecological, social, economic or cultural, and they may be distributed equally or disproportionately among individuals, populations or geographical areas, now or in the future. Because systems are complex and outcomes are not always predictable, it becomes extremely important for decision-makers to specifically identify the parameters that are used to assess the potential effects of a proposed activity. Moreover, the standard against which an effect is measured must also be defined. Asking whether a proposed agricultural or industrial chemical is safer for use than another, for example, is very different from asking whether either is necessary at all. Alternatives analysis, further discussed below, can be used to

identify the potential consequences associated with choices among options in a given circumstance.

Scientific uncertainty

Recognition of scientific uncertainty is central to the precautionary principle. Even when harm is unintended, human activities often have effects that are difficult to predict or even to recognize until damage is done. Complex systems may react to change in non-linear ways that are sometimes far removed in time and space. Sometimes a system crosses a threshold and operates at a new state of relative equilibrium from which there is no turning back. Cause-and-effect relationships may be difficult or impossible to establish with certainty. Nevertheless, failing to act – or continuing a harmful action – until uncertainty is resolved is in itself a form of action with consequences.

Understanding cause-and-effect relationships in complex systems is limited by different kinds of uncertainty. Uncertainty sometimes results from more than a simple lack of data or inadequate models and is not easily reduced because of the nature of the problem being studied. In these circumstances, requiring absolute “proof” of harm before action can be taken is either ideologically motivated or deprived of a fundamental understanding of the limits of science.

Most complex problems have a mixture of three general kinds of uncertainty – statistical, model and fundamental – each of which should be considered explicitly.

Statistical uncertainty

Statistical uncertainty is the easiest to reduce or to quantify with some precision. It results from not knowing the value of a specific variable at a point in time or space but knowing, or being able to determine, the probability distribution of the variable. An example is the intelligence quotient (IQ) or quantitative intelligence estimate of an individual within a given population. In this case, decisions can be based on

knowing the likelihood of that variable having a particular value.

Typically, however, real-world decisions are made in the context of multiple, interactive variables. For example, the incidence of cancer attributable to exposure to a carcinogen in genetically and geographically diverse people is inherently more difficult to determine than the incidence of cancer in a group of genetically similar rodents exposed to the same carcinogen living in controlled laboratory conditions. When more than one variable is involved, a model is typically constructed with certain assumptions and simplifications, introducing a new kind of uncertainty – model uncertainty.

Model uncertainty

Model uncertainty is inherent in systems with multiple variables interacting in complex ways. Even if the statistical uncertainty surrounding the value of a single variable can be defined or reduced, the nature of relationships among system variables may remain difficult to understand. This is especially problematic for any model of complex systems. People may decide that the system will tend to behave in a certain way, but the likelihood of that behaviour is difficult to estimate.

Moreover, complex models can include only a finite number of variables and interactions. The real world, however, is a confluence of biological, ecological, social, cultural, economic and political systems. No experimental model can fully account for each of these and their interrelationships. Ongoing research, monitoring and refining models may help to reduce uncertainty, but imprecision is inevitable. Indeterminacy, which increases when moving from statistical to model uncertainty, is more correctly called ignorance at some point.

Fundamental uncertainty

Fundamental uncertainty encompasses this extension of indeterminacy into ignorance. Ignorance that results from the complexity or uniqueness of a system is of particular concern.

This kind of uncertainty is inherent in novel or complex systems in which existing models do not apply. Lack of valid information about the likelihood of a specific outcome results in fundamental uncertainty. It can also result from no knowledge of what some of the outcomes may be. Here people do not even know what they do not know. Chemical regulators, for example, were unaware of the existence and functions of a stratospheric ozone layer that would be damaged by chlorofluorocarbons when they allowed them to be marketed as safe for commercial use. Fundamental uncertainty is extremely difficult to reduce or otherwise manage and demands respect and humility.

Scientific uncertainty and scientific proof

Proof is a value-laden concept that integrates statistics, empirical observation, inference, research design and research agendas into a political and social context. This section discusses the uses and misuses of some of the criteria commonly used to establish proof. Strict criteria may be useful for establishing “facts”, but by the time a fact or causal relationship has been established by rigorous standards of proof, considerable avoidable harm may already have occurred. The effects of lead exposure on children’s brain development or asbestos on lung cancer risk are examples. In each case, people were damaged over many decades, long after substantial evidence of serious health effects was established, while lead and asbestos advocates contested epidemiological “proof” of causation. Guided by the precautionary principle, people are as concerned with the weight of the available evidence as they are with establishing facts by rigorous standards of proof. The weight of the evidence can guide preventive action, whereas waiting for proof may allow damage to occur.

By convention, a considerable amount of consistent evidence is necessary to establish factual “proof” of a cause-and-effect relationship. Traditionally, in a study of the relationship between two variables, a correlation is said to be statistically significant only if the results show the two to be linked,

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independent of other factors, with greater than 95% likelihood that the positive results of the study did not occur by chance. But correlation does not establish causation. In epidemiology, a series of additional criteria, for example, those of Hill (1965), are usually added before causation can be claimed. Hill criteria include not only establishment of a statistically significant correlation between two variables but also require that the causal variable precede the effect, a dose–response relationship, elimination of sources of bias and confounding, coherence with other studies and understanding of a plausible biological mechanism. Tobacco smoking, for example, was known to be associated with lung cancer for more than 50 years before a plausible biological mechanism was finally described. At that point, denying that tobacco “causes” cancer became impossible.

People’s adherence to conventions or choices among criteria expresses their willingness to make type I or type II errors. A type I error is the mistake of concluding that an association or phenomenon exists when, in truth, it does not. Conversely, a type II error is the mistake of failing to recognize an association or phenomenon when it does exist. Each kind of error has consequences. Type II errors may, for example, lead people to allow a harmful activity to go forward and are the inevitable result of a consistent bias towards avoiding type I errors. Type I errors will result in invalid concerns about a product or activity and may lead to unnecessary restrictions. Establishing type I and type II error rates is a choice that reflects certain biases and is largely done by convention, often without considering the consequences. For example, by convention, interpretations of scientific data generally favour type II over type I errors. People generally require strong evidence that something is scientifically “true” before being willing to say so.

An historical basis for error bias

A general theme that has gained currency in many countries is that people are autonomous individuals who are free to live as they wish and do as they want, provided that they do not

cause harm to others. This concept has set up a tension between the individual and society at large in terms of establishing the limits of tolerance and defining harm. In *On Liberty*, first published in 1859, John Stuart Mill (1978 (1859)) explored the nature and limits of power that can be legitimately exercised by society over the individual. He concluded that the only purpose for which power can be rightfully exercised over any member of a civilized community, against his or her will, is to prevent harm to others. Mill was concerned that, in a democratic society, the majority would set the limits to tolerance – that the majority would interfere with the creative individual’s inclination to invent and develop and to explore new frontiers. He also worried that the majority would go so far as to define “harm”, using inappropriate assertions of “harm” as a blockade to progress. In short, he feared the “tyranny of the majority” and their inclination to favour the status quo.

This tension is at the heart of many of today’s policy debates. Not only must harm be defined but people also have to decide how to act or how to legitimately exercise power when the probability of harm (risk) is uncertain. Though decisions must be based on what is known at the time, if “proof” of harm is required before limiting an activity or choosing an alternative, as Mill would have, there is a risk of failing to prevent harm.

Seeing how Mill’s fears are reflected in today’s policies in many countries throughout the world is easy. In general, the burden of proof of harm falls on the general public or individuals who assert that another party has injured them. High standards of “proof” add to this burden, even when the weight of the evidence suggests that harm has occurred or is likely. In other words, a bias towards type II errors – established by convention in interpreting scientific data – has also crept into social, political and judicial policy. Asking whether such a bias is appropriate for preventing harm or for choosing among optional human activities is fully legitimate. Further, it may be legitimately ask how such a bias is likely to influence the ways that human activities alter complex

ecological systems that define the world to be left to future generations – a consideration at the core of sustainability.

Children's health, uncertainty, sustainability and precaution

The various kinds of harm, proof and scientific uncertainty become important in practice in children's health. Focusing on children's health shows concern for the very young, their future and future generations. Sustainability also implies concern about the future, the integrity of ecosystems that support life on earth and the kind of world that current generations will leave to those who follow. Understanding today's patterns of children's health and the current status of global ecosystems is difficult because they reflect the confluence of multiple interacting factors. Predicting future patterns and making wise choices based on current understanding of complex ecological relationships are even more challenging. Our understanding and predictive capacity are limited by statistical, model and fundamental uncertainty that has several sources. This section briefly reviews some of the factors that complicate decision-making for children's environment and health. The precautionary principle encourages scientists and policy-makers to design research and decision-making approaches that take these complicating factors into account.

Long latency

Conditions with long latency periods between an action and an outcome are difficult to study. Study design is necessarily complex and implementation is expensive. Intervening variables that must be considered in a comprehensive study complicate the analysis. Subjects may also be lost to follow-up during a prolonged study. For example, the effects of fetal exposure to a chemical agent that disrupts the normal development or functioning of the reproductive system may not become apparent until an individual has reached reproductive age or beyond. At that point, reconstructing the circumstances that may have caused the adverse outcome is extremely difficult, and studying a potentially causal

relationship systematically in a population is even more difficult.

Nonspecific or subtle endpoints

Adverse health outcomes or significant ecological changes are often nonspecific as well as multifactorial in origin. Many diseases, such as asthma or developmental disorders, for example, are caused by complex interactions of many different factors and are not easily linked to single variables. As a result, determining causation precisely is difficult, if not impossible, and some residual uncertainty will always remain. The task of policy-makers or health care providers then becomes to decide how to act in the face of uncertainty.

Investigative challenges are also increased when the health outcome is subtle and detectable only by detailed, complex testing. For example, subtle changes in functioning of the immune system or brain may have significant practical importance but be difficult to document easily.

Multiple and interacting variables

As noted earlier, predicting the impact of modifying single variables is often difficult when multiple factors interact in complex ways within a system. The nature, degree, timing and place of even a single intervention in the system are each important for determining the outcome. When systems exist near a threshold, small perturbations at a critical point may be sufficient to cause a shift to a new dynamic equilibrium or more chaotic activity, whereas a more stable system may easily be able to absorb such an intervention. Children's nervous system development is more vulnerable to the effects of lead exposure among families living in stressful socioeconomic conditions with suboptimal nutritional status than among families living in more favourable circumstances (National Research Council, 2000).

Circumstances are even more complicated when multiple factors or mixtures of factors are changed. This guarantees model and fundamental uncertainty, and "proof" of harm (or

safety) is extraordinarily difficult to achieve. Nevertheless, lack of “proof” of harm is often used to justify ongoing or proposed activities when the weight of credible evidence suggests that harm is plausible and perhaps even likely. Given the limits of scientific inquiry in the world of complex systems, establishing a high bar of proof as a prerequisite for taking action is certain, in some instances, to result in unnecessary and often irreversible harm (Beauchamp & Steinbock, 1999; Kriebel et al., 2001 (reproduced as Chapter 9 of this publication)).

Limits of current policy-making procedures: risk assessment versus precaution

As noted previously, individual and collective human activities have fundamentally altered the world’s ecosystems, including patterns of disease. Current decision-making policies and procedures do not demonstrate comprehensive understanding or concern for the magnitude of change and their implications for the future. Moreover, current policies are largely reactive to individual problems and fail to incorporate mechanisms for predicting harm, forestalling adverse outcomes and diverting resources towards more sustainable activities.

A quantitative risk assessment approach to public policy decision-making dominates in the United States and many other parts of the world. With few exceptions, risk assessment attempts to estimate the potential risks of proposed products or activities on a case-by-case basis without considering the complete context in which the activity will be carried out. Risk assessment deals with incremental change caused by single agents. Moreover, it rarely deals with any comparative consideration of alternatives to the proposal (O’Brien, 2000).

Quantitative risk assessment usually responds to narrowly framed questions and is often flawed by simplifying assumptions that fail to address multicausal pathways and complex interactions among variables. Risk assessment almost always fails to consider a full range of biological, ecological,

social, cultural and economic effects and how they are distributed.

The relationship between the precautionary principle and quantitative risk assessment highlights several differing views, including how much is known, how much can be known, how broadly questions should be framed, which questions should be asked, who should frame the questions, the value of non-human life, responsibility to future generations and how humans plan for the future.

Advocates of a regulatory system dominated by quantitative risk assessment sometimes argue that it is inherently precautionary because it uses conservative assumptions and safety factors. However, risk assessors often fail to distinguish among various kinds of uncertainty and tend to misclassify some model and fundamental uncertainty as statistical, to which they apply “uncertainty” factors. When model and fundamental uncertainty predominate in a system, this approach becomes more likely to result in large errors in estimates of risk, failure to predict adverse effects removed in time and space and complete failure to predict surprises or novel effects.

Risk assessors often claim that the precautionary principle is “anti-science” or a tool to keep certain technologies from the marketplace. In fact, a precautionary approach encourages more science rather than less, acknowledging the need for precautionary action while addressing the scientific uncertainty that may be intractable using available tools. Not only is research needed into the potential harm of existing technologies and products, but the emerging fields of green chemistry, green engineering and biomimicry offer exciting new possibilities for technologies that do not damage the planet or impair health.

Decision-making in the face of uncertainty is necessary and frequently difficult and requires assessing relative risks. Guided by an overarching commitment to precaution, however, this assessment is not the exclusive domain of risk

analysts, can be fully participatory and can fully consider a range of alternatives.

Precautionary action

The precautionary principle prescribes precautionary action under conditions of uncertainty. It does not prescribe what this action should be in every case, but depending on underlying values, the nature and plausibility of potential harm and the degree and kind of uncertainty, the following guides will be useful.

Protect resilience and diversity

Resilient and diverse systems are, in general, more resistant to fundamental shifts than stressed systems operating near thresholds.

Learn and adapt

Experiment on scales of space and time that are “safe to fail”. Some ecologists have pointed out that experimentation and precaution are compatible when the experiment is carried out at a different scale than the scale at which precaution is a primary necessity (Carpenter, 2003). For example, studying the effects of neurotoxicants on rodents or in a test tube allows learning without damaging the brains of an entire generation of human children. Confined experiments that go awry are far less problematic than those from which there is no return. Under the precautionary approach, appropriate research and monitoring are essential, especially after a decision to release a technology or chemical into the world. Decisions must be periodically re-examined based on new information. The research agenda of private and public institutions should be designed to reflect broad social goals that extend well beyond developing marketable products. In this way the precautionary approach is designed with feedback loops that search for and take into account new information and the unintended consequences of provisional decisions.

Shift the burden of proof

Under the precautionary principle, the advocate of an activity has the burden of proving the safety of the activity. The precise nature of this burden may shift with the nature of the harm and the scientific uncertainty. This approach suggests that the burden of proof is better thought of as the burden of persuasion and responsibility, which avoids the fruitless assertion that absolute safety can never be “proven”. It acknowledges that, as the potential for serious, irreversible harm and scientific uncertainty increase, the proponent of an activity has an increasing obligation to account for the consequences of the activity and to take responsibility for the adverse effects that may result from it. Then, more comprehensive testing, monitoring and assumption of liability shift the onus onto the proponent. This does not mean that activities must cease until some unattainable, absolute level of proof has been achieved. It does mean, however, that advocates of an activity must make a persuasive case for what they wish to do and must accept responsibility for it. Shifting the burden of proof establishes a series of obligations. For instance, under this burden shifting, proponents of potentially damaging activities have an obligation to test their products or technologies, publicly disclose information about potential for harm and pay for damage and restoration should harm occur. People should be able to make informed decisions about what they choose to use and activities they undertake. This “right to know” gains a new urgency on today’s planetary stage.

Set goals

Setting goals is particularly important for establishing environmental and health policies. Goal setting requires asking: “Where do we want to be at some future time? What are we trying to accomplish?”. Starting with agreed goals and then looking at the current situation can help in developing a strategy for getting from here to there. Not all goals are generally agreed upon or represent shared visions. But as goals are made explicit, the values and assumptions underlying decision-making processes will also become more

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transparent and may result in processes for reconciling differences.

Assess alternatives

A truly precautionary approach includes examining a range of options for meeting policy goals. Currently, most settings have few requirements for comprehensively assessing a range of alternatives to proposed activities. For example, current regulatory policies emphasize a risk assessment and risk management framework. This approach attempts to estimate the probability of harm (risk) from a proposed activity and then asks whether that harm is acceptable. Risk management techniques are intended to minimize the risks of the proposed activity but not to question whether the activity is necessary for achieving broader goals.

Alternatives assessment instead asks whether the harm is necessary and whether there might be other ways to achieve the agreed goals that would avoid harm altogether. When alternatives assessment is applied earlier rather than later in policy decision-making, innovative approaches that reflect societal goals, ecological principles and the values that underlie the precautionary principle are more likely to emerge. Assessing alternatives can also lead to action that truly respects the level of uncertainty in given circumstances.

Adopt transparent, inclusive and open processes

A precautionary approach requires open, inclusive and transparent processes that are initiated early in decision-making, beginning with goal-setting, when the health and well-being of the public and environment are at stake. A participatory approach is justified by a belief in the fundamental fairness of democratic decision-making and by the thought that a broad range of experience leads to better science and decision-making. Transparency also helps to ensure accountability among decision-makers.

Analyse uncertainty

A precautionary approach requires explicitly recognizing the scientific uncertainty inherent in understanding the potential for harm from an ongoing or proposed activity.

Statistical uncertainty may be reduced by collecting more data, but model and fundamental uncertainty is more difficult to reduce. When model or fundamental uncertainty predominates, requiring uncertainty to be resolved as a prerequisite for decision-making shows a fundamental lack of understanding of the limits of science or, alternatively, may be nothing more than a tactic to maintain the status quo. For example, the uncertainty inherent in predicting global warming includes statistical, model and fundamental uncertainty. Using the aggregate of these types of uncertainty as a basis for rejecting action has no basis in an understanding of the science.

Options for precautionary action

Choices among potential precautionary actions are made only after potential harm and scientific uncertainty are fully analysed. Precautionary action can take many directions. At the level of regulation, when research and development of a product or technology are complete and only regulatory approval is needed for production and marketing, the options are ordinarily limited to yes, no, with limits, with monitoring, with labelling or with the posting of a performance bond.

At a pre-regulatory level, however, precautionary action might include a closer look at problems that proposed technologies are intended to solve. How was the problem defined and by whom? Was the problem framed in the only or best way? Are there alternatives to the proposed technology?

Evaluating a full range of possible precautionary measures again requires a multidisciplinary, participatory approach to elicit relevant knowledge and set priorities. Responses to scientific uncertainty, as well as various kinds of harm, legitimately vary among individuals, societies and cultures.

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Considering alternatives, multiple sources of information and priorities earlier in the process is easier than when a developed product or technology is presented for regulatory approval.

Conclusion

Although many measures of human health and circumstances have improved in some parts of the world, human activity during the 20th century caused both inexorable, incremental degradation of ecological systems throughout the world and fundamental shifts in ecosystem functioning on a planetary scale. These changes, including their associated effects on patterns of human health and disease, demand that old approaches to public health be re-examined and new institutions developed to respond to global problems. The precautionary principle, based on the ethical notions of taking care and preventing harm, is a new institution that will allow people to respond in wise and innovative ways. It arises from recognition of the extent to which scientific uncertainty and inadequate evaluation of the full effects of human activities have contributed to ecological degradation and harm to human health. It can be used to help address these circumstances, bringing together ethics and science and illuminating their strengths, weaknesses, values or biases. The precautionary principle encourages research, innovation and interdisciplinary problem-solving. It serves as a guide for considering the effects of human activities and provides a framework for protecting young and old humans, other species and life-sustaining ecological systems now and for future generations.

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6. The precautionary principle in decision-making: the ethical values

Pietro Comba, Marco Martuzzi & Caterina Botti

The precautionary principle implies adopting a set of rules aimed at avoiding possible future harm associated with suspected, but not ascertained, risk factors (Kourilsky & Viney, 2000). When an adverse effect is ascertained, it is avoided based on prevention and not on precaution. At the other end of the spectrum, when little or nothing is known on the health effects of a risk factor, precaution cannot be invoked to stop technological development or ban a substance whose future adverse effects can merely be hypothesized in the absence of any evidence. The domain of precaution thus lies between the domain of proper prevention and instances with no indications of adverse health effects.

A WHO Regional Office for Europe (2002) workshop extensively discussed a central issue in the implementation of the precautionary principle: defining “a prudent approach to risk”. It was stated, among other things, that adopting the precautionary principle often implies some sort of immediate action followed by a second stage of undertakings, including scientific investigations and search for alternatives. Action inspired by precaution is characterized by uncertainty, and the policy framework should thus regularly be reviewed.

Uncertainty, however, characterizes much of contemporary decision-making in environment and health. The relevance and application of the precautionary principle has attracted substantial attention because it encompasses many of the underlying dimensions of decision-making under uncertainty and provides a framework to support it. Several philosophical, economic and societal questions contribute to the complexity of this (Marchant, 2003; Sharp, 2003). The purpose of this chapter is to discuss one of these components: the ethical background and implications of decisions inspired by the

precautionary principle in environment and health.

A preliminary question that may be helpful to address is the existence of two major philosophical approaches to decision-making in uncertain settings: the Bayesian-utilitarian approach and the “maximin” approach.

In the Bayesian-utilitarian approach, as elaborated by Harsanyi (1979), which is largely used in public health, choosing the course of action with the most favourable outcome for all involved is rational. The outcome of an action is measured using a utility function: a synthetic indicator of the health and well-being of the population in question. Given a certain action, the expected value of the utility function is the weighted sum of all possible consequences of the action, and the weights are given by the probabilities associated with each consequence; probabilities are usually based on prior knowledge, hence the Bayesian notion. Although the aim is some form of “universal” welfare that takes into account all individuals, the realistic objective is to maximize the utility function, which in turn tends to be equivalent to an average. Thus, the Bayesian-utilitarian approach, aiming towards the most good for the most people, tends to favour the option that maximizes the average utility and may overlook inequality in the population distribution. Taking this approach to the extreme, a choice that concentrates the adverse consequences of an action in a small minority may have a higher utility than an option in which all members of society have smaller adverse effects. This paradox may apply to many environmental risk factors with, for example, a linear, no-threshold effect on morbidity or mortality.

Maximin, from *maximum minimorum*, is an alternative principle in decision-making. Maximin is based on a rule according to which, in decision-making, attention should be paid to the worst outcome that could possibly occur in any course of action, which should be taken into account in the decision-making process (Rawls, 1971). Alternative policy options are classified based on their worst possible result, and the worst alternative consequences should be avoided even if

highly improbable. The Bayesian-utilitarian approach is based on maximizing the utility function, whereas the maximin approach prescribes ranking policy options according to their worst possible outcome, regardless of its likelihood, and selecting the one with the least worst such outcome. Again, this characterization is somewhat simplistic and refers to literal application of the principle, but the maximin principle tends to favour policy options inspired to precaution, prescribing a “better safe than sorry” approach.

Both approaches are concerned with social welfare and aim at protecting and enhancing a community’s overall health status, but the Bayesian-utilitarian view identifies this as the amelioration of the total or average well-being, whereas the maximin approach is mainly concerned with the welfare of the most disadvantaged population subgroups and results in reducing the gap between those who are better off and those who are worst off. Such a gap is not necessarily of concern in Bayesian-utilitarian evaluation. Thus, the maximin strategy is considered more adequate to deal with the problem of distributive justice; inequality is allowed inasmuch as it maximizes the long-term expectations of the worst-off part of society, but a policy option that may produce marked inequality is normally rejected. In fact, one society can be said to be better than another if the worst-off members of the former do better than the deprived members of the latter, even if the overall utility may be lower.

Before these two approaches in decision-making in environment and health are compared, note that risk management strategies based on establishing a relevant evidence base and applying cost–benefit analysis have provided major contributions to public health (Vineis & Soskolne, 1993). One of the crucial issues in applying the Bayesian-utilitarian approach is how to address the dimension of equity in the distribution of exposure between population subgroups; this point requires some additional comments.

“Mainstream” environmental epidemiology, providing some of the essential information for risk assessment exercises,

generally deals with diffuse types of exposure, often of limited intensity, whose adverse health effects may consist of a moderate increase in the risk of occurrence of a disease, shared by a large number of people. Detecting and measuring this kind of effect requires complex study designs (Steenland & Savitz, 1997; Hertz-Picciotto, 1998). Although the risks involved are typically small, the fact that large numbers of people are affected results in sizeable effects on public health. For example, slight differences in the choice of protective standards or exposure limits might have important public health implications. At the same time, reducing exposure or imposing more restrictive limits for widespread types of exposure normally has great costs for society. Balancing these costs with the expected health benefits is therefore a crucial exercise in these circumstances, and clearly formulating the cost–benefit relationship is of great value. Adopting the Bayesian-utilitarian approach is therefore natural to choose the option that is expected to cause the greatest benefit to the greatest number of people involved, maximizing health returns for each unit of money spent.

A complementary approach may be pursued for relatively less frequent situations, such as those involving limited numbers of subjects exposed to relatively high levels of a specific noxious agent. In these circumstances, measures of exposure abatement aimed at the general population are likely to produce limited benefits, resulting in ineffective health returns per unit of money spent. Such measures tend thus to be rejected based on cost–benefit considerations. However, although the attributable risks may be very small among the whole population, they can be substantial within the exposed subgroups. Such subgroups, ultimately, are asked to carry most of the burden of disease associated with the type of exposure in question. Such an obvious equity problem is often made worse by social disparity. For example, Bullard & Wright (1993) investigated the non-random distribution of locally unwanted land uses and health risks. Communities with hazardous waste incinerators, for example, generally have large ethnic-minority populations, low incomes and low property values. Abandoned toxic-waste sites and wastewater

pipes from polluting industries have been shown to cluster in socioeconomically deprived districts, thus determining, among else, contamination of groundwater. Some adverse health effects associated with deprivation and with proximity to hazardous waste sites, such as the risk of birth defects, may coincide to some extent, thus justifying the urgent requirement of adopting appropriate epidemiological study designs aimed at appreciating both sets of risk factors and their potential synergy effects.

The awareness of the existence of high-risk communities and of the non-random distribution of environmental risks and social deprivation has both triggered specific research projects and developed public health action inspired by criteria of environmental justice and distribution of exposure. In more practical terms, these perspectives can be used as a basis for policy-making on the ever-delicate issue of allocating finite and normally scarce resources in protecting environment and health. Sexton, Olden & Johnson (1993), for example, recommend defining risk-base priority-setting for environmental health problems. This procedure aims to ensure that scarce resources are used to address the “worst” problems first. Since environmental protection is a right for all individuals, they suggested adopting a procedure by which vulnerable subgroups are given priority, identified through residence in certain geographical areas. In these areas or neighbourhoods, environmental pollution coupled with socioeconomic deprivation is more likely to damage human health, through exposure that disproportionately affects the people who are least capable of protecting themselves (Finkel & Golding, 1993).

This strategy inherently represents a maximin approach, which will lead to concentrating efforts to mitigate exposure among the most affected population subgroups and pursuing an equitable distribution of risks, whether natural or induced by industrialization or technological development (Shrader-Frechette, 1991). This may not be enough to ensure fairness of outcome, but it will certainly contribute to the fairness of the decision-making process.

For the sake of the debate around the precautionary principle, explicitly addressing these dimensions is important. This approach is consistent with several of the prescriptions of the precautionary framework, for at least three reasons. Firstly, the specific types of exposure under consideration (such as the health effects of incinerators, waste-disposal sites, groundwater pollution, airborne chemicals around industrial sites and power-frequency electromagnetic fields) often represent possible or suspected but not always ascertained hazards, so that the uncertainty not only concerns the magnitude of the risk but its very existence. Secondly, remedial or cautionary action has to be taken despite such uncertainty, and this process requires that all efforts be made to maximize the use of available scientific information. Finally, the precautionary framework requires that involuntary exposure, especially if it may be viewed as inequitable, should be a priority. The mere fact of making these connections more explicit, it is hoped, can contribute to more effective and equitable decision-making in environment and health.

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7. Late lessons from early warnings: improving science and governance under uncertainty and ignorance¹

David Gee & Andrew Stirling

The European Environment Agency (EEA) is an independent Agency of the European Community, which was founded in 1993. Its main task is to provide information to the policy-making bodies of the European Union (EU) and its Member States that can be of direct use for improving decision-making and public participation in the fields of environment and sustainable development. The main background against which these activities are set is the growing scale and pace of scientific and technological innovation, with the nature of the consequences increasingly outstripping any social capacity for prediction (WBGU, 2000). Decision-makers therefore often need information in situations of scientific uncertainty and ignorance. Herein lies the increasing relevance of the precautionary principle, enshrined, along with the principles of prevention and the polluter pays, in the Maastricht Treaty on European Union (European Commission, 2000).

The precautionary principle is not just an issue for the European Union: its potential impact on trade means that its application can have global repercussions. There are currently disputes both between and within the EU and the United States on the use and application of precaution to hormones in beef, genetically modified organisms (GMOs), and climate change. In 2001 the EEA published *“Late Lessons From Early Warnings: The Precautionary Principle 1896-2000,”* to examine the use, or neglect, of information and precaution in protecting both human and ecosystem health. The report was based on an historical approach to scientific uncertainty (Gee,

¹ From *Precaution, Environmental Science, and Preventive Public Policy* by Joel A. Tickner, ed. Copyright © 2003 Island Press. Reproduced with permission of Island Press, Washington, D.C.

1997). Since discussions on precaution are sometimes hampered by confusion about the meaning of terms used in the debate, we felt it was important to analyze and learn from past experiences in the use and non-use of precaution in controlling hazardous technologies and to do so with a common approach and terminology. Analysis of these histories generated useful definitions of some of the key terms used in debates on precaution and prevention (Box 1).

Box 1. Uncertainty and precaution – towards a clarification of terms		
Situation	State and dates of knowledge	Examples of action
Risk	‘Known’ impacts; ‘known’ probabilities e.g. asbestos causing respiratory disease, lung and mesothelioma cancer, 1965–present	Prevention: action taken to reduce known hazards e.g. eliminate exposure to asbestos dust
Uncertainty	‘Known’ impacts; ‘unknown’ probabilities e.g. antibiotics in animal feed and associated human resistance to those antibiotics, 1969–present	Precautionary prevention: action taken to reduce potential risks e.g. reduce/eliminate human exposure to antibiotics in animal feed
Ignorance	‘Unknown’ impacts and therefore ‘unknown’ probabilities e.g. the ‘surprises’ of chlorofluorocarbons (CFCs) and ozone layer damage prior to 1974; asbestos mesothelioma cancer prior to 1959	Precaution: action taken to anticipate, identify and reduce the impact of ‘surprises’ e.g. use of properties of chemicals such as persistence or bioaccumulation as ‘predictors’ of potential harm; use of the broadest possible sources of information and long term monitoring

Source, EEA, 2001.

Late lessons from early warnings: learning from history

In trying to understand the reasons for inaction on early evidence of harm, and the resulting costs, an examination of historical cases such as that of asbestos (see Box 2) has rarely been conducted. The *Late Lessons* report attempts to help fill that gap.

Box 2

In 1898, Lucy Deane, a UK Factory Inspector, observed: “The evil effects of asbestos dust have also instigated a microscopic examination of the mineral dust by HM Medical Inspector. Clearly revealed was the sharp glass-like jagged nature of the particles, and where they are allowed to rise and to remain suspended in the air of the room in any quantity, the effects have been found to be injurious as might have been expected.” (Deane, 1898)

One hundred years later, in 1998, the UK government decided to ban “white” asbestos, a decision that was echoed by the European Union (EU) the following year. The current asbestos-induced death rate in the United Kingdom is about 3 000 deaths per year, and some 250 000–400 000 asbestos cancers are expected in Western Europe over the next 35 years, due to past exposures (Peto, 1999).

Fourteen case studies were chosen from a range of hazards to workers, the public and the environment, where enough was known of their impacts for conclusions to be drawn about how well they were dealt with by governments and civil society (see Box 3). Obviously, there are other public health impacts and environmental disasters that were not looked at, such as thalidomide (James, 1965), lead (Millstone, 1997), and the Aral Sea (Small, van der Meer J & Upshur REG, 2001). These provide further lessons about unintended consequences, and about the conflict between short and long term interests. The authors of the case studies were asked to structure their chapters around four key questions:

- When was the first credible scientific “early warning” of potential harm?
- When and what were the main actions or inactions on risk reduction taken by regulatory authorities and others?
- What were the resulting costs and benefits of the actions or inactions, including their distribution between groups and across time?
- What lessons can be drawn that may help future decision-making?

Authors were also asked to base their conclusions on ‘the information available at the time and not on the luxury of hindsight.’ The objective was to see what could be learnt from the histories which could help prevent, or at least minimize, the impacts of current and future economic activities that may turn out to be harmful, and to do so without stifling innovation or compromising science.

Box 3. Late Lessons from Early Warnings: the Case

Studies Fisheries

Radiation

Benzene

Asbestos

Polychlorinated Biphenyls (PCBs)

Halocarbons and the ozone layer

Diethylstilbesterol (DES)

Antimicrobials as growth promoters

Sulphur dioxide

MTBE in petrol

Chemical contamination of the Great Lakes

Tributyltin (TBT) antifoulants

Hormones as growth promoters

“Mad cow disease” (BSE)

The case studies and authors were chosen with a transatlantic audience in mind. Three chapters are focused either on a

North American issue (pollution of the Great Lakes) or primarily on the North American handling of issues that are also directly relevant to Europe (benzene, and DES administered in pregnancy) and are authored by scientists from North America. Three chapters cover issues of some conflict between North America and Europe (hormones as growth promoters, asbestos, and MTBE in petrol); and all other chapters are as relevant to the environments and public health of North Americans as they are to Europeans. The case study authors are not without their own views, being for the most part active participants in the process of making the histories summarized in each chapter. However, as respected scientists in their fields, the authors attempted to adopt an objective position in answering the four questions put to them.

The case studies are all about “false negatives” in the sense that they are agents or activities that were regarded at one time as harmless by governments and others, at prevailing levels of exposure and “control,” until evidence about their harmful effects emerged. While the editors wanted to include some examples of “false positives,” where action was taken on the basis of a precautionary approach, such examples were difficult to find. Our attention was drawn to a US publication, *Facts versus fears* (Lieberman & Kwon, 1998), which attempted to provide some 25 examples of “false positives” but on closer examination these turned out not to be robust enough for those who recommended them to accept our invitation to write case studies for this report. The challenge of demonstrating “false positives” remains: possible candidates that have been mentioned include the ban on dumping sewage sludge in the North Sea, and the “Y2K millennium bug.”

An early use of the precautionary principle: London, 1854

The Introduction to the “Late Lessons” report illustrates an early use of the precautionary principle in Europe: When in the midst of a cholera outbreak in 1854 London, the physician John Snow recommended removing the handle off the Broad Street Pump, based on observation of patterns of the disease.

The removal of the pump handle, despite the absence of strong proof that polluted water was causing the cholera, or an understanding of the etiology of the disease, helped control the outbreak.

The story of John Snow and cholera contained several of the key elements of precautionary policy-making:

- the long time lag between “knowing” about a hazard and its likely causes and “understanding” the chemical and other processes underlying the causal links;
- a focus on the potential costs of being wrong in acting, or not acting;
- and the use of minority scientific opinions in policy-making, as the majority of experts then thought that polluted air caused cholera.

There are many differences between cholera, asbestos (which came into use at about the time of Snow’s action), and the other harmful agents in the case studies, not least being the time lag between exposure to the harmful agent and the health damage: hours in the case of cholera but decades in the case of asbestos and most of the other agents studied. Had governments adopted a similar approach to precautionary prevention as Dr Snow, once the early warnings on asbestos were published, much of the tragedy and the huge costs of asbestos exposure could have been averted.

Politicians today are working in similar conditions of scientific uncertainty and stress to Dr Snow, but now made more difficult by the greater risks and uncertainties (economic, health and ecological) of larger-scale activities (Beck, 1992) and by greater pressure from the mass media (Smith, 2000). They also work with more democratic institutions, and are accountable to a better-educated and involved citizenry which has greater access to information. Globalization and free trade issues add further complications, as does the emerging science of complexity, which adds to the need for greater humility and

less hubris in science. It is in these circumstances of trying to prevent potentially serious and irreversible effects, without disproportionate costs, that the precautionary principle can be useful.

Learning from history?

The European Scientific Technology Observatory (ESTO) project on technological risk and the management of uncertainty (Stirling, 1999) provided an initial framing for this analysis. The ESTO project sets out a comprehensive structure for the consideration of issues relating to precaution. The most difficult question for the EEA case study authors to answer, was “what were the resulting costs and benefits of the actions or inactions?” This difficulty arose partly from the authors’ lack of an economic background, and partly because precise characterization of counterfactual history is intrinsically highly problematic. Also, the incommensurable nature of different effects and their diverse social distributions militate against any definitive assessment of the general pros and cons of alternative courses of action.

In many of the EEA case studies, adequate information about potential hazards was available well before decisive regulatory advice was taken. However, the information was often either not brought to the attention of the appropriate decision-makers early enough, or was discounted by them and other stakeholders.. It is also true that in some of the case studies, early warnings – and even loud and late warnings – were effectively ignored by decision-makers because of short-term economic and political interactions (for example asbestos, PCBs, the Great Lakes, and sulphur dioxide and acidification). Many of the late lessons therefore relate to the type, quality, processing and utilization of information within the context of more participative and democratic processes. The scale and scope of such integrated and comprehensive processes of hazard and options appraisal needs to be related to the likely scale of the potential consequences (environmental, health, social, and economic) of the activity in question. For example, the global and generational consequences of GMOs would

merit a more comprehensive options appraisal than the local consequences of a road by-pass.

Twelve late lessons from early warnings

The report authors generated twelve particular lessons for improving science and governance about uncertain, complex risks.

1. Respond to ignorance as well as uncertainty

A central lesson of the EEA report concerns the importance of recognizing and fully understanding the nature and limitations of our knowledge. What is often referred to as “uncertainty” actually hides important distinctions. All of the activities in the case studies were subjected to some form of (formal or informal) assessment of risk. What remained neglected, however, was the virtual certainty that there would be factors that remained outside the scope of the risk assessment. This is the domain of ignorance – the source of inevitable surprises, or unpredicted effects (see Box 14.1).

Just as one basis for scientific research is the anticipation of positive surprises – “discoveries” – so it can yield the corresponding prospect of negative surprises. By their nature, complex, cumulative, synergistic or indirect effects in particular have traditionally been inadequately addressed in regulatory appraisal. At first sight, responding to ignorance may seem impossible. How can strategies be devised to prevent outcomes, which, by definition are not known? Analysis of the case studies suggest that it is possible to do, for example:

- *Use knowledge of the intrinsic properties of a substance or activity* when assessing possible impacts, e.g.. a chemical substance that is persistent and bioaccumulates carries a significant risk of a long-term hazardous impact.
- *Use a diversity of robust and adaptable technological options to meet needs.* This helps to limit technological

“monopolies” such as that of asbestos, CFCs, PCBs and thereby the scale of any “surprises.”

- *Use a variety of scientific disciplines* as well as “lay” and “local” knowledge in risk assessments in order to more effectively gather whatever information is available in society.
- *Reduce specific exposures to potentially harmful agents* on the basis of credible early warnings of *initial* harmful impacts, thus limiting the size of any *other* surprise impacts from the same agent (e.g., PCBs and asbestos).
- *Reduce the general use of energy and materials* via greater *eco-efficiencies*, so as to reduce overall environmental burdens, thereby limiting the scale of future surprises.
- *Use liability measures* (e.g. legal duties and insurance bonds) to compensate for potentially harmful impacts and to provide an investment fund if no “surprise” occurs.
- *Use of prospective analyses and scenarios* to help foresee unintended consequences.
- *Use more long-term environmental and health monitoring* to help detect “earlier warnings” of surprises.
- *Use more and better research, and its more effective dissemination on “early warnings”* so as to encourage earlier action to reduce risks.

2. Research and monitor for “early warnings”

Well-planned research and long term monitoring are essential to the systematic identification of areas of uncertainty and to increase the prospect of timely alerts to problems arising out

of ignorance. Awareness of uncertainty and ignorance helps in posing appropriate research questions. The case studies illustrate that even ‘critical path’ issues, identified at an early stage, were not necessarily followed up in a timely or effective fashion. For example, BSE was first identified as a new disease in cattle in 1986, but research to verify its supposed absence of maternal transmission – important to the early position of the UK Ministry of Agriculture, Fisheries and Food (MAFF) – was not initiated until 1989. Maternal transmission did occur. Experiments concerning the transmissibility of sheep scrapie to cattle (a favored hypothesis of the source of the disease) were not begun until 1996. No surveys of the number of infectious, but asymptomatic, cattle entering the food chain were conducted. Yet reassurances on the part of the UK government continued prominently to cite the absence of evidence, when no evidence was actually being sought.

As human economic activities become geographically more widespread and sometimes less reversible, the use of the ‘world as a laboratory’ (the only one we have) requires more intelligently targeted, ecological and biological surveillance. Research may reduce uncertainties and ignorance but this will not necessarily be the case. There are examples where research can compound uncertainty and reveal new sources of ignorance. For example, a Canadian mathematical model of the interactions between various fish species suggested that these became more unpredictable as progressively more biological data were incorporated into the model. Calls for more research should be as specific as possible about the scientific questions that need to be addressed; the time such research may take; and the independence of the relevant organization carrying it out.

3. Search out and address “blind spots” and gaps in scientific knowledge

The confirmation of an Antarctic ‘ozone hole’ in 1985 was a by-product of an experiment conducted for other purposes. A dedicated satellite observation program to monitor stratospheric ozone had earlier detected major depletion, but

the results were considered suspect and set aside. Another blind spot can occur where technological change is purported to solve historic problems, even when the hazard is long term. For example, successive claims were made that earlier health impacts from asbestos were due to working conditions that had been solved. Yet, even with improvements in working conditions, disease was still identified and it took decades to identify the risks at each successively lower level of exposure. A more precautionary approach means systematically searching out such blind spots using multiple disciplines and other sources of knowledge which can help stimulate the interactions between disciplines that are more likely to expose uncertain assumptions and blind spots.

4. Identify and reduce interdisciplinary obstacles to learning

When hazardous impacts arise in a particular area (ie veterinary health) this can lead to the regulatory appraisal becoming unduly dominated by a particular discipline, such as medicine in the asbestos case and veterinary science in the antimicrobials case. This implicitly created a form of institutional ignorance. The risk appraisal for MTBE was based mainly on knowledge concerning engines, combustion and air pollution. Water pollution aspects associated with persistence and significant taste and odor problems were essentially disregarded, though the information was available. With regards to mad cow disease, UK veterinary officials considered the possibility of BSE transmissibility to humans as acceptably slight. This contrasts with the attitude in the United States, where the possible link between sheep scrapie and human Creutzfeldt-Jakob disease (CJD) had been regarded as a possibility since the 1970s, when the entry of infected animals into the food chain was banned.

5. Ensure that real world conditions are fully accounted for

Real world conditions can be very different from theoretical assumptions, with serious consequences. In the real world, bioaccumulated metabolites of PCBs were found to be more toxic than indicated by experiments using original commercial PCB formulations. It was also assumed that PCBs could be

contained within ‘closed’ operating systems. This proved impossible, resulting in releases into the food chain from accidents and poorly maintained equipment, and illegal disposal. Optimistic assumptions about the performance of halocarbon containment equipment, and of the efficiency of decommissioning, played a role in reducing the effectiveness of control measures. Scientific advisory committees on growth promoters only considered circumstances relating to authorized use, and to assessments of individual growth promoters, rather than in combination. It was many decades after the early warnings of asbestos harm before authorities acknowledged that asbestos users (or even local residents around a factory), as well as asbestos manufacturing workers, could be at risk from exposure to the dust.

6. Systematically scrutinize and justify the claimed pros and cons

The regulatory appraisal process generally does not systematically examine the claims made about the benefits of a technology or product, including an identification and assessment of the real world conditions under which the claimed benefits could arise.

In the DES case study, the data from 1953 trials showed that DES was ineffective as a means of reducing risks of spontaneous abortion in certain groups of mothers. It was not for another 20–30 years that use of this drug was actually banned in some countries, due to the discovery in 1970 of an increase in a rare cancer of the vagina in daughters of treated women. Had greater critical attention been paid at the outset to the claims of efficacy, then some of these second-generation cancers might have been avoided.

The need to formally justify the claimed benefits of a technology is rare. The ionizing radiation case study is a rare example of such a “justification principle,” developed by the International Committee on Radiological Protection in the 1950s. This was in response to the growth of a variety of dubious or ineffective uses of radioactive materials, such as in

fitting shoes for children, the cosmetic removal of hair, and the treatment of mental disorders. Surveys of radiography practices over the past decade or so have concluded that, while radiation doses have reduced considerably, a large proportion of medical X-rays are still of dubious clinical benefit.

Consideration of the full environmental and health costs and benefits of various options is also important. The failure, in cases like asbestos, halocarbons and PCBs, to include full environmental and health costs in market prices gave these products an unjustifiable advantage in the marketplace. This in turn helped to keep technically superior substitutes off the market for longer than necessary. Although the mechanisms for the internalization of external environmental costs, and the practical implementation of liability regimes, are controversial, such measures are essential if both efficiency and equity objectives are to be addressed effectively.

7. Evaluate alternatives and promote robust, diverse and adaptable solutions

Even where the pros are scrutinized alongside the cons, if attention is restricted simply to isolated technologies or products then important practical insights may be missed. One concern is that, once a technological commitment is made, a host of institutional and market processes act to reinforce its position, even if it is markedly inferior to potential alternatives.

For example, while in principle the function of MTBE might be substituted by alternative oxygenates such as bioethanol, by improved engine technology, or by an increase in the octane rating of the fuels themselves, little formal scrutiny of these alternatives appeared to have been undertaken at the time of the promotion of MTBE. The ozone-depleting properties of second-generation CFC substitutes were perhaps also unduly tolerated, because of their relatively low ozone impacts when compared with the original substances. The existence of more benign substitutes, with less global warming potential, was not properly examined. Broader consideration of problems may

give rise to more beneficial solutions than simple “chemical for chemical” substitution.

The promotion and production of alternatives needs to take place within a culture of eco-efficiency, clean production and closed-loop material flows so as to minimize the size of any future surprises in the use and impact of all technologies, including those considered to be safer than those they are replacing.

8. Use lay and local knowledge as well as all relevant specialist expertise

Knowledgeable lay people may include industry workers, users of the technology and people who live in the locality or, who because of their lifestyle or consumption habits, are most strongly affected. The value of involving lay people lies not in assumptions that they are more knowledgeable, or environmentally committed, but in the complementary value of their perspectives that are often broader in scope, more firmly grounded in real world conditions or more independent than the narrow professional perspectives that can accompany specialist expertise. The histories of asbestos and PCBs provide examples of workers being aware of hazards well before the regulators.

Another form of lay knowledge concerns remedial measures. For example, although fishers can be less precautionary about stock depletion than others, there are many examples where fishers wish to act in a precautionary manner but are prevented from doing so because of a systems failure. There is an increasing emphasis in Canada and elsewhere on the need to involve fishers in management, and take full account of their knowledge and perspectives. Swedish farmers’ knowledge of alternative animal husbandry techniques allowed them to promote animal health and growth without the large-scale use of antimicrobials. Not only did they bring valuable insights to the regulatory debate, but they were able to undertake voluntary controls in advance of regulatory requirements.

Lay knowledge should also receive critical scrutiny, as lay citizens are not immune to the pitfalls and difficulties noted in these conclusions about specialist expertise. One example is the “pensioners’ party fallacy” amongst asbestos workers who pointed to the presence of healthy pensioners at the firm’s Christmas party as evidence of the apparent harmlessness of asbestos, overlooking that those who had been harmed would of course not be able to attend a party.

9. Take account of wider social interests and values

Social and political conflicts can be aggravated by a regulatory preoccupation with expert judgments and a lack of attention to public perspectives and values. This is critical to the wider assessment of the pros and cons. The implicit assumptions and values of specialists and interest groups need to be aired and shared. The Swedish farmers in the antimicrobials case study show how lay views can help ensure that the regulatory process reflects enlightened public and consumer values.

While expert institutions tend to focus on scientific analysis, a public aversion to situations outside the bounds of normal experience (“common sense”), or at least a desire to proceed with caution, can be defended as a rational response to scientific uncertainty. A key feature of the public reaction to the emerging evidence of BSE was the surprised revulsion that ruminants were being fed on offal and bodily wastes. It seems likely that avoiding offal in ruminant feed would have at least significantly limited the scale of the subsequent BSE and CJD problems.

10. Maintain regulatory independence from economic and political special interests

There is evidence in the case studies that interested parties are often able to influence regulators unduly. As a result decisions that might reasonably have been made on the basis of the available evidence were not taken. Benzene was demonstrated to be a powerful bone marrow poison in 1897; the potential for acute respiratory effects of asbestos was first identified in 1898; and the first cases of PCB-induced

chloracne were documented in 1899, with effects on workers known by the late 1930s. Yet it was not until the 1960s and 1970s that significant progress began to be made in restricting the damage caused by these agents. Similarly, the temporary lifting of the ban on DES as a growth promoter in the United States in 1974 followed strong pressure from the farming lobby, and occurred despite the availability of alternatives.

Independent information institutions are thus a key element of authentic regulatory independence and robust governance and appraisal. This is increasingly being recognized, for example by the shifting of advisory committees from producer directorates in the European Commission (for example, agriculture) to the Health and Consumer Directorate. The setting up of independent food agencies in some Member States and at the EU level also reflects this concern for more independent hazard appraisal institutions.

11. Identify and reduce institutional obstacles to learning and action

The asbestos, benzene and PCB case studies provide examples of how the short-term horizons of government and businesses can militate against social welfare in the medium and long term. However, institutional obstacles against timely protection of health and the environment can take other forms as well. The case studies illustrate three other areas: those resulting from periods of transition (for example between succeeding elected administrations), or from tensions between different departments or levels of government and “their” agencies, or from differing national approaches.

An official UK commission in 1979 recommended the setting of minimum processing standards in the rendering industries. A new administration later that year decided to withdraw the resulting proposed regulations, finding them to be an unnecessary burden on industry. It is not clear to what extent such tighter standards might actually have inhibited the later BSE outbreak, but it is notable that the implementation of

standards of this sort featured prominently among that same government's later responses to the BSE crisis in 1996.

12. Avoid paralysis by analysis and apply precautionary measures where there are reasonable grounds for concern

The general tenor of the lessons so far is to 'know more'. But how much information about potential hazards is deemed enough to trigger risk reduction measures? There is a danger of paralysis by analysis where either information overload, or lack of political will, lead to a failure of timely hazard reduction measures. One example is the anti-precautionary straightjacket imposed upon U.S. benzene regulation by a Supreme Court decision, which required layer upon layer of additional information before regulatory action to reduce risks was possible, resulting in a ten year delay in the occupational benzene standard.

Experts have often argued at an early stage that we know enough to take protective action. For antimicrobials the UK Swann Committee in 1969 concluded: 'despite the gaps in our knowledge ... we believe ... on the basis of evidence presented to us, that this assessment is a sufficiently sound basis for action ... the cry for more research should not be allowed to hold up our recommendations'. Other case studies, such as asbestos and BSE, suggest that more, or better-targeted, research, at an earlier stage, would have helped minimize future costs. Similarly, for fisheries, the Ecosystems Principles Advisory Panel to the US Congress concluded: "There will always be unmeasured entities, random effects, and substantial uncertainties, but these are not acceptable excuses to delay implementing an ecosystem-based management strategy."

The level of proof (or strength of evidence) needed to justify hazard reduction measures will vary with the size and nature of the claimed benefits of the economic activity, its likely costs, the significance of the uncertainties and types of ignorance involved, and the availability of alternatives. The choice of

which level of proof to use is a political choice based on values and ethics as well as science.

The usual assumption in the case studies was that an activity was harmless until proven harmful by the public authorities. However, where activities are considered to be intrinsically harmful, as with pesticides and pharmaceuticals, the burden of demonstrating at least some evidence of harmlessness is placed on the proponents of the activity. The Swedish Chemicals Act of 1975 provides a clear illustration of both different *levels of proof* and different locations of the *burden of proof* in the same legislation. It requires the Public Authority to take precautionary action on a chemical substance based on a “scientific suspicion of risk” but then the burden of proof passes to the producer of the substance, who has to show that it is harmless “beyond all reasonable doubt.” This example illustrates that a high level of proof is needed to show harmlessness when there is already evidence of potential hazard, whereas a lower level of proof is needed to demonstrate potential harm when harmlessness is assumed.

Burdens of demonstrating harmlessness can involve obligations to:

- **justify** the technology in relation to the benefits claimed;
- **show that alternative ways** of meeting needs are likely to be more hazardous or disproportionately costly.
- **monitor** the impacts of the technology; and
- **investigate “early warnings.”**

Conclusion

The EEA report provides a rich empirical history to underpin the twelve “late lessons” with which it concludes. Taken together, these lessons may help to minimize the future costs of being wrong about environmental and health risks. In the

past, conventional scientific method has been biased towards avoiding the overstating of risks, sometimes at the expense of public safety and the environment. As Underwood (Underwood, 1999) concludes: ‘Typically there has been little concern about Type II (a ‘false negative’) error. The chances of erring in “favor” of the environment (a Type I error) is deliberately kept small, whereas the chances of erring “unfavorably” to environmental issues is not!’ Participants at a recent European workshop of policymakers concluded, among other things, that “there should be a more efficient and ethically acceptable balance between the generation of ‘false positives’ and ‘false negatives’” (Swedish Environment Ministry, 2001). If implemented, the EEA’s lessons should contribute both to fewer ‘false negatives’ and to lower costs from any “false positives” that may occur.

A further key finding of the EEA report is that we need to be more precise and rigorous about what we mean by ‘uncertainty.’ Risk, uncertainty and ignorance each warrant different treatment. More attention should be given to the handling of complexity, indeterminacy, ambiguity, and disagreement within or between technical disciplines (Wynne, 2001; Stirling 1999, 2003). In short, risk assessment should become more reflective and humble. There is nothing scientific about the ‘pretence at knowledge’ (von Hayek, 1978). As the NRC (1996) and others in the United States (Omen et al., 1997) and the United Kingdom (RECP, 1998) have concluded, the prior framing of hazard appraisal requires open public deliberation on issues such as the questions to be addressed by science, the weighting of different risks and benefits, the balance to strike between comprehensiveness and specificity, and the interpretation of uncertainty, ambiguity and ignorance.

As long as these issues remain neglected or implicit, the ‘pretence at knowledge’ in risk assessment has the effect of undermining the authority and credibility of the associated institutions, and even of science in general. As Stirling (1999, 2003) has pointed out, the precautionary principle has nothing to do with anti-science. Indeed, it embodies a more rigorous

and robust approach to scientific uncertainty and systems complexity.

The tools for participatory approaches are in various stages of development, and the challenges are far from trivial. But this has to be set against traditional approaches, where the costs of failure can also be high even for industry, as illustrated by the European public rejection of irradiated foods and the European response to many of the food applications of GMOs.

These considerations indicate the importance of acknowledging the interpenetration of facts and values. Popper pointed out long ago that is rationally impossible to derive a proposal for a policy from facts alone (Popper, 1962). Policies that unduly emphasize the factual basis of decisions, without explicitly acknowledging, and engaging with, the value judgments that frame and constitute the relevant facts, are unlikely to lead to robust decisions, or to achieve public acceptance (RMNO, 2000).

Critiques of the precautionary principle often cite its supposed stifling of innovation. However, the implementation of the EEA's twelve late lessons would stimulate the application of some emerging tools for the fostering of environmental innovations. By maximizing the breadth of available information and focusing on constructive solutions, approaches like integrated environmental assessment (EFIEA, 2000; Dowlatabadi & Rotmans, 2000), multi-criteria mapping (Stirling & Mayer, 1999), constructive technology assessment (Rip et al 1996), technology options analysis (Ashford 1991, 1984; Tickner, 2000), alternatives analysis (O'Brien, 2000), and 'what-if' scenarios and participatory scenario development techniques, can all assist in the management of ambiguities, uncertainties and societal ignorance, while encouraging technological, scientific, and social innovations.

Technological systems have a tendency to 'lock' into particular configurations at a relatively early stage in their development, thus foreclosing other options and raising the costs of shifting to alternatives. The particular technologies that gain

ascendancy in this way may do so for arbitrary reasons which may have little to do with intrinsic qualities, and everything to do with chance and “first-leader” advantage. A technology can then virtually monopolize the meeting of some societal needs, as the histories of asbestos, CFCs, benzene, and PCBs illustrate. Application of the above ‘precautionary’ approaches to technology appraisal early on in the innovation process can often promote environmental innovations that are more cost effective than when introduced after harmful technologies have become ‘locked in’.

There is one final implication of the EEA’s lessons for risk science and policy. Following episodes such as BSE in the United Kingdom, dioxins in Belgium, and HIV-contaminated blood in France, public trust in risk science is at a very low ebb in Europe. Governments are increasingly aware of this and are developing responses, such as the EU White Paper on European Governance (July 2001). This includes recommendations for improving public participation in managing the inter-reactions between science, technologies and society, issues which other public authorities outside Europe are also promoting (eg Ministry of the Environment, New Zealand, 2001, National Oceans Office, Australia, 2001). The need for broader engagement in risk decision making, highlighted in many of the EEA lessons, links directly with these wider imperatives for the democratizing of scientific expertise. The stakes are high, not just for public health and the environment, but for how we go about choosing our future technological pathways and for who has control.

Postscript

Since the European Environment Agency published *Late lessons from early warnings: the precautionary principle 1896–2000*, there have been a number of criticisms of the precautionary principle. Some have enriched the debate, but many are based on misconceptions. The most common misconceptions are identified and clarified below.

- The precautionary principle is not a prediction – it is a process that may or may not lead to measures to reduce exposure.
- The precautionary principle is not the same as “prevention”, which is concerned with “known” risks. “Precaution” is concerned with uncertain and unknown hazards and risks. For example, bans on asbestos or tobacco smoking in the 1950s and 1960s would have involved both precaution and prevention, but bans in 2003 are simply prevention because the risks are now well known.
- The precautionary principle is not based on zero risk but aims to reduce lower and more acceptable risks and hazards with lower overall costs, both quantifiable and non-quantifiable.
- The precautionary principle does not ensure against misuse or poor decision-making, as with any other policy tool.
- The precautionary principle is not the same as risk assessment. It is broader, deeper and supplementary to risk assessment.
- The precautionary principle is not oblivious to costs of all kinds and in both directions (that is, of acting or not acting to reduce risks and hazards), including secondary costs and benefits.
- The precautionary principle is not one-sided. It applies to substitutes and alternatives as well.
- The precautionary principle is not based on anxiety and emotion but rather uses the best of the systems sciences of complex processes to make wiser decisions in the face of uncertainty.

- The precautionary principle does not guarantee consistency or predictability between cases and decisions. Each case is different and has different facts and values.
- The precautionary principle does not brake but rather stimulates innovation and can combat monopoly technologies that might inhibit innovation such as chlorofluorocarbons, asbestos and polychlorinated biphenyls.

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8. Applying the precautionary principle in environmental risk assessment to children

Philip J. Landrigan & Leonardo Trasande

Introduction

Infants and children are not little adults. They are qualitatively different from mature humans in many aspects of their behaviour and biology and thus are more vulnerable than adults to many environmental toxicants. Lead, mercury, pesticides, tobacco smoke, alcohol, dioxins and polychlorinated biphenyls are among the chemicals that have been found to be especially toxic to children (Harada, 1968; Amin-Zaki et al., 1979; McConnochie & Roghmann, 1986; Bellinger et al., 1987; Ogston, Florey & Walker, 1987; Haddow et al., 1988; Reed & Lutz, 1988; Strachan, Jarvis & Feyerabend, 1989; Needleman et al., 1990, 2002; Weitzman et al., 1990; Martinez, Cline & Burrows, 1992; Chilmonczyk et al., 1993; Eskenazi, Prehn & Christianson, 1995; Jacobson & Jacobson, 1996; Longnecker, Rogan & Lucier, 1997; Eskenazi, Bradman & Castorina, 1999; World Health Organization, 1999; Blanck et al., 2000; Lanphear et al., 2000; National Academy of Sciences, 2000; Weisglas-Kuperus et al., 2000). The *Second national report on human exposure to environmental chemicals* of the United States Centers for Disease Control and Prevention (2003) has determined that children bear significantly heavier body burdens than adults of many environmental chemicals. For example, children have a two-fold higher urine level of the pesticide chlorpyrifos and a nearly three-fold higher serum level of cotinine, the principal metabolite of second-hand cigarette smoke.

Risk assessment and risk management are the tools currently used to protect populations against toxic environmental hazards. These methods, as currently practised, have major shortcomings: they consider only one chemical at a time; they fail to account for the unique exposure and special vulnerability of susceptible groups within the population, such

as infants and children; and they presume, even in the absence of toxicological testing data, that chemicals cause no injury to health until injury is irrefutably proven. For these reasons, traditional risk assessment fails to protect the health of infants and children.

Evidence is increasing steadily that children's inadequately controlled exposure to toxic chemicals is responsible for a range of chronic diseases, including asthma, cancer, certain birth defects, and neurodevelopmental disabilities. The incidence rates of all of these diseases are rising. Chronic diseases – asthma, developmental disabilities, cancer, autism and obesity – are the predominant causes of sickness, disability and death today among children in industrialized countries. The rates of many of these diseases are on the rise. These illnesses have been termed the new paediatric morbidity (Haggerty & Rothman, 1975). Their increasing incidence represents a failure of prevention and signals a need for enhanced research into the causes and for change in prevention policy.

This chapter describes the weaknesses of traditional risk assessment that underlie its failure to protect children's health. We argue that the risk assessment paradigm must be modified if human health is to be preserved, and especially to protect infants and children. We argue that the precautionary principle, when judiciously combined with traditional risk assessment and risk management, will do a superior job of protecting children from environmental hazards. We suggest three specific applications of the precautionary principle within the risk assessment paradigm.

- The worst chemicals must be banned outright, as has happened intermittently in the past.
- The current practice of releasing untested and potentially problematic chemicals to the environment to learn only years or decades later of their hazards must end; careful pre-market testing is needed.

- Health-protective safety factors must be built into the traditional risk assessment paradigm to protect children's health when the available data are insufficient to support a strictly mathematical approach to the computation of risk.

We argue that children will continue to suffer disproportionate health effects from environmental toxins until risk assessment embraces and incorporates the precautionary principle.

Traditional risk assessment

Risk assessment and risk management are the core components of the methods currently employed to protect populations against environmental hazards (National Academy of Sciences, 1983). These methods, as traditionally practised, fail to protect the health of infants and children (National Research Council, 1993). Traditional approaches to risk assessment account for neither children's unique vulnerability nor their unique patterns of exposure to environmental toxins. This failure contributes to the current widespread failure of disease prevention.

Risk assessment is a mathematical approach to computing risk and preventing diseases of toxic environmental origin that is based on the proposition that there are quantitative dose–response relationships between the level of exposure to a chemical and the frequency and severity of disease. The underlying hypothesis is that knowing the dose–response relationship between a chemical and the disease or dysfunction it has caused allows a scientifically based standard to be developed that will protect human health.

Risk assessment appears straightforward, precise and logical. For these reasons, it is extremely attractive and its application has become widespread. However, as currently practised, both risk assessment and risk management are deeply flawed. One flaw is that risk assessment has traditionally studied only one chemical at a time. This approach fails to recognize the reality that people are exposed to hundreds of chemicals that

probably have multiple interactions and synergistic effects on human health. Risk assessment is not a sufficiently powerful tool to address these complexities.

Another flaw inherent in risk assessment, as traditionally practised, is that it has assumed that entire populations consist of healthy adults – a “one size fits all” approach. This overly simplistic assumption ignores the reality that populations are highly heterogeneous. It fails to consider the differential impact that environmental toxins may have on infants, children and other vulnerable groups. It also ignores the differing susceptibility and exposure people may have to environmental toxins. The Human Genome Project is beginning to elucidate the complexity of the gene–environment interactions that affect individual susceptibility to environmental chemicals (Kelada et al., 2003). One recent study (Lammer et al., 2004), for example, found a fourfold increased risk of orofacial clefts among infants with the NAT1 and NAT2 genetic polymorphisms born to mothers who smoked. Further understanding of the role of genetic polymorphisms and of their interaction with environmental toxins will further undermine this basic premise of homogeneity that lies at the core of risk assessment as currently practised.

A final and perhaps most profound shortcoming of the traditional risk assessment and risk management paradigm is that it presumes that chemicals are innocent until proven guilty. It assumed that a chemical is harmless until data have been assembled that demonstrate with a minimum statistical significance of 0.05 that a chemical can cause harm. Unfortunately, most chemicals have not been assessed at even the most basic level for their potential to cause toxicity in animals or in humans. Even less information is available on developmental toxicity and toxicity among children (EPA, 1998a). In the absence of such data, harm becomes impossible to prove. Thus populations continue to be exposed to chemicals in a potentially dangerous and uncontrolled natural experiment.

More than 80 000 new synthetic chemicals have been developed and disseminated in the United States over the past 50 years. Children are at special risk of exposure to the 2 800 high-volume chemicals that are produced in quantities greater than 450 000 kg per year and that are most widely dispersed in air, water, food crops, communities, waste sites and homes (EPA 1998a). Fewer than half of these high-volume chemicals have been tested for their potential toxicity, and fewer still have been tested for their possible developmental toxicity to fetuses, infants and children (National Academy of Sciences, 1984; EPA, 1998b).

Why are children especially vulnerable to environmental toxins?

In the past decade, researchers and policy-makers have increasingly recognized that children have unique exposure and special vulnerability to environmental chemicals and therefore require special consideration in risk assessment (National Research Council, 1993).

Children have disproportionately heavy exposure to many environmental agents

Children drink more water, eat more food and breathe more air per kilogram of body weight compared with adults. For example, children in the first six months of life drink seven times as much water, and children ages 1–5 years eat three to four times as much food on a body-weight basis than the average adult. The air intake of a resting infant is twice that of an adult. The implication of these findings for health is that children will have substantially greater exposure than adults to any environmental contaminants present in water, food and air (National Research Council, 1993). Two additional characteristics of children further magnify their exposure: their hand-to-mouth behaviour and their play close to the ground.

Children's ability to metabolize, detoxify and excrete environmental agents differs from that of adults

In some instances, children are better able than adults to deal with environmental agents (Spielberg, 1992; National Research Council, 1993) because they cannot create the active metabolite required for toxicity. In other instances, children are less able to deal with toxic chemicals and thus are more vulnerable to them (Spielberg, 1992; National Research Council, 1993). Metabolism also differs between prenatal and postnatal life and may vary over the course of pregnancy. An additional source of vulnerability in fetuses and young children is that the blood–brain barrier is not fully developed, and xenobiotics may therefore be more easily able to enter the central nervous system (Rodier, 1995).

Developmental processes are easily disrupted during rapid growth and development before and after birth

Rapid growth and development occur during embryonic and fetal life as well as in the first years after birth. In the brain, for example, billions of cells must form, move to their assigned positions and establish precise connections with other cells (Rodier, 1995). Development of the endocrine and reproductive organs is guided by a complex and precisely timed sequence of chemical messages. If cells in an infant's brain are destroyed by chemicals, if connections between neurons fail to form or if false signals are sent to the developing reproductive organs by endocrine disrupters, nervous system or reproductive dysfunction may result (Bellinger et al., 1987; Needleman et al., 1990; Jacobson & Jacobson, 1996). The effects can persist throughout life.

Children have more years of future life and thus more time to develop diseases initiated by early exposure

Because children have more future years of life than most adults, they have more time to develop chronic diseases that may be triggered by early exposure. Many diseases caused by toxic agents in the environment require decades to develop. Many of those diseases, including cancer and

neurodegenerative diseases, are thought to arise through a series of changes within cells that require many years to evolve from initiation to actual manifestation of illness. Exposure to environmental agents early in life, including prenatal exposure, appears more likely to produce chronic disease than similar exposure encountered later (Gray et al., 1991; Ekblom et al., 1997; Landrigan et al., submitted). Thus, there are likely to be critical windows of exposure, even for these chronic diseases, that need to be further explored.

The incidence of several chronic diseases has been increasing among children in the United States. This new paediatric morbidity (Haggerty & Rothman, 1975) has become the main cause of illness and death among children in the United States. Increases in the rates of these diseases have raised the urgency of applying the precautionary principle to protect children from environmental toxins. Many diseases of great importance to children in the United States today have been shown, or at least suspected, to be caused or aggravated by chemicals in the environment. Examples include asthma, for which incidence and mortality have more than doubled in the past decade (United States Centers for Disease Control and Prevention, 1995a). These increases are particularly evident in urban localities. In New York and in other major cities, asthma has become the leading cause of admission of children to hospitals and the leading cause of school absenteeism (United States Centers for Disease Control and Prevention, 1995b). The increasing prevalence of asthma and the higher asthma morbidity among children in the United States, albeit still unexplained, suggest that, compared with adults, children are more likely to develop asthma and asthma exacerbation and/or be exposed to chemical or other factors that cause or trigger asthma episodes.

The reported incidence of childhood cancer has also increased substantially in the United States in the past two decades (Devesa et al., 1995). Although death rates have declined as a consequence of early detection and vastly improved treatment, data from the National Cancer Institute show that the reported incidence of acute lymphoblastic leukaemia increased

by 27% from 1973 to 1990, from 2.8 cases per 100 000 children to 3.5 per 100 000. Since 1990, the incidence of acute lymphoblastic leukaemia has declined in boys but continues to rise in girls (Robison et al., 1995). From 1973 to 1994, the incidence of brain cancer increased by 40%, with nearly equal increases in boys and girls (Schechter, 1999).

Neurodevelopmental disorders, including learning disabilities, dyslexia, mental retardation, attention deficit disorder and autism, are widespread and affect 5–10% of the 4 million babies born in the United States each year. Some clinical investigators have reported that prevalence is increasing, but existing data are not of sufficient quality to either sustain or refute that position (American Academy of Pediatrics, 2001). A report from the National Research Council (2000) concluded that 3% of developmental disabilities directly result from neurotoxic environmental exposure and that another 25% arise from the interplay of environmental factors and individual genetic susceptibility (environment was defined broadly in this report and included diet, alcohol, tobacco and other lifestyle factors as well as toxic chemicals).

Although the causes of most of these chronic diseases are not well understood, the lack of understanding has taken a significant economic toll on United States society. Environmental diseases among United States children now account for at least US\$ 54.9 billion per year or 2.8% of the nationwide costs of illness. This estimate is probably conservative, because it considered only the diseases for which environmental links are best understood and did not account for the pain, deterioration in quality of life and emotional distress that children, families and relatives suffer from these diseases (Landrigan et al., 2002).

Past success of the precautionary principle: the National Research Council report on pesticides in the diets of infants in children

The question of whether to regulate and at what level of certainty is perennial in environmental health. Advocates of

aggressive regulatory prevention point to John Snow's triumph in halting the London cholera epidemic by removing the handle of the Broad Street pump more than three decades before discovery of *Vibrio cholerae*, the epidemic's causative agent.

Over the past several decades, the United States has intermittently been highly precautionary in regulating chemicals and thus in protecting children's health. The United States banned the use of chlorofluorocarbons in aerosols in 1977, several years before several European countries interceded. Manufacture of polychlorinated biphenyls was banned in 1977 in the federal Toxic Substances Control Act. Diethylstilbestrol was outlawed as a growth promoter in beef as early as 1972, well before the European Union banned its use in 1977 (Gee et al., 2002). And the National Research Council (1993) report on *Pesticides in the diets of infants and children* represents the most profound success of the precautionary principle in protecting children from environmental risks to date. Its publication was a critical event in raising awareness about children's unique exposure and vulnerability and represents a paradigm for applying the precautionary principle in protecting children from environmental health hazards.

The National Research Council (1993) report recommended that risk assessment move beyond consideration of "average" exposure based primarily on adult characteristics to an approach that accounted for the heterogeneity of exposure and for potential differences in sensitivity at various life stages, especially during prenatal development, infancy and childhood. The report built on guidelines that the EPA (1986, 1991) had published for developmental toxicity risk assessment in 1986 and revised in 1991. It also built on other published documents such as *Similarities and differences between children and adults: implications for risk assessment* (Guzelian, Henry & Olin, 1992).

The National Research Council (1993) report noted that "children are not little adults" and called for the development

of new risk assessment methods that would incorporate better data on children's exposure to pesticides during fetal development, infancy and childhood. To "provide a more complete characterization of risk", the National Research Council Committee on Pesticides in the Diets of Infants and Children recommended the use of exposure distributions, recognizing that levels of exposure could differ by several orders of magnitude between children and adults. The report also recommended that exposure assessment be expanded to consider exposure to multiple chemicals with multiple routes of exposure.

The National Research Council Committee also recommended the development of pharmacokinetic models that could incorporate the unique physiological features of young developing humans. It recommended that bioassay protocols incorporate the relative contributions of exposure at different ages to lifetime risk. In addition, the Committee noted the lack of "appropriate toxicological tests for perinatal and childhood toxicity" that could be used to incorporate toxicity to these populations in risk assessment models.

Given the admitted uncertainty about childhood exposure and toxicity at different stages of development, the National Research Council Committee concluded that, "in the absence of data to the contrary, there should be a presumption of greater risk to infants and children". To validate this presumption, the Committee recommended that "the sensitivity of mature and immature individuals should be studied systematically to expand the current limited database as to relative sensitivity". To provide enhanced protection to children during vulnerable periods of early development, the National Research Council Committee recommended that a child-protective safety factor of up to 10-fold be considered in risk assessment "when there is evidence of developmental toxicity and when data from toxicity testing relative to children are incomplete".

The Committee noted that the EPA and United States Food and Drug Administration had historically divided the no-

observed-effect level obtained in animal test results by an uncertainty factor of 100-fold in establishing a reference dose for toxic effects other than cancer or heritable mutation. This uncertainty factor incorporates a 10-fold uncertainty to account for extrapolating data from animals to humans and a second 10-fold uncertainty to accommodate variation within the human population.

While the Committee acknowledged that the latter uncertainty factor “generally provides adequate protection for infants and children”, the Committee nevertheless recommended consideration of a third, child-protective safety factor in risk assessment. This safety factor was proposed to account for the great gaps in developmental toxicity testing data for many chemicals.

Following publication of the National Research Council report, most of its recommendations were incorporated into the Food Quality Protection Act of 1996, the principal federal statute on pesticides in the United States, which was passed by unanimous vote of both houses of the United States Congress. It requires that standards for agricultural pesticides be set at levels sufficiently strict to protect the health of infants and children. It directs the EPA to use an additional tenfold safety factor in assessing the risks to infants and children to take into account the potential for pre- and postnatal toxicity, particularly when the toxicology and exposure databases are judged to be incomplete. The statute authorizes the EPA to replace this default tenfold “Food Quality Protection Act safety factor” with a different factor only if, based on reliable data, the resulting margin would be adequate to protect infants and children. This requirement was intended by Congress to stimulate the generation of data on developmental toxicology and on exposure in early life. As of July 30, 1999, the Food Quality Protection Act child safety factor has been applied to 3 290 of 9 721 (34%) of pesticide tolerances evaluated by EPA (EPA, 1999a). A review of current reference doses and reference concentrations to which safety factors are applied to pesticides suggests that some pesticides should actually

receive a 30- to 50-fold child safety factor (Castorina & Woodruff, 2003).

The Food Quality Protection Act has also led to outright bans of certain uses of toxic pesticides that place children at risk. In 2000, after reviewing data on the fetal neurotoxicity of the commonly used organophosphate pesticide chlorpyrifos, EPA chose to ban residential use of this pesticide (EPA, 2000). Similarly, on August 2, 1999, EPA Administrator Carol Browner announced the voluntary cancellation of many of the most significant food crop uses of methyl parathion, in large part because of its developmental risk assessment under the Food Quality Protection Act (EPA, 1999b).

Recent epidemiological studies indicate that applying the precautionary principle is an effective intervention against exposure to toxic substances. Children who ingest solely food that is organically grown excrete one sixth as much urinary organophosphate metabolites as children who ingest foods grown with pesticides (Curl, Fenske & Elgethun, 2003).

A dangerous trend threatens to undermine the successful application of the precautionary principle in United States pesticide regulation. The industry has begun to conduct small studies in humans to assess the health effects of pesticides. The apparent motivation for these studies is to substitute for rigorous, larger-scale studies that can assess subtle health effects or health effects with a relatively long latency period. However, these studies raise significant ethical concerns and fail to meet the evidentiary standards approved for new pharmaceuticals by the United States Food and Drug Administration (Oleskey et al., 2004). Nevertheless, the United States National Academy of Sciences (2004) recently recommended that the EPA accept human testing studies provided that they have been reviewed by an appropriate review body, inform existing risk assessments and meet other ethical and scientific requirements. Debate on the ethics of human testing continues (Sass & Needleman, 2004).

Consequences of failure to apply the precautionary principle

A devastating example of the failure to apply the precautionary principle occurred in the regulation of benzene in the late 1970s and early 1980s. In 1978, the United States Occupational Safety and Health Administration reduced the standard for permissible exposure for benzene from 10 parts per million (ppm) to 1 ppm. Shortly thereafter, the Fifth Circuit Court of Appeals blocked this ruling, and in 1980, the Supreme Court overturned the regulation, citing insufficient evidence of benefit. As a result, until 1997, when the standard was lowered again, an estimated 9 600 United States workers were exposed to benzene at levels between 1 and 10 ppm, and an additional 370 were exposed at levels above 10 ppm. Between 30 and 490 excess deaths from leukaemia are anticipated to result from occupational exposure to benzene exceeding 1 ppm between 1978 and 1987, and additional deaths will likely occur from aplastic anaemia and lymphoma (Nicholson & Landrigan, 1989).

Early disease outbreaks of environmental origin in children have also failed to produce proactive response and regulation to protect children. The history of lead use in the United States provides a chilling reminder of the failure to use the precautionary principle. Lead poisoning in young children was first recognized in 1904 in Queensland, Australia, where a clinical and epidemiological investigation traced the source of an outbreak to the ingestion of lead-based paint by children playing on verandas (Gibson, 1904). This led to the banning of lead-based paint in many countries.

The removal of lead from gasoline has been indicated as a successful application of the precautionary principle. The argument is that this contributed dramatically to reducing the mean childhood blood lead level by 90% from 1976 to 1999 and produced economic benefits for each year's cohort of 3.8 million two-year-old children ranging from US\$ 110 billion to US\$ 319 billion (Grosse et al., 2002). However, although the success of this initiative should not be overlooked, the primary rationale

for removing lead from gasoline was to protect the catalytic converters installed in many new cars in 1975 to reduce auto air pollution emissions. Lead was not legally required to be eliminated from all gasoline until 1985, more than 50 years after the danger to children of tetraethyl lead in gasoline was recognized (EPA, 1985).

Other current environmental threats to children remain unheeded despite recognized public health epidemics that could have resulted in prudent prevention. A report from Minamata, Japan, in the 1960s described an epidemic of cerebral palsy, mental retardation and convulsions among children living in a fishing village on the Inland Sea. This epidemic was traced to ingestion of fish and shellfish contaminated with methylmercury. The source of this mercury was found to be a plastics factory that had discharged metallic mercury into the sediment on the floor of Minamata Bay. The mercury was transformed by microorganisms into methylmercury and then bioaccumulated as it moved up the marine food chain, eventually reaching children who ate fish and shellfish. The most devastating effects were seen among children exposed in utero (Harada, 1978).

Despite this public health lesson, mercury emissions from power plants also remain a significant environmental problem. The 1999–2000 National Health and Nutrition Examination Survey of the United States Centers for Disease Control and Prevention found that 8% of women of childbearing age in the United States had mercury levels in blood exceeding the EPA's reference dose of 5.8 $\mu\text{g/l}$ (Schober et al., 2003). Clearly, the evidence that supports the need for the precautionary principle is only increasing, and preventable chronic diseases in children will continue to increase in prevalence if it is not applied.

Conclusion

Opponents of the precautionary principle argue that it will stifle technological innovation and harm public health and the environment by diverting attention from known to speculative

environmental hazards (Graham, 2004). This concern must be addressed and resolute efforts to study the health effects of environmental chemicals must continue so that people can act with the most information possible.

Fundamentally, however, opponents' concerns are misguided and overstated. They miss the point that protecting the health of vulnerable populations, especially children, is the core mission of public health. They do not recognize that risk assessment and risk management, as currently practised, fail to provide this protection.

We argue that the current approach to risk assessment needs to be modified by applying the precautionary principle to protect children's health. Chemicals need to be presumed potentially toxic until proven safe; the current practice of releasing untested and potentially problematic chemicals to the environment to learn only years or decades later of their hazards cannot continue. The worst chemicals need to be replaced outright, as has happened intermittently in the past. Safety factors need to be inserted into the traditional risk assessment paradigm to protect children's health when the available data are insufficient to support a strictly mathematical approach to computing risk.

The spirit of the precautionary principle is to react proactively to significant environmental threats before they cause harm. Children deserve especially proactive implementation of the precautionary principle because of their unique vulnerability and patterns of exposure to environmental toxins. Although the United States has made significant strides in reducing the prevalence of lead poisoning among children, the public is learning ever more about the significant health effects of newer chemicals such as phthalates that have already been disseminated widely in the environment (Heindel et al., 1989; Gray et al., 2000). The lead epidemic may pale in comparison to the environmental epidemics of the future if regulators do not prudently apply the precautionary principle to protect the world's most valuable resource – children.

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9. The precautionary principle in environmental science²

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Introduction

There are few pressing social issues that depend as heavily on scientific information as do environmental problems. Most scientists and policy makers agree on the importance of science in environmental policy debates, even when they can agree on almost nothing else about the health of the ecosphere. Thus, environmental scientists play a key role in society's responses to environmental problems, and many of the studies performed by environmental scientists are intended ultimately to affect policy. The precautionary principle has been proposed as a new guideline in making environmental policy (O'Riordan & Cameron, 1994; Freestone, 1996). In this paper we examine the implications of the precautionary principle for environmental scientists. Specific objectives are to define the precautionary principle and illustrate it through three brief examples; identify aspects of conventional science that may inhibit precautionary policies; identify new directions for scientific research that would better inform precautionary policies; and promote dialogue among environmental scientists about the usefulness and potential applications of the precautionary principle.

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Definition of the precautionary principle

A 1998 consensus statement characterized the precautionary principle this way: “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” (Raffensperger & Tickner, 1999). The statement went on to list four central components of the principle: taking preventive action in the face of uncertainty; shifting the burden of proof to the proponents of an activity; exploring a wide range of alternatives to possibly harmful actions; and increasing public participation in decision making. The term “precautionary principle” came into English as a translation of the German word *Vorsorgeprinzip*. An alternative translation might have been “foresight principle,” which has the advantage of emphasizing anticipatory action—a positive, active idea rather than precaution, which to many sounds reactive and even negative. Although the principle has its roots in German environmental policy, over the past 20 years it has served as a central element in international environmental treaties addressing North Sea pollution, ozone-depleting chemicals, fisheries, climate change, and sustainable development (Raffensperger & Tickner, 1999). Precaution is one of the guiding principles of environmental laws in the European Union.

The precautionary principle in practice

Historical links

The precautionary principle encourages policies that protect human health and the environment in the face of uncertain risks. In this broad sense it is not a new concept, and some may object to giving it a new name, when similar ideas go by different names in other disciplines. For example, public health practitioners use the term *primary prevention* to mean much the same thing. The physician’s obligation to first do no harm is a precautionary approach to treating a sick person. The governments of several Scandinavian countries have made regulatory decisions about electromagnetic fields and other hazards using a concept called *prudent avoidance*, which

is also similar (WHO, 2001; Aasen et al., 1996). The term precautionary principle has the advantage that it provides an overarching framework that links environmental sciences and public health.

Motivating factors

The precautionary principle has arisen because of the perception that the pace of efforts to combat problems such as climate change, ecosystem degradation, and resource depletion is too slow and that environmental and health problems continue to grow more rapidly than society's ability to identify and correct them. In addition, the potential for catastrophic effects on global ecologic systems has weakened confidence in the abilities of environmental science and policy to identify and control hazards. There are also the apparent contradictions of our regulatory process: if the laws governing toxic chemical release are effective, then why are mercury levels in freshwater fish so high that pregnant women should not eat them (U.S. EPA, 1997; Schettler, 1997)? How is it possible that human breast milk may not meet U.S. Food and Drug Administration contaminant limits for baby food (Abadin, Hibbs & Pohl, 1997; Pohl & Hibbs, 1996)? The great complexity, uncertainty, and potential for catastrophe from global climate change are among the strongest motivators for those urging precaution in environmental policy. The earth warmed over the twentieth century by an estimated 0.6°C (Albritton et al., 2001). The trend was not uniform, though, and warming is occurring faster during the winter and at night (Easterling et al., 1997), and the winter warming is occurring faster at high latitudes than near the tropics (Houghton et al., 1996). For human populations, the rates of change and wide swings in weather are of chief concern, as ice core records indicate that increased climatic variability may be associated with rapid climate change events and changes in the ocean thermohaline circulation (Meyewski, personal communication). Together, warming and more extreme weather have begun to alter marine life and the weather patterns that affect infectious diseases, their vectors, and hosts. The unprecedented scale of this hazard justifies

reexamination of environmental monitoring systems and paradigms (Lubchenco, 1998).

Frustration with policy concerning toxic chemicals has also stimulated interest in the precautionary principle. The risk assessment process is perceived by a growing segment of the population as antagonistic to strong environmental protection and as excessively complex and full of hidden assumptions that have the effect of disenfranchising all but the experts from the decision-making process. Current U.S. environmental policy often seems to be more reactionary than precautionary, requiring a high degree of certainty of harm before preventive action is taken, and emphasizing the management of risks rather than their prevention. The precautionary principle, by calling for preventive action even when there is uncertainty, by placing the onus on those who create the hazard, and by emphasizing alternatives and democracy, is viewed by environmentalists as a way to shift the terms of the debate and stimulate change.

Points of opposition

A lively debate is now underway about the usefulness of the precautionary principle (Bishop, 2000; CEC, 2000; Holm & Harris, 1999; Stirling, 2000; Danish Environmental Protection Agency, 1998; Applegate, 2000). Perhaps the most frequently voiced criticisms are *a)* current regulatory procedures are already precautionary; for example, the safety factors used in risk assessments insure precaution; *b)* the precautionary principle is not scientifically sound because it advocates making decisions without adequate scientific justification; and *c)* if it were implemented, the precautionary principle would stifle innovation by requiring proof of safety before new technologies could be introduced. Each of these concerns has been addressed by proponents of the principle (Wynne, 1993; Ashford, 1999; Myers, 2000) and this article is not intended as a comprehensive response to critics. The objective instead is to discuss the implications of the precautionary principle for the work of environmental scientists.

Case illustrations

Cellular telephones in airplanes

When the flight attendant explains the safety procedures before takeoff, there is an instruction not to use various electronic devices during takeoff and landing and not to use cellular telephones any time during flight. There is some very limited (anecdotal) evidence that these devices may interfere with the essential navigational and control systems of the aircraft. In 1999, in response to inquiries about the necessity of this ban, the U.S. Federal Aviation Administration (FAA) commissioned a study to gather stronger evidence for or against the hypothesis that consumer electronic devices interfere with aircraft functions (McCarthy, McSweeney & Watrous, 2000). The study failed to find any evidence of this interference. Nevertheless, the FAA ruled that, in the absence of strong evidence of safety, the ban would continue in effect.

Most people agree that the inconvenience of not being able to talk on the phone in flight is offset by even a small risk of an airplane crash. This illustrates the first component of the principle: taking action in the face of uncertainty. The second aspect of precaution deals with burdens of proof, and here, too, there would probably be little controversy. Most would agree that those who would change the rule on cellular telephone use in flight should have the responsibility to show that the change will not cause unreasonable risk. But suppose concerns about portable electronic devices in airplanes had not been raised initially, and so airline passengers were currently using their cellular telephones in flight. Now suppose that a few isolated malfunctions occurred in the navigational systems of a small number of aircraft while cellular telephones were in use, and concerns were raised. Should cell phone use be banned? At that point there would be a quantifiable economic loss from ending the practice. It seems quite likely that implicitly or explicitly a cost–benefit analysis would be run, and to do this, it would be necessary to estimate the risk—something that would be, and is, very hard to do with any confidence. Some might call this approach more “science based,” but it would be a highly uncertain process, and one in

which the risks being evaluated might be very small, but the consequences potentially catastrophic. Fortunately, the way events have actually unfolded, it is not necessary to estimate the risk—precautionary action was taken. The availability of an economically viable alternative (in-flight telephones) may have made it easier to act in the absence of strong evidence, which highlights the potential for the precautionary principle to stimulate the search for safer technologies.

Pesticides in schools

Recently the Los Angeles Unified School District, the largest public school system in the United States, announced a new policy on the use of pesticides in schools (“Preferring the Least Harmful Way”, 2000). The policy states unambiguously that pesticides pose risks to the health of children and the environment, that they shall be used only after nonchemical methods have been considered, and that if there is a choice among pest control methods, the least harmful one shall be chosen. There is no mention of balancing risks and benefits, nor a list of banned substances. The precautionary principle is a long-term objective of the policy, according to its authors.

Critics worry that the precautionary principle will encourage technology choices based on fear and emotions, rather than on science. But another interpretation would be that the Los Angeles Unified School District is saying that all pesticides should be assumed to be hazardous, while acknowledging a great deal of uncertainty about exactly how hazardous.

The intention to prefer nonchemical methods and to choose the least toxic method encourages a search for alternatives, while at the same time not preventing the use of a toxic chemical if it is found to be necessary and irreplaceable. The new policy also requires consideration of the service or function that a pesticide provides. For example, a pesticide being used for aesthetic purposes may be determined to be less important than one that serves a hygienic function. The former may be more readily eliminated than the latter, if no alternative can be found.

Polyvinyl chloride toys

Polyvinyl chloride (PVC) is an extremely versatile material, made into thousands of products. By adding varying amounts of a chemical called a plasticizer, the pliability of PVC can be modified from hard and brittle to soft and almost spongy. There is evidence that several of the plasticizers, members of the phthalate chemical family, are reproductive toxicants in animals. They may also cause reproductive toxicity in humans, although this evidence is quite limited (Expert Panel Report, 2000; European Scientific Committee on Toxicity, Ecotoxicity, and the Environment, 2001; Tickner et al., 2001). Until 1999, many PVC plastic toys specifically designed to be sucked and chewed contained the plasticizer diisononyl phthalate. Many of the manufacturers of toys that formerly contained this chemical have now voluntarily stopped using this plasticizer, or in some instances completely phased out PVC in these toys, in response to consumer and government concerns about toy safety. But the evidence for human health risks is weak and uncertain. Producers of PVC products have argued that there is no evidence of harm from use of their products, given 40 years of use without apparent ill effects. There is a flaw in this reasoning, however, because the absence of evidence of harm is not the same thing as evidence of the absence of harm. Of course, absolute safety can never be proven. But a lengthy and costly risk assessment, followed by an equally lengthy and acrimonious risk management process would be the likely outcome of the present one-substance-at-a-time approach to chemicals policy.

The precautionary principle seeks to minimize the limitations of a risk assessment based regulatory policy by encouraging a search for alternatives whenever a potentially hazardous chemical is identified. If a clearly safer alternative exists, why accept even a small, highly uncertain risk? The Danish Environment Agency used just this logic in taking action to eliminate phthalates from toys (Seedorf, personal communication). They said, in essence, that there is exposure to these compounds, there is animal toxicity data, the exposure is to children who by definition are particularly

susceptible to many toxic substances, there are alternatives, and the product serves no necessary function. Considering all these factors, they concluded that the plasticizer should not be used in toys.

Limitations of conventional scientific methods

Environmental scientists study highly complex, poorly understood systems. Often the most informative experiments cannot be conducted for logistical or ethical reasons (there is only one Atlantic Ocean to study; potential carcinogens cannot be administered to humans in double-blind trials). At the same time, this work is of great interest to those who seek to balance economic growth and environmental protection. In this complicated and contested terrain, it is useful to examine the methodologies of science and to consider ways that, without compromising integrity and objectivity, research can be more or less helpful to those who would act with precaution. It would, for example, be useful to policy makers if scientists were more explicit about the limits of knowledge and about the nature and amount of uncertainty in research findings. Presented below are examples of the ways that science is currently conducted that may make it more difficult to set precautionary policies. There may be alternatives to these methods, well within the bounds of good practice, that would be more helpful to policy makers faced with high-stakes decisions and great scientific uncertainty.

Hypothesis formulation

Einstein said that the theory decides what can be observed, and at the more practical level, the formulation of specific research hypotheses determines to a large degree the sorts of results that can be found. Where does the particular formulation of a hypothesis come from? Often the hypothesis is formulated in a way that is feasible to test with the time and resources available. There is also a tendency for researchers to refine understanding of old problems rather than risk investigating new ones (Kuller, 1999). Greater and greater levels of detail are sought about well-defined problems, rather than the higher stakes enterprise of searching for entirely new

phenomena. For example, we refine understanding of the mechanisms of toxicity of asbestos, lead, and polychlorinated biphenyls, rather than evaluating effects of other, less well-studied toxicants. Funding agencies and skeptical peer reviewers reinforce this tendency by favoring tightly focused proposals that repeat or incrementally build upon work in well established areas.

Emphasis on independent effects, not interactions

There is a tendency to assume that the mechanisms underlying the phenomena being studied are driven primarily by the independent actions of a few causal factors. If they interact, this is assumed to be of secondary importance. This implicitly assumes that things are not connected and leads to an atomized worldview. In reality, complex biological systems such as ecosystems, human populations, or individual physiology are composed of feedback loops and other interactions which make cause–effect relationships far from direct or linear. But many times the effects of hypothesized causal factors are considered in research to be decomposable into additive components that are measured individually. For example, when studying a mixture of pollutants, the emphasis is on identifying which component of the mixture is problematic. Interactions are difficult to study, but this should be seen as a challenge to develop more sensitive and complex methods, rather than as an inherent limitation of science.

Narrow definition of uncertainty

The formal evaluation of error or uncertainty in many environmental science papers is limited to a presentation of p values or confidence intervals for the main results. Beyond this, there may be a qualitative examination of limitations of the findings, which is relegated to the discussion section at the end of the paper. The standard p -values and confidence intervals indicate the magnitude of potential error in the statistical parameter estimates due strictly to sampling variability. But in observational studies of complex, poorly understood systems, this may be the least important source of uncertainty. Potentially more important are errors in the

independent variables, errors arising from choice of the wrong form for the model(s) used to analyze and interpret the data, and biases from problems in the conduct of the study.

For example, a study of the effects of an environmental contaminant on reproductive success in fish would typically report the amount of sampling error around the final estimate of the degree of association found between the contaminant and the measure of reproductive behavior. But this would typically not take into consideration the error in measuring the levels of the contaminant in the fish or in the environment and would not investigate the sensitivity of the findings to the choice of statistical models used to link exposure with reproductive outcome. It is sometimes argued that scientists are trained to read papers critically and that they are able to factor in these other sources of uncertainty in their evaluation of a study. But applied scientists are also communicating to nonscientists who may mistakenly take the limited characterization of sampling error as the best estimate of all the uncertainty.

Setting Type I and Type II error rates

Errors due to sampling variability are routinely quantified. However, standard practice has led to a conservatism that perhaps hinders precautionary action. When a scientific investigation is designed to test a hypothesis, there are two kinds of errors that one seeks to minimize. A Type I error is the mistake of concluding that a phenomenon or association exists when in truth it does not. (Technically, the Type I error is rejecting the null hypothesis when it is really true. The paraphrasing above, while valiantly railed against by statistics teachers everywhere, is the way it is thought of in everyday practice.) By convention, Type I (or alpha) errors are guarded against by setting that error rate low, usually at 5%. In other words, the finding must be so strong that there is less than a 5% probability that this result would have been seen by chance alone in a world in which no such phenomenon actually exists. In this case the result is called statistically significant (with the clear implication that one is supposed to believe it).

The Type II error, failing to detect something that actually does exist, is, by convention, often set at 20% (although practical limitations of sample size often result in a substantially higher or lower Type II error). Twenty percent of the time, a real phenomenon will be missed because the data were not strong enough to convincingly demonstrate its existence. There is an implicit bias here: the test is set up to be more cautious about falsely detecting something than about failing to detect something. Should Type I and Type II error rates be set explicitly and *a priori*, depending on the purposes that the study is meant to serve? Bayesian statistical methods promise a way out of these conundrums by shifting the focus from formal testing to calculating the weight of evidence provided by a particular study and the degree to which this study should shift *a priori* beliefs. At present, Bayesian methods are little used in practice, but research to make them more accessible and practical is now under way (Malakoff, 1999; Carlin and Louis, 1996; Greenland & Poole, 1994).

Type III errors

A Type III error occurs when one provides an accurate answer to the wrong problem (Schwartz & Carpenter, 1999). The cliché about looking under the street light for the keys lost down the block (because the light is better there) comes to mind to illustrate this common problem. To some degree, this is another aspect of hypothesis formulation discussed above. Citizen groups who ask a scientist for help with a particular environmental concern frequently experience the consequence of Type III errors. The citizens have a broad concern about, for example, potential health effects of a power plant in the neighborhood. The scientist hears the concern, and translates it into a problem that he or she is able to solve with the tools at hand, such as, do the power plant emissions exceed current health standards? This translation almost inevitably narrows the focus to something manageable and solvable. But often the citizens are frustrated with the results because scientists did not adequately address the initial concerns. On the other hand, the scientist is puzzled or, worse, concludes that the citizens are “antiscience.”

Disciplinary divisions

The citizens group's concerns about the power plant would probably be better addressed by an interdisciplinary investigation, using a wide variety of different methods and looking for an integrated understanding of the facility's impacts. Traditional boundaries between academic disciplines make it difficult to bring together the broadest possible set of research tools; combining for example quantitative and qualitative methods.

Scientific methods to inform precautionary policy

As noted at the beginning of this paper, science plays a critical role in environmental policy by providing insights into the normal functioning of natural systems and the ways they are disrupted by technologies and other human activities. Environmental scientists use a wide variety of methods, and these are to a large degree determined by the problem at hand. In some fields, prediction is an essential part of scientific proof. In others, it is useless or impractical. The simple accumulation of confirming cases is of no use in fields that hold to a high standard of mathematical proof, and in some disciplines controlled experiments are essential. But in many environmental sciences where observational studies are the rule, experiments are often infeasible or unethical, and it is impractical to wait to see if predictions are borne out. Other types of evidence are used, and usually sufficient proof for action comes from the accumulation of plausible inference from independent lines of work. For instance, environmental causes of cancer may be identified from the geographic distributions of cancers; time trends in cancer frequency; the occurrence of cancers in highly exposed working populations; animal experiments; and experimental knowledge of chemical pathways of cancer induction. And once it is demonstrated that a particular molecule is carcinogenic, similar molecules are at least suspect. Any one line of argument is imperfect, and fault can be found with the details of most separate methods. It is the preponderance of evidence that finally prevails. It is never easy to determine the moment in this process when there is sufficient evidence to act as if a causal

connection exists, but scientists can and should play an important role in this decision, as they are the ones who know the data and the methods best. A shift to more precautionary policies creates opportunities and challenges for scientists to think differently about the way they conduct studies and communicate results. The following paragraphs briefly summarize some of the positive implications that such a policy shift might have for the conduct of science.

What is studied

There is a great need for better methods to study whole systems and the interactions of various causal factors. The cumulative and interactive effects of multiple insults on an organism or ecosystem are very difficult to study. There are often many levels of a system (individuals, families, communities, nations), and hazards often exert effects at multiple levels. Current methods in many disciplines are not well suited to such investigations. As noted above, multidisciplinary teams will be more likely to find new ways to frame hypotheses that lead to insights not possible from narrow disciplinary viewpoints. The recent recognition of the problem of endocrine disruption provides an example. A review of many different types of evidence on the effects of persistent pollutants on wildlife in the Great Lakes led to the hypothesis that a common mechanism of action might be causing a variety of reproductive and developmental effects (Colborn & Clement, 1992; Krimsky, 1999). Because of the fragmentation of scientific disciplines, no single researcher was able to develop a coherent hypothesis. An interdisciplinary conference (Colborn & Clement, 1992) provided the opportunity for many different fields to meet and share insights. The conference organizers summarized the outcome (Colborn & Clement, 1992): “so shocking was this revelation [about the widespread observation of endocrine disruption in wildlife] that no scientist could have expressed the idea using only the data from his or her discipline alone without losing the respect of his or her peers.”

Research methods

Uncertainty is a positive aspect of knowledge because it clarifies what is known and unknown and thus stimulates further investigation. But there is also a strong desire on the part of scientists to be precise. This may result from a confusion of uncertainty of information with quality of information; but the two concepts are distinct (Funtowicz & Ravetz, 1990). It is possible to produce high-quality information about greatly uncertain phenomena. Most scientists are aware that their p -values and confidence intervals do not fully capture all of the likely error in their results, but standard methods do not exist for characterizing other aspects of uncertainty. There is a great need for research to find ways to characterize, express, and communicate uncertainty. Scientists develop intuition or professional judgment about the strength of a particular result. The Bayesian view of statistical inference, an increasingly popular alternative to standard frequentist methods, acknowledges that we have beliefs about the phenomena under study and seeks to formalize the role these play in the way we view our data (Carlin & Louis, 1996). The role of data, according to this perspective, is to shift our *a priori* beliefs about the phenomena under study. Strong results may shift beliefs a lot, producing a posterior probability that may be far from the prior probability that the researcher had assigned to the hypothesis before conducting the research. But weak data will have little impact, leaving posteriors close to priors.

There is increasing awareness that Bayesian statistical methods correspond more closely to common approaches to logical inference in everyday life. Methods development work is still needed in most fields, however, before Bayesian statistics can be routinely applied.

Uncertainties that derive from the choice of research methods and mathematical models should also be more fully investigated and discussed. Formal sensitivity analyses in which the investigator assesses the degree to which results are changed by using different assumptions or analytic methods

should become standard practice (Greenland, 1996). Current methods seldom encourage a search for patterns within noisy data and “clusters of clusters” of similar effects in different species.

Conservation medicine is a new academic initiative that links human and animal health with ecosystem health and global change (Tufts Center for Conservation Medicine, 1999). It begins from the premise that the health of ecosystems is directly related to the health of species, including humans. The initiative arose from a growing understanding that human impacts on ecosystems were multiple and integrated. Conservation medicine uses interdisciplinary teams of veterinary and medical health professionals to develop a greater understanding of the ecological context of health and advance biodiversity conservation and ecosystem health.

If society chooses to act with incomplete information, it must be acknowledged that one kind of risk is being accepted to avoid another. One risk being accepted is that the policy choice may have been wrong. Fortunately, the effects of a policy can often be evaluated for beneficial or detrimental unintended consequences. Thus a strong environmental monitoring program and formal evaluations of the interventions or controls are essential parts of a policy of precaution (Goldstein, 1999). Despite the need for more and better systems research, it remains true that much useful information is learned by taking a system apart and testing its components. The development of new approaches should supplement current scientific methods, not replace them. There is also an important role for those who can synthesize the results of the work of many disparate disciplines to reach insights not possible by the individual researchers. This has been called “joining edge” research (as opposed to “cutting edge”).

Conclusions and recommendations

It is important to clearly distinguish between the development of scientific information about an issue and the setting of policy, but in practice, there is not always an unambiguous

demarcation. Policy makers set agendas that determine the questions asked of scientists; scientists formulate hypotheses in ways limited by their tools and their imaginations; thus, the information they provide to the policy makers is limited and to a degree socially determined.

There is a complicated feedback relation between the discoveries of science and the setting of policy. While maintaining their objectivity and focus on understanding the world, environmental scientists should be aware of the policy uses of their work and of their social responsibility to do science that protects human health and the environment (Lubchenco, 1998). The precautionary principle highlights this tight, problematic linkage between science and policy, which can be summarized in the following seven points:

1. Scientific studies can tell us something about the costs, risks, and benefits of a proposed action, but there will always be value judgments that require political decisions.
2. The scientific data used for making policy will nearly always be limited by uncertainty. Even the best theory and data will leave much that is not known about estimates of risks, benefits, or costs.
3. In conducting their research, scientists must make assumptions, choices, and inferences based on professional judgment and standard practices, that if not known by the public or policy makers, may make scientific results appear to be more certain and less value laden than is warranted.
4. Although there are some situations in which risks clearly exceed benefits no matter whose values are being considered, there is usually a large gray area in which science alone cannot (and should not) be used to decide policy.
5. In these gray areas, status quo activities that potentially threaten human and environmental health are often allowed to continue because the norms of traditional science demand high confidence in order to reject null hypotheses, and so detect harmful effects.

6. This scientific conservatism is often interpreted as favoring the promoters of a potentially harmful technology or activity when the science does not produce overwhelming evidence of harm.
7. The precautionary principle, then, is meant to ensure that the public good is represented in all decisions made under scientific uncertainty. When there is substantial scientific uncertainty about the risks and benefits of a proposed activity, policy decisions should be made in a way that errs on the side of caution with respect to the environment and the health of the public.

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10. The precautionary principle: a central and eastern European perspective³

Janos Zlinszky

Introduction

The purpose of governments is to secure the free exercise of people's inalienable rights, such as the right to life, liberty and the pursuit of happiness (such as enshrined in the Declaration of Independence of the United States). Lengthy explanation is not required to recognize that life is connected to health. So is the pursuit of happiness, as soon as health is understood – as it should be – as complete physical, mental and social well-being in accordance with the WHO Constitution. In addition, people and communities crippled by health problems will have little freedom to actively pursue social or cultural betterment. Risks to human health are risks to the common good.⁴

Governments exist to help communities and individuals to avoid – or at best manage – threats to their common good and to increase their chances of improving their lot. In this endeavour, government has to navigate well-known straits: it should seek options for solutions; it should assess the extent and nature of risks associated with the options available for directions and measures to be taken; it should make decisions

³ Paper based on the presentation, *The Precautionary Principle: A CEE Perspective*. Presented at the WHO Meeting on Precautionary Policies and Health, Paris France September 12-13, 2003.

Paper based on an address with the same title, given at the workshop September 2003, Paris.

⁴An ecologist considers most of these risks environmental in the sense that they originate from the environment of the individual. This is especially true since the term environment can be defined as the complete set of stimuli that will provoke physiological or psychological reaction.

and act (or refrain from action); and then it should monitor and evaluate the consequences of its behaviour, thus improving the chances of success for the next cycle. Intensive communication with and active participation of those governed is necessary throughout. The pursuit of sustainable development lifts this process from a time scale of day-to-day or year-to-year to the scale of whole generations.

In an optimum world, good governance ought to be based on a solid knowledge of the context of decision-making: the ecological, social and economic status quo, a vision for the future and the framework conditions for change. Uncertainty related to this necessary knowledge is a problem in its own right in all aspects of governance. Changes at the personal or community level – regarding both the composition of governments and processes of governance – should (ideally) be incremental: small steps. The evolution of personal and community behaviour should be guided by two needs: the advancing towards the goals, that is, the “ideal” position of the community, while reacting to eventual changes in the environment. In other words, governance has proactive and reactive sides (I want to act, for I want a change; and I have to act, for a change happened “to me”). Information and tools for this evolution are provided by research and development activities. Keeping the community of the decision-makers and leaders up to date with knowledge is a necessary prerequisite for proactive governance and is essential for preventive management of problems.

In the life of any community, however, there can be cases, situations and even periods of time in which knowledge on which to base policy decisions is lacking. Facing new technologies or situations, decision-makers may lack the usual familiarity with the situation or the likely consequences of their decisions. Time pressure, whether real or perceived, often prevents policy-makers from carrying out the research they would need to make a fully informed decision. Such situations require a precautionary approach.

This chapter discusses the needs and possibilities for applying the precautionary principle in governance – permits, policy-making, legislation and enforcement – in the countries in transition in the eastern part of the European Region of WHO at present and for the foreseeable future. These thoughts are offered from the perspective of central and eastern Europe.⁵

The institutional experience of my points stems largely from the experience of the Regional Environmental Center for Central and Eastern Europe (REC) (<http://www.rec.org>, accessed 17 May 2004). Since 1991, the REC has worked to assist the economic and political transition in central and eastern Europe. An independent international organization supported by 27 governments and the European Commission, the REC has been an international facilitator, mediator and enabling institution for environmental stakeholders in and beyond the 16 countries hosting REC offices, including the latest one in Turkey. The institutional memory of the REC is based on impressions and experiences from central Europe to central Asia, from the Baltics to the Balkans, of colleagues from literally dozens of different countries in eastern and western Europe.

These experiences and observations demonstrate that the precautionary principle is a tool of special importance for the civil servants in the eastern part of the European Region of WHO. In this rich yet fragile natural and cultural environment, a socioeconomic experiment unprecedented in scale and speed has been progressing since the early 1990s and is likely to continue for some time. The many aspects of this experiment called the transition together inevitably create a great degree of uncertainty in decision-making. Responsible

⁵This chapter defines central and eastern Europe as Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Serbia and Montenegro, Slovakia, Slovenia and The former Yugoslav Republic of Macedonia.

management of these changes is nearly impossible without a precautionary approach to many of the risks involved.

Countries in transition: resources and vulnerabilities

Countries in transition are vulnerable: they have unique social, cultural, historical and ecological treasures, and these are fragile. The last intact wilderness ecosystems of the European continent are in this region. Intact wilderness means areas that measure hundreds of thousands of hectares, have had little economic activity in the past century and would therefore qualify as the “factories” of evolution in Europe and the temperate and Arctic zone of the Northern Hemisphere in general. In the European Union, the density and the economic activity of the population ended such areas long ago. The natural capital of central and eastern Europe includes many other areas of special scientific interest or natural beauty as well, or those harbouring many endangered species and ecosystems – similar to some counterparts in western Europe but altogether featuring a considerably higher quantity, density and diversity of wildlife than those in the more developed parts of Europe.

The natural and social capital of these countries is also still rich. By European standards, the countries in transition have many indigenous nations and communities – communities that have lived in the same area for many centuries, even millennia, still maintaining an extensive hunting and gathering or agricultural way of life that is highly adapted to their natural environment. Both intact nature and the embedded intact human communities are at great risk from economic development pressure and technical civilization. Without decisive protection, their days are numbered.

Central and eastern Europe in particular, and the countries in transition in general, also have a legacy of a unique and diverse built environment. Buildings and townscapes – including industrial monuments – of great architectural value of the pre-communist period are still found everywhere: very often derelict or in poor repair, but sometimes in good

condition. These ailing areas awaiting repair could become attraction centres for settlements and wider communities but are currently threatened by the trend of the funds flowing into greenfield investments (new industrial parks and residential areas), leaving old buildings with the prospect of demolition rather than rejuvenation.

Last but not least, many communities of central and eastern Europe still retain aspects of a disappearing lifestyle, with different consumption patterns, personal value systems and networks of social ties from what are experienced in the consumer society. Sustainability and health also requires fulfilling people's non-material needs, a reality the rich North seems increasingly to forget. Changes in lifestyle and habits may add to individual comfort at the expense of the quality of the commons – such as changing the modality and/or ownership of local and long-distance transport. In many respects, the way of life of individuals and communities in countries in transition is still more sustainable and sometimes healthier than the new way of life that is being marketed to them.

The challenges of rapid change

The transition of central and eastern Europe and the entire eastern part of the WHO European Region must move on several parallel tracks. The transition from oligarchy and autocracy to democracy, transition from a centrally planned economy to a free (and international) market economy, joining global international policy coordination processes, and embarking on sustainable development were processes launched consecutively but must now be carried out simultaneously. The international community previously had the opportunity to witness countries embarking on one or another of these transitions as a single issue (democratization, establishment of a market, emerging from international isolation, etc.). Patience and perseverance brought many successes; other transitions such as that toward sustainable development seem to be still a nut too hard to crack even for the most industrialized countries. No doubt, the achievements

of multidimensional transition of the eastern part of the WHO European Region in the past 14 years have been unprecedented. So are the tasks still lying ahead – creating the danger that policy-makers' attention will be split among too many competing agendas and dimensions.

Thus, the countries in transition are also vulnerable on another account: their civil service, politicians and communities face too many demands simultaneously at any given time. Change has been rapid and has occurred in nearly all aspects of life: the values for which to strive, the institutions to which to turn, the ownership patterns to respect, the rules to obey, the players, stakeholders and partners with which to work, the processes to follow, the goods available and social and employment status have all become uncertain and prone to change. At this speed, change management is next to impossible: there are simply too many variables, too many unknown factors and too little time for consideration. In such a decision-making environment, calculating, modelling, simulating and planning for sound decisions at any level is very difficult, be it personal, community, national or international.

Environment and health in countries in transition

Mutatis, mutandis: what was true in the general, national context about the multifaceted character of pressures and demands is also true for individual policy fields such as environment and health. Here, too, many needs, old and new, have to be dealt with at the same time.

Many environmental problems inherited from the past still present complex challenges. Environmental hot-spots, time bombs of past pollution, are a particular problem in the eastern part of the WHO European Region. Some of these polluted sites are well known and labelled and priorities have been set and queues made for pollution containment, if not yet abatement. Sometimes whole towns or vast areas of the countryside are thus affected. Other hot-spots are stumbled upon by chance during building activities or demolition

projects. Even without hidden, dangerous deposits, the mere dismantling, dumping and disposing of old materials presents health hazards. Sloppy record-keeping and poor law enforcement, let alone inadequate building standards, all contributed to a situation in which, more often than not, new developers do not know which materials to prepare for at a given site. Radioactive and hazardous waste can be expected from energy, mining, industry, agriculture and even hospital or office buildings. In this context, it is no wonder that brownfield investing is problematic.

In addition to the problems from the past, the material streams arising from new activities also pose dangers. The import, production and release of new hazardous materials requires strict monitoring and control. Both central and eastern Europe and the Commonwealth of Independent States countries find it difficult to avoid importing outdated technologies and materials from some of the more developed countries in the Organisation for Economic Co-operation and Development. In addition to receiving materials and technologies with known risks, the countries in transition are also in danger of becoming an experimental area for new technologies, from mobile telecommunication to genetically modified organisms, from new chemicals to new waste-disposal methods.

The new economic possibilities and the opening up of resources in eastern Europe for the G7 industrial countries and other trading partners often means unsustainable or harmful pressures on ecosystems with renewable (such as forests) or nonrenewable (such as oil and gas) reserves. Large ecosystems are being destroyed at an alarming pace and scale, which will have long-term effects on the environmental commons such as water availability and quality, air quality, climate and biodiversity (including soil availability and fertility). Some of these risks can only be brought into the decision-making process by allowing time and means for complex analysis and would likely indicate effects on an intergenerational time scale.

These considerations are but a reminder of well-known pressures and risks, listed with the intention of illustrating the complexity of problems faced by every area of government.

Resource limitations

Managing the social, health and environmental governance aspects of a multidimensional transition process requires adequate means and well-prepared human resources. But for the countries in transition, the money, infrastructure and human resources required to address these challenges are all in short supply.

A great majority of these countries were left with heavy foreign debts as they made the transition out of communism. The incoming democratic governments had little if any ability to alleviate this burden; the foreign debt of most of the transition countries has grown rather than decreased in the past 14 years. Generous bilateral and multilateral financial and technical assistance programmes were launched and are still in place in many countries. But this international assistance is dwarfed by the scale of the problems to be tackled. For example, of all the environment protection investment undertaken during the transition in central and eastern Europe, only about 5% was supported by international donors;⁶ money for the rest had to be found at home.

After more than a decade of considerable effort and progress, there are still substantial monetary needs. For example, the infrastructure for both health care and environment protection badly needs further repair, restoration, upgrading and extension. At present, laboratories at universities and government agencies are too few and often ill-equipped;

⁶International assistance has had some important side effects. In particular, the strings attached to western funding (requirements concerning application, evaluation, management and reporting procedures) helped to create new skills and standards in the recipient countries. Transparency and opportunities for public participation are two notable areas in which this influence has been felt.

underfunding usually prevents the available scientific instruments from being fully used.

The most important resource for governance tasks is human resources. The quality of human capital in central and eastern Europe is enviable concerning science, engineering, philosophy and art. The high quality of higher education in central and eastern Europe is widely acknowledged. But most of the government skills that are readily available in the bureaucracy were originally geared for highly centralized planning and management. Thus, those responsible for managing the enormous changes occurring at every level of society must simultaneously learn new skills themselves. They must learn to change the most basic attitudes and instincts that they learned under the previous system, and to pass on to younger colleagues something they themselves were not taught.

When facing their counterparts in other countries or the technocrats of multinational firms, even the best civil servants of the countries in transition are at a disadvantage. Coping simultaneously with demands and advice to cut down the size of the civil service, adopt and comply with new regulations, learn new languages, inform and involve the public, become faster and more accessible and participate in training is very difficult. The civil service, if underpaid, understaffed, ill-equipped and overloaded, will hardly be well positioned for carrying out sound, balanced, informed, participatory (and therefore time-consuming!) decision-making processes.

Addressing environment and health in countries in transition: a rationale for precaution

Transition may be a suitable term to indicate most of the aspects of the social, political and economic processes taking place in central and eastern Europe; yet it can be misleading when the situation and tasks of environment and health authorities are contemplated. Transition would indicate that something from the past is left behind, in exchange for something new. Alas, nothing could be further from the truth

concerning the demands on authorities responsible for public health or environment protection. As indicated earlier, the legacy of the past is all too present; it cannot be left behind but presents urgent problems to solve. At the same time, approaches to address the new realities – the very status to which the transition should lead – have to be planned (optimally) or simply tried.

Authorities are expected to discover and map problem areas, be they in the area of pollution or disease; the pre-abatement status quo has to be reliably established if progress in alleviation and restoration programmes is to be measured with any degree of accuracy. Risks such as harmful emissions need to be reliably monitored, and the trends in any changes need to be tracked. New (or simply hitherto uninvestigated) materials, methods, standards must be tested. Linking environment and health data and identifying coincidences and causal links requires sophisticated data management and statistical processing.

All these activities of monitoring, measurement, data analysis and interpretation have to be carried out – in principle – with substantial independence, accuracy and speed, achieving a high level of efficiency while minimizing costs.

Such analysis and interpretation would establish the scientific basis for the governance work of the environment and health authorities. This is the basis on which policy-making, granting permits, communication and enforcement is supposed to rest. In these fields of governance, too, demands on and expectations of decision-makers abound.

A full review of old policies is underway with regard to new requirements (such as European Union approximation) and framework conditions (such as democratic rules and new institutional partners). New types of coordination have been introduced before policies are finalized: international coordination abroad and public participation at home, both of which require a certain degree of transparency of policy development. The main task of the new authorities has

remained to reduce the level, number and diversity of health risks posed by environmental conditions. The credibility of the improved policies and the new, democratic authorities can only be established through consistent, reliable enforcement; all these must occur while focusing on the moving target of improving standards and services as suggested by the west, especially European Union countries.

All this is easier said than done: skills are mostly gained on the job, and practice starts at the deep end. As discussed above, the means and tools are modest and the time pressure for quick decisions grows. Channels of communication for policy development have yet to be established or widened in relation to both the different sectors of government and the different interest groups of society. Training for personnel of public institutions as well as their partners in civil society is an essential prerequisite for the necessary capacity-building. Nevertheless, a vicious circle is common in which the available number of civil servants is so low and pressure so high that few or none can be freed to work on increasing staff capacity. The continuing education of high-level, well-trained civil servants with good language skills is especially problematic because these people are not available for training. They are simply too busy.

Besides the dwindling personnel of authorities, other human factors drain the basis for sound decision-making. Old attitudes such as the deep-rooted, instinctive mistrust between the governing and the governed (“us and them”) survive, especially because both sides are still used to public authorities behaving in an authoritative rather than service-oriented manner toward the public. When decisions are not thoroughly and publicly justified and explained, they are arrived at more quickly but are more likely to be opposed. However authoritative the civil “service” may seem to be to the public, in central and eastern Europe and beyond, they live in a constant state of uncertainty because of the lack of job security. Especially for the higher-ranking civil servants, political polarization within the civil service has resulted in sweeping replacements of staff after every change of

government. In this climate, compliance with the expectations of supervisors – or indeed powerful partners from the business sector – would overrule the duty of conducting a well-based, broad, investigative, cautious, participatory decision-making process when, for example, permitting investment or imports.

Thus, a climate of uncertainty has been the rule rather than the exception in political and administrative bodies in countries in central and eastern Europe and other regions in transition. The difficulty in achieving certainty when evaluating policy alternatives – or facing up to the lack of alternatives – is the cumulative result of many processes and conditions that reinforce one another.

Yet these decisions incrementally determine the fate of precious and often unique resources and the dignity, health and well-being of communities. Harm to humans and their natural and cultural environments is even more difficult to heal than economic or technical damage. Ultimately, the governance of the health and environmental aspects of the transition process will reflect back – for better or worse – on the political evaluation of the whole transition towards the “western” model of democracy and market economy.⁷

Conclusion

In the countries of transition, the present “size” (workload) and “weight” (level of risk involved) of tasks to be undertaken are enormous, while the financial, technical, regulatory and human means of the responsible institutions are limited. As a result, these institutions cannot achieve the high degree of certainty required for the common good of present and future generations within the time frame given for decision-making

⁷The political history of the transition already clearly demonstrates how the price paid by the individual citizen in exchange for macroeconomic improvements contributes to the widening frustration with political formations and processes that are perceived to advocate for or require these changes.

processes. Additional means are needed to break out of this vicious circle. Introducing a clear policy and regulatory framework for applying the precautionary principle in the face of uncertainty is an important possibility that could and would greatly improve the outcomes of the transition process in Europe.

The civil service of the health and environment sector of the transition countries can benefit particularly from this new tool of governance. The availability of the precautionary approach as an alternative process for decision-making would assist public health efforts and favour a more cautious approach in handling natural and cultural assets. As a result, both short-term and long-term risks from trade and investment would decrease, and sustainability would be enhanced.

The benefits of applying the precautionary principle widely would be multidimensional, with many positive collateral effects. When facing scientific uncertainty, the wide implementation of the precautionary approach would contribute to increasing the research and innovation capacity of the eastern part of the WHO European Region. Part of the investment supporting the increase of capacity would come from the private sector, thus shifting away the financial burden from the already overloaded taxpayer and the heavily indebted state. The shift would support capacity-building through education and training and create jobs in the education, health and environment sectors.

Experience gained from the wide application of the precautionary approach is likely to spill over and influence similar situations of decision-making in which the uncertainty is not directly derived from the lack of scientific proof. Equipped with reliable audits and decision alternatives, authorities would more readily engage in multi-stakeholder dialogues for purposes of visioning, planning and decision-making about changes, whether in the areas of granting permits, investing or regulating. This, in turn, would increase public confidence in the authorities and help avoid the delays that result from simple distrust (a kind of “uncertainty” very

typical at present); it would also help to address the current demand for more built-in checkpoints for public control.

Creating the room for precaution is simply evoking a very basic European tradition, the ultimate standard for care and responsibility – that of the *bonus pater familias*, the good father of the family. At the personal level, we can admit that we all know and apply this approach when our decisions affect our loved ones, those for whom we are directly responsible. The demand for a precautionary approach in politics has been – in principle, on paper – a cornerstone of the environment and health policy of many European countries for decades, both inside and outside the European Union. From a central and eastern European perspective, it would be wise and fair to allow governments struggling with the present historical transition to equip themselves with this tool, to use it for the benefit of present and future generations. The sooner this occurs, the better.

References

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11. Implementing precaution: assessment and application tools for health and environmental decision-making

Andrew Stirling & Joel A. Tickner

Current difficulties in the precaution debate

On both the national and the international stage, few current policy issues are as topical in their profile, controversial in their nature or pervasive in their implications as the precautionary principle. Under these circumstances, it is understandable that discussions should suffer from a certain amount of expedient ambiguity and rhetorical smoke. Nevertheless, amid the confusion, some substantive difficulties are quite readily diagnosed and addressed.

Firstly, demarcating the scope and significance of the precautionary principle is important. Much of the policy discussion over application of the precautionary principle centres around what threshold of information, assessment or uncertainty must be met before the principle is invoked. This discussion is based on the assumption that the precautionary principle is primarily reactive rather than proactive. Although the precautionary principle needs to be applied to effectively identify and control potential harm, the value of precaution can be seen in a broader context. Indeed, in its original formulations, the *Vorsorgeprinzip* was a principle for taking the future into account – a principle that would drive comprehensive measures to forestall environmental harm and stimulate innovation in environmental technologies and economic development. This broader planning-focused notion of precaution has been explicitly linked to the general economic and environmental goals of the state (Boehmer-Christiansen, 1994; Raffensperger & Tickner, 1999). Secondly, taking a proactive and broader approach to precaution requires developing tools for scientific assessment and the appraisal of policy options.

This chapter outlines the basic elements in a framework for applying precaution and examples of decision-making and regulatory frameworks and concrete tools for applying precaution. We conclude that, without clear yet flexible frameworks for applying the precautionary principle, the full value of the principle will not be achieved in stimulating more health-protective and forward-looking decisions under uncertainty.

Elements of a precautionary decision-making framework

Any effective approach to implementing precaution in decision-making processes must satisfy several practical policy criteria. At a minimum, these criteria might include: (i) improving the scientific basis for decisions; (ii) enhancing the quality of surveillance of health and interventions; (iii) fostering greater transparency and inclusiveness in the decision-making process; and (iv) promoting the development of practical technology and policy alternatives. All this must be achieved in a fashion that allows for proportionate, efficient and timely decision-making (European Commission, 2000). To these ends, a series of more detailed elements might be considered important aspects of any practical framework for implementing precaution, as we describe below.

Improving the scientific basis of decisions

Precaution is often defined as a risk management principle invoked after scientific inquiry takes place (European Commission, 2000). This scientific stage in the process is often considered synonymous with risk assessment. Risk assessment can be a powerful tool if uncertainties are familiar and well understood, but precaution is essential, since many uncertainties are much more challenging than this. It is far from scientific to pretend otherwise. Likewise, risk assessment can result in the adoption of a rather narrow perspective in appraisal, often involving only a small subset of the relevant scientific disciplines.

Precaution encourages a more broadly based approach, enhancing the ability of science to address complex interactions in complex environmental systems and thus to help detect and investigate early warnings. This may, in turn, identify promising new options that might otherwise be missed in risk management. In short, precaution helps to improve the scientific basis for decision-making by prompting greater rigour in the choice of methods and wider inclusion of different scientific disciplines. This ensures that the most salient information is gathered and the uncertainty is not artificially understated (Wynne, 1992; Stirling & Calenbuhr, 1999).

Even when conventional risk assessment techniques are considered sufficient, precaution has a further contribution to make to the scientific basis for decision-making – before the “risk management” stage. Conventional procedures for the setting of levels and burdens of proof are not objective and intrinsic to science but raise non-scientific questions over the most appropriate values to apply. There are great questions, for instance, related to who should bear the burden of gathering the evidence and conducting the analysis. Should it be the beneficiaries or those who are potentially at risk?

In many areas of scientific research, requiring high levels of proof before accepting a new hypothesis is appropriate. This approach gives privilege to well-established existing understandings and thus helps to avoid the unproductive pursuit of new hypotheses that may turn out to be false. For risky new technologies (or even existing ones considered safe until demonstrated harmful), however, this raises serious questions. Is presuming that a risk is absent more scientific than presuming that it is present? When the stakes include public health or irreversible environmental harm, the appropriateness of this same degree of conservatism can be problematic. By downplaying the need for investigating possible harm, a presumption of safety can actually serve to inhibit scientific activity. By encouraging scientists to be more critical and reflective over the adoption of hypotheses and the setting of levels and burdens of proof, precaution actually

serves to promote the conduct of science (Kriebel et al., 2001 (reproduced as Chapter 9 of this publication); Gee et al., 2002).

Precaution offers to improve the scientific basis for decision-making in a third way. Precaution urges greater humility over the definitive status of any particular body of scientific findings. It involves recognizing that the answer science gives to questions of safety and risk typically depends on the specific question asked, how this is framed and the assumptions that are made in developing a response (Jasanoff, 1990; Wynne, 1996). Science means about being rigorous not only about the quantitative data but also about how these data are sensitive to assumptions. Here, precaution prompts greater attention to public participation and deliberation, but this attention to participation is motivated by scientific and not political reasons. It means being as rigorous in validating the questions as in providing the answers. Valuing scepticism and dissent is key to science. Rather than accepting a simple process in which science delivers apparently definitive answers to policy-making, precaution encourages a more dynamic, reflective and critical relationship between policy-makers, scientific advisers and wider stakeholders (Stirling, 2003).

Applying prevention

Precaution and public health prevention pursue similar goals in identifying the causes of risks and reducing or preventing them when possible at their source rather than seeking to control proximate risk factors and to remedy damage after it is done. *Reducing risks, promoting healthy life: the world health report 2002* (World Health Organization, 2002) notes that “in order to protect and improve health around the world, much more emphasis is needed on preventing the actual causes of important diseases – the underlying risks to health ...”. Reducing and preventing risks is critical to promoting sustainable development.

The terms precaution and prevention are often used interchangeably, but a preventive decision need not be precautionary – such as the decision to phase out lead in

gasoline or action to prevent smoking. These were responses to concrete scientific evidence of harm in which uncertainty played very little role. But precautionary decisions should always be preventive – they should not simply transfer risks from humans to ecosystems, from workers to consumers and so on. Ideally, implementing precaution involves shifting attention upstream in the chain of determinants of health and addressing – as a priority – additional questions about risk.

For example, before asking “What level of risk is acceptable?” or “How much degradation can a human or ecosystem assimilate?”, a proactive, truly preventive strategy would first ask “How much contamination can we avoid while still achieving our goals?” and “What are the alternatives or opportunities for prevention?”. The goal of prevention is not to eliminate technologies or activities that could have important public health and development benefits but rather to determine whether these benefits can be achieved more safely. Far from impeding innovation, this kind of prevention actually serves to encourage creativity and innovation (Tickner, 1999).

An integral part of prevention and precaution is seeking to avoid creating new problems while solving existing ones. Well-intended, precautionary public health interventions can themselves result in serious adverse consequences (Goldstein, 1999). Indeed, almost any technology involves some hazards, and changes undertaken to reduce exposure can sometimes produce unintended consequences, including adverse ones. Thus, ensuring that precaution is self-consistent requires taking the same degree of care in appraising the likely alternatives as in assessing the particular technology or policy option under scrutiny (O’Brien, 2000; Tickner, 2002).

Public health has several types of prevention, all of which are important in applying precaution. Primary prevention involves intervening in systems to address the root factors of disease before diagnosis; secondary prevention is early detection, allowing minimal time lag time between identifying disease and intervention (such as surveillance); and tertiary prevention is control of damage and curative action once

disease occurs (such as rapidly cleaning up and protecting from the harmful effects of contaminated sites) (Leavell & Clark, 1958). A fourth type of prevention could be termed primordial prevention: action taken based on knowledge about what might happen in the future, such as increases in smoking and subsequent cardiovascular disease in developing countries or increases in infectious disease caused by climate change. These types of prevention can be applied at the population level and used in an overlapping fashion.

Transparency, accountability and empowerment

Precaution conforms to the general principle that decisions on environment and health should be informed by and consistent with the available scientific evidence. In the broad sense of the German *Vorsorgeprinzip*, it also upholds the wider imperative that policy-making should pursue the technology and policy options that are most favourable for society as a whole. This means maximizing the economic and wider benefits and minimizing the risks, costs and other adverse effects. In all these areas – central to precaution – the crucial role played by public values is increasingly being recognized. For these reasons, effectively implementing precaution involves particular attention to transparency, accountability and empowerment.

As already noted, the answers science gives depend on the questions asked. For instance, does regulation ask whether technologies are tolerable, safe enough, safe, the safest available or as safe as possible? The choice among these questions depends on the values held, and the crucial role of public values becomes even more important when attention extends to appraising economic and wider benefits and comparing different kinds of risk and cost. What weight should be placed on present versus future risks? On risks to workers versus risks to the general public? On risks to children versus risks to adults? On injuries versus disease versus death? On human health versus the environment? There is no single definitive way to compare these apples and oranges. Precaution recognizes that the only way to deal

effectively with this dilemma is to ensure that everyone who has an interest or who is likely to be affected is effectively engaged in the decision-making process.

Interested stakeholders, local communities or members of the public are not necessarily either well-informed or cautious about risks. Indeed, the reverse may sometimes be the case. However, the precautionary rationale for participation rests on more subtle insights. Wider engagement is not an alternative to expert knowledge but a complement. It is well established, for instance, that, by thinking more broadly and escaping disciplinary constraints, non-experts can sometimes see problems, questions, issues, connections and solutions that experts can miss (National Research Council, 1996; Omen et al., 1997; Royal Commission on Environmental Pollution, 1998; United Kingdom House of Lords Select Committee on Science and Technology, 2000; Gee et al., 2002). Including outsiders helps to avoid uncritical group thinking. Non-specialists have no interest in advancing particular disciplines, exaggerating expertise or understating uncertainty. As workers, consumers or local people, they may sometimes have knowledge about real-world conditions of a kind that might otherwise be missed or simplified in the expert models. All these factors are important elements in adopting a precautionary approach to appraisal.

Precautionary assessment

Precautionary assessment (Tickner, 2000, 2003) represents a framework and set of procedural steps designed to embed precaution in both the science and policy of environmental decision-making. It incorporates broad framing of problems, thorough examination of alternatives and an approach to science that expands the considerations, disciplines and constituencies involved in collecting and weighing scientific evidence and in the ultimate process of decision-making.

Precautionary assessment incorporates a process flow that emphasizes flexibility. This differs substantially from the more rigid, formulaic four-step approach to risk assessment and

management set forward by the National Research Council (1983) in the United States but is consistent with approaches to sound decision-making proposed in many business texts (Hammond, Keeney & Raiffa, 1999). An iterative process flow may be more useful than the prescriptive rules currently used in environmental decision-making for several reasons.

- Each decision is different – with different types of evidence, uncertainty, affected communities and availability of alternatives.
- A more generalized approach permits a wider range of information to be used in the decision-making process and allows for more qualitative judgements in the face of uncertainty and complexity.
- A process flow does not oversimplify or narrow the decision-making process. Rather, it lays out a series of procedural steps that should be considered in all sound environmental and health decision-making processes.

Although the process of precautionary assessment (Box 1) may appear cumbersome, it should be thought of as providing a heuristic device and normative considerations to guide sound, preventive environmental decision-making rather than an inflexible set of steps that must be completed in a particular way. Beginning with a holistic definition of the problem is clearly important, as this affects each of the following steps.

Environment and health assessment

A centrepiece of precautionary assessment is environment and health assessment, which weighs the science of hazards and exposure. In this step, evidence of risk and uncertainty is examined to determine the possibility (and plausibility) of a significant health threat and the need for precautionary action. As many environmental risks are complex and highly uncertain, such an analysis must involve both the totality of the evidence and individual pieces thereof to plausibly indicate effects. The goal is to build a coherent picture of potential

effects – a “story”. In precautionary assessment, this analysis is completed using a research synthesis (Stoto, 2000) or weight of the evidence approach (International Joint Commission, 1994).

The environment and health assessment should consider the wide range of sources of information and plausible harms and effects identified during the problem-scoping (the process of defining the problem and potential effects). Evidence of potential effects and uncertainty should be gathered from as diverse an array of disciplines and constituencies as possible, including: observational studies, worker case reports, toxicological studies, studies of wildlife and domestic animals, cellular studies, ecological assessment, community health studies, modelling and monitoring. The effects examined in the analysis should include effects on human health and ecosystem health; acute and chronic effects; interactive and cumulative effects; direct and indirect effects; and socioeconomic, historical and aesthetic effects. Since the list of plausible effects might be very large, setting priorities based on the effects of greatest concern from the scientific and political viewpoints is useful.

The four steps of environmental and health assessment are hazard analysis, exposure analysis, magnitude analysis and uncertainty analysis.

- Hazard analysis: the purpose of this step is to understand the strength and quality of the evidence that there is or could be a detrimental effect. Inherent properties in the activity or substance that could lead to adverse effects are considered.
- Exposure analysis: this step gathers evidence of actual or potential exposure from various sources. The nature (direct, dispersive, controlled or closed-system) and intensity of exposure are analysed as well as when and to whom exposure occurs, including the potential for cumulative and interactive exposure.

- Magnitude analysis: this step examines evidence on the seriousness of potential effects, including: the spatial and temporal scales of effects; potential catastrophic effects; any susceptible subpopulations; the reversibility of adverse effects; and the degree of connectivity of effects. When the potential magnitude of effects is large, weaker evidence provides a cause for concern.
- Uncertainty analysis: this step assesses both qualitative and quantitative gaps in knowledge. Uncertainty should be analyzed broadly in terms of type (parameter, model, systemic or ignorance), sensitivity to changing assumptions and the feasibility of reducing uncertainty.

Unpacking information on hazard, exposure, magnitude and uncertainty rather than obtaining a single risk number improves flexibility, understanding of the nature of potential effects and opportunities for preventive interventions in decision-making. The results of these subanalyses are combined into a final environment and health assessment that can be presented in a categorical fashion (such as significant threat, minimal threat, etc.) with a concise, detailed narrative outlining the rationale for the categories, the evidence on which the determination was based and other quantitative and qualitative considerations.

The environmental and health assessment narrative should be clear about what is known, what is not known and what can be known about the threat, the limitations of scientific studies to understand the threat and gaps in information, including research needs. It should also indicate the extent to which uncertainty, and especially ignorance, can be reduced through additional research. The plausibility and probability of various outcomes should also be considered (the sensitivity of the results). The analysis determines, based on the weight of the evidence, whether an activity is associated with or may cause harm and the potential severity of that harm.

Alternatives assessment

The other centerpiece of precautionary assessment is thorough evaluation of any alternatives to prevent or minimize harm. Alternatives assessment is the heart of the solutions-oriented approach of the precautionary principle and is central to sound, forward-looking environmental decision-making. This focuses decision-making attention on opportunities rather than simply the hazards associated with a narrow range of options (O'Brien, 2000). The acceptability of a risk should be a function not only of hazard and exposure but also of uncertainty, the magnitude of the potential effects and the availability of alternatives or preventive options. Availability of a safer alternative can obviate the need for costly, contentious and potentially misleading quantitative risk assessment.

The goal of alternatives assessment is to identify and examine opportunities to prevent an activity from adversely affecting environment and health. A secondary goal is to drive innovation towards more environmentally friendly and sustainable technologies, products and practices. Thus, alternatives assessment should consider not only existing, easy and feasible options but also those that can be developed – those that are on the horizon. Alternatives assessment often has the greatest impact when undertaken early in a decision-making process – in the development phase.

Nevertheless, alternatives assessment requires tools to analyse comprehensively not only the risks but also the feasibility of alternative technologies and products. Numerous methods exist for these types of evaluations (Tickner, 2000). Alternatives assessment should examine and understand the effects and purpose of the activity; identify a wide range of options; analyse alternatives comparatively; and select alternatives.

- Examine and understand the effects and purpose of the activity: the purpose of this step is to better understand the service that the activity provides and

whether it can be provided in a less damaging way; how hazardous materials are used (materials accounting); and the potential effects and benefits of the activity.

- Identify a wide range of options: a diverse group of stakeholders should brainstorm a wide range of options that could lead to multiple opportunities to reduce risk.
- Analyse alternatives comparatively: this aims to thoroughly examine and compare the technical feasibility and the economic, environmental, health and safety effects and benefits of the existing or proposed activity and identified alternatives.
- Select alternatives: the alternatives plan should analyse the selected alternative, how it will be implemented (including how barriers will be addressed) and a plan for follow-up, continuous improvement and monitoring for potential adverse effects. Interim alternatives may be able to be implemented while long-term alternatives with greater environmental health benefits are being developed.

Precautionary action analysis

The last part of precautionary assessment is to determine the appropriate courses of action. This could be considered the “risk management” phase of the decision-making process but is fully integrated into all of the previous steps. Precautionary action analysis involves weighing the information gathered earlier to determine how much and what type of precaution should be taken. Policy tools for implementing precautionary action (see below), ranging from further study to banning the activity, are chosen based on the severity of the risk, uncertainty involved and availability of feasible alternatives. Finally, a feedback and monitoring scheme is developed to measure the benefits and provide early warning of potential

problems. Action is determined not based on a specific threshold for action but rather considering all the available evidence to take the most health-protective, yet reasonable, course of action. Precautionary assessment may also result in a decision that an activity is unlikely to cause harm or that its effects would be minimal – in which case instituting a monitoring scheme may be the most appropriate action. Decisions made under a precautionary assessment should not be considered permanent but part of a continual process of increasing understanding and reducing overall effects. Regular follow-up can stimulate continual improvement in environmental performance and technological innovation.

Box 1. The steps of precautionary assessment

The steps of precautionary assessment are described below. A first step in the process is for authorities (and, when appropriate, with stakeholders) to identify whether the threat is of sufficient concern (either scientifically or in terms of public perception or concern) to justify using public health resources for further examination and analysis of alternatives. For threats that are well established, proceeding directly to examining alternatives and preventive interventions would be reasonable.

Problem-scoping

- Broadly frame and define the problem.
- Outline the range and types of plausible effects (including direct and indirect ones).
- Identify the populations affected and those that might be disproportionately affected.
- Identify research and information needs about health effects and alternatives.
- Identify who is responsible for studying the risk, providing information or taking appropriate preventive action.
- Identify who should be involved in the decision-making process and at what points during the process this involvement should occur.

Environment and health assessment

- Hazard analysis: weigh the strength of the evidence of plausible effects. Broadly examine the evidence of hazards from multiple sources and disciplines and set priorities among the concerns. Consider the quality of the studies.
- Exposure analysis: examine the potential for exposure from various sources. Consider the nature and intensity of exposure and who is exposed (if one group may be exposed at an especially sensitive time). Consider the potential for cumulative and interactive exposure.
- Magnitude analysis: examine the magnitude and severity of potential effects including the spatial and temporal scale, susceptible subpopulations, reversibility and connectivity.
- Uncertainty analysis: examine the magnitude and type of uncertainty and the feasibility of reducing uncertainty and the potential effects on outcomes.
- Consider the weight of the evidence on association, exposure and magnitude together to determine the potential threat to health or the environment. Develop a narrative with a rationale, the limitations in studies and the research needed.

Alternatives assessment

- Examine and understand the effects and the purpose of the activity.
- Identify a wide range of alternatives.
- Conduct detailed comparative analysis of the alternatives: advantages and disadvantages, including economic, technical, health and safety.
- Select the “best” alternative and institute implementation and a follow-up plan.

Precautionary action analysis

- Determine the appropriate level of precaution needed based on the level of threat of harm, uncertainty and the availability of alternatives.
- Determine what other considerations must be included in the decision, such as cost–effectiveness, the least burdensome option, technical feasibility, political and cultural feasibility or adaptiveness.

- Determine the types of interventions needed to ensure adoption of the precautionary changes – such as technical assistance, information or technology support.
- Determine a precautionary feedback regimen to minimize unintended consequences and to ensure continual improvement.

A precautionary framework for the general regulation of risk

The previous section outlined a tool for applying precaution in assessment processes. The question that results is how such an assessment tool could be integrated into regulatory decision-making processes. In an attempt to reconcile some of the themes discussed so far with more conventional approaches to risk regulation, an international team of academics working in Europe has developed a proposal for a novel general framework for the precautionary regulation of risk, potentially addressing a range of different industrial sectors and policy areas. The proposal was developed under the auspices of the Precaupri Project financed by the European Commission as a result of a series of collaborative workshops involving chemical and biotechnology industry corporations, nongovernmental environmental, consumer and public health organizations, representatives of various national government agencies and intergovernmental bodies and practicing regulatory lawyers and legal scholars (Renn et al., 2003).

Among other things, the central aim of this new framework is to focus directly on a series of challenging questions that are often raised as criticisms of the precautionary principle. For instance, what is the precise relationship between precaution and established approaches to risk management based on risk assessment? Exactly how does precaution relate to parallel principles of good governance, such as openness, participation, accountability, effectiveness and coherence? How can the precautionary principle be harmonized with binding legal commitments concerning non-discrimination, proportionality and fundamental rights?

Questions of this kind quickly demonstrate that neither precaution nor conventional approaches to risk management can usefully be seen simply as mechanical decision rules. For instance, risk assessment is often considered a complete operational tool for handling the absence of certainty. Risk assessment results are typically presented in a precise and apparently definitive fashion, as if they presented an unambiguous basis for science-based policy-making. Ironically, this is a rather unscientific perspective. In fact, in formal scientific terms, risk assessment is applicable only under limited special conditions – when all the possible outcomes can be fully defined and their respective relative likelihoods confidently determined. This leaves risk assessment inherently incapable of addressing a range of important kinds of incomplete knowledge. These include uncertainty in the strict sense, in which the possible outcomes are known but not their likelihood. It also includes ambiguity, in which the possible outcomes themselves are unclear or subject to different interpretations. Finally, there is the condition of ignorance, under which not only the likelihood but even the outcomes themselves are unknown. Here, scientists face the prospect of surprise.

Although conventionally expressed with confidence and precision, different (and equally reasonable) risk assessment studies typically deliver radically different results under these more intractable conditions (Stirling, 1994; Saltelli, 2001). This state of affairs is not scientifically sound, nor does it offer a practical basis for robust decision-making on risk. As an operational decision rule to informing general decision-making under uncertainty, then, the procedures of risk assessment are seriously incomplete.

Rather than treating the precautionary principle simply as an alternative decision rule substituting for risk assessment, the proposed new framework sees precaution in regulatory appraisal as a broader and deeper process of learning and enquiry (Wynne, 1992; Stirling, 2003). Risk assessment remains appropriate and applicable under the true circumstances of risk – when probabilities can be determined

and the complete range of possible outcomes measured. Beyond this, however, the challenge is to ensure that the process of regulatory appraisal can gather further salient information in the most effective and efficient way.

Under the proposed general framework for regulating risk, imperatives to non-discrimination and proportionality are reconciled with the demands of addressing uncertainty, ambiguity and ignorance by designing an initial screening process to be implemented before the full appraisal of the various types of threat. A series of clearly specified screening criteria are developed to identify conditions of uncertainty, ambiguity and complexity. These are then used to set priorities in treating different types of threat and to decide on the most efficient and effective approach to subsequent regulatory appraisal.

One set of screening criteria is designed to identify threats that are definitely serious, giving priority to immediate attention to preventing unacceptable forms or levels of harm. Another group of screening criteria seeks sociopolitical ambiguity – for instance concerning the distribution of effects across different groups or political, cultural, ethical or religious issues. Such issues are then addressed through open-ended participatory deliberation, using well-established procedures such as consensus conferences and stakeholder fora. With regard to precaution, a key set of screening criteria is specifically designed to diagnose scientific uncertainty of a kind that precludes the confident application of risk assessment techniques. Under these conditions, the subsequent regulatory appraisal process takes the form of precautionary appraisal. This includes a broader and more demanding array of elements than is usually explicitly included in conventional risk assessment (see the discussion of precautionary assessment above) (Stirling & Calenbuhr, 1999; Tickner, 2000; Gee et al., 2002):

- deliberately favouring those who stand to be harmed (rather than those who benefit) in assigning responsibility for the funding of analysis and gathering of evidence and in setting the level of proof and burden of persuasion (Tickner, 1999);
- placing greater weight on empirical field research and scientific monitoring rather than relying heavily on theoretical models or laboratory analyses (Jackson & Taylor, 1992; Tickner, 1999; Gee et al., 2002);
- taking account of the comparative merits of alternative options rather than restricting attention to the acceptability of a single option (O'Brien, 2000);
- examining benefits and justifications as well as the adverse effects of various technology or policy options and weighing these together (Jackson & Taylor, 1992; MacGarvin, 1995);
- considering technological and production systems as a whole, including resource chains and life cycles, rather than a single product or technology viewed in isolation (Jackson & Taylor, 1992; MacGarvin, 1995; Tickner, 1999);
- looking at the general systemic properties displayed by different portfolios of options, including diversity, resilience, flexibility and adaptability (Collingridge, 1982; Holling, 1994; Stirling, 1994; Farber, 1995); and
- addressing the innovation process at the earliest stages before firm financial and institutional commitments are made (Rip, Misa & Schot, 1996; Grove-White, Macnaghten & Wynne, 2000).

In this way, the proposed framework avoids the forced standardized application of risk assessment techniques to challenges of ambiguity or uncertainty that simply cannot be met. On the other hand, the screening process helps ensure

that much more straightforward cases of prevention, or simple routine forms of risk, are not addressed using unduly cumbersome, protracted and costly precautionary procedures. The design and implementation both of the screening and of the subsequent appraisal process is subject to continual, inclusive and deliberative review. Accordingly – as a reflective process rather than a threshold or decision rule – the framework as a whole might be considered to be precautionary without requiring that resources be devoted equally to all cases irrespective of their uncertainty or potential seriousness. This may reconcile the apparently conflicting imperatives of precaution and proportionality in the regulatory appraisal of risk.

Concluding thoughts: developing policy options and tools for applying the precautionary principle

In addition to the importance of developing assessment and regulatory frameworks for integrating precaution into decision-making structures, tools for effecting precautionary and preventive action should be outlined and developed. Such tools (Annex) should be case-specific depending on the nature of the risk and its preventability. They should help advance precautionary goals such as action on early warnings and seeking out a range of alternatives and should address, where possible, multiple risks at once, as well as internalizing precautionary thinking at the government, firm or societal level. Feasibility and cost are important considerations, and such tools must be politically and culturally appropriate. Application of these tools should be combined with efforts to eliminate institutional, financial and technical barriers to implementing precaution and prevention.

The application of prevention and precaution represent important steps towards achieving the long-term goal of sustainable development. According to the World Commission on Environment and Development (1987), rather than being a static formula, sustainable development is a process of change in which exploitation of resources, investment, technology and institutional policies are made consistent with present as well

as future needs. It is solution-oriented, emphasizing a long-term view for improving the quality of life for everyone. It focuses on equity, including ensuring the rights of poor people and future generations. It stresses qualitative development over quantitative growth. Like precaution and prevention, the challenge of sustainable development requires systems thinking – understanding the interactions between the environment, economy and society so as to identify root causes of degradation and focus on more sustainable patterns of production and consumption that can leave a safer, cleaner and more economically prosperous world for the future.

Annex

Tools for applying precaution and prevention in practice

Cleaner production and preventing pollution

Cleaner production and preventing pollution involve changes to production systems and products to reduce pollution at the source (in the production process or during product development). This includes reducing the raw material, energy and natural resource inputs (dematerialization) as well as reducing the quantity and harmful characteristics of toxic substances (detoxification) used in production systems and products (Jackson, 1993; Geiser, 2001). A central aspect of cleaner production is understanding the service that a production system or product provides and seeking out safer alternatives to provide that same service (for example, chlorinated solvents provide degreasing, and pesticides control pests). Many countries – including many countries in transition – have established cleaner production programmes, which have demonstrated success in reducing industrial and product-related pollution, while reducing costs and improving productivity.

Cleaner production concepts can also be applied to the use of pesticides (integrated pest management in agriculture and housing, which uses a wide range of tools to control pests) and to the design of cities, living spaces and building materials. Environmentally sound building provides basic principles for

more healthy and environmentally friendly design that minimizes hazardous and non-hazardous materials; is energy efficient but allows sufficient fresh air ventilation; minimizes the build-up of allergens; and locates residential districts to minimize adverse environmental effects and improve air quality (such as designing cities to minimize air pollution from transport and production facilities). Land-use planning can help avoid problems of sprawl, poor transport infrastructure and sedentary lifestyle that have been important risk factors for disease.

Setting goals in environment and health

Goal-setting is a common practice in public health and is important to achieving sustainability. It involves establishing aggressive, preventive health goals (such as eradicating childhood smoking or preventing sexually transmitted disease or pollution) and developing policies and measures to achieve these goals (and to reduce barriers to their implementation) while minimizing social disruption (also known as backcasting (Dreborg, 1996)). Goal-setting focuses not on what future scenarios are likely to happen but on how desirable futures can be obtained.

Environmental health indicators

An environmental health indicator is a “characteristic of the environment that, when measured, characterizes the magnitude of stress, habitat characteristics, degree of exposure to a stressor, or degree of ecological response to the exposure” (International Joint Commission, 1995). Indicators (which can include human or ecosystem health aspects) have several purposes, including: providing decision-makers with information about the health status of a community or a population and raising awareness and understanding about environmental degradation by measuring progress towards established environmental health goals. By tracking progress and noting benchmarks, public health professionals and politicians, as well as the general public, can assess the efficacy of current practices, programmes and policies and find ways to develop and implement more preventive approaches.

For example, if a programme intended to reduce the incidence of an environmentally mediated disease is found to be ineffective in meeting its goal, then public officials and the general public should implement alternative programmes that have promise in meeting the intended goal of preventing the disease in the future.

WHO has been collecting data on a wide range of indicators, including: health status indicator data on mortality, hospital admissions for home accidents and the incidence of childhood cancer; exposure indicator information on indoor and outdoor pollutants, such as environmental tobacco smoke, water supply and water sanitation; and policy indicator data on legislative, policy and programmatic interventions to improve air quality, water supply and children's nutritional and safety needs.

Information dissemination and education

Information and education represent an important subset of market-based mechanisms, especially for countries in transition and developing countries, that are relatively low cost and can have substantial influence in reducing the adverse environmental effects of activities. Many institutions are interested in implementing some precautionary measures or undertaking research and development of a safer technology but lack the capacity to do so. Information and education can provide that important capacity and can inform citizens about more environmentally friendly choices. Information has several benefits, including: understanding the risks of materials and activities and their alternatives; identifying gaps in knowledge; identifying priority pollutants or activities of concern; allowing comparison of hazards and preventive actions across sectors, countries and companies; and improving enforcement of environment and health policies. Most important, information is critical to public empowerment and accountability. If people know about risks and options to prevent them, they can take personal action to reduce them or hold government authorities or those who create them accountable for prevention. Information can also

serve to discourage risky behaviour by providing an incentive for those creating risks to consider and internalize the effects of their activities and seek alternatives.

In occupational health, hazard communication has provided an important tool for workers to understand the potential effects of chemicals used in the workplace and to demand safer working conditions. Prior informed consent – in which a county can deny access to a pesticide or hazardous chemical restricted in other countries – is an important tool for developing countries to understand in making decisions on risks. Right-to-know laws in many countries have proven useful in encouraging business managers to reduce their pollution. Finally, labelling products – such as those produced using organic methods, those that contain potentially hazardous materials or those that are environmentally friendly – can provide a tool for consumers to choose products with the fewest adverse environmental effects for a particular need.

An agenda for precautionary environment and health research

Supporting precaution, the protection of children's health and sustainability requires developing a new paradigm of environment and health research. It must be centred on the needs and exposure of children and future generations as well as on sustainability (Landrigan, 1999). Currently only a small percentage of environmental research budgets focus on children (who represent a major proportion of the population) or prevention.

Environment and health research must form a central part of any prevention strategy. A prevention-oriented research agenda would include tools for rapidly identifying environmental hazards as well as potential exposure. It would develop tools to broaden understanding of the unique susceptibility of some populations to environmentally related illnesses. It would broaden the understanding of the complex set of determinants of environmentally related disease,

including proximate and more fundamental risk factors for specific effects as well as the interactions between broad categories of risks (chemical, physical, climate and social), the cumulative effects of multiple risks. It would also project the long-term implications of action today for future generations (through, for example, integrated assessment methods). It would examine and develop a range of preventive options to reduce environmental risks while achieving good living standards for everyone. It would also include measurement and surveillance techniques (such as health indicators) to measure progress towards reducing environmental risks and achieving more sustainable forms of development as well as identifying early warnings of adverse effects.

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12. A compass for health: rethinking precaution and its role in science and public health

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