27 More or less precaution?

David Gee

Despite its presence in a growing body of EU and national legislation and case law, the application of the precautionary principle has been strongly opposed by vested interests who perceive short term economic costs from its use. There is also intellectual resistance from scientists who fail to acknowledge that scientific ignorance and uncertainty, are excessively attached to conventional scientific paradigms, and who wait for very high strengths of evidence before accepting causal links between exposure to stressors and harm.

The chapter focuses on some of the key issues that are relevant to a more common understanding of the precautionary principle and to its wider application. These include different and confusing definitions of the precautionary principle and of related concepts such as prevention, risk, uncertainty, variability and ignorance; common myths about the meaning of the precautionary principle; different approaches to the handling of scientific complexity and uncertainty; and the use of different strengths of evidence for different purposes.

The context for applying the precautionary principle also involves considering the 'knowledge to ignorance' ratio for the agent in focus: the precautionary principle is particularly relevant where the ratio of knowledge to ignorance is low, as with emerging technologies.

A working definition of the precautionary principle is presented that aims to overcome some of the difficulties with other definitions, such as their use of triple negatives; a failure to address the context of use of the precautionary principle; no reference to the need for case specific strengths of evidence to justify precaution; and overly narrow interpretations of the pros and cons of action or inaction.

The chapter also points to the need for greater public engagement in the process of framing and decision-making about both upstream innovations and their downstream hazards, including the specification of the 'high level of protection' required by the EU treaty. A precautionary and participatory framework for risk analysis is proposed, along with some 'criteria for action' to complement criteria for causation.

The capacity to foresee and forestall disasters, especially when such action is opposed by powerful economic and political interests, appears to be limited, as the case studies in *Late lessons from early warnings* illustrate. The chapter argues that with more humility in the face of uncertainty, ignorance and complexity, and wider public engagement, societies could heed the lessons of past experience and use the precautionary principle, to anticipate and minimise many future hazards, whilst stimulating innovation. Such an approach would also encourage more participatory risk analysis; more realistic and transparent systems science; and more socially relevant and diverse innovations designed to meet the needs of people and ecosystems.

'The precautionary principle has, within the space of a decade, experienced a meteoric rise' Nicolas de Sadeleer (2010).

27.1 Introduction

Since the publication of Volume 1 of *Late lessons from early warnings* in 2001, the precautionary principle (PP) has received increasing attention and is now included in many laws and constitutions. It has also been the focus of much intense public and scientific debate in the European Union and its Member States, particularly in France where it was enshrined into the national constitution in 2005.

The debate on GMOs in France in the years 1997–2005 (Marris, 2005) is just one example of how debates on the PP can trigger the examination of wider issues, moving from narrow questions of risk and scientific uncertainty to broader questions about the future of agriculture, the direction of scientific research and innovation, and public engagement. Where a political process opens up rather than closes down debates, the result can be 'empowering wider social agency in technology choice' (Stirling, 2008). Debates on future innovation pathways do not necessarily eliminate conflict between stakeholders but often clarify 'what [the] conflict is really about' (de Marchi, 2003).

These realities are reflected in Chapter 19 on genetically modified (GM) crops and agro-ecology, which analyses two contrasting innovation pathways to global food security and sustainable agriculture. It finds that, in addition to some 'top down' genetic engineering, 'bottom up' approaches to agricultural innovation 'are proving capable of getting sustainable, participatory and locally adapted solutions into the hands of those that need them most'.

A catalyst for debate and for timely action

The PP seems to have two roles. First, as a trigger for broad debates on what kind of future we want in a water-, energy- and resource-constrained world and what innovation pathways could lead towards such futures (WBCSD, 2011; WEF, 2012; WBGU, 2012; OECD, 2012; UNEP, 2011; EEA, 2010). And second as a legal and moral justification for more timely actions on early warnings about potential hazards.

The case studies in this volume furnish evidence that contributes to a wider understanding of both roles. While there is much more emphasis on its role in justifying actions on early warnings, the chapters in Parts B and C, on emerging lessons and issues, begin to illustrate the PP's role in facilitating debates around innovation pathways and technological choices. In addition, Chapter 26 on science and Chapter 24 on justice for early warning scientists and late victims, illustrate the PP's role in stimulating discussion about reforms within environmental science, the law and scientific organisations.

The case studies addressing substances or chemicals that are now widely known to be hazardous focus on the combination of early warnings and (usually) late actions. The studies address asbestos, benzene, BSE (mad cow disease), diethylstilboestrol (DES) tributyl tin (TBT) and polychlorinated biphenyls (PCBs) in Volume 1 and DDT, dibromochloropropane (DBCP), vinyl chloride monomer (VCM), lead in petrol, mercury, beryllium, and booster biocides in Volume 2. They primarily illustrate how more precautionary action could be applied to chemical risks emerging now, such as those from Bisphenol A (BPA) and other chemicals, nicotinoid pesticides, and endocrine disrupting substances which are present in some consumer products, including pharmaceuticals, such as ethinyl oestrodiol in the pregnancy pill, discussed in Chapter 13.

The histories of well known technologies, such as X-rays, fishing techniques, fossil fuel power sources and early nuclear plants, can also provide lessons for prudent action on the potential hazards of such emerging technologies as nanotechnology, genetically modified (GM) food, radio-frequency from mobile phones, and the new generation of nuclear plants. The chapters on alien species, floods, and ecosystems, as well as the late actions on climate change, also provide insights into how the management of ecosystems could develop.

Taken together, the examples of late action on known hazards illustrate the high cost of inaction. Globally that cost has been paid in millions of lives and cases of disease and dysfunction, much damage to the environment and species, and very large economic penalties, some of which are described in Chapter 23 on the costs of inaction.

The case studies are not all negative, however. Five of the 34 case studies describe precautionary actions: the European ban on hormones in cattle feed; the regulations and some member state actions on GMOs in Europe; the ban on TBT in France in 1984; the ban on the pesticide Gaucho in France in 1999; and, arguably, the belated but still precautionary European ban on some antibiotics when used as growth promoters in farm animals. These actions,

along with the histories of the 88 claimed false positives analysed in this volume, also illustrate the value of the PP in minimising harm and societal costs.

There are other examples where action was taken quite quickly but only after serious and compelling human evidence became available, sometimes from an observant clinician (in the cases of DES and VCM) or from the victims themselves (DBCP). In these three examples, just four to seven cases of very rare cancers or sperm reduction (DBCP) were sufficient to justify prompt regulatory action.

Barriers to wider use of the PP

One obvious question that emerges from the case studies is 'how can the PP be more widely used, both as a justification for early policy action and as a broad trigger for wider, more upstream debates about innovation pathways?'

Looking across the case studies, there appears to be a number of common barriers to using the PP to justify more timely responses to early warnings. Taken together, these barriers explain much about the decades-long delay between warnings and action. These barriers include:

1 opposition from powerful corporations — supported by some scientists, policymakers and politicians — who fear high economic, intellectual and political costs to themselves from early and sometimes even late actions to reduce risks;

2 key misunderstandings about the PP's definition and meaning;

3 difficulties understanding and dealing with complex biological and ecological systems that are characterised by multi-causality, scientific uncertainty, ignorance and scientific 'surprises';

4 scientific and political tensions between the high strength of evidence needed for scientific causality and the lower strength of evidence needed for timely public policy;

5 inadequate analysis of the costs and benefits of proposed actions and inactions; and unrealistic market prices for hazardous agents that fail to reflect the costs to society of their production, consumption and wastes;

6 political and financial short-termism;

7 a failure in most cases to engage with civil society and the public to help counter the power of the corporate and other stakeholders that may wish to dismiss early warnings.

Barriers 1, 6 and 7 mainly concern political and economic power, whereas barriers 2–5 primarily relate to the more technical process of applying knowledge to policymaking.

There is, of course, no clear-cut separation between these two aspects of regulatory activities or between the roles that scientists play as 'experts' in the process of evaluating the regulatory science used in the policy process. As Jasanoff (1990 and 2011) has pointed out:

> 'Policy relevant science comes into being in a territory of its own that is subject to neither purely scientific nor wholly political rules of the game.'
>
> 'It is not so much scientists (but) experts, who govern the production and evaluation of policy relevant science.'

To help encourage broad and wise use of the PP, this chapter will briefly examine the barriers to its use, focusing initially on the first barrier, relating to corporate power. This is followed by consideration of the more technical barriers 2–5, using the EEA definition of the PP as the framework for the analysis.

Thereafter, Section 27.7 of this chapter briefly addresses political and financial short-termism, before considering wider public engagement as part of the process of creating and managing innovations and their attendant hazards.

27.2 The power of corporations to oppose action

Chapter 11 on DDT notes Rachel Carson's observation that corporations have often focused on 'making a dollar at whatever the costs'. Although this overstates the situation, the case studies provide ample evidence of how corporations responded to early warnings about possible hazards from their products by organising 'product defence' campaigns. Chapter 7 on environmental tobacco smoke describes seven key strategies that the tobacco companies used to defend their products.

The tobacco industry was certainly not alone in using similar tactics, as case studies on lead, VCM, beryllium and climate change illustrate. Indeed it

seems likely that other industries with hazardous products to defend today would employ similar strategies, including trying to control, directly or indirectly, the relevant scientific research.

This was a key objective of the leaded petrol industry, which maintained a virtual monopoly on leaded petrol research from immediately after the 'one day trial' of leaded petrol in 1925, when early warnings emerged from some senior public health scientists, until the 1970s. Without access to independent research the regulatory authorities were vulnerable to corporate influence on the scientific evidence made available to them. This was an issue that Clair Patterson, lead expert and eminent palaeontologist, noted with some vehemence in evidence to the US Congress:

> 'It is not just a mistake for public health agencies to cooperate and collaborate with industries in investigating and deciding whether public health is endangered; it is a direct abrogation and violation of the duties and responsibilities of those public health organisations.' ([1])

Today scientific research agendas are often determined by more independent academics and public sector organisations. However, the way in which technological and hazard problems are framed can result in research that focuses much more on developing products than on the need to find out whether those products are harmful.

For example, over the past two decades public research funding by the EU on nanotechnology, biotechnology and information technology was heavily biased towards product development, with only about 3 % of the EUR 28.5 billion budget spent on investigating their potential hazards. There was a similar imbalance on research into genetic modification in the US, where over the period 1992–2002 the US Department of Agriculture spent USD 1.8 billion on biotechnology research, of which just 1 % went to risk-related research (Mellon, 2003, cited in Chapter 19).

In some areas where research is dominated by issues of intellectual copyright, such as GMOs, there have been problems with access to the organisms in question. There has recently been some opening up of research on GM seeds, however, following a letter of complaint from 26 academics in the US, whose research was inhibited by the lack of access to GM seeds owned by the corporations (Pollack, 2009).

The funding of different innovation pathways is also an issue. For example, the European Commission's Standing Committee on Agricultural Research (SCAR, 2012) has called for increased support for research on the economic and social dimensions of new technologies and farming practices, calling for the highest priority be given to funding low-input high-output systems, which 'integrate historical knowledge and agro-ecological principles that use nature's capacity' (cited in Chapter 19).

There is also a strong bias in the environmental sciences towards research on well known problems rather than on emerging issues (Chapter 26).

Corporations have also realised that the language used in debates about the hazards associated with their products is also important. An example of the use of loaded language was the claim by the leaded petrol industry that 'normal' levels of lead in blood were 'natural' and therefore safe. 'Sound science' was another common term taken over by public relations companies for the tobacco industry to mean science that supports the industry position (Baba et al., 2005). The term has since been used by other industries engaged in product defence who characterise science that does not support the industry position as 'unsound'.

The strategy of 'manufacturing doubt' out of uncertainties in the science was also a key part of product defence in several of the case studies, such as those on tobacco, lead, asbestos, beryllium, benzene and climate change (Michaels, 2008; Oreskes and Conway, 2010).

The long history of corporate misconduct begs the question why corporations adopt strategies of 'product defence' and how such actions could be minimised for the public good. Chapter 6 on beryllium concludes with some reflections on this question by Tee Guidotti, who suggests that corporations quickly lock themselves into product defence because of 'fear, denial and risk of loss'. His conclusion is that if corporations are expected to reverse course as the evidence of harm from their products increases, then 'there must be room for them to turn around'. It seems likely that his suggestions that this may involve 'forgiving past liabilities and reducing punitive damages' will be controversial, whereas his call for more active shareholder engagement on the question of responsible corporate behaviour is likely to be welcomed.

([1]) Senator Muskie Hearings on Air Pollution, 1966, cited in Chapter 3 on leaded petrol.

Chapter 25 addresses the question of why businesses do not react to early warnings with precaution in more depth, looking more closely at the issue of corporate behaviour. It notes that 'blaming business, in particular with hindsight ... may not always be constructive' as it often misses the 'complex or even contradictory set of motives and drivers that businesses face'. The authors, Le Menestrel and Rode, find that corporate decisions are influenced by a mixture of economic, epistemological, regulatory, cultural and psychological factors. Economic motives dominate: 'in virtually all reviewed cases from both volumes of *Late lessons from early warnings*, it was perceived to be profitable for industries to continue using potentially harmful products or operations'.

Corporate short-term interests have dominated over longer-term public interests mainly because the costs of damage to people and environments were, and still are, largely externalised to society as a whole. The external costs of climate change are described by former chief economist to the UK Treasury, Nicholas Stern, as 'the biggest market failure ever' (cited in Chapter 14). This means that corporations bear few of the costs of harm from their activities, except in cases where victims win compensation or ecosystems are restored, where possible. Even here, however, the sums may be largely covered by insurance.

As noted in Chapter 23 on the costs of inaction, external costs need to be internalised into the accounts of corporations via regulations, taxes, charges and permits. Anticipatory assurance bonds would also be helpful, as illustrated by Robert Constanza using the example of *Deepwater Horizon* (Chapter 24).

To deal with some of the non-economic factors influencing corporate responses to early warnings, Le Menestrel and Rode suggest distinguishing between the economic and the 'political' roles of businesses that are given ample opportunity to influence the regulatory process (Scherer and Palazzo, 2011; UCS, 2012). They also call for new institutional arrangements involving rigorous and explicit exposition of the dilemmas and trade-offs involved in reconciling value conflicts, and the organisational pressure to deny the reality of the early warnings. These 'institutional approaches would more realistically complement initiatives based on the idealised principle that being socially responsible is economically profitable'.

Finally, the historical case studies also reveal one or two examples of responsible corporate behaviour, albeit by companies selling hazardous products rather than by their manufacturers. For example, some companies stopped using asbestos in the 1970,; and Johnson & Johnson stopped using CFCs in their aerosols in 1977, eight years before the ozone hole was discovered.

More recent case studies such as on BPA illustrate that some user companies abandoned BPA for some products some years before the European Commission took action on its use in baby toys. The marine and forest stewardship councils encourage responsible environmental actions; and some nanotechnology companies, such as BASF, are working with civil society organisations to agree codes of conduct on the responsible use of nanotechnology in both research and products (EU, 2010). Hewlett Packard has likewise been very active in getting lead and other hazardous compounds out of its electronic goods and Astra Zeneca is working on reducing the envionmental impact of pharmaceutials, by, inter alia, researching the potential for 'green' medicines. There is even some action on the issue of more environmentally realistic accounting, with Puma leading the way.

Meanwhile, as part of the broader debate about innovation pathways from current unsustainable economic activities in an increasingly resource-, energy- and water-constrained world, the World Business Council for Sustainable Development has produced its business vision for the way forward (WBCSD, 2010).

27.3 The precautionary principle — key elements and misunderstandings

Public health decisions about moving from 'evidence to action' are a balancing act between what needs to be known and what ought to be done (Weed, 2004). It took more than 40 years of much scientific endeavour and public debate between the 1940s and the 1980s, before what was known about smoking and lung cancer was applied to protect public health, following sustained opposition from economic and political interests. In this case, the opportunity for **precautionary** action on a **likely hazard** in the 1950s and 1960s was lost. By the 1990s only **prevention of known harm** was possible.

Numerous international treaties and other instruments refer to the PP, as summarised in Box 27.1. Many share common elements but there is also variance in the definitions with respect to: the standard of scientific evidence required to invoke the PP; the extent of the obligation imposed on public bodies to apply the principle; the objectives

Box 27.1 International treaties relevant to the case studies illustrating key elements of the precautionary principle

Rio Declaration on Environment and Development, 1992: 'Where there are threats of serous or irreversible harm, lack of full scientific certainty shall not be used as a reason for postponing costs effective measures to prevent environmental degradation.'

European Union's Treaty on the Functioning of the EU, Article 191(2): 'Union 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 Union, 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 at source, and that the polluter should pay.'

Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Preamble: 'the need to do more to protect public health and the environment in accordance with the precautionary principle'. In addition, Article 69 provides that: 'To ensure a sufficiently high level of protection for human health, including having regard to relevant human population groups and possibly to certain vulnerable sub-populations, and the environment, substances of very high concern should, in accordance with the precautionary principle, be subject to careful attention.'

UN Framework Convention on Climate Change, 1992: 'The parties should take precautionary measures to anticipate, prevent or minimize the causes of climate change and mitigate its adverse effects. Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing such measures, taking into account that policies and measures to deal with climate change should be cost-effective so as to ensure global benefits at the lowest possible cost. To achieve this, such policies and measures should take into account different socio-economic contexts, be comprehensive, cover all relevant sources, sinks and reservoirs of greenhouse gases and adaptation, and comprise all economic sectors.

EU Directive 2001/18/EC on deliberate release of GMOs, Article 4 (1): 'Member States shall, in accordance with the precautionary principle, ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs'.

Cartegena Protocol on Biosafety, 2000, Article 11(10): 'lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects.'

Regulation (EC) No 178/2002 establishing the European Food Safety Authority and procedures in matters of food safety, Article 7: Precautionary principle: 'In specific circumstances where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment.'

EU Regulation 1107/2009 on plant protection products, Article 1(4): 'The provisions of this Regulation are underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment. In particular, Member States shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks with regard to human or animal health or the environment posed by the plant protection products to be authorised in their territory.'

London International Maritime Organisation Convention on the control of Harmful Anti-fouling Systems on Sips, 2000, Articles 6(3) and (4): 'Where the Commission is of the view that there is a threat of serious irreversible damage, lack of full scientific certainty shall not be used as a reason to prevent a decision to proceed with the evaluation of the proposal … (which involves considering) whether the proposal has demonstrated a potential for unreasonable risk of adverse effects on non-target organisms or human health.'

Box 27.1 International treaties relevant to the case studies illustrating key elements of the precautionary principle (cont.)

European Court of Justice in the BSE case (Case C-157/96, National Farmers Union and others, 1998, ECR 1-2211): 'Where 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.'

Stockholm Convention on Persistent Organic Pollutants, 2001: 'Acknowledging that precaution underlies the concerns of all the Parties and is embedded within this Convention …'

WTO Agreement on Sanitary and Phytosanitary Measures (SPS Agreement), Article 5(7): 'In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members.'

European Commission communication on the precautionary principle, 2 February 2000: 'The precautionary principle applies where scientific evidence is insufficient, inconclusive or uncertain and preliminary scientific evaluation indicates that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be inconsistent with the high level of protection chosen by the EU.'

of applying the PP; and the inclusion of elements such as provisions on costs and benefits or public participation.

The EEA's working definition of the PP

It is not surprising that many debates about the PP are confused and lengthy, given the variations apparent in the instruments and statements listed in Box 27.1. During the last decade of discussions arising out of Volume 1 of *Late lessons from early warnings*, the EEA has produced and refined a working definition of the PP that has proved useful in helping to achieve a more common understanding of the PP:

> 'The precautionary principle provides justification for public policy and other actions in situations of **scientific complexity, uncertainty and ignorance**, where there may be a need to act in order to avoid, or reduce, potentially serious or irreversible threats to health and/or the environment, using an **appropriate strength of scientific evidence**, and taking into account **the pros and cons of action and inaction** and their distribution.'

This definition is explicit in specifying situations of uncertainty, ignorance and risk, as contexts for considering the use of the PP. It is expressed in the affirmative rather than the triple negatives found in, for example, the Rio Declaration. It explicitly acknowledges that the strength of scientific evidence needed to justify public policy actions is determined on a case-specific basis, and only after the plausible pros and cons, including their distribution across groups, regions, and generations, have been assessed.

The three key sets of issues highlighted in the EEA definition above are explored in Sections 27.4–27.6 below.

27.4 Complex biological and ecological systems

The *Late lessons from early warnings* case studies cover a vast range of complex systems so it is useful to focus on reproductive and developmental hazards as an illustration of such systems.

Many of the case studies have demonstrated developmental and reproductive harm from exposures to agents such as mercury at Minamata, TBT, DES, PCBs, tobacco, lead, VCM, ethinyl oestradiol from the contraceptive pill, BPA and radiation from X-rays.

These cases have shown that serious damage to health can be initiated in the early life stages of humans and other species but may not become apparent until much later in adult life, and even

Box 27.2 Reproductive and developmental harm

Developmental periods are highly sensitive to environmental factors, such as nutrients, environmental chemicals, drugs, infections and other stressors. 'Many of the major diseases — and dysfunctions — that have increased substantially in prevalence over the last 40 years seem to be related in part to developmental factors associated with either nutritional imbalance or exposures to environmental chemicals …The conditions that are affected by nutritional or environmental chemical exposures during development include the pathophysiologies, diseases, and syndromes that constitute major public health problems across the globe: obesity, diabetes, hypertension, cardiovascular disease, asthma and allergy, immune and autoimmune diseases, neurodevelopmental and neurodegenerative diseases, precocious puberty, infertility, some cancer types, osteoporosis, depression, schizophrenia and sarcopenia' (Baruoki et al., 2012).

The mechanisms of biological action in each of these earlier experiences are not yet well established, despite decades of research. However, it seems clear that it is more the timing of the dose, rather than the dose itself, which, inter alia, distinguishes harmful from harmless exposures to reproductive and developmental toxicants (Gee, 2006, 2008; Grandjean et al., 2008; Kortenkamp et al., 2011; Chemtrust, 2008; EEA, 2012).

Such harm is often irreversible and sometimes multigenerational, causing life-time personal and societal costs that cannot be offset by any benefits to the individual from intrauterine exposures. Thus, biology, economics, equity and morals all justify early actions to prevent developmental and reproductive harm. However, establishing sufficient evidence for action on such complex hazards is much more difficult than it was for tobacco and lung cancer, where there was clear evidence that just one agent, albeit a complex mixture like tobacco smoke, caused a specific cancer that was relatively rare before smoking became widespread.

in subsequent generations, as in the DES case (see EEA, 2001). Such examples illustrate the realities of complex biological and ecological systems that are characterised by multi-causality, scientific uncertainty, ignorance and scientific 'surprises'.

From monocausality to multicausality

The biological processes that lead to chronic diseases such as breast or prostate cancer, or to reproductive or developmental harm, appear to involve some or all of at least eight main events in the disease process: preparation within the host; initiation; promotion; retardation; progression; disease onset; the strengthening or weakening of severity; and prevalence of the disease. These steps in the causal chain of the disease process can be affected by many interdependent, co-causal risk factors, where the timing of exposures is usually critical. Some factors, including chance, may operate at one or several stages of the same disease process.

It is therefore a challenging task to identify the 'causal' and often co-causal factors needed to prevent or reduce the population burden of such ill health, given that exposures occur at different developmental stages; are often interactive, mixed, and usually low level; and affect people with specific environmental histories and susceptibilities.

Within the history of the public health sciences there has long been a tension between the monocausal, reductionist approach to investigating disease causation and multicausal, more holistic approaches. A similar tension exists within ecology between 'diversity' and 'variable ' approaches to complex ecosystems — see Chapter 17 on ecosystems. Some scientists frame their studies around the view that it is the germ, or the gene, the oncogene, or a single risk factor, which is mainly 'responsible' for disease. Others look to the overall environmental history of the host for the many factors and influences that, if taken together, may explain disease causation (Sing et al., 2004).

Concentrating research on particular parts of the puzzle, rather than on the causal puzzle itself, may inhibit the clarification of causality. For example, some 4 000 chemical substances have been identified in tobacco smoke, of which more than 100 are classified as toxic. However, the precise disease process that leads to cancer or heart disease in some smokers but not in others is still largely unknown after more than 40 years of research.

Despite ignorance about the disease process associated with mixtures of chemicals, it has still been possible to prevent some harm by reducing exposures to the whole mixture, such as smoke from burning tobacco and fossil fuels, from complex welding and rubber fumes, and from fine particles of air pollution.

The practical difficulties of studying and understanding complex multicausal biological processes have meant that the attraction of a monocausal approach remains strong. Reductionism and the metaphor of the body as a machine are powerful paradigms that continue to support the idea of linear relationships between specific causes, long after knowledge about irreducible uncertainties, emergent properties and non-linear dynamics became available (Di Guiliio and Benson, 2002).

From confounders to co-causal factors?

The tools available to unravel multicausal, complex and dynamic disease processes are not well developed or used (Cory-Slechta, 2005). As a consequence, most epidemiologists try to identify specific risk factors while eliminating possible confounding factors via various statistical techniques. Such 'statistical surgery' or 'context stripping' may remove many confounders from the analysis that are really co-causal factors. If the focus is on just one toxicant, then other 'environmental properties tend to be regarded as marginal and designated as covariates or confounders: treating such environmental conditions as confounders is equivalent to defining genetic differences as confounders. 'A true evaluation of toxic potential and its neurobehavioral consequences is inseparable from the ecologic setting in which they act and which creates unique, enduring individual vulnerabilities that warrant the same status as genetic predispositions and are imprinted as forcefully' (Weiss and Bellinger, 2006).

Even with a well-studied phenomenon, such as lead poisoning, there is a growing realisation that lead exposure, environmental deprivation and enrichment, and neurotoxicity are complex and 'perhaps bidirectional' (Bellinger, 2007). For example, an enriched and intellectually stimulating home environment seems to reduce the harmful effects of a toxicant such as lead, while lead exposure can reduce the benefits of such enriched environments. Similarly, a deprived socio-economic environment can increase the harmful effects of lead while reducing the beneficial effects of a reduction in lead exposure. More fundamentally, scientists have also noted that bidirectional relationships, such as cell signalling and crosstalk, imply that causality may be circular (Soto and Sonnenschein, 2006).

Similar scientific challenges emerge from the field of endocrine disruption in wildlife, as well as within ecotoxicology more generally (Newman, 2001). These arise from having to investigate and draw inference across biological scales, from population level to lower levels of biological organisation and back again, in order to show, for example, whether harm to individual fish can cause fish population decline (Chapter 13 and Kidd et al., 2007).

It would seem then that the 'key to understanding these causal processes is clearly the ability to elaborate and understand complexity: the interacting systems involved will always overwhelm predictions of independent effects of any single factor, reducing them to very limited and uncertain information' (Bellinger et al., 1985).

It also follows that in complex systems very small changes in key variables can have profound effects. 'Small' can be very significant in finely balanced non-linear systems, where, as Heraclitus observed centuries ago, there is a 'harmony of opposites'. Removing even the 'smallest' link in an interdependent causal chain can sometimes break at least pathway to disease.

Such complex and multi-causal factors are also evident in ecological systems and species as illustrated in Chapter 14 on climate change, Chapter 16 on bees, Chapter 17 on ecosystems and Chapter 20 on invasive alien species.

How then can we identify possible or probable causality from observed associations in such complex biological and ecological systems, so that some co-causal priorities for public health and environmental protection can be agreed?

Multicausality and the Bradford Hill 'criteria' for causality

'With preventive medicine in mind the decisive question is whether the frequency of the undesirable event B will be influenced by a change in the environmental feature A' (Bradford Hill, 1965). Building on the tobacco controversy, Bradford Hill identified nine characteristics of scientific evidence that, if taken together, could help scientists to move with some confidence from observing associations to asserting causation. His

Box 27.3 The Bradford Hill 'criteria' for identifying causation

1. Strength of association
2. Consistency
3. Specificity
4. Temporal relationship (temporality)
5. Biological gradient (dose-response relationship)
6. Plausibility (biological plausibility)
7. Coherence
8. Experiment (reversibility)
9. Analogy

Source: Bradford Hill, 1965.

subsequently misnamed 'criteria' are still widely used today in both the health and environmental fields (WHO, 2002; Collier, 2003; Maxim and van der Sluijs, 2010).

Bradford Hill's explicit approach to deriving causation from association was essentially based on monocausality, that is, on finding the specific cause of a specific disease.

He was aware that several factors would be implicated in disease but that removing one of them may reduce its frequency, or incidence, without necessarily eliminating the disease entirely. He also acknowledged the other, simpler type of multicausality, which is where one disease can have several different independent causes, noting that: 'diseases may have more than one cause. It has always been possible to acquire a cancer of the scrotum without sweeping chimneys or taking to mule spinning in Lancashire' (Bradford Hill, 1965).

The Bradford Hill 'criteria' need to be reappraised in the light of multicausality and complexity. This is particularly important because the absence of some or all 'criteria' is often used in current controversies to deny the possibility of causality. More generally, the criteria seem less robust now as reasons for dismissing associations than they did in the world of the 1960s, when issues were perceived in largely monocausal terms.

For example, the criterion of **consistency** between the results of different studies into the same phenomena, when present, clearly adds much confidence to assertions of causality. However, multi-causality can make consistency very difficult to achieve: 'if all studies of lead showed the same relationship between variables, one would be startled, perhaps justifiably suspicious' (Needleman, 1995). The sources of variability arise both from the study and the investigator, such as the framing and initial assumptions; the models, methods and statistical analyses used; the choice of population group; the presence of susceptible sub-groups; and the data selected. Other sources of variability and bias have been noted (Bailar, 2007) and the limitations of conventional epidemiology have been explored from a precautionary perspective (Grandjean, 2008). In addition, there are the sources of variability in populations arising from the 'sociomics' of environments and the epigenetics of individuals.

It is hardly surprising therefore that, after decades of research, most lead studies can still only 'explain' 30–40 % of the variance in most lead-linked biological end-points, and sometimes far less (Bellinger, 2007). As inconsistent results are to be expected from complex biological and ecological systems the absence of consistency between studies does not imply an absence of causality.

Bradford Hill included a **linear dose-response relationship** between a toxicant and its effects as another important criterion. However, where the timing of exposure is more important than the dose itself, and where non-linear, 'low-dose' effects are present, the absence of a linear dose-response relationship does not provide robust evidence against causality.

The condition of **temporality** anticipates that a cause must precede the effect. This is obviously so, except where there are multiple causes arising at different times, and with varying rates of increase or decrease, which may therefore reverse, stabilise, or accelerate the overall disease trend, depending on their relative strengths. If this feature of reality is not taken into account then some widely used interpretations of temporality in relation to overall disease trends can lead to shaky conclusions.

For example, in a review of the evidence on falling sperm counts and endocrine-disrupting chemicals, it was concluded that, as overall sperm counts began to fall in some countries in advance of the rise of chlorine-based chemistry, such chemical exposures could not be a cause of change in the overall trend (WHO, 2002). In the context of multicausality, where the combined effects of several causes together determine the overall time trend of a disease, such a conclusion is not soundly based.

Such time-dependent factors within multicausal systems also mean that obtaining evidence based on the **experiment** criterion — i.e. demonstrating the impact of removing one cause of a disease affected by many causes — can be very difficult, as with changes in IQ or sperm counts.

Less weight should also be placed on **specificity** as a criterion, given the widespread prevalence of 'many to many' cause and effect relationships, and the capacity of many substances, such as tobacco PCBs, asbestos, lead and mercury, to cause many types of harm.

The **strength of association**, which Bradford Hill put first in his list of features, is clearly still very relevant but with caveats that arise from multicausality. Even a 'low' relative risk of say, 1.5, if replicated in several studies, can be very robust for a multicausal disease as is the case with smoking and heart disease. Such a 'low' relative risk will also represent much harm if the background rate of the disease is large.

The criteria of **biological plausibility** and **coherence** are dependent on the established knowledge of the day and therefore are not robust criteria for dismissing early warnings, where relatively novel science, at the frontiers of scientific knowledge, is often used.

Whereas multicausality seems to weaken most of the criteria, **analogy** becomes more necessary given the difficulties of establishing clear causality from complex systems. If precautionary actions are needed then analogies from past experiences may be particularly valuable. Box 27.4 provides some 'criteria for action' to complement the criteria for causation, based on experiences of past ecological and biological hazards, including by analogy, which may provide quite robust evidence of emerging potential hazards.

In judging strength of association, Bradford Hill also warned against the overuse and misuse of statistical significance testing: 'we waste a deal of time, we grasp the shadow and lose the substance, we weaken our capacity to interpret data and to take reasonable decisions whatever the value of P. And far too often we deduce "no difference" from "no significance".'

Although similar cautions have been repeated regularly since then (Cohen, 1994; Poole, 2000; Hooper, Stang and Rothman, 2011), the misinterpretation of statistical significance and the relative neglect of confidence intervals continue (see also Chapter 26 on science for precautionary decision-making).

In the circumstances of multicausality and complexity the Bradford Hill criteria are characterised by a strong element of asymmetry. The presence of the criteria can be robust evidence for a causal association, whereas the absence of the criteria is not robust evidence that there is no causal association. Bradford Hill drew attention to this asymmetry with several of his criteria but some of his followers have forgotten

Box 27.4 Criteria for precautionary action: some features of evidence about the hazardous potential of agents that may justify precautionary action

1. Intrinsic toxicity/ecotoxicity data
2. Novelty (i.e. where there is a low 'knowledge/ignorance ratio')
3. Ecological or biological persistence
4. Potential for bio-accumulation
5. Large spatial range in the environment e.g. potential for global dispersion.
6. Seriousness of potential hazards
7. Irreversibility of potential hazards
8. Analogous evidence from known hazards
9. Inequitable distribution of hazardous impacts on particular regions, people and generations
10. Availability of feasible alternatives
11. Potential for stimulating innovation
12. Potential and time scales for future learning

this in their use of the criteria to dismiss possible hazards (Ashby, 1997; WHO 2002). When addressing biological and ecological complexity, such asymmetry in the application of the Bradford Hill criteria is even more pronounced than it was when he introduced them.

Another barrier to early action arises from the systemic biases towards not finding a causal link, specifically biases within the epidemiology and toxicology methods that tend to generate false negatives (i.e. assertions that something is safe when it turns out not to be). These methodological biases are illustrated by Grandjean in Chapter 26.

Both policymakers and scientists need to acknowledge and take account of these main directions of methodological error when they evaluate the methods and results of research. Many scientists do (Grandjean, 2004 and 2005) but awareness of these methodological biases among many stakeholders appears to be low.

Finally, the issue of funding bias, whereby research results can be closely associated with the source of funding, has been observed in the tobacco literature (Barnes, 1998) and then identified in other fields such as pharmaceuticals (Goldacre, 2012; Lexchin, 2003) the food and beverage industry (Levine, 2003) BPA, (Vom Saal, 2005), mobile phones (Huss et al., 2007), food, (Levine, 2003), biomedics (Bekelman, 2003), GMOs (Diels, 2011). The explanation for this bias is not clear (Krimsky, 2006, 2010). Funding bias is also to be found in the transport and constructions fields, where underestimation of costs and construction times by the developers is routine, and in cost-benefit analysis where the direction of bias is routinely in the direction of those who fund the study.

Other concepts related to the PP and complexity are likewise often understood differently by different actors. An important example is the distinction between uncertainty and ignorance, which constitute quite different states of knowledge. For example, both the asbestos-induced mesothelioma cancer and the hole in the ozone layer caused by CFCs were complete scientific 'surprises', arising from a state of ignorance. They were not gaps or uncertainties in existing states of knowledge.

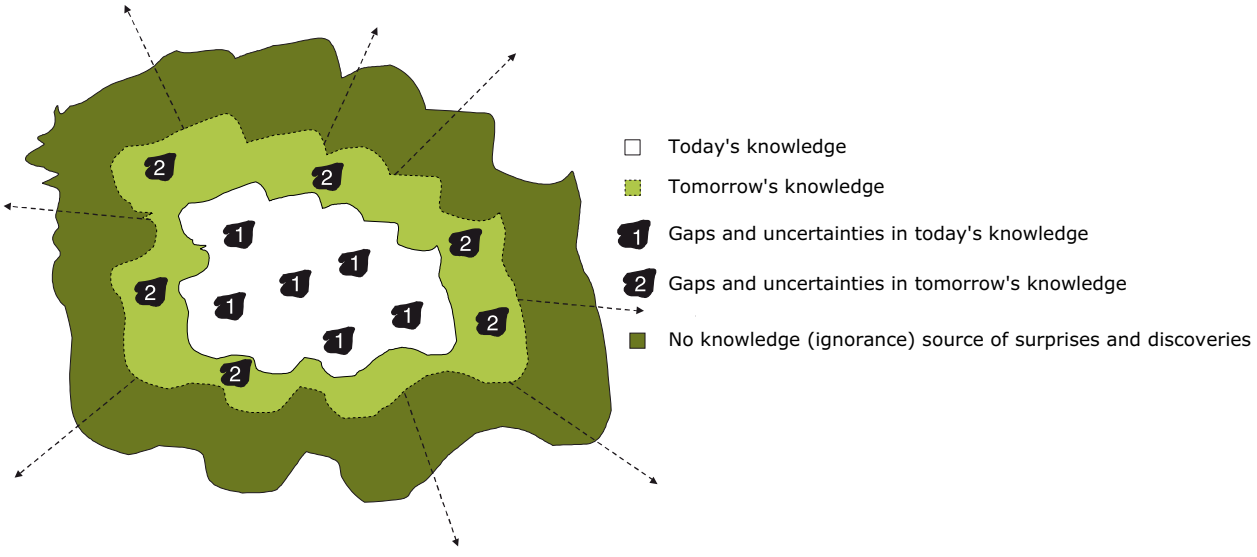
To be uncertain one has to be uncertain about something and any 'gaps' in knowledge relate to current knowledge. Both 'uncertainty' and 'gaps' relate to a stock of existing knowledge. 'Ignorance', on the other hand (or more elegantly, 'nescience', i.e. 'no knowledge') relates to 'unknown unknowns'.

More research can close some gaps in knowledge and reduce some uncertainties but such research will also uncover new sources of uncertainty and gaps in knowledge, as well as raising awareness about new areas of ignorance. Learning to live with and manage irreducible uncertainties is as necessary as trying to reduce them.

The knowledge-to-ignorance ratio

Acknowledging ignorance raises questions about how much knowledge we have in a given field

Figure 27.1 Expanding knowledge, continuing uncertainties



compared to ignorance. This issue was noted in the World Conservation Strategy (IUCN, 1980), which advised people to :

> 'keep in mind that, in spite of present knowledge, **what we know about the biosphere, ecosystems and their interrelationships is less than what we do not know.** Consequently, it is often difficult to accurately predict the effects of human actions. Gaps in knowledge should be filled where possible.. but in the meantime risks should be reduced' (emphasis added).

This may be dismissed as a trivial observation but it does draw attention to the need for scientific humility even when considering the large stocks of current knowledge on many hazards. Scientists in many of the case studies failed to show scientific humility, instead being guilty of what has been termed 'the sin of hubris' in the context of marine ecosytems and fisheries science (MacGarvin, 1994).

While the knowledge-to-ignorance ratio cannot be quantified, it is possible to get an informed qualitative appreciation of the balance in the various fields covered by the case studies. For example, there is clearly a difference between the current stock of accumulated knowledge, on, say, asbestos, ionising radiations and tobacco, compared to our stock of knowledge on nanotechnology, GM food, or on non-ionising radiations when used in recent consumer products such as mobile phones. And while there will still be a lot of new knowledge that could be gained about even a well known substance like asbestos ([2]) the practical need to search for more knowledge about asbestos is very minimal, as we know more than enough to avoid its dangers successfully.

In contrast, there is a vast ocean of scientific ignorance surrounding nanotechnologies, biotechnologies and non-ionising radiation technologies and chemicals used in consumer and other products. This remains to be explored. What is known in these relatively immature fields can perhaps be likened to the few 'pebbles' of knowledge that Sir Isaac Newton gathered from his scientific work and that he contrasted to that 'great ocean of undiscovered truth', which remained to be explored and which encouraged scientific humility ([3]).

Where the 'knowledge-to-ignorance ratio (KIR)' is high (implying much knowledge and little practically necessary ignorance), as with, for example, lead, asbestos and mercury, there is little need for either more research or for precautionary (as distinct from merely preventative) measures. Where the KIR is low, however, there is a need for both precautionary measures following credible early warnings and for novel research, rather than the 'scientific inertia' of excessive research on well known substances described in the Chapter 26. As de Sadeleer (2010) has observed, 'it may be impossible to carry out a full risk assessment because such investigations operate at the frontiers of scientific knowledge, ... (where scientists) must even point to the limits of their knowledge or, where appropriate, to their ignorance.'

The limitations of scientific knowledge imply moral courage in taking precautionary action in time to avert harm. As Lewontin has observed: 'Saying that our lives are the consequence of a complex and variable interaction between internal and external causes does not concentrate the mind nearly so well as a simplistic claim; nor does it promise anything in the way of relief for individual and social miseries. It takes a certain moral courage to accept the message of scientific ignorance and all that it implies' (Orrell, 2007).

Table 27.1 attempts to clarify concepts such as ignorance and uncertainty that often arise in debates on the PP.

27.5 Conflicts between the high strength of evidence needed for scientific causality and the lower strength of evidence needed for timely public policy

All responsible applications of the precautionary principle require some plausible evidence of an association between exposures and potentially harmful impacts. For example, the European Commission's communication on the precautionary principle (EC, 2000) specifies that 'reasonable grounds for concern' are needed to justify action. However, it does not explain that these grounds will vary with the specifics of each case, nor does

([2]) It is only recently that new Dutch analyses of the epidemiological data on asbestos has shown that the difference in harmful potency between blue and white asbestos, claimed by some scientists, practically disappears when the exposure estimates are scrutinised more carefully (Lenters et al., 2012).

([3]) 'I do not know what I may appear to the world, but to myself I seem to have been only like a boy playing on the sea-shore, and diverting myself in now and then finding a smoother pebble or a prettier shell than ordinary, whilst the great ocean of truth lay all undiscovered before me' (Newton, 1855).

Table 27.1 Some common concepts used in PP debates

Situation	Nature of knowledge	Type of action taken
Risk	**'Known' impacts** and **'known' probabilities**, e.g. regarding asbestos from 1930.	**Prevention**: action to reduce known hazards, e.g. eliminating exposure to asbestos dust
Uncertainty (*)	**'Likely' impacts** but **'unknown' probabilities**, e.g. regarding antibiotics in animal feed and associated human resistance to those antibiotics, from 1965.	**Precaution**: action taken to reduce exposure to plausible hazards, e.g. the EU ban on antibiotic growth promoters in 1999.
Ignorance	**'Unknown' impacts** and therefore **'unknown' probabilities**, e.g. the then unknown but later 'surprises' of the ozone layer 'hole' from CFCs, pre-1974; the mesothelioma cancer from asbestos pre 1959; the rate of Greenland ice sheet melting pre-2007.	**Precaution**: action taken to anticipate, identify earlier, and reduce the extent and impact of 'surprises' e.g. by using intrinsic properties of chemicals e.g. persistence, bioaccumulation, spatial range; using analogies; long-term monitoring; and using robust, diverse and adaptable technologies that can help minimise impacts of 'surprises'.
Ambiguity	Concerning the different **values and interpretations** about information used by stakeholders. E.g. in invasive alien species cases where a species can be welcomed by some but not others.	**Participatory precaution:** stakeholder engagement in decision- making about innovations and their potential hazards.
Variability	The natural differences in population or ecosystem exposures and sensitivities to harmful agents.	**Obtain more information** in order to minimise simplistic assumptions about average exposures and sensitivities
Indeterminacy	Unpredictable uses of technologies e.g. use of X-rays in children's shoe shops in the 1950s.	**Pre-market benefit assessment** of novel uses of a technology with potential hazards.

Note: * Different types, sources and levels of uncertainty can be identified (Walker, 2003).

it explicitly distinguish between risk, uncertainty and ignorance as important factors in judging the 'reasonableness' of the grounds for action.

The strength of evidence deemed to be reasonable justification for action varies between different jurisdictions and cases and can be quite low. In Sweden, for example, a 'scientific suspicion of risk' constitutes sufficient evidence for restricting an existing chemical substance. Similarly, for the World Trade Organization, 'pertinent scientific information' can be sufficient to justify protective measures under the Agreement on Sanitary and Phytosanitary Measures whenever there is an insufficiency of science to permit a comprehensive and robust risk assessment.

The strength of scientific evidence appropriate to justify public policy or other actions depends on the pros and cons of action or inaction in the specific circumstances of each case. These circumstances include the nature and distribution of potential or plausible harm; the justification for and the benefits of the agent or activity under examination; the availability of feasible alternatives; and the overall goals of public policy. Such policy goals include 'high levels of protection' of the public, consumers, and the environment, as required by the Treaty of the European Union.

The use of different strengths of evidence for different purposes is not a new idea. Legal practice has long employed several tests, such as 'beyond all reasonable doubt' in criminal courts and the lower 'balance of probabilities' used in many civil courts.

Moreover, public health practitioners have long advocated the use of varying strengths of evidence in different circumstances. For example, Bradford Hill (1965) concluded his classic paper on association and causation in environmental health with a 'call for action' in which he proposed the use of case-specific and differential strengths of evidence, observing that:

> 'It almost inevitably leads us to introduce **differential standards** before we convict. Thus on **relatively slight evidence** we might decide to restrict the use of a drug for early-morning sickness in pregnant women. If we are wrong in deducing causation from association no great harm will be done. The good lady and the pharmaceutical industry will doubtless survive. On **fair evidence** we might take action on what appears to be an occupational hazard, e.g. we might change from probable carcinogenic oil to a non-carcinogenic oil in a limited environment and without too much injustice if we are wrong. But we should need **very strong evidence**

> before we made people burn a fuel in their homes that they do not like or stop smoking the cigarettes and eating the fats and sugar that they do like' (emphasis added).

In the field of cancer, the International Agency for Research on Cancer also uses several types of scientific evidence to categorise their strengths of evidence on carcinogens (Cogliano, 2007).

Failing to acknowledge the reality of different strengths of evidence for action has led to several ill-founded debates. For example, opponents of the PP often cite the North Sea Ministerial Declaration, which calls for: 'action to avoid potentially damaging impacts of substances, **even where there is no scientific evidence to prove a causal** link between emissions and effects' (emphasis added).

Critics claim that this definition justifies action even when there is 'no scientific evidence' that associates exposures with effects. However, the North Sea Declaration clearly links the words 'no scientific evidence' with the words '**to prove a causal link**'. There is a significant difference between the evidence needed to show a **plausible link** between a pollutant and harm, and evidence which is robust enough to 'prove' a causal link. Once evidence reaches the level of 'proving' a causal link there is no need for the PP as the issue is then firmly in the 'prevention principle' area where the risks are well characterised.

Similar confusion arose in interpreting the different strengths of evidence for association and causality set out in a 13-country study of brain cancers and mobile phones (the Interphone study) (see Chapter 21 on mobile phones).

The confusion of commentators, including the media, in these cases arose because scientists were not transparent and clear about the difference between the very strong evidence needed to establish 'causality' and the suggestive evidence of plausible risks.

For example, the Interphone concluded that:

> 'There were **suggestions of an increased risk** of glioma, and much less of menigioma, at the highest level of exposure….. (but) biases and errors limit the strength of the conclusion we can draw from these analyses and **prevent a causal interpretation**'.

One consequence of not clarifying the difference between the low and high strengths of evidence embedded in these two sentences was that readers of the Interphone conclusion, particularly the media, interpreted the study as providing either no evidence of cancer or evidence of cancer. Both conclusions were strongly cited by different and similarly weighty parts of the media.

In the United Kingdom, for example, the *BBC* (17 May 2010) reported that 'No proof of mobile cancer risk, major study concludes'. On the same day, *The Telegraph* asserted that 'Half an hour of mobile use a day increases brain cancer risk'.

Beneath the strong evidence of 'scientific causality' there is a large evidentiary space containing a continuum of strengths of evidence that can be used to justify action under the precautionary principle, depending on the case-specific circumstances. The question remains, however, where, in that continuum, is 'sufficient evidence' located?

Identifying an appropriate strength of evidence for action has been an important issue in climate change debates. The Intergovernmental Panel on Climate Change (IPCC) discussed this issue at length before formulating its 1995 conclusion that 'on the balance of evidence' mankind is disturbing the global climate. It further elaborated on this issue in its 2001 report, which identified seven strengths of evidence that can be used to characterise the scientific evidence for a particular climate change hypothesis (see Panel 14.1 in Chapter 14 on climate change). By 2007 the IPCC was able to conclude with 'high confidence' that the evidence for human-induced climate change had strengthened to 'very likely' (IPCC, 1995, 2001 and 2007).

Table 27.2 presents five of these strengths of evidence based on the IPPC approach and illustrates their practical application to a variety of different societal purposes.

The decision about when there is sufficient evidence to justify preventive action clearly involves more inputs to decision-making than merely science. The strength of evidence that is deemed appropriate depends on such non-scientific criteria as the costs of being wrong with actions or inactions (including their nature and distribution between different groups and generations); the justification for, and benefits of, the agents or activities that pose potential threats to health; and the availability of feasible alternatives.

The term 'no established or conclusive evidence' is often used to characterise the absence of some strength of evidence that would convince the particular scientists doing the risk assessment that an agent causes harm. The different consequences

Table 27.2 Different strengths of evidence for different purposes: some examples and illustrations

Strength of evidence	Illustrative terms	Examples of use
Very strong (90–99 %)	Statistical significance	Can be part of strong scientific evidence of 'causation'
	Beyond all reasonable doubt	Most criminal law, and the Swedish Chemical Law 1973, for evidence of 'safety' of substances under suspicion — placing the burden of proof on manufacturers
Strong (65–90 %)	Reasonably certain	US Food Quality Protection Act, 1996
	Sufficient scientific evidence	To justify a trade restriction designed to protect human, animal or plant health under World Trade Organization Sanitary and Phytosanitary Agreement, Art. 2, 1995
Moderate (33–65 %)	Balance of evidence	Intergovernmental Panel on Climate Change 1995 and 2001
	Balance of probabilities	Much civil and some administrative law
	Reasonable grounds for concern	European Commission Communication on the Precautionary Principle 2000
	Strong possibility	British Nuclear Fuels occupational radiation compensation scheme 1984 (20–50 % probabilities triggering different awards up to 50 % + which triggers full compensation)
Weak (10–33 %)	Scientific suspicion of risk	Swedish Chemical Law 1973, for sufficient evidence to take precautionary action on potential harm from substances — placing the burden of proof on the regulators
	Available pertinent information	To justify a provisional trade restriction under World Trade Organization Sanitary and Phytosanitary Agreement, Art. 5.7, where 'scientific information is insufficient'
Very weak (1–10 %)	Low risk	Household fire insurance
	Negligible and insignificant	Food Quality Protection Act, 1996 (USA)

for those for whom the evidence is 'not established' (i.e. risk takers or risk makers) is seldom discussed. Nor are the purposes for which the evidence could be conclusive discussed, for example to justify warning labels, or low cost exposure reductions, or a ban.

Decision-makers must also be aware of the common mistake of assuming that 'no evidence of harm' is 'evidence of no harm', when the relevant research has not been done, a feature of many case studies which is picked up in Chapter 26, where 'authoritative but unsubstantiated assertions of safety' are described.

Finally, interpreting 'convincing evidence' only as the high strength of evidence needed to establish 'scientific causality' is of little practical use in helping to apply the precautionary principle or in averting, as opposed to observing, future harm. This means that risk assessment committees may need to consider the consequences of their judgements as well as just causation, as Bradford Hill and the IPCC have demonstrated. It may be argued that it is for risk managers to deal with the consequences of decisions about causation. Nevertheless, scientists involved in risk assessments are well placed to contribute to analysis of consequences, as was acknowledged by the European Court when it noted that a scientific risk assessment should provide the competent public authority with sufficient, reliable and cogent information so that it also understands:

> '…the **ramifications** of the scientific question raised and can decide upon a policy in full knowledge of the facts' (ECR, 1999 and 2002) (emphasis added).

27.6 The pros and cons of actions and inactions

The EEA definition of the PP widens the conventionally narrow and quantifiable interpretation of costs and benefits to embrace wider and sometimes unquantifiable 'pros and cons'. These include, for example, a loss of trust in science after the public experiences harm that scientists had assured them would not occur. Such unquantifiable costs can sometimes be as significant as the economic costs, as in the case of BSE (EEA, 2001) and the nuclear accidents at Chernobyl and Fukushima (Chapter 18).

Chapter 23 on costs of inaction illustrates how the costs and benefits of action and inaction are

skewed towards the tangible short-term compliance costs of regulatory action, which usually fall on specific, often powerful actors, and against the long-term diffuse benefits to society as a whole of timely actions. The polluter pays principle and the internalisation of external costs are essential components of approaches to achieving a more economically efficient and equitable distribution of the pros and cons of action and inaction. Such measures would bring the market prices of hazardous agents into line with their real costs, encouraging earlier development of substitutes and other economic and technological innovations (EEA, 2012).

Several of the case studies (asbestos, lead, mercury, PCBs, CFCs, benzene) indicate that early actions can stimulate innovations and conversely illustrate how late actions have consolidated technological monopolies for products, at unrealistically low prices, which served to keep smarter substitutes out of the markets for many years.

Other work has demonstrated the role that strong and smart environmental regulations, tax incentives and other measures can play in stimulating innovation (Porter, 1995; Ambec, 2011; Ashford, 1979, 2011a, 2011b and 2012).

27.7 Political and financial short-termism

The time horizons of democratic politics are very short in comparison to the long timescales associated with successfully managing the harm to environments and people illustrated in the case studies. This is a deep-seated problem but some countries have begun to devise some institutional responses to protect the long-term interests of society. For example, countries like Finland, Israel, New Zealand and Hungary have been experimenting with nominating ombudsmen or committees charged with caring for the long term (Roderick, 2010; Ward, 2012).

The financial sector is even more limited by short termism but since the financial crash there has been some effort to establish more long-term perspectives (Mainelli and Giffords, 2009).

27.8 Public participation in hazard and options analysis

There are many value judgements involved in hazard and risk analysis, from the framing of the issue and the questions to be addressed to the ethical choice of the appropriate strength of evidence that should justify action to reduce hazards in a particular case.

As several authoritative bodies have highlighted in recent years, the public should be involved in decisions about serious hazards and their avoidance, and at all stages of the risk analysis process (US PCR, 1997; RCEP, 1998; German Advisory Council on Global Change, 2001; Codex Alimentarius Commission, 2007; JRP/IPCS, 2007; Health Council for the Netherlands, 2008; NAS, 2009)

Figure 27.2, based on the above reports, illustrates the circular, iterative nature of risk assessment, risk management and risk communication; the links and feedback loops between them; and the involvement of stakeholders at every stage, albeit with different intensities of engagement — greater at the problem framing and options choice stages, less so at the scientific risk assessment stage.

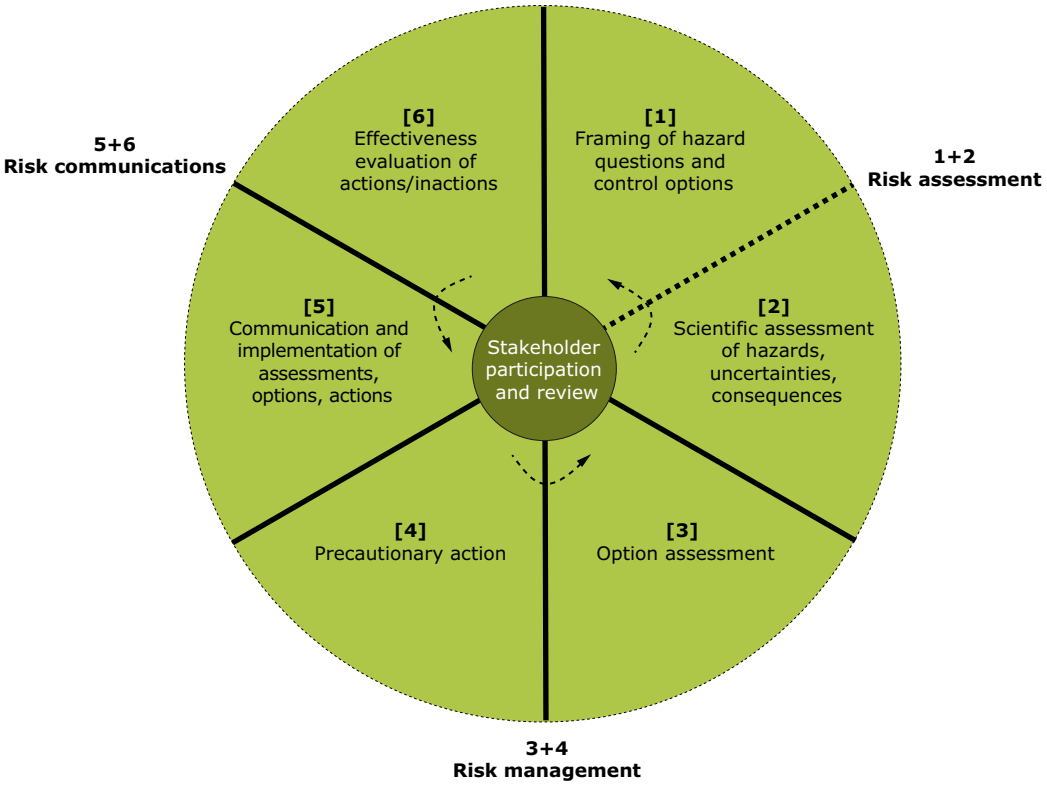
The report from the US National Academy of Sciences on Risk Assessment, *Science and decisions: advancing risk assessment* (NAS, 2009), strongly recommends such stakeholder involvement, especially at the crucial problem framing stage.

These recommendations for enhancing stakeholder participation in the hazard and options analysis process do not appear to be reflected in most existing international and European arrangements for analysing risks and setting public exposure limits e.g. relating to contaminants in food (JRC/IPTS, 2007). European authorities are continuously improving, albeit at speeds that fail to satisfy all stakeholders.

Changes are nevertheless in the air. The European Commission increasingly involves stakeholders in risk assessment by, for example, asking for public comments on the questions to be put to risk assessors and holding stakeholder consultative meetings ([4]). There have also been recent improvements in the way that uncertainties are handled in the food (EFSA, 2009; Hert, 2010) and emerging issues fields (SCENIHR, 2012), building on the earlier work of the IPCC on

([4]) See the stakeholder dialogue procedures in EC (2009). The European Food Safety Authority (EFSA), for example, organises a Stakeholder Consultative Platform for food industry stakeholders and widely publishes agendas, minutes, and scientific opinions as part of its response to Articles 38 and 39 of its founding regulation on openness and transparency in the governance of food safety risks.

Figure 27.2 A participatory and precautionary framework for analysis of hazards and options



Note: The dotted line indicates feedback.

Source: EEA, based on NRC (1996), US Presidential Commission on Risk (1997), UK Royal Commission on Environmental Pollution (1998) and NAS, 'Science and Decisions' (2009).

how to manage and communicate uncertainty. As Chapter 15 on floods illustrates, balancing timely early warnings against false alarms is a very challenging task for decision-makers under conditions of complexity, uncertainty and ignorance.

There have also been improvements in the transparency of risk assessments, including, most recently, improved public access to the scientific data submitted by companies to regulatory authorities for product authorisations (EFSA, 2013). The need for this openness has emerged as a strong lesson from several case studies — from Minamata to the bio- and nanotechnology fields — and the improvements follows recent controversies over the food additive aspartame and GM maize (Seralini et al., 2012; Genewatch, 2012).

From uncertain risks to relevant and responsible innovation?

In the introduction to this chapter the debates in France on GMOs were used to illustrate the potential of the PP to trigger or facilitate debates that go well beyond the issue of risks and into the area of responsible and socially relevant innovation.

One or two other case study chapters also raise this question. For example, the Chapter 3 on leaded petrol reviewed the technological 'roads not taken' and Chapter 19 on GM crops analysed 'top down' and 'bottom up' innovation pathways to agricultural futures. Chapter 5 on Minamata disease and Chapter 16 on bees also raised questions concerning the value of current democratic institutions in dealing with complex socio-technical issues. More involvement of the public in hazard and options analysis, discussed above, may also lead to wider discussions about technological choices and directions of innovation.

Richard Owens, co-author of the Chapter 13 on the 'birth pill' has further developed these ideas in a forthcoming book on 'responsible innovation' (Owens et al., 2013).

Box 27.5 Responsible research and innovation

Responsible research and innovation is a transparent, interactive process by which societal actors and innovators become mutually responsive to each other regarding the ethical acceptability, sustainability and social desirability of the innovation process and its marketable products. Social desirability is currently essentially determined by market mechanisms, however, as universal principles on what counts as socially desirable are not easily agreed upon.

The 'Innovation Union' flagship initiative is a central part of the EU's Europe 2020 strategy and is seen as means to deliver 'smart growth', defined as 'developing an economy based on knowledge and innovation' (EC, 2011).

From this macroeconomic perspective, innovation is assumed to be steerless but inherently good, as it produces prosperity and jobs and meets societal challenges, addressed through market mechanisms.

Modern societies lack a specific forum or policy for evaluating particular technologies in terms of benefits and risks within the legislative context. We only have formal safety, quality and efficacy assessment procedures evaluating the properties of products in the course of passing these three market hurdles.

The benefits of technologies are 'demonstrated' only by market success, whereas the potential negative consequences are evaluated under formal risk assessment schemes. The state is responsible for defining the risks of technologies under product authorisation procedures and product liability law and ensuring market operators compliance, whereas society lacks a particular responsibility for what could count as positive impacts of technologies.

Modern 'Frankensteins' are not intentionally created by a single actor. If they arise they are more likely the unforeseen side effects of collective action. Indeed, techno-scientific applications can remain ethically problematic even in cases where scientists and engineers have the best possible intentions and users have no conscious intention to misuse or abuse ([5]).

This situation constitutes the major ethical challenge we face today. Ethics focused on the intentions and/or consequence of actions of individuals are not appropriate for allocating responsibilities for the impacts of innovations.

Responsible innovation therefore requires ethics of co-responsibility for ensuring the right impacts and avoiding negative consequences, whether these impacts are intentional or not and whether they can be fully foreseen or not.

The challenge is to arrive at a more responsive, adaptive and integrated management of the innovation process. A multidisciplinary approach involving stakeholders and other interested parties should lead to an inclusive innovation process whereby technical innovators become responsive to societal needs and societal actors become jointly responsible for the innovation process. That includes contributing to defining socially desirable products that reflect basic needs and public values, for example by focusing on the great challenges of our times such as climate change and food security.

Effecting such changes requires a paradigm shift in innovation policy. The state must assume responsibility for positive outcomes of innovation, reflect basic public values beyond consumer market preferences and move away from technology-oriented research and innovation policy and towards an issue-oriented approach.

Source: Edited extracts from von Schomberg, 2013 ([6]).

([5]) The concept of collective co-responsibility in response to the shortcomings of professional roles — responsibility in science and engineering is outlined in von Schomberg (2007).

([6]) René von Schomberg is at the European Commission, Directorate General for Research. The views expressed here are those of the author and may not in any circumstances be regarded as stating an official position of the European Commission.

Box 27.5 includes a short description of responsible innovation written by Rene Schomberg, a contributing author to the Owens book (Owen et al., 2013). Innovation 'with a human purpose' is also being proposed as a means to rebalance market-focused innovation and to meet the environmental challenges posed by meeting human needs in a resource-, energy- and water-constrained world (van den Hove, 2012).

The field of public engagement on risks, hazards and innovations is large (Wynne, 2007; Stirling, 2008 and 2010; Wesselink and Hoppe, 2011; Wesselink, 2011; Hoppe, 2012) and extends well beyond the bounds of the present study. However, the evidence from *Late lessons from early warnings* provides further grounds for boosting public and corporate engagement in responsible innovation.

27.9 Conclusion

The case studies and this chapter have illustrated the need for wider use of the PP both as a justification for timely actions on early warnings and as a trigger for broader debates about technological pathways to the future. Mistakes will be made, surprises will occur. But if the quality of the scientific and stakeholder processes used to arrive at such decisions are sound, and the best of science is used, then living with the consequences, of such decisions, both pleasant and unpleasant, will be more acceptable.

The capacity of people to foresee and forestall disasters appears to be limited, however, especially when such action is opposed by powerful economic and political interests, as the case studies in *Late lessons from early warnings* illustrate. It is not just corporations that have the capacity for denial when confronted with evidence of impending disaster — as the financial collapse of 2009 demonstrated. 'Wilful blindness' and human 'folly' are general human traits that thwart our capacities to do the right thing (Heffenan, 2010; Tuchman, 1984).

If we adopt optimism of the will to counter pessimism of the intellect, however, it is possible to believe that human behaviour could improve. Decision-makers could heed the lessons of past experience. Armed with more humility in the face of scientific uncertainty and ignorance, and supported by broad and effective public engagement, they could apply the precautionary principle more widely. In so doing, they would help anticipate and minimise many future hazards, while stimulating innovation.

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