16. Twelve late lessons

Editorial team

16.1. Introduction

The case studies provide a wealth of 'late lessons' for future policy. To attempt to summarise them all would effectively replicate the studies. Returning to the four broad questions that we posed to the authors and trying to distil a number of specific lessons seemed more useful. These then might be applied to future policy in order to minimise repetition of the mistakes — or at least the oversights — of the past.

The first question posed was when was the first credible scientific early warning? The second was when and what were the main actions or inactions on risk reduction taken by regulatory and other responsible bodies? The key point here is the length of the gap between the specific problem being identified and effective action being taken. The answer for many case studies was that the gap was long, certainly many years or decades, and in some cases over a century. This might not be so surprising before the need for the precautionary principle had been explicitly identified in the 1970s and 1980s. But even after that, examples of unequivocal precautionary action were relatively scarce. It is also notable that, while the precautionary principle debate has sometimes been characterised as a battle between the European Union (EU) and North America, the case histories suggest another story, one of different degrees of acceptance of the need for precaution within different institutions in both North America and Europe.

In many of the case studies, adequate information about potential hazards was available well before decisive regulatory advice was taken, but the information was either not brought to the attention of the appropriate decision-makers early enough, or was discounted for one reason or another. It is also true that in some of the case studies, early warnings — and even 'loud and late' warnings — were effectively ignored by decision-makers because of short-term economic and political interactions (see the case studies on asbestos, PCBs, the Great Lakes, and sulphur dioxide and acidification).

The third question was what were the resulting costs and benefits of the actions or inactions? This proved to be the most difficult question for the case study authors to answer, at least in a comprehensive manner. In part this is due to the background of many of our authors, who are generally technical experts in the field, rather than experts in assessing the economic costs and benefits, or the wider pros and cons of action. But this is also an intrinsically difficult and controversial area. There is no credible way of reducing the pros and cons of alternative courses of action to a single figure, economic or otherwise, not least because of the problem of comparing incommensurables and because the pros and cons are unlikely to be spread evenly across all interest groups. There are constructive ways of dealing with these complications, but ultimately a general analysis lay beyond the scope of the current publication.

However, dealing with some aspects of costs and benefits is inevitable when addressing the fourth question posed to the authors, namely, 'what lessons can be drawn that may help future decision-making?'. For the purposes of this publication, this is a key issue.

The European Scientific Technology Observatory (ESTO) project on technological risk and the management of uncertainty (see, for example, Stirling, 1999) provided the initial framing of this analysis. This sets out a comprehensive structure for the consideration of issues relating to precaution. Not only did this help in organising the consideration of the lessons, it also gave an opportunity to test or elaborate many of the points arising from the ESTO studies against the large body of historical material contained in the case studies. Most of the key issues that emerged from the case studies could be addressed by 12 late lessons:

1. Acknowledge and respond to ignorance, as well as uncertainty and risk, in technology appraisal and public policy-making.
2. Provide adequate long-term environmental and health monitoring and research into early warnings.

3. Identify and work to reduce 'blind spots' and gaps in scientific knowledge.
4. Identify and reduce interdisciplinary obstacles to learning.
5. Ensure that real world conditions are adequately accounted for in regulatory appraisal.
6. Systematically scrutinise the claimed justifications and benefits alongside the potential risks.
7. Evaluate a range of alternative options for meeting needs alongside the option under appraisal, and promote more robust, diverse and adaptable technologies so as to minimise the costs of surprises and maximise the benefits of innovation.
8. Ensure use of 'lay' and local knowledge, as well as relevant specialist expertise in the appraisal.
9. Take full account of the assumptions and values of different social groups.
10. Maintain the regulatory independence of interested parties while retaining an inclusive approach to information and opinion gathering.
11. Identify and reduce institutional obstacles to learning and action.
12. Avoid 'paralysis by analysis' by acting to reduce potential harm when there are reasonable grounds for concern.

The distinctions between these different aspects are intended to be illustrative, rather than definitive. Many are clearly interlinked. Some might be combined together or further distinguished. However, the issues summarised here provide a basis for the practical implementation of the precautionary principle. Many of the lessons relate to the type, quality, processing and utilisation of information set within the context of a more participative and democratic process. Such an integrated and comprehensive process of hazard and options appraisal clearly needs to be related to the likely scale of the potential consequences (environmental, social, economic) of the activity in question.

In elaborating these lessons the rule was of not to introduce material extraneous to the case studies. However, in a final section some more general points are raised, which attempt to set the conclusions within the context of other developments in the field.

16.2. Twelve late lessons

16.2.1. Respond to ignorance as well as uncertainty

A central lesson of this book concerns the importance of recognising and fully understanding the nature and limitations of our knowledge. What is often referred to as 'uncertainty' actually hides important technical distinctions (see Box 16.1.). All the activities in the case studies were subjected to some form of (formal or informal) assessment of risk. What remained neglected, however, was the virtual certainty that there would be factors that remained outside the scope of the risk assessment. This is the domain of ignorance — the source of inevitable surprises, or unpredicted effects.

No matter how sophisticated knowledge is, it will always be subject to some degree of ignorance. To be alert to — and humble about — the potential gaps in those bodies of knowledge that are included in our decision-making is fundamental. Surprise is inevitable. Just as one basis for scientific research is the anticipation of positive surprises — 'discoveries' — so it will always yield the corresponding prospect of negative surprises. By their nature, complex, cumulative, synergistic or indirect effects in particular have traditionally been inadequately addressed in regulatory appraisal.

Thus a key element in a precautionary approach to regulation involves a greater willingness to acknowledge the possibility of surprise. This does not mean resorting to blanket opposition to innovation. But acknowledging the inevitable limits of knowledge leads to greater humility about the status of the available science, requiring greater care and deliberation in making the ensuing decisions. It also leads to a broadening of appraisals to include more scientific disciplines, more types of information and knowledge, and more constituencies.

The consequences of ignorance can be dramatic, as demonstrated by the case study on halocarbons. Prior to the hypothesis of a mechanism for stratospheric ozone depletion in 1974, the now well-known impact of chlorofluorocarbons (CFCs) was a very strong candidate for ignorance extending over many decades. Not only the likelihood, but the very possibility of an 'ozone hole' was unappreciated. Chemicals that were relatively inert and benign under 'normal' conditions

Box 16.1. Risk, uncertainty and ignorance

The precautionary principle is seen principally as a way to deal with a lack of scientific certainty. A basic foundation for our conclusions concerns the nature of scientific certainty itself. There is an urgent need for a more complete and systematic basis for thinking about the different ways in which scientific uncertainty may pervade regulatory appraisal.

First there is the familiar condition of **risk**, as formally defined in probability theory. This is where all possible outcomes are known in advance and where their relative likelihood can be adequately expressed as probabilities. Where this condition prevails, risk assessment is a valid technique that can save lives, prevent damage to the environment and provide a robust basis for decision-making. Still, the judgements over what is defined as at risk, and over the right balance to strike in decision-making, are necessarily laden with subjective assumptions and values.

Under the condition of **uncertainty**, as formally defined, the adequate empirical or theoretical basis for assigning probabilities to outcomes does not exist. This may be because of the novelty of the activities concerned, or because of complexity or variability in their contexts. Either way, conventional risk assessment is too narrow in scope to be adequate for application under conditions of uncertainty. Although techniques such as safety factors, scenario or sensitivity analysis can be useful, they do not provide a way adequately to assess the impacts of different options. Here, more than ever, judgements about the right balance to strike in decision-making are laden with subjective assumptions and values.

Many case studies in this book involve examples where regulatory appraisal laboured not only under a lack of certainty as to the likelihood of different outcomes, but where some of the possibilities themselves remained unknown. Here, decision-making is faced with the continual prospect of surprise. This is the condition formally known as **ignorance**. Even more than uncertainty, this underscores the need for a healthy humility over the sufficiency of the available scientific knowledge and, crucially, for an institutional capacity for open reflection on the quality and utility of available bodies of knowledge. Regulatory appraisal must explicitly address the implications of alternative assumptions and systematically document how these relate to the perspectives of different social groups and to the environment.

Once it is acknowledged that the likelihood of certain outcomes may not be fully quantifiable, or where certain other possibilities may remain entirely unaddressed, then uncertainty and ignorance, rather than mere risk characterise the situation. The adoption of robust, transparent and accountable approaches towards the various aspects of risk, uncertainty and ignorance can be identified as one crucial means of regaining public confidence in regulatory decision-making.

The decision-making process needs to be more explicit and systematic about the level of proof needed to justify reducing hazards. Examples include 'scientifically based suspicion', 'reasonable grounds for concern', the 'balance of evidence' and 'beyond reasonable doubt'.(see Table 16.1., in the last section of this chapter, and its elaboration in the last part of this report). There is therefore a range of choices of levels of proof for determining the basis for action, each with different cost and benefit implications for different groups. These different levels of proof provide a more sophisticated basis for the weighing up of potential benefits and harm than do simple pronouncements of truth or falsity.

(and less conventionally hazardous than the substances they replaced) turned out to behave very differently under conditions that were not considered in the risk appraisal. The effects of the synthetic oestrogen diethylstilboestrol (DES) on the next generation of the treated patient came as a complete surprise, while the accumulation of organotins in top predators, arising from tributyltin (TBT) antifoulants was simply not envisaged. According to the authors of the antimicrobials case study: 'The justification for the later dilution of (the Swann Committee's) conclusions and compromises on its recommendations was based mainly on narrow considerations of what was precisely known rather than on taking account of what was not known, of the ignorance within the field ... In other words science that embraces complexities, uncertainties and unknowns with more humility and less hubris is needed.'

The lesson seems clear. Rather than focusing only on the most straightforward and direct impacts, the process of regulatory appraisal should extend attention to as wide a range of conditions and effects as can reasonably be anticipated. Whilst accepting that even the broadest appraisal processes may still fail to foresee 'surprises', there is much that can be done to guard against some of the consequences of the ubiquitous experience of ignorance and surprise.

This insight lies at the heart of the case studies and is a central element of what it means to be precautionary. At first sight, responding to ignorance may seem to ask the impossible. How can strategies be devised to prevent outcomes, which, by definition are not known? Yet the case studies suggest that it is possible to do rather better than in the past.

For example, although not quite as simple as it seems, account can be taken of the potential irreversibility of actions, even if the consequences might not be known. For halocarbons, polychlorinated biphenyls (PCBs) and methyl tert-butyl ether (MTBE), as artificial chemicals, their very novelty might be taken as a warning sign. Enough was known at the outset regarding their persistence in the environment to serve as another warning. They would also readily disperse to become ubiquitous throughout the physical environment — one more warning. It could have been deduced from the outset that if these substances were

released into the environment, and if a problem subsequently developed, it would take many years for both them and the problem to 'go away'. The Great Lakes case study illustrates long-term hazards associated with other persistent organic pollutants (POPs). For other cases, while it may not have been known in the first instance how irreversible an action was, when this did become apparent regulators were often slow to react. It was relatively quickly established that TBT was more persistent than first assumed; and the permanence of asbestos dust has been known to be part of the problem for many decades. In neither case did hazard reduction actions take account of the long-tem effect early enough. If persistence and bioaccumulation are used as screening for eliminating potential hazards, then the size and seriousness of future 'surprises' are likely to be smaller.

Of course, irreversibility is not restricted to the possible consequences of chemicals. Resistance to antimicrobials, it is now known, is long term. For fisheries, stocks can take a long time to recover from a crash, if ever. Consideration of the irreversibility, or slow reversibility, of actions is a necessary component of a more broadly based approach to the appraisal process. The scale of the potential hazard, particularly if global, where there is only one 'experimental' model, is also a relevant consideration in the appraisal.

The case studies also provide some confirmation that potential problems can be anticipated. For antimicrobials in animal husbandry, confidence over the low risks of transmission of antibiotic resistance to humans was progressively qualified as new understandings developed. Yet as early as the 1960s the UK expert Swann Committee had anticipated many of the subsequent difficulties. This early example of sensitivity to possible sources of ignorance was subsequently overwhelmed by scientific over-confidence in the safety of antimicrobials. Similarly, for PCBs, early results — such as those obtained in animal testing in 1937 — might have been taken as more of a warning.

If a harmful property of a chemical is identified, then it may be prudent to consider that this may be correlated with other potentially harmful but less obvious effects. Of the case studies, short-term acute effects that were readily identified preceded — sometimes by many decades — less obvious chronic problems for sulphur dioxide emissions, ionising radiation, benzene, asbestos, TBT and PCBs. However this should not necessarily be taken as a general rule. At the very least the relationship is an asymmetrical one. While the presence of acute effects may be correlated with chronic impacts, chronic effects will not necessarily be preceded by acute ones — as illustrated by bovine spongiform encephalopathy (BSE) and halocarbons. Similarly, harmful effects seen in wildlife can be useful 'sentinel events' warning us of potential hazards for humans. This calls for integrated ecological and health hazard appraisals.

It is also necessary to draw a distinction between a condition of ignorance that is located at the point of decision-making itself and a condition of ignorance endemic throughout society as a whole. The former predicament, which might be termed 'institutional ignorance', refers to a situation where information relevant to the decision may be extant in society, but is not available to the decision-makers. Here, the consequent 'surprises', though they can be serious, may be quite localised. This problem is exemplified in most of the case studies in this book. It can be remedied by a series of provisions for more effective communication and social learning. The latter condition of 'societal ignorance' is more intractable. This problem is also exemplified in many of the case studies (including BSE) and requires rather different remedies, involving scientific research and the fostering of greater diversity, adaptability and flexibility in decision-making and technological choices. These issues are returned to in the final section of this chapter.

16.2.2. Research and monitor for 'early warnings'

General research and long-term monitoring can be dismissed as being too expensive and unfocused. Yet well-planned research and monitoring are essential to the systematic identification of areas of uncertainty. It is, however, necessary to consider how to conduct general monitoring to increase the prospect of timely alerts to problems arising out of ignorance. Awareness of uncertainty and ignorance helps the posing of appropriate research questions for scientific evaluation. It follows that the adequate funding of research and monitoring intended to pick up early warnings is central

to a robust approach to regulatory appraisal of potential hazards.

The case study on halocarbons and the ozone hole carries a mixed message. It was 'curiosity driven' general research for another purpose that resulted in the discovery of stratospheric ozone depletion in the Antarctic. The discovery was essentially serendipitous (see next section). While emphasising the value of purely academic scientific enquiry, it is hardly a reassuring reflection on the status of deliberate monitoring.

Many case studies indicate the value of thorough, long-term, monitoring. While for asbestos, benzene and PCBs evidence was accumulating of the adverse health effects as early as the 19th century, no role was then played by systematic monitoring. Data were either not collated (benzene), or became available only in a slow and rather *ad hoc* fashion over a period of many decades. Presumably the assumption was made that if there were harmful effects, evidence would emerge of its own accord and in good time for corrective action. A different attitude could have prevented harmful effects at an earlier stage. As for the current relevance, if the trend is for human actions to become geographically more widespread and less reversible, then the use of the 'world as a laboratory' becomes increasingly problematic. It is probably still true that in many cases the underlying assumption remains that any major problems will emerge in good time for corrective action. However, there ought to be more ecological and biological surveillance of the only biosphere we have.

It is also a feature of the case studies that even 'critical path' issues, identified at an early stage, were not necessarily followed up in a timely or effective fashion. For BSE, research into a number of crucial issues was not undertaken in the United Kingdom until late in the story. BSE was first identified as a new disease in cattle in 1986, but research to verify its supposed absence of maternal transmission in cattle — important to the early position of the UK Ministry of Agriculture, Fisheries and Food (MAFF) — was not initiated until 1989. Ultimately it showed that maternal transmission did occur. Similarly, experiments concerning the transmissibility of sheep scrapie to cattle (a favoured hypothesis of the source of the disease) were not begun until 1996. No surveys of the number of infectious but asymptomatic cattle entering the food chain have ever been conducted. Yet, throughout this period, reassurances on the part of the UK government continued prominently to cite the absence of evidence, when no evidence was actually being sought. This was a classic example of 'no evidence of harm' being misinterpreted as 'evidence of no harm'.

Similar delays in the conduct of relevant scientific research are documented in other cases. Regarding the routine use of antimicrobials in livestock management, concerns over the implications of the development of resistance, identified by the 1967 Swann Committee, were not followed up until the 1990s. This was despite longstanding knowledge that widespread antibiotic usage could lead to the rapid development of resistance. Likewise for asbestos, there was no systematic monitoring of health impacts, despite clear warnings and recommendations on mortality studies between 1898 and the 1920s, and despite the fact that techniques for workforce health monitoring were well within the capabilities of the day. The authors of the TBT case study concluded that: 'Though frequently underrated, baseline studies play a vital role in the early detection of adverse trends and may consequently serve the application of precaution'. The case studies on MTBE and PCBs also comment on the relative lack of research on identified causes of concern. Monitoring alone is not enough. Adequate reporting, dissemination and utilisation of research and monitoring results are also essential.

However, neither long-term monitoring specifically, nor environmental science in general, offers a panacea. They may answer some questions, but they raise others and the science progresses from relatively simple and often linear proposition to more dynamic and complex 'system' science. Research may convert some aspects of our ignorance into uncertainty — and even uncertainties into risks — but this will not necessarily be the case. There are examples where research can compound uncertainty and reveal new sources of ignorance. For fisheries, a Canadian mathematical model of the interactions between various fish species suggested that these became more unpredictable as progressively more biological data were incorporated into the model. For the Great Lakes, intensive research amplified the uncertainties. It

progressively raised more questions about the possible causes of the observed bird population crashes. At face value this presents a serious challenge to the notion that further scientific research is necessarily a precautionary measure, or indeed whether broadening out the appraisal process to different disciplines is necessarily precautionary (see Identify and reduce interdisciplinary obstacles to learning, below). Of course, where thorough research genuinely reveals that concerns over particular agents are unfounded — perhaps by demonstrating a convincing alternative mechanism for an observed effect — then it is in no way precautionary to persist in restricting the original agent of concern.

Other case studies, such as those on antimicrobials, sulphur dioxide and PCBs, illustrate the opening up of the research domain and of sources of ignorance as increasing complexities are discovered. Finally, as the antimicrobials case study illustrates, hazard appraisals should be as specific as possible about the nature of the scientific question that further research needs to address; the time such research may take and the source of the funding needed; and the independence of the relevant organisation carrying it out. The appraisal should also say, as the Swann Report did, whether actions to reduce hazards should happen before or after the research is completed.

16.2.3. Search out and address 'blind spots' and gaps in scientific knowledge

Several of the case studies illustrate blind spots existing within the dominant discipline involved in the regulatory appraisal process. For halocarbons the chemical mechanism for depletion of stratospheric ozone was identified in the prestigious journal *Nature* in 1974. Nevertheless, this did not prevent regulatory neglect until firm empirical evidence of actual effects became available. Even then, as has already been noted, the manner of the emergence of that empirical evidence presents a salutary lesson. The confirmation of an Antarctic 'ozone hole' in 1985 was essentially by accident — a by-product of an experiment conducted for other purposes. A dedicated satellite observation programme to monitor stratospheric ozone had earlier detected major depletion, but the results were considered suspect and set aside. This provides a pertinent example of where assumptions adopted in analysis can prejudge the results, leading to serious blind spots for policy-making. In this case these were not only at the centre of the main scientific disciplines involved in regulatory appraisal, but they involved both the theoretical mechanism and the empirical evidence.

A blind spot within a scientific discipline was also apparent in the case of agricultural antimicrobials. Evidence available in 1968 to the UK Swann Committee allowed explicit anticipation of a series of potential environmental, animal welfare and human health problems that were to become of pressing concern. Although initially influential, the Swann recommendations became marginalised over the ensuing decades. Had they been implemented and sustained, they might at least have mitigated the difficulties now recognised. Similarly, for MTBE the key problematic property of persistence was apparent at the outset, and this might reasonably have been expected to lead to more questions over the potential environmental problems of widespread use of this chemical than were actually raised in the formal regulatory process. In the case of TBT, rates of degradation were based on assumptions about the nature of the marine environment that were evidently incorrect for many areas. For hormones as growth promoters there was a failure to appreciate that young children with low natural levels of oestrogens were the likely 'at risk' group. Radiation risk estimates of typical doses long overlooked the uncertainties resulting from their derivation largely from the health records of the survivors of the atomic bombings in Japan at an atypical high dose and dose rate.

Another blind spot can occur where the adoption of a new practice is held, of itself, to have solved historic problems. For asbestos successive claims were made that past health impacts were due to conditions that had been superseded. The long lineage of claims that 'the disease is not so likely to occur (in future)' can be traced back to 1906. With each successive minor incremental improvement in conditions, the persistent risks associated with the new conditions would then in turn take further decades to become evident. Remarkably, when the recognised magnitude of the health effects eventually prompted asbestos substitution, this was initially attempted with fibrous minerals that shared some of the properties that had led to the effects of asbestos (such as fibre size). In their turn, these substitutes also

came — eventually — to be recognised as sources of essentially similar, if much lower, risks. For sulphur dioxide, the building of taller smokestacks, while helping to ameliorate local effects, did not address the wider problem arising from cumulative emissions and long-range transport.

A more precautionary approach therefore means systematically searching out blind spots at the heart of the disciplines historically involved in the regulatory process. This will be easier if multiple relevant disciplinary and other sources of knowledge are engaged, helping to stimulate the sometimes uncomfortable interactions that will be more likely to expose false assumptions and other questions. This leads directly to the next lesson.

16.2.4. Identify and reduce interdisciplinary obstacles to learning

Where effects that are the domain of a particular specialist field may initially be more pronounced, or discovered at an earlier stage, this can lead to a situation where regulatory appraisal becomes unduly dominated by, even 'captive' to, a particular discipline. This can lead to a form of 'institutional' ignorance, as opposed to the society-wide ignorance discussed above. For both asbestos and ionising radiation the setting of standards was strongly influenced by the preoccupation of medical clinicians with immediate acute effects. In both cases, the toxicology and epidemiology of long-term chronic effects remained relatively neglected. The introduction of MTBE was based on bodies of knowledge concerning engines, combustion and air pollution. The water pollution aspects associated with persistence and significant taste and odour problems were essentially disregarded, though the information was available. For sulphur emissions the regulatory appraisal was initially focused on human health concerns. When ecological effects became apparent, a regulatory process constructed to address health issues experienced problems assimilating and reacting to these. Similarly, for the use of hormonal growth promoters in livestock, the initial emphasis was also on human health effects. Although concerns over the impact on wildlife were raised, they initially appeared to attract little attention from the regulators.

In contrast, for both livestock antimicrobials and BSE, considerations of the human impacts were initially marginalised by the regulatory focus on veterinary science. Indeed, for antimicrobials this concern underlay the early 1968 recommendation, by the Swan Committee, that a single advisory process be established which 'should have overall responsibility for the whole field of use of antibiotics and related substances whether in man, animals, food preservation, or for other purposes'. This recommendation was not taken up, in the United Kingdom or elsewhere, for many years. In the case of BSE, UK veterinary officials considered the possibility of transmissibility to humans as acceptably slight. This contrasts with the attitude in the United States, where the possible link between sheep scrapie and human Creutzfeldt-Jakob disease (CJD) had been regarded as a possibility since the 1970s, when the entry of infected animals into the food chain was banned.

16.2.5. Ensure that real world conditions are fully accounted for

'Real world' conditions can be very different from theoretical assumptions, and these differences can have serious consequences. In principle this problem is well recognised, and it is possible to considerably reduce exposure to oversights of this type. Yet in practice the case studies reveal a variety of incomplete assessments, resulting in erroneous regulatory appraisals and decisions.

In the human sphere it is often assumed that technologies will perform to the specified standards. Yet real life practices can be far from ideal; and it may be a long time before we realise that this is the case. Sometimes actions are taken that appear to be in defiance of prior experience. The leakage from petrol station storage tanks was underestimated in the US regulatory appraisal of MTBE and so led to an underestimation of the resulting exposures. Although storage tanks can be redesigned to reduce the chance of leakage, this benefit can be lost by incorrect installation. For PCBs it was assumed that these could be constrained within 'closed' operating systems. This proved impossible, resulting in accidents such as Yusho and Yucheng, losses from poorly maintained equipment and even illegal disposal into the human food chain. Similarly optimistic assumptions as to the performance of engineered containment equipment, or the efficiency of decommissioning, also played a role in reducing the effectiveness of halocarbon

control measures. While some aspects of public exposure to benzene have received rigorous control, these are not necessarily the routes of greatest exposure. The failure to develop mitigation practices, or even warnings, regarding benzene exposure via petrol is one notable example. For the clinical use of radiation, the importance of establishing, and using, the optimal dose for any examination can be traced back to 1949. Yet the dosage for the same examination in different hospitals can still vary by a factor of 100. And for growth promoters scientific advisory committees such as the WHO / FAO Joint Expert Committee on Food considered only a restricted range of options, including just those circumstances relating to authorised use, and assessments of individual growth promoters, rather than in combination. They also gave little attention to the misuse of growth hormones, such as higher doses than recommended, inappropriate injection sites, failure to withdraw hormone implants from slaughtered animals and shortened withdrawal periods.

A gap can also open between assumptions and the real world when applications change without corresponding adjustments to their regulation, such as the expansion of the use of asbestos in consumer products and housing as well as boiler insulation. Asbestos is also notable for the long delay before it was acknowledged that real world conditions meant that users (or even local residents around a factory), as well as workers, could be at risk from exposure. Significantly, the 2001 World Trade Organization Appellate Body ruling on asbestos concluded that 'controlled use' risk management could not be relied on to protect workers' health in real world conditions.

In some cases there will be deliberate non-compliance. Apart from the illegal disposal of PCBs already noted, this included poor practice in the agricultural use of antimicrobials that increased the spread of resistance, and the circumvention of attempted regulation of fisheries that helped deplete stocks. Similarly, unrealistic assumptions were made about the implementation of changes to UK slaughterhouse practices as a crucial part of the response to the BSE crisis. Acute human effects observed in Puerto Rico and Italy were blamed on the illegal or incompetent use of animal growth promoters. Similarly, the smuggling of halocarbons is threatening the effectiveness of global controls.

False assumptions about the real world also affect our interpretation of events in the natural environment. The PCBs case study describes the surprising potential for these chemicals (along with certain other POPs) to concentrate disproportionately on a global scale in high-latitude regions. Also for PCBs, in the real world bioaccumulated PCBs were found to be disproportionately more toxic, with the result that the effects were greater than those indicated by experiments using the original commercial formulations. For fisheries, stock assessment models tend to concentrate on single stocks, downplaying the interactions between stocks or other marine species. There are enormous, perhaps insoluble, problems in broadening the scope using the stock modelling approach. Nevertheless, the single stock approach does not reflect actual conditions. The unexpected consequences of halocarbon degradation in the stratosphere is another example of the unanticipated complexity of the real world. In these, and many other cases, the behaviour of real natural systems can prove far removed from the standard assumptions made in regulatory appraisals and consequent decisions. The issue of hormone growth promoters illustrates how the real world also contains groups of particularly sensitive individuals (young boys, for example) who may react differently to exposures compared with assumptions based on the 'average' response.

16.2.6. Systematically scrutinise and justify the claimed 'pros' and 'cons'

One feature of debates about environmental risk is how all protagonists typically call for greater and more systematic attention to be paid to the claimed benefits of the technologies in question. Some are concerned that undue attention on, or inaccurate appreciation of, the risks might diminish recognition of the anticipated benefits of their favoured technologies. Others are concerned that the justification for new technologies, and claims as to their efficacy, are insufficiently critically scrutinised. Either way, both positions effectively call for the regulatory appraisal process to more deliberately and systematically examine the claims made about the benefits of a technology or product, including an identification and assessment of the conditions under which the

claimed benefits might, or might not, materialise.

Problems can arise from the partial assessment of environmental protection measures. Raising the height of smokestacks and shifting to smokeless fuel were an effective response to the serious episodes of respiratory illness from European sulphur emissions and urban air pollution in the 1950s. Yet this very effectiveness may have inhibited attention to the problems of long-distance transport of acid gases and the consequent acceleration of environmental problems in vulnerable areas. This was a classic case of an end-of-pipe 'solution' only creating other, less visible hazards. A more integrated approach eventually reduced all the problems. Similarly, because MTBE apparently promised a simple solution to the serious environmental problems caused by lead emissions from motor vehicles, the environmental problems associated with taste and odour in combination with persistency in groundwater were perhaps more readily overlooked than might otherwise have been the case. The introduction of hormonal growth promoters can also be considered to be an example of narrow and partial assessments of the pros and cons. Human health issues, possible environmental impacts and farm animal welfare were 'not given significant attention', according to the case study authors.

Another dimension of the sulphur dioxide case study was that the distribution of the pros and cons between the United Kingdom and the Scandinavian countries was very different, or at least was perceived to be very different. In relation to the effects on the natural environment, Sweden seemed to be suffering the most. It was only with the realisation of major damage to buildings in the United Kingdom — caused by air pollution — that both countries realised that they were suffering from the impact of acid emissions.

In two cases, BSE and fisheries (the Canadian cod collapse), the pros and cons of taking early action were identified prior to the event. But because the uncertainties were significant, and the financial costs of action high, limited action was taken. This resulted in the far greater costs (many of which were anticipated) when the measures proved inadequate. In the case of fisheries, even in the absence of stock collapses, major economic, social and environmental benefits accrue from allowing depleted stocks to recover.

One might think medicines would be validated for efficacy. However, for DES, the data from 1953 trials showed that DES was ineffective as a means of reducing risks of spontaneous abortion in certain groups of mothers and that it was positively harmful. This seems not to have been appreciated at the time. As a result the rate of reduction in use of the drug was more gradual than might have been the case; there was no regulatory action; and marketing continued unabated. It was not for another 20–30 years that use of this drug was actually banned in different countries, in response to the discovery of an increase in a rare cancer of the vagina in daughters of treated women. Had greater critical attention been paid at the outset to the claims of efficacy, then some of these second-generation cancers might have been avoided.

A step beyond passive assessment of the pros and cons is actively directed prior to justification. Ionising radiation is a rare example of such a 'justification principle', developed by the International Committee on Radiological Protection in the 1950s. This was a response to the burgeoning of a variety of dubious or ineffective uses of radioactive materials (for instance in countering ringworm, fitting shoes for children, the cosmetic removal of hair and the treatment of mental disorders). Yet even with this criterion, the degree to which exposure to ionising radiation is justified by the benefits remains open to question. Surveys of radiography practices over the past decade or so conclude that, while doses have reduced drastically, a large proportion of medical X-rays are still of doubtful clinical use. The reduction of the use of antimicrobials, initially in Sweden, can also be considered to be an example of the wider assessment of the pros and cons.

The appropriate allocation of costs and benefits is an essential pre-condition for optimising resources between technological options. A host of risk management measures are available under the broad remit of the 'polluter pays principle' — including taxes, subsidies and liability regimes, which offer a way to ensure more equitable social distributions of the costs and benefits associated with risk governance decisions. The failure, in cases like asbestos, halocarbons and PCBs, to reflect full

environmental and health costs in market prices gave these products an unjustifiable advantage in the marketplace. This in turn helped to keep technically superior substitutes off the market for longer than was optimal from society's point of view. Although the mechanisms for the internalisation of external environmental costs and the practical implementation of liability regimes are controversial, such measures are essential if both efficiency and equity objectives are to be addressed effectively.

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

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

So while in principle the function of MTBE might be substituted by alternative oxygenates such as bioethanol, improved engine technology or an increase in the octane rating of the fuels themselves, little formal scrutiny appeared to have been undertaken at the time of adoption of MTBE. In California, the search for a successor to MTBE has recognised that all the proposed alternatives must be fully evaluated. The authors of the TBT case study note that 'Broader consideration of problems may give rise to more beneficial solutions than simple 'chemical for chemical' substitution', and give examples of such alternatives. For ionising radiation, substitutes for the diagnostic use of X-rays remain underutilised. The ozone-depleting properties of second-generation CFC substitutes were perhaps also unduly tolerated, simply because of their relatively low impacts when compared with the original substances, and the existence of more benign substitutes or alternative approaches was not properly looked at. And while effective husbandry practices not involving the routine large-scale administering of antimicrobials are increasingly used in a number of European countries, these more benign alternatives are not actively promoted.

This raises some challenging issues about the relationship between regulatory processes and product development by private companies. The promotion and production of alternatives needs to take place within a culture of 'eco-efficiency', 'clean production' and closed-loop material flows so as to minimise the size of any future 'surprises' in the use and impact of technologies. These issues are returned to in the concluding section of this chapter.

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

The importance of ensuring that regulatory appraisal includes the full range of relevant disciplines has already been covered. A related but distinct lesson concerns drawing upon knowledge held by lay people. These may include industry workers, users of the technology and people who live in the locality or, because of their lifestyle or consumption habits, stand to be most strongly affected. The point is not that lay people are necessarily more knowledgeable or environmentally committed. Rather the benefit of attending to lay knowledge rests in its complementary character, its sometimes firmer grounding in real world operational conditions — as already discussed — and the associated independence from the narrow professional perspectives that can be a downside of specialist expertise. Often too, lay knowledge of a technology or risk may be based on different assumptions about what is salient, or what degree of control is reasonable to expect or require, whereas technical specialists may simply respond to granted authority without further reflection.

One prominent contribution from lay knowledge relevant to the regulatory process concerns workplace awareness of emerging patterns of ill health. The histories of usage of asbestos and PCBs provide examples where workers were aware of what regulators subsequently recognised to be a serious problem. Similarly, local communities may become aware of unusual concentrations of ill health before the authorities, such as the Love Canal example cited in the Great Lakes case study.

Another form of lay knowledge concerns remedial measures. Fisheries highlight several aspects and, although fishers can be less precautionary about stock depletion than others, there are many examples where fishers wish to act in a precautionary manner but are prevented from doing so because of a

systems failure. There is an increasing emphasis in Canada and elsewhere on the need to involve fishers in management, and take full account of their knowledge and perspectives. Similarly for livestock antimicrobials, Swedish farmers' knowledge of alternative animal husbandry techniques allowed them to promote animal health and growth without the large-scale use of antimicrobials. Not only did they bring valuable insights to the regulatory debate, but they were able to undertake voluntary controls in advance of regulatory requirements. Another aspect to emerge from this case study is the need for knowledge to be widely based in order for less harmful alternatives to be effectively implemented — indeed it is fundamental to ensuring that the existence of possible alternatives is actually recognised.

Another aspect of lay knowledge is where workers know that real practices do not match the theoretical assumptions of risk assessors. The UK slaughterhouse rules over BSE separation of 'specified bovine offal' from meat were widely flaunted, yet failures in the inspection regime meant that this was not drawn to the attention of the regulators. In this case, workers in the industry in question were apparently better informed about the operational realities than were high-level regulatory advisers and officials.

Of course lay knowledge should be subject to the same intensity of critical scrutiny as specialist expertise. Lay perspectives are not immune to the pitfalls and difficulties noted in these conclusions — and may be more vulnerable. One example is the 'pensioners' party fallacy' amongst asbestos workers who pointed to the presence of healthy pensioners at the firm's Christmas party as evidence of the apparent harmlessness of asbestos.

Nevertheless, workers, users and neighbours evidently can bring important information to the regulatory appraisal process, requiring greater attention to be devoted to the development of methods to enable those groups with potentially valuable knowledge to provide this, and for this to be fully taken into account. Such broadening of the knowledge base can strengthen the appraisal, improve governance and democracy, and enhance the acceptability and legitimacy of the process.

16.2.9. Take account of wider social interests and values

Gathering available knowledge is not the only reason for opening up the appraisal process. Historically there is little doubt that social and political conflicts can be aggravated by a regulatory preoccupation with expert judgements and a lack of attention to public perspectives and values. In part this relates to a wider assessment of the pros and cons, as already discussed. The meeting of specialists and interest groups with different viewpoints can be productive, helping ensure a reflective approach, and allowing the implicit assumptions of all parties to be tested. The Swedish farmers in the antimicrobials case study show how lay views can help ensure that the regulatory process remains (or becomes) attached to prevailing ethical and socio-cultural values.

It is implicit that the intuitions embodied in public values may sometimes prove quite robust in relation to the framing of the regulatory science itself. An aversion to situations far outside the bounds of normal experience, or at least a desire to proceed with caution, can certainly be defended as a rational response to uncertainty. A key feature of the public reaction to the emerging evidence of BSE in the late 1980s was the surprised revulsion that ruminants were being fed on offal and bodily wastes. It seems likely that avoiding offal in ruminant feed would have at least significantly limited the scale of the subsequent BSE and CJD problems. Similarly, had widespread public misgivings over the use of antimicrobials in animal husbandry been heeded, the development of resistance would have been held in check. The fisheries study illustrates how the objectives of a precautionary approach — to prevent stock collapses, to maintain maximum sustainable yields or to ensure the protection of other species — depend on the value judgements of the interest groups.

16.2.10. Maintain regulatory independence from economic and political special interests

A major element of a broader approach to regulatory appraisal is to ensure that an appropriate distance is maintained between those responsible for regulatory appraisal and various contending interest groups seeking to influence their decisions. It is a necessary part of the regulatory process that claims over the pros and cons should be actively advanced and argued by interested

parties. It then becomes a matter for independent, accountable institutions to adjudicate between the contending claims.

There is evidence in the case studies that interested parties are often able to unduly influence regulators. As a result decisions that might reasonably have been made on the basis of the available evidence were not taken. Benzene was demonstrated to be a powerful bone marrow poison in 1897; the potential for acute respiratory effects of asbestos was first identified in 1898; and the first cases of PCB-induced chloracne were documented in 1899, with effects on workers known by the late 1930s. Yet it was not until the 1960s and 1970s that significant progress began to be made in restricting the damage caused by these agents. One factor in the slow UK response to BSE was that the governmental regulatory body was responsible first to the industry and only second to consumers. Similarly, the temporary lifting of the ban on DES as a growth promoter in the United States in 1974 followed strong pressure from the farming lobby, and occurred despite the availability of alternatives.

It is also notable how poorly substantiated some of the sustained 'refutations' of critical findings have been. This was true of the identification of PCBs as widespread environmental pollutants in the 1960s and of the UK response to the impact of acid deposition in the 1970s and early 1980s. Asbestos provides a clear example of persistent obstruction and misinformation by vested interests, and of drastic miscalculation in the wider regulatory process. The accumulation of medical and pathological evidence, while having very little impact on regulation, was sufficient to make parts of the US and Canadian insurance industry wary about providing cover by 1918; a precautionary attitude that ironically was not maintained as evidence accumulated — an error that was to cost the insurance industry billions of dollars. Although benzene had been unequivocally identified as a human carcinogen, human health protection measures continued to be impeded by claims over a lack of evidence for animal carcinogenicity. Similarly demonstrably erroneous claims (based, for example, on basic statistical errors) were later repeated regarding evidence of effects arising from very low benzene exposures.

Even where the evidence is essentially not contested, data and reports are sometimes suppressed, or publishers intimidated, as reported in the Great Lakes case study. For antimicrobials, research that might have been expected to reinforce a critical position was delayed. Efforts were made in the case of BSE and asbestos unjustifiably to discredit independent critics. In the Californian sardine fishery in the 1930s, critical agency scientists were dismissed. 'Shooting the messenger' has been a typical response to those bearing disturbing news ever since Galileo, but it rarely, if ever, promotes societal welfare. BSE provides an explicit example of independent expert advisory committees who advise the regulators subjecting themselves to self-censorship, based on a judgement of what was 'realistic' or 'achievable'. The Southwood BSE Committee considered in 1988 that a ban on the use of all cattle brains in the human food chain might be justified on scientific grounds, but it was considered not to be a politically feasible option.

Regulatory appraisal frequently fails due to the dependence of risk assessment on information produced and owned by the very actors whose products are being assessed. Independent sources of risk information are a necessary, if not sufficient, condition of independent, rigorous and trustworthy regulatory appraisal. Independent information about risks and possible risks was often lacking in the cases studied. In some of the examples cited above, for example benzene, PCBs, asbestos, halocarbons and DES, knowledge concerning hazards was available long before any regulatory action was decided. Not all of these cases demonstrate the delaying or distorting effect of non-independent sources of such knowledge. Nevertheless, the emergence of hazard evidence can be accompanied by vigorous though often low public profile interpretative jockeying to try to justify inaction. What is very difficult to dispute is that had such information — from wherever it emerged — been taken to be the rightful subject of control and disseminated by an independent public body whose very *raison d'être* was the provision of salient public policy information, then the corresponding interpretative debate about policy intervention would have been more open, and more pluralistic. Diverse interests would have been more equitably, thoroughly and probably more rationally represented. Independent information institutions, allied

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

16.2.11. Identify and reduce institutional obstacles to learning and action

The progressive unfolding of the asbestos, benzene and PCB episodes from the late 19th century provide various examples of how short-term horizons, notably government and business cycles, can militate against social welfare in the medium and long term. However, institutional obstacles against timely protection of health and the environment can take other forms as well. The case studies illustrate three other areas which can present difficulties: those resulting from periods of transition (for example between succeeding elected administrations) or from tensions between different departments or levels of government and 'their' agencies, and the issues that can arise from differing national approaches.

One instance where a change in political administration may have contributed to poor implementation of prior knowledge is provided by the case of BSE. An official UK commission in 1979 recommended the setting of minimum processing standards in the rendering industries. A new administration later that year decided to withdraw the resulting proposed regulations, deeming them to be an unnecessary burden on industry. It is not clear to what extent such tighter standards might actually have inhibited the later BSE outbreak, but it is notable that the implementation of standards of this sort featured prominently among that same government's later responses to the BSE crisis in 1996.

Similarly, in the Californian sardine fishery, what was in effect a precautionary programme of stock conservation was reversed with a change in government. The Californian fishery also provides a clear example of tension between different levels of government, albeit dating back to the 1930s, where the state agency's recommended precautionary action was strongly opposed by the US Federal Bureau of Fisheries on the grounds that it would unduly inhibit commercial activity. An example of similarly fraught communication between different governmental departments may be found in the case of BSE in the United Kingdom. Here, the Department of Health was not informed by MAFF about the emergence of the new disease until some 17 months after MAFF was first alerted, and only then because its assent was required for a decision not to remove clinically affected cattle from the human food chain. Regulatory agencies can face a difficult relationship with government, who can exercise more or less subtle influence, even where the agency has explicit independence. Difficulties can also arise where the regulatory agency becomes part of the issue through its past decisions. Both situations are illustrated by BSE, where identification and recognition of the problem was influenced and delayed as a consequence of wider policy considerations (the economic impact on farming) and the concern that lack of consistency would undermine the credibility of government and agencies alike.

Scepticism over the scientific results obtained in other countries was a key feature of the attitude of UK regulatory authorities to the sulphur emissions in the mid-1980s. Although research results suggesting both the seriousness of the environmental effects, and the identity of the responsible agent, were accepted in Norway in 1976, it was not until 1985 that the scientific case for a causal link was acknowledged in the United Kingdom. As already noted, during this period the distribution of pros and cons was perceived to be unevenly balanced between the contesting parties, and it would not have been surprising if this influenced the level of scepticism on the part of the United Kingdom.

Similar tensions have existed between Sweden and the EU in the case of antimicrobials, where different regulatory systems were based on different presumptions. Whatever one may consider to be the pros and cons of the argument, EU membership requirements were an institutional obstacle to the continued implementation of a national policy. At a different level, global problems clearly require a global response. This is brought into focus by the circumstances surrounding the TBT issue. Here, effective action to

regulate the use of antifouling biocides on the hulls of wide-ranging commercial vessels is dependent on agreement within global institutions such as the International Maritime Organization.

For BSE it is notable that the same scientific evidence was available to the United States and the United Kingdom in the mid-1970s concerning the transmission of scrapie and possible links between scrapie and CJD. However, it led the US Department of Agriculture, but not the UK MAFF, to decide that scrapie-affected animals should not be used in human or animal foods. The different timing of national decisions on the use of DES both as a pharmaceutical and as a growth promoter in animals also illustrates how widely decisions can vary even though based on the same information. In these, and other examples, institutional obstacles appear to have played a role.

16.2.12. Avoid paralysis by analysis

The general tenor of the lessons so far is to 'know more', for example by searching out blind spots within disciplines, reaching out to other disciplines, accessing lay and local knowledge, and taking account of wider social perspectives. One response is to ask how much information is enough to justify action to reduce potential hazards. An obvious concern is that of the danger of paralysis by analysis where either information overload or lack of political will leads to a failure of timely hazard reduction measures. One example is the evidently anti-precautionary 'straightjacket' imposed upon US benzene regulation by a Supreme Court decision, which required layer upon layer of additional information before regulatory action to reduce risks was possible.

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

On the other hand, the Great Lakes study argued that more uncertainty was generated as the field was opened up to new disciplines, and that this indeed could lead to paralysis by analysis if a precautionary approach was applied. The Great Lakes case raises a very important issue that is best understood by appreciating the significant distinction between this and the other case studies. Most deal with concerns raised in relation to particular identified agents. The issue in such cases is the 'prospective' assessment of risks, starting with an agent and seeking possible effects. The Great Lakes case, however, is an example of a rather different, 'retrospective' process. This starts with the documenting of a series of manifest health or environmental effects and seeks the identification of possible agents. The broadening out of prospective appraisal is precautionary because it has the effect of focusing attention on a greater number of possible effects. The broadening out of retrospective appraisal, however, may have the effect of raising uncertainties over the basis for regulating individual agents.

As has been pointed out in discussing monitoring, it is in no way precautionary to persist in restrictions of the wrong agent. However, the precautionary principle applies as much to uncertainties over agents as to those over effects. If a broad-based retrospective process raises scientific uncertainties or ambiguities about the grounds for targeting a particular agent, the precautionary principle may nonetheless be invoked, entirely legitimately, to defend continued action on this agent, until such uncertainties are resolved.

The fact that the precautionary principle was not invoked in this fashion in the Great Lakes case is more a reflection of the value judgements in the prevailing legal and socio-political context than it is of intrinsic inconsistencies in the concept of precaution itself. The prospects for successful appeal to the precautionary principle will depend on the culture within which the appeal is made. If the culture is not prepared to act even when there is demonstrable evidence of cause and effect, then appeals to precaution are unlikely to succeed. In reality the regulatory and wider culture of a society may vary between these extremes, and even

between different regulatory sub-cultures (cf. the differing US approach in the case studies on BSE, fisheries, MTBE, benzene and the Great Lakes).

Whether or not the need for more information risks 'paralysis by analysis' or is merely part of a 'prudent and careful evaluation' of the situation, will be influenced by the individual, social or interest group's assessment of the likely pros and cons as they impinge upon them. If the benefits of taking early precautionary action are large, and the adverse consequences deemed relatively small, and if these are evenly spread across interest groups, then early action is likely to be considered. If the advantages are less certain and, like the costs, are very unevenly spread across different interest groups, or time periods, then reaching consensus about the appropriate amount of research, or about actions to reduce hazards, will be more difficult.

Of course, it may be that in some cases it will be necessary to severely curtail or end innovation in a particular field or technological direction where society judges the risks to be unacceptable. But there is an enormous difference between the discouraging of a particular innovatory pathway, and the channelling of innovation into alternative routes. As illustrated by asbestos, halocarbons, PCBs and antimicrobials, the curtailment of a particular option may actually serve to foster and intensify innovation in other areas. It may also provide a competitive edge to the economies of the countries leading such innovations. The intelligent use of foresight and the precautionary principle may therefore not only reduce overall costs to society of some economic developments, but can stimulate innovation, encourage better and more systems-based science, and improve public decision-making.

Some of these wider implications of a more precautionary approach to potential hazards and innovation are further elaborated in the next section.

16.3. The wider implications of precaution

The 12 broad lessons for policy-making on risk just described have been developed under a number of criteria. First, they are well grounded in the empirical detail of particular case studies. Second, they are sufficiently general in nature to be found relevant to virtually any risk management problem. Third, taken together, they address a balanced and fairly comprehensive range of considerations, spanning a large part of the current debate on the management of hazards and the implementation of the precautionary principle. Finally, although necessarily general in nature, they are sufficiently concrete to inform practical policy measures and institutional procedures, even though the precise nature of these in a given case will necessarily be defined by variable local circumstances.

That said, it is not possible to anticipate in one short discussion, or one set of 'lessons', the full range and diversity of detailed practical precautionary measures and procedures, still less to explore the specific contextual considerations bearing on their application. Such matters are the subject of a wide and burgeoning literature (see, for example: O'Riordan and Cameron, 1994; Harding and Fisher, 1999; Raffensperger and Tickner 1999; Stirling, 1999; O'Riordan *et al.*, 2001). Although not always labelled as 'precaution', many of these lessons have been strongly developed and elaborated by a variety of influential policy studies in industrialised countries over recent years.

In the United States, for instance, the seminal study by the National Research Council (NRC), 'Understanding risk' (NRC, 1996) and the subsequent report by the presidential commission (Omen *et al.*, 1997) documented the limitations of conventional narrow risk assessment and highlighted the importance of interdisciplinary, lay knowledge and divergent stakeholder viewpoints in the characterisation of risk issues and of appropriate assessment approaches. The 1998 report of the UK Royal Commission on Environmental Pollution developed this theme (RCEP, 1998), underscoring the potential significance of uncertainty and different 'framing assumptions' in the shaping and interpretation of formal appraisal. In France (Kourilsky and Viney, 1999) recommendations on implementation of the precautionary principle stressed the need to organise systematically national expertise capacities, including both scientific and technical expertise, alongside economic and social expertise. In Germany, the importance of more broad-based discursive procedures is recognised in the major report of the German Advisory Council on Global Change

— WBGU (WBGU, 2000). The development of the Swedish chemicals policy is based on recognition of many of the lessons noted here concerning the fundamental limitations of risk assessment, particularly the use of persistence and bioaccumulation as 'proxies' for unknown but possible impacts.

Various specialists have also detailed the general points of these lessons in respect of the structural limitations of EU regulatory risk assessment of genetically modified organisms (GMOs) (van Dommeln, 1997). In the light of these cogent critiques of the overly reductionist and narrow character of European scientific risk assessment of GMOs, it is worth remembering that this same EU risk assessment is regarded by US counterparts as irrationally exaggerated when measured against what they define as 'sound science'. At any rate, it is abundantly clear that in most of these issues, a scientific framing of the questions as if they were all resolvable by existing or available knowledge of risks is radically incomplete — and not only in respect of the answers, but more particularly in respect of the questions which are deemed salient to address even if answers are difficult or impossible to achieve.

In the light of recognition of these wider dimensions, some practical yet more broadly based institutional procedures such as consensus conferences and scenario workshops have been developed in Denmark and the Netherlands to try to articulate public questions and values with respect to scientific presumptions about the answers, and these have been exported widely over recent years (Renn *et al.*, 1996). In the United Kingdom, the advent of new 'strategic commissions', on food, human genetics, and agricultural genetics and environment, is a recent innovation that opens up the risk policy process in the way suggested by some of these lessons. Detailed policy appraisals in areas such as BSE (Phillips *et al.*, 2000) and mobile phones (IEGMP, 2000) have seen various of these lessons explored in some detail, with specific recommendations on how to handle issues such as institutional conflicts of interest and unrealistic expectations of the role of science as a touchstone, or arbiter, of ultimate truth.

The twelve lessons should be useful aids to policy-making. However, one should avoid caution against over-reliance on any single set of prescriptions for what constitutes a 'precautionary approach' in any given case. The implementation of the precautionary principle involves drawing on an entire spectrum of methods, procedures and instruments, many falling on the same continuum as orthodox risk management approaches. The business of deciding upon one particular set of responses rather than another must necessarily remain, at some level, an essentially political business — subject to all the normal processes of rational policy deliberation, professional review and democratic debate and accountability.

Finally, it is worth remembering that the precautionary principle began life as an environmental policy approach but it has been rightly recognised that constructive and effective environmental policy demands integration of environmental objectives into all areas of decision-making and technological, as well as public policy, commitment. Therefore it is axiomatic that a proper framework for measured and effective precautionary policy-making must encompass these wider domains, even if only indirectly. Beyond the twelve lessons, some general principles and specific practical messages are proposed, covering the relationships between precaution and science, precaution and innovation, and precaution and governance.

16.3.1. Precaution and science

The precautionary principle raises important issues for science. Some are to do with what many might perceive as the mechanics of science, such as issues of statistical proof and the framing of hypotheses. But it also raises some very fundamental interdisciplinary issues regarding the very nature of knowledge-gathering.

'Statistical proof' and the framing of hypotheses

For the environmental sciences, issues of proof and precaution often come up via the interpretation of statistics. Given that it is impossible to prove a hypothesis (such as 'all swans are white'), only to disprove it (the discovery of Australia, and with it the Australian black swan), the statistical workaround is to attempt to falsify a 'null hypothesis'. This is the opposite of the hypothesis of interest, for example that chemical concentrations have increased. If an increase exceeds, by some arbitrary threshold, that which might be expected by chance fluctuation, the null hypothesis is rejected and it is assumed that an increase has occurred. However it is still possible that the result is a freak and that the increase is

due to chance. This is known as a 'Type I' statistical error, or a 'false positive'. Traditionally there has been a strong emphasis on avoiding Type I errors. In the example here, a recorded increase in the chemical would be assumed to reflect a real underlying change only if there is a very small probability of the change occurring by chance — typically less that 1 in 20 or 1 in 100 (a result that is significant at the 95 % or 99 % level). In effect not being wrong is more important than being safe. However this issue is being increasingly recognised in policy. Table 16.1. gives some examples of policy action taken at different levels of proof. This is further elaborated in the 'Implications' part of this report.

Table 16.1. **Different levels of proof for different purposes: some illustrations**

Source: EEA

Verbal description	Examples
'Beyond all reasonable doubt'	Criminal law; Swedish chemical law, 1973 (for evidence of 'safety' from manufacturers)
'Balance of evidence'	Intergovernmental Panel on Climate Change, 1995 and 2001
'Reasonable grounds for concern'	European Commission communication on the precautionary principle
'Scientific suspicion of risk'	Swedish chemical law, 1973, for evidence required for regulators to take precautionary action on potential harm from substances

But there is another fundamental statistical problem. Because environmental monitoring is expensive it is usually limited in scope. Yet the smaller the sample size and/or the greater the natural variation, the less likely it is that a real increase could be identified through the statistical noise. The possibility of calling a real effect false is known as a 'Type II' error, or a 'false negative'. Underwood (1999) concluded 'Typically there has been little concern about Type II error. The chances of erring in 'favour' of the environment (a Type I error) is deliberately kept small, whereas the chances of erring 'unfavourably' to environmental issues is not!' A great deal of money can be wasted, for example on expensive ship-borne marine monitoring, if the actual amount of sampling that can be carried out on a few trips has no prospect of separating adverse effects from statistical noise, that is, it has low statistical power (HELCOM, 1996). On top of this come complications arising from the formulation of the hypothesis to be tested, and of experimental design: for example, asking the wrong question; dismissing a factor from assessment due to an erroneous prior assumption that it is unimportant; deciding when, what and how frequently to monitor; the importance to be accorded to rare events; or deciding how to deal with complex interactions, or non-linear responses such as chaos.

Similarly, even small misclassifications of exposure in epidemiological studies can result in major reductions in relative risks, with associations being more likely to be missed than falsely implicated (Copeland *et al.*, 1977). In general, the power of epidemiological studies to detect relevant risks is critical but often overlooked, leading to a false sense of security from so-called 'negative' studies that fail to find a risk.

The bias in science towards avoiding false positives inevitably involves generating false negatives, which, if they are human and or environmental disasters, as in most of these case studies, is not sound public policy. Clearly, such a bias in favour of generating false negatives does not conform to the precautionary principle, and is an issue that is taken up briefly in the 'Implications' part of this report.

While such issues are often seen as simply a matter of scientific judgement, in fact they lead on to some rather deeper points.

Fundamental issues

The commonly used word 'uncertainty' needs to be differentiated at least into risk, uncertainty and ignorance. A wider examination of just how agreement can be reached on what are the 'facts' would have to take account of other distinct dimensions such as complexity, indeterminacy, ambiguity, and the nature of disagreement (Wynne, 2001; Stirling, 1999). The concept of precaution has resulted in new thinking in the fields of sociology of science and in philosophy, and with it the recognition of new kinds of ignorance underlying the very processes of knowledge procurement. Authors such as Krohn and Weyer (1994) have explained how full knowledge of the consequences of innovations can only be

gained by treating society and the larger environment as themselves the experimental laboratory. This point has profound though as yet unrealised implications for democratic policy-making about new, and indeed existing, technologies.

Society's growing commitment to the precautionary principle is essentially a response to a growing tension between two aspects of science: its growing innovative powers were increasingly outrunning its capacity to anticipate the consequences. Moreover, too often from within the scientific community there was a denial of the waning ability to predict those consequences. This encouraged the reasonable democratic response of demanding more circumspection. This circumspection was not about innovation and risk themselves, but about our ability to know. In other words, it was about science and its presumed powers. It is not at all anti-scientific to raise such questions. Indeed it could be said that it is anti-scientific to deny them. There is nothing scientific about the 'pretence at knowledge' (von Hayek, 1978). Such pretence has the consequence of undermining the authority and credibility of the institutions of science — society's most powerful intellectual resource.

With this in mind some further observations are relevant. For example, in discussions between peers, it is accepted that the nature of scientific proof is essentially complex, open, and always provisional. Yet externally it has in some quarters become a requirement that science provide the policy process both with simple answers and certainty. This dual identity for 'science' causes considerable tensions, not least because the contradiction between intrinsic provisionality and pretended certainty often goes unacknowledged — but not, it appears, unnoticed.

This brings us to a deep dislocation between policy institutions and the public about understandings and representations of scientific uncertainty and ignorance. Public surveys in relation to GMOs on both sides of the Atlantic (Levy and Derby, 2000; Wynne *et al.,* 2000), indicate that non-experts do make a basically correct distinction between uncertainty and ignorance. Whilst scientific risk assessment focuses on (known) uncertainties, public concerns instead centre on unacknowledged ignorance lying behind even the best science. Especially with the rapid expansion of very novel innovations, a major public concern is the possible consequences of ignorance. The reaction can be summed up as 'if we can never fully know the consequences, then we had better at least ensure that the purposes driving the enterprise, and the interests which control the responses to the resultant surprises, are good ones' (Wynne, 1992 and 2001). In other words the issues of what are the driving purposes and who benefits are foremost in people's minds.

Yet the policy response, in order to reassure the public, has often been to intensify research on identified uncertainties, with the intention of demonstrating intellectual mastery of the issue, and to show that concern about (known) risks is unfounded. These policy responses to what are believed to be misconceived public demands for zero risk and zero uncertainty are futile, because they presume the problems of public mistrust lie with the public's erroneous expectation of certainty, and the public's supposed misunderstandings of science, risk and uncertainty. This institutional approach fundamentally misunderstands typical public attitudes and expectations; and it only feeds public mistrust by inadvertently demonstrating its own denial of ignorance and lack of intellectual mastery — which the public appears intuitively to understand rather better than does institutionalised science itself.

Thus whereas some views critical of precaution see it as pandering to populist anti-science sentiment, in the form of supposed demands for certainty before sanctioning any innovative commitment, there is ample evidence that people are typically quite ready to accept a much more radical kind of uncertainty than institutional science is able to acknowledge — namely ignorance, and corresponding lack of control. As Stirling (1999) and colleagues have elaborated in detail elsewhere, the precautionary principle has nothing to do with anti-science, and everything to do with the rejection of reductionist, closed and arbitrarily narrow science in favour of sounder, more rigorous and more robust science.

Perhaps the most fundamental general insight to emerge is that scientific uncertainty, like scientific knowledge itself when deployed to provide authority to policy, is emphatically not just a private matter for

scientific bodies to autonomously resolve, define, or otherwise interpret on behalf of the public policy domain, before it is rendered visible to the latter. As the NRC (1996) in the United States and the RCEP (1998) in the United Kingdom independently concluded, prior questions need public deliberation. These include: what questions should the science be addressing, what are the salient factors and what general principles should define good science (for example, the balance between comprehensiveness and precision) for environmental policy, as distinct from other more confined domains such as engineering risks.

These questions lead on to the importance of distinguishing between facts and values. It is sometimes assumed that, having agreed to adopt a precautionary approach, this should automatically lead to one 'correct' outcome. This is an oversimplification. What is at issue itself will vary. Preferred outcomes will also vary depending on people's interests, objectives and values. As Popper pointed out long ago, it is rationally impossible to derive a proposal for a policy from facts alone (Popper, 1962). Policies that unduly emphasise the factual basis of decisions, without explicitly acknowledging and engaging with the value judgements that are also part of such decisions, are unlikely to achieve consensus, or at least acceptance, where substantial divisions of opinion exist. (RMNO,2000)

It is for these reasons that the involvement of stakeholders in regulatory appraisal needs to begin at the beginning rather than being artificially confined to the later 'risk management' stages of the conventional approach. The stages of hazard and risk appraisal, management and communication are not sequential, as in the traditional model, but require stakeholder involvement at the earliest stage. This has been recognised by the NRC, the RCEP and the Nice Council of Ministers conclusions on the precautionary principle in 2000.

Again, it is emphasised that the raising of such issues should not be seen as creating a new form of 'paralysis by analysis'. The case studies, and the lessons that emerge, do provide a positive and robust way forward. But if these complexities are not explicitly addressed, progress will be slower and the mistakes made will be more serious.

16.3.2. Precaution and innovation

In the Introduction it was noted that, the German *Vorsorgeprinzip* ('foresight' or 'precautionary' principle) of the 1970s considered the stimulation of innovation, employment and forward planning to be integral components of the precautionary principle. An overarching principle arising from all the case studies, as well as from much wider analysis and experience, is that the polarised processes of technological innovation and risk regulation need to become less separate and antagonistic. Many of the lessons are as applicable to the innovation process itself as to the regulation of the resulting products and technologies. Indeed, accommodating them within the innovation process could overcome the adversarial relationship between innovation and regulation.

For example, traditional risk assessments of chemicals concentrate on the risks associated with a particular chemical. The use of the chemical is identified, but this identification of use is not then used in a more integrated way to assess the potential of alternatives. It is not the first time that the need for the integration of innovation and risk regulation, and for the integration of technology-appraisal approaches more generally is identified. It is addressed, for instance (at least in part), by the techniques of constructive technology assessment (CTA) developed in the Netherlands (Rip *et al.*, 1996; Wynne *et al.*, 2001). CTA starts from recognition that technologies are more than hardware. Their promotion and adoption depends upon the goals, relationships, understandings and skills of different sectors of society. The greater the scope, power, complexity or interconnectedness of the technological systems concerned, the more important a consideration of these social and institutional aspects becomes. In essence, CTA attempts to foster the recognition of this neglected but fundamental dimension of technology and innovation. By a variety of means it aims to improve integration, from the outset, of the perspectives of innovators, regulators, users and other stakeholders. In this way, innovation benefits from creative inputs at a stage when these may realistically be harnessed, rather than forcing such wider social interaction simply to take the form of an (often adverse) downstream reaction to a technology already developed through a more closed process. The analysis underlying CTA recognises how technological systems otherwise have a tendency to 'lock-in' to

particular configurations at a relatively early stage in their development, thus foreclosing other options and raising the costs of shifting to alternatives. The particular technologies that gain ascendancy in this way may do so for arbitrary reasons which have nothing to do with intrinsic qualities, and everything to do with chance and first-leader advantage. CTA attempts to highlight such questions and to provide the intellectual resources for resolving them.

The potentially positive relationship between regulation and innovation is also emphasised in the technological options analysis (TOA) approach, developed in the United States (Ashford, 1981 and 1994; Tickner, 2000). Here, a variety of practical procedures are routinely employed in order to include consideration of 'off the shelf' and 'on the horizon' alternatives alongside the technology or process in question. Again, like CTA, TOA can be performed by regulatory agencies or private companies, depending on the context. Together, they form part of a broader culture of 'alternatives assessment' (O'Brien, 2000), which highlights the importance of innovation and understands this as an open-ended process, subject to deliberate choices and commitments. These innovative approaches represent a more reflective and intelligent approach to the design, assessment, choice and implementation of technologies. By addressing innovation at the earliest stages, they offer a means to implement the lessons developed here in a fashion that minimises economic inefficiencies and social tensions, and actively fosters innovation pathways that are more sustainable over the longer term.

The promotion of robust, diverse and adaptable technologies not only helps to stimulate innovation but it can also provide 'insurance' against surprises, such as the case study examples of the asbestos cancer, mesothelioma, and the halocarbon damage to the ozone layer. This is because the size of any future surprises will be smaller if there are several competing technologies that are being used to meet human needs, rather than just one, global, near monopoly, as was the case with asbestos, halocarbons and PCBs. Diverse technologies and other ways of meeting needs can help deal with the seemingly intractable problem of 'societal ignorance' and attendant surprises.

16.3.3. Precaution and governance

'Governance' is about the manner in which something is governed by methods of management and systems of regulations, be they formal or informal. More broadly, it refers to the conduct of life or business in general and the mode of living, or behaviour, in society. The challenges which the precautionary principle heralds involve more than simply new decision rules and technical instruments, and this implies a learning process in public policy, industry, science and civil society at large. Here three aspects of governance relevant to precaution are considered, namely: how current institutions associated with the appraisal of risk might evolve to take account of precaution; the relevance of participatory approaches and subsidiarity; and the importance of greater awareness within civil society, including ethical awareness, so as to better exercise both rights and responsibilities.

Evolution, not revolution

Beyond the disciplines of CTA, there are a variety of perspectives to be found among established approaches to the regulatory appraisal of risk which could be constructively enlarged and developed. Suitably amended and interpreted, many of these offer ways to respond to the lessons discussed here. Multi-criteria mapping (MCM), for instance, combines the flexibility and scope of qualitative approaches with the transparency and specificity of quantitative disciplines. It offers one way to accommodate a diverse array of stakeholder perspectives with different technical and scientific factors, including uncertainties, without placing undue constraints on the divergent framings of the issues in question (Stirling and Mayer, 1999). Likewise, life cycle analysis (LCA) has developed an array of methods to ensure that attention extends to encompass the full technical life cycles and resource chains associated with different options (van den Berg, 1995). Cost-benefit analysis, for all its idiosyncrasies and serious limitations, is unusual in upholding the importance, emphasised in these lessons, of considering the 'pros' (justifications and benefits) alongside the 'cons' (risks and costs) (Hanley and Spash, 1993). Although rather infrequently used, sensitivity and scenario analysis techniques offer ways to explore the implications of different assumptions and perspectives and so be more 'humble' about the status of any particular understanding of a risk issue (Godet, 1992).

One broad approach that has emerged over the past decade or so, integrated environmental assessment (IEA), offers an architecture for constructing a new synthesis of these kinds of positive attributes in existing approaches to the appraisal of the pros and cons of contending alternatives (EFIEA, 2000; Dowlatabadi and Rotmans, 2000). Specifically developed to address large, complex environmental problems, IEA provides a means to integrate such methods into the kind of broad-based, multi-perspective and more humble and open-ended approach highlighted in these lessons. IEA in its present form addresses the interface between science-engineering and policy with emphasis on the need for interdisciplinarity; integration across the environmental media: water, air and soil; mass balance accounting in society and sectors; and analysis of alternatives. In view of the lessons identified in the case studies, equal emphasis on the following issues would improve the perspectives of IEA: more openness and deliberation about framing agendas; distinguishing between risk, uncertainty and ignorance; taking better account of the risk and consequences of being wrong; accounting for all values; expansion of cost-benefit analysis to the appraisal of wider pros and cons (as defined in this book); and much earlier involvement of these broader concerns in the relevant decision-making processes. Here, the use of 'what-if' scenarios and participatory scenario development techniques can assist greatly in the management of surprises and uncertainties.

Participatory approaches and subsidiarity

The historic trend of legal and economic regulation has been to centralise at global, regional or national government level, and to disenfranchise many interest groups. While there are signs of change, attempts to create participatory approaches are as vulnerable as any other initiative to centralising pressures. For example, the consensus conference, without safeguards, can potentially degenerate into little more than a form of consultation driven by the sponsor's agenda. Appeals procedures may also involve participatory approaches, but at far too late a stage in the process of regulation to deal with anything other than marginal issues. It follows from the 'late lessons' that participation of interest groups should be at an early stage, broadly drawn, and carried down to the appropriate local level.

Of course, local involvement is only meaningful in the context of democratically legitimate strategic frameworks of innovation and overall policy. The basic point is that often experts involved in technological developments — and officials in government — need better sensitivity to (often under-articulated) public values, priorities and concerns, at a variety of levels, from local to international. This can be achieved without the need for what would be paralysing indiscriminate full public participation in every single decision. In addition to European examples already mentioned, there are also developments outside the EU worthy of evaluation. These include the environmental laws of New Zealand, where the principle of subsidiarity has been introduced as an alternative approach to centralised regulation (Ministry for the Environment, 2001), and where the stated aim is for procedures for local participation and consensus-building to take prominence over central regulation. Both the development and implementation of Australia's ocean policy include significant attempts to involve stakeholders (National Oceans Office, 2000). Among many other findings, the research underlying the ocean policy made the relevant point that the views of local interest groups are not necessarily identical to their national or international equivalents, be these, for example, environmental non-governmental organisations or industry.

The tools for participatory approaches are in various stages of development, and the challenges are far from trivial (Brookes, 2001). But this has to be set against traditional approaches, where the costs of failure can also be high, as illustrated by the public rejection of irradiated foods, the abandoned attempt to dump the North Sea Brent Spar oil installation and the response to GMOs.

Awareness and ethics

Participatory approaches cannot work without heightened awareness, interest and engagement on the part of stakeholders and the public at large. Broadening the scope of environmental assessment will have a lower chance of success without a development of society's attitudes, responsibilities and ethics in relation to the environment. Parallel efforts are needed to increase society's awareness, foster discriminating involvement, and increase the educational basis for consensus building, by increased knowledge

of all aspects of the environment over the whole range of the disciplinary spectrum. This process starts at home and school and reaches its full potential by engagement in participatory procedures as a matter of interest and commitment. In stating this indoctrination to any one point of view is not implied, but rather the development of skills to critically assess arguments, express a point of view and engage in the democratic process.

A related area is the professional communication of the issues surrounding precaution. It is evident that at least some communication of the complexities involved is necessary to move forward, for the sake all interest groups. It is therefore ironic that the media and other professional communicators have been moving in the opposite direction, emphasising only 'positive knowledge' and the 'clear and simple message' in a sound-bite culture. This tends to exclude the communication of ignorance, of complexity and of responsibility in face of the essential limits of all knowledge.

There is also an ethical and cultural issue raised by the important need for institutional recognition of ignorance as well as uncertainty. This arises because of the way in which the ethical boundaries of acknowledged responsibility for uncertainties about the consequences of human innovative commitments have been drawn by scientific knowledge. Any possible future consequence which lies beyond existing scientific knowledge and predictability is deemed by definition to be beyond responsibility. This is defined as such even though it is known that such surprises will occur as a result of choices and commitments. The precautionary principle implies the need, as a matter of cultural change, for society's institutions to enlarge existing notions of ethical responsibility to encompass these unknowns, which are predictable in principle even though not in specifics. Suggestions have been made as to how this process of intellectual enlargement might begin, starting with the twelve late lessons.

This report expresses the honest conviction that to achieve sustainable environmental policies and a properly balanced practice of the precautionary principle requires the achievement of a cultural shift towards a greater civil sense of responsibility and involvement in policy-making (including science policy and technological innovation). This in turn will demand that the expert-led institutions of science, industry and policy learn to trust, to challenge and to build the opportunities and the frameworks for civil society to take on those responsibilities.

From the case studies, the 12 late lessons and these wider considerations of science, innovation and governance, it is evident that the precautionary principle — the need to exercise foresight — once accepted, leads far beyond the simple definition. Rather it is playing its part in the development of civil society and policy-making during the early 21st century which, it appears, will have its own distinctive character, as great in its differences as those which set apart previous centuries.

16.4. References

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