Part I

The precautionary principle – why so much fuss about such a simple idea?

1 Precaution as common sense: "Look before you leap"

What do thalidomide, asbestos, PCBs (polychlorinated biphenols), nuclear waste, depletion of international fisheries, and climate change have in common? They are serious public health and/or environmental problems with some common elements in their histories. In every case, activities undertaken for good reasons – to serve demands that were genuine, to reduce costs or keep them low, and in the process to raise standards of living – led eventually to enormous damage and expense, or the prospect thereof. What went wrong? After all, our societies were not born yesterday. They are aware of the risks posed by innovation, resource exploitation, and overstressing our environmental systems, and they maintain institutions to assess risks and regulate potentially harmful activities. Yet, these institutions failed quite clearly to prevent or minimize the potential harm.

In each of these cases, the standard approaches to risk management failed in several or all of the following ways: they did little to prevent the threat; were slow to diagnose it; tolerated far too much dispute about harm and cause before taking action; and acted only after the problem was obvious, widespread and built into the economy, society, and way of life, so that remedies were enormously expensive and relatively ineffective. Because remedies were implemented too late to forestall the damage or restore the *status quo ante*, they necessarily were focused more on remediation, mitigation, and adaptation.

Around 1960, many countries approved thalidomide for use in treating morning sickness in pregnant women, with (what turned out to be) inadequate pre-release screening and testing. In short order, about 10,000 children were born with serious birth defects (Box 8.3). The earliest indications that asbestos was harmful were noted at the beginning of the twentieth century, but it took most of the century before use of asbestos was banned in the USA and the European Union (Boxes 1.1 and 5.4). From the 1920s to the 1970s, PCBs were produced and used for a considerable variety of purposes. Known global PCB production was of the order of 1.5 million tons.

Despite evidence of toxicity dating to the 1930s, PCB manufacture and use continued with few restraints until the 1970s, when production was banned. Subsequent US expenditures on clean-up and remediation of PCB-damaged sites have exceeded $50 billion (Box 9.2), and the job is far from complete. Secure storage of nuclear waste remains an unsolved problem six decades after the first peaceful uses of nuclear technology (Box 9.10). Depletion of international fisheries continues, even though many countries have achieved some success in managing to sustain their national fisheries (Chapter 13). Although a scientific consensus has converged around a positive relationship between greenhouse gas (GHG) concentrations and climate change, global GHG emissions continue to accelerate and the major climate models predict a non-trivial likelihood of temperature rises sufficient to cause drastic damage (Weitzman 2009). While economists debate whether meaningful progress in limiting climate change can be achieved at reasonable expense, the fact is that concerted action on a global scale remains a distant prospect (Box 9.11).

In the cases of thalidomide, asbestos, PCBs, nuclear waste (and perhaps nanotechnology, although we don't seem yet to be hearing much public outcry), we sense a broad public impatience with the "charge ahead and, if necessary, clean-up the mess later" approach to risk management. In the cases of nuclear technologies, biotechnology, and perhaps nanotechnology, we observe a growing sense among the public that technology is developing the capacity for damage on a scale so vast that it is, for that reason alone, threatening. Depleted fisheries and climate change exemplify the difficulty of recognizing and acting to forestall the negative effects when familiar systems exposed to cumulative stress (e.g. unsustainable harvests or pollution loads), in the course of business-as-usual, experience drastic and damaging change.

Box 1.1 Murphy (2009) on asbestos

Proving cause and effect is a difficult undertaking. Consider the example of asbestos and mesothelioma. Asbestos was suspected of harming human health as far back as 1906. In 1911, studies of asbestos on rats suggested harm. In the 1930s and 1940s cancer cases were reported in workers involved in the manufacture of asbestos. Not until 1998–9 was there a complete ban on asbestos in the European Union and France. A Dutch study estimated that 34,000 lives could have been saved in the Netherlands alone if precautionary measures had been taken in the 1960s when it was deemed likely, but was still unproven, that asbestos caused mesothelioma (UNESCO 2005).

How different things would be, it might be reasoned, if we could get ahead of the game by pre-screening and testing new technologies for safety before they become dispersed throughout the environment and embedded in the economy. How different things would be, if the complex systems we depend upon were monitored systematically so we would be warned of potential overstress in time to take early and relatively inexpensive action to stabilize the systems.

Jablonowski (2007) has argued that the standard approaches to risk, where risk is identified *ex post* and assessment practices are based on the "safe until proven harmful" null hypothesis, can be expected to result in risk dilemmas – cases where the potential harm is horrific but so too is the cost of prevention or remedy (Box 9.12).

By the 1970s, these concerns began to crystallize in the form of the precautionary principle (PP) which emerged first among German environmentalists who urged a prominent role for the *Vorsorgeprinzip*, i.e. foresight principle (Raffensperger and Tichner 1999). The PP has been proposed as a guide for public policy in areas where there may be extraordinary risk, uncertainty, and gross ignorance about future consequences. It is fundamentally a claim that, when making multi-dimensional public decisions, acting to avoid and/or mitigate potential but uncertain harmful consequences should be accorded high priority. We already have theory and methods for decision making under risk, risk assessment, and risk management, but the whole PP movement is founded on the claim that something more, something stronger than customary risk management, is needed.

The idea of precaution

The concept of caution (noun: care and close attention to avoiding risks and hazards) is relevant at the level of individuals, firms, and public policy. Individuals may be comfortable playing the averages – technically, betting whenever the expected value (EV) of the bet is positive – when the risks are modest, i.e. the potential loss is small relative to the endowment and there will be repeated chances to play the game. Caution is something else. It is expressed by refusing positive EV bets when, for example, there is potential for a loss large enough to diminish one's future prospects – in the extreme, large enough to take one out of the game. One way in which individuals exhibit caution is by offering to purchase insurance at prices higher than the EV of potential losses if uninsured.

We might ask why insurance is available – are not firms cautious, too? If the game is stationary and well-specified, so that the possible outcomes, their probabilities, and the associated pay-offs are known, insurance providers have little reason for caution. The expected pay-out for an insurance contract is readily calculated, and an insurer who assembles a large pool of contracts with a representative group of individuals faces a very predictable aggregate pay-out, as "the law of large numbers" would predict. Under these conditions, cautious individuals rationally may be willing to pay more than the EV of potential losses to obtain coverage but, because individual risks are idiosyncratic (Chapter 3), the insurer faces very little risk so long as the game is unchanging.

When governments seek to protect individuals from some kinds of risks and hazards, an interesting question is how much protection should be provided. If we look at it from a national accounting perspective, the resources of government are large enough that it is an efficient self-insurer. Therefore, some economists reason, government should reduce hazards only to the point where the costs of further hazard reduction equal its EV at the margin. Yet, citizens commonly argue for a greater degree of protection than that. Individuals have reason to be cautious and some of them argue that government should be cautious on their behalf. In health, safety, and environmental regulation, this kind of caution is expressed most commonly by setting standards that include a margin of safety, such that modest exceedances of the standard present little risk to individuals (Chapter 10).

While well-specified games of chance have provided such a compelling analogy that the theory of decisions under risk is modeled upon them, real life tends to be not so orderly. The instinct for caution may well be stimulated when the magnitude of potential losses is unpredictable and their likelihood can only be guessed, and when the effectiveness and cost of preventive and remedial strategies are speculative. In such cases, caution may well apply to firms as well as individuals, and insurance might not be offered. Damage outcomes from climate change are poorly specified and we are not confident that we know their likelihoods, but that is not all. Many of the important climate risks may be systemic (Chapter 3) – e.g. coastal communities will suffer highly correlated losses if and when the sea-level rises. It follows that insuring against losses from climate change is a much tougher challenge. In the face of a poorly understood and systemic risk like climate change, individuals, firms, and governments may all exhibit caution.

Thus far, we have been discussing caution but not precaution. The prefix *pre-* means before, in advance, or preparatory. In the case of precaution, an interesting question is before what? The most common response, I think,

is before we are sure about harm and cause, because early action provides opportunity, perhaps the only opportunity, to forestall harm. This reasoning puts great value on early warning of potential harm, and on acting upon such warning. There is another plausible response to the "before what?" question: before the agent causing the threat is widespread and embedded in business-as-usual practice. The cases of asbestos, PCBs, and nuclear waste demonstrate that the "charge ahead and, if necessary, clean-up the mess later" strategy can prove really expensive. Clearly *before* in this sense is relevant only when there is opportunity for precautionary intervention before the agent is widely dispersed and integrated into the way we live. In some cases, *before* in this sense is relevant, and in some cases it is not. Two kinds of situations, quite different from a precautionary perspective, can be distinguished on the basis of this second meaning of *before*.

Novel interventions

Novel interventions include new substances (e.g. synthetic chemicals), species that may be introduced to serve some particular purpose, and new technologies (e.g. biotechnology and nanotechnology) – anything that is novel in some important way and would be introduced into a system that has not been exposed to it previously. Novel interventions call for a go/no-go decision, and before that decision is made there is opportunity to study the intervention and, if it can be confined securely, to do some serious testing under controlled conditions, to learn about its properties and potential impacts on the system before it is released. Both kinds of *before* are relevant: we have the opportunity to regulate the intervention before we are sure that it presents a serious threat, and before it is released and dispersed widely. These are the cases that present the broadest menu of precautionary remedies, and perhaps the best prospects for cheap and effective hazard reduction. It follows that they are well adapted to "look before you leap" strategies – the discussion of the Hippocratic Oath (Chapter 3) applies to these cases.

Business-as-usual stresses

The systems upon which life and well-being depend have their limits (sometimes called carrying capacity) and, when overstressed (e.g. by unsustainable harvests or pollution loads) in the course of business-as-usual, may experience sudden and adverse regime shift. An obvious goal is to manage such systems sustainably, but many natural systems experience more variability

than we anticipate, so that it is not always easy to read the signals. It seems often we are wrestling with fragmentary evidence and asking whether what we observe is a blip or a trend.

In these cases, the simple analogy is "be careful not to drive over the cliff," and the "rivet popper" discussion (Chapter 3) applies. The point of "be careful not to drive over the cliff" is that driving is a familiar business-as-usual activity but, without foresight and systematic gathering and interpretation of relevant information, we cannot be sure whether a cliff exists and whether the planned trip poses a danger of going over it. Managing for sustainability means alertness for evidence suggesting the system is at risk of regime shift, and willingness to act upon such evidence. Early warning tends to make action more likely to succeed and less expensive; but early warning is not always feasible and when the alarm comes late in the game, remedies may be drastic and highly disruptive of business-as-usual. Sometimes the cause of system overstress is simple (overfishing) and the remedy (suspension of harvest until the fishery recovers) may be locally disruptive, but is manageable in the larger scheme of things. In other cases, the causes are complex and remedies may require a whole suite of drastic changes in business-as-usual.

In cases of overstress from business-as-usual, we may be able to act before we are sure of causes and remedies, and there may be rewards for acting earlier rather than later, but there is no opportunity to act before the system is exposed to harm.

It is clear that novel interventions, before the go/no-go decision, provide the most fertile opportunities for precautionary intervention. But suppose we decide to charge ahead and, if necessary, clean-up the mess later. Then, the distinction between novel interventions and system overstress from business as usual disappears. Having forfeited the opportunity for pre-release caution, precaution can be expressed only by alertness to early warnings of damage and willingness to implement remedies before we can be sure of cause and effect. Asbestos, PCBs, and nuclear waste all fell into this category and, in the cases of asbestos and PCBs, early warnings made little impression, perhaps because taking them seriously would have been economically disruptive. In the end, of course, the procrastination bet was lost and remediation of asbestos and PCBs was undertaken at great cost.

Formalizing the PP

There are many definitions of the PP in the literature (Cooney 2004), but most of them can be grouped into three broad categories, on a weaker–stronger

scale. The threads common to all three categories are the focus on uncertain consequences and precaution, which together imply not just aversion to demonstrated risk, but caution to forestall uncertain future harm. Below are examples of each category, with emphasis added to highlight key differences:

- Uncertainty about harmful consequences *does not justify failure to take precautionary action* (Bergen Declaration 1990).
- Plausible but uncertain harm *justifies precautionary intervention* (UNESCO 2005).
- Uncertain harm *requires intervention, and the burden of proof is shifted to the proponent of the proposed risky action* (Wingspread Statement).[1]

Adoption by governments and international bodies

Beginning in the 1980s, international conferences, agreements, and treaties endorsed precautionary measures (the Montreal Protocol on ozone-depleting substances, 1987; and the Framework Convention on Climate Change, 1992), the precautionary approach (the Rio Declaration on Environment and Development, 1992; the Cartagena Protocol on Biosafety, 2000; and the Stockholm Convention on Persistent Organic Pollutants. 2001), and the precautionary principle (the Third North Sea Conference, 1990; the [Maastricht] Treaty on European Union, 1992; and the UNESCO World Commission on the Ethics of Scientific Knowledge and Technology, 2005). Some commentators argue that choice of noun matters (Peel 2004) – to some, the precautionary approach signals more flexibility than the precautionary principle, especially in regard to social, economic, and political caveats. Furthermore, US negotiators, perhaps fearful of protectionism in international trade as well as excessive litigation at home, have insisted on precautionary "measures" or "approaches," rather than "principle" in multilateral environmental agreements (Shaw and Schwartz 2005).

Government entities including the European Union and Canada have committed to the PP as a guiding principle (European Commission 2000, Canadian Perspective … 2001). The US has been more circumspect about the PP (Wiener and Rogers 2002).

In US environmental matters, the endangered species laws remain one of the few applications of a systematic precautionary approach – threatened species are identified and monitored, and serious protections are provided for the critical habitats of those identified as endangered. Nevertheless, US endangered species laws often are criticized (even by PP proponents)

for invoking remedies too late in the game, at which point drastic restrictions are required. In protection of the environment and public health and safety, the US approach typically is to wait until there is evidence of damage and then set a regulatory standard. Frequently the standard provides a margin of safety – which suggests an element of caution, but not *pre*-caution. In management of natural resources (e.g. fisheries), management for sustainability introduces an element of precaution, and restrictions on harvest often are invoked when evidence suggests a possible breach of the sustainability constraint.

The potential influence of the PP extends well beyond environmental and natural resources issues. Pharmaceutical products are tightly regulated by the Food and Drug Administration, which requires evidence of safety and effectiveness before approving drugs for general release. However, the US does not go as far as some other countries where patent law denies patentability for potentially harmful medical technologies (Kolitch 2006). There has been serious discussion of a possible role for the PP in clinical trials. The PP has been invoked in discussions addressing the security concerns of recent years. Bronitt (2008) appeals explicitly to the PP in justifying robust measures to deal with airplane incidents. Scholars have asked whether the PP justifies pre-emptive military strikes against rogue nations and/or those that may be sheltering terrorists (Wiener and Stern 2006), a matter of recurring debate in the blogosphere.

The case for precaution as commonsense

Proponents often claim that the PP is little more than ordinary commonsense: extraordinary risks call for extraordinary precaution (Raffensperger and Tichner 1999, Willis 2001, Murphy 2009). Rather than attempt to summarize the argument for precaution as commonsense, I think it best to reproduce in full with minimal editing a statement of this point of view by the Science and Environmental Health Network (SEHN 2000), addressed to a general (rather than scholarly or specialized) audience.

What is the precautionary principle?

A comprehensive definition of the precautionary principle was spelled out in a January 1998 meeting of scientists, lawyers, policy makers and environmentalists at Wingspread, headquarters of the Johnson Foundation in Racine, Wisconsin. The

Wingspread Statement on the Precautionary Principle summarizes the principle this way:

When an activity raises threats of harm to the environment or human health, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.

Key elements of the principle include taking precaution in the face of scientific uncertainty; exploring alternatives to possibly harmful actions; placing the burden of proof on proponents of an activity rather than on victims or potential victims of the activity; and using democratic processes to carry out and enforce the principle – including the public right to informed consent.

Is there some special meaning for "precaution"?

It's the common sense idea behind many adages: "Be careful." "Better safe than sorry." "Look before you leap." "First do no harm."

What about "scientific uncertainty"? Why should we take action before science tells us what is harmful or what is causing harm?

Sometimes if we wait for proof it is too late. Scientific standards for demonstrating cause and effect are very high. For example, smoking was strongly suspected of causing lung cancer long before the link was demonstrated conclusively, that is, to the satisfaction of scientific standards of cause and effect. By then, many smokers had died of lung cancer. But many other people had already quit smoking because of the growing evidence that smoking was linked to lung cancer. These people were wisely exercising precaution despite some scientific uncertainty.

Often a problem – such as a cluster of cancer cases or global warming – is too large, its causes too diverse, or the effects too long term to be sorted out with scientific experiments that would prove cause and effect. It's hard to take these problems into the laboratory. Instead, we have to rely on observations, case studies, or predictions based on current knowledge.

According to the precautionary principle, when reasonable scientific evidence of any kind gives us good reason to believe that an activity, technology, or substance may be harmful, we should act to prevent harm. If we always wait for scientific certainty, people may suffer and die, and damage to the natural world may be irreversible.

Why do we need the precautionary principle now?

Many people believe that the effects of careless and harmful activities have accumulated over the years. They believe that humans and the rest of the natural world have a limited capacity to absorb and overcome this harm and that we must be much more careful than we have been in the past.