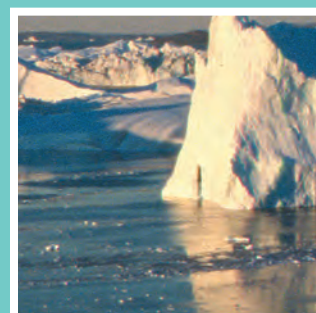


Late lessons from early warnings: science, precaution, innovation

Summary

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Preface

An investment in knowledge pays the best interest
— Benjamin Franklin 'The Way to Wealth' (1758).

There is something profoundly wrong with the way we are living today. There are corrosive pathologies of inequality all around us — be they access to a safe environment, healthcare, education or clean water. These are reinforced by short-term political actions and a socially divisive language based on the adulation of wealth. A progressive response will require not only greater knowledge about the state of the planet and its resources, but also an awareness that many aspects will remain unknown. We will need a more ethical form of public decision-making based on a language in which our moral instincts and concerns can be better expressed. These are the overall aims of Volume 2 of *Late lessons from early warnings*.

Volume 1 of *Late lessons from early warnings* was published at a time when the world was experiencing an economic slowdown, China had joined the World Trade Organization and western Europe was still a 15-member Union. Global grain production had declined for the third time in four years due mainly to droughts in North America and Australia, and the world saw major recalls of contaminated meat, foot and mouth disease and bovine spongiform encephalopathy (mad cow disease). Global temperatures continued to climb and many bird populations were in decline, but the United States of America had rejected the Kyoto Protocol. We were seeing ourselves through the lens of the first human genome sequence, yet we were trying to manage chemicals known to be harmful to humans and ecosystems, through international conventions and treaties such as the Basel Convention to deal with toxic waste dumping in the developing world; the OSPAR/HELCOM Conventions to reduce the discharges, emissions and the loss of hazardous substances into the sea and the Montreal Protocol, to phase out ozone-depleting substances. The destruction of the World Trade Center had just happened.

Since then, we have witnessed a period of extraordinary hubris. Most visibly, the financial

profligacy of the first decade of the century led inexorably to the crises of 2007–2009 whereby the major components of the international financial system were weakened to the extreme by indebtedness, mispriced products, lax monetary policies and mis-engineered protection against risks and uncertainty. The world experienced more not less volatility. Political systems became silted up by vested interests and a determination by citizens to protect assets accumulated in easier times, and beneath it all lay a deeper environmental crisis epitomised by climate change and biodiversity loss.

There was also a collapse of trust, not only in financial institutions but in big companies, as they abandoned staff, pensions and health care schemes. Recent evidence from social psychology has shown that despite rising levels of education and innovation in products and services, people trust only those they know and not strangers. As Stephen Green said in *Good value: reflections on money, morality, and an uncertain world* in 2009:

'There has been a massive breakdown of trust: trust in the financial system, trust in bankers, trust in business and business leaders, trust in politicians, trust in the media, trust in the whole process of globalisation — all have been severely damaged, in rich countries and poor countries alike'.

The scientific elites have also been slowly losing public support. This is in part because of the growing number of instances of misplaced certainty about the absence of harm, which has delayed preventive actions to reduce risks to human health, despite evidence to the contrary.

Suddenly, our problems have grown into what Charles W. Churchman in 1967 termed *wicked problems* — difficult or impossible to solve because of incomplete, contradictory and changing requirements, difficult to recognize, resistant to resolution because of the complexity of their interdependencies and needing to be tackled not by one but via many forms of social power. Solving

them requires a new combination of hierarchical power, solidarity and individualism.

What could this mean, for example, for the 100 thousand chemicals currently in commercial use?

To begin with we have more conventions and treaties in place than a decade ago: the 2004 Rotterdam Convention on the Prior Informed Consent (PIC) Procedure covering international trade of 24 pesticides, four severely hazardous pesticide formulations and 11 industrial chemicals; the 2004 Stockholm Convention on Persistent Organic Pollutants to protect human health and the environment from substances which are highly toxic, persistent, bio-accumulative and move long distances in the environment, such as DDT, PCBs, various industrial chemicals, and a set of unintentional chemical by-products such as dioxin. But these conventions only address the top-down hierarchical approach to power.

At the same time Europe has put in place legislation to achieve a global regulatory influence including the EU Cosmetic Directive banning the use of chemicals known or strongly suspected of being carcinogens, reproductive toxins, or mutagens causing cancer, mutation or birth defects; the EU Restriction of Hazardous Substances Directive, which restricts the use of hazardous materials in the manufacture of various types of electronic and electrical equipment including lead, mercury, cadmium, hexavalent chromium, the flame retardants polybrominated biphenyls and polybrominated diphenyl ethers, and which encourages the substitution to safe/or safer alternatives in the electric and electronic equipment industry; the closely linked 2006 EU Waste Electrical and Electronic Equipment Directive for collection, recycling and recovery of electrical goods; the 2006 Strategic Approach to International Chemicals Management (SAICM); and the 2007 EU Registration, Evaluation and Authorisation of Chemicals, widely known as REACH, to assign greater responsibility to industry to manage the risks from chemicals and to provide safety information on substances. The effects of these regulatory tools are described in different chapters, but once again point to the main economic actors rather than communities or individuals.

One thing that has become clearer over the past decade is that certain chemical substances are highly stable in nature and can have long-lasting and wide ranging effects before being broken down into a harmless form. The risk of a stable compound is that it can be bio-accumulated in

fatty tissues at concentrations many times higher than in the surrounding environment. Predators, such as polar bears, fish and seals, are known to bio-magnify certain chemicals in even higher concentrations with devastating consequences for both humans and ecosystems. So exposure to toxic chemicals and certain foodstuffs are at risk of causing harm, especially to vulnerable groups such as foetuses in the womb or during childhood when the endocrine system is being actively built. Even with small dose exposures, the consequences can in some instances be devastating with problems ranging from cancer, serious impacts on human development, chronic diseases and learning disabilities. Here the power to act could be more properly set by well-informed individuals and communities.

The relationship between knowledge and power lies at the heart of Volume 2. In many chapters, the implicit links between the sources of scientific knowledge about pollutants, changes in the environment and new technologies, and strong vested interests, both economic and paradigmatic, are exposed. A number of authors also explore in greater depth, the short-sightedness of regulatory science and its role in the identification, evaluation and governance of natural resources, physical and chemical hazards. By creating a better understanding of these normally invisible aspects, it is hoped that this volume will enable communities and people to become more effective stakeholders and participants in the governance of innovation and economic activities in relation to the associated risks to humans and the planet.

Much of what we are able to learn from the histories of past environmental and public health mistakes is also directly applicable to the better regulation and governance of global institutions and financial and economic risks. Robin G. Collingwood argued in his *Autobiography* (1939), that:

'History can offer something altogether different from [scientific] rules, namely insight. The true function of insight is to inform people about the present...we study history in order to see more clearly into the situation in which we are called upon to act... the plane on which, ultimately, all problems arise is the plane of 'real' life: that to which they are referred for their solution is history.'

In this volume, we go further. Whilst still drawing lessons from such widely accepted tragedies as leaded petrol, mercury poisoning in Japan's

Minamata Bay and older pesticides which sterilised many men who used it, we have ventured into the uncertainties of potential yet contested harm, from genetically modified products; nanotechnologies; chemicals such as Bisphenol A; new pesticides and mobile phones. There is also an examination of the 80 or so potential 'false positives' where there had been indications of harm but where it was subsequently claimed that there were in fact no risks to prevent: these cases too can provide information that can help to improve future decision-making about innovation and emerging technologies.

A major part of effective decision-making lies in the way issues are framed. In the case of climate change, the first order question is whether it is worth worrying about at all. US Vice President Al Gore chose to make the question a matter of choice between believers and sceptics. However, problems arose when the public was asked to make a scientific decision when too few people had the qualifications to make any kind of reasoned judgement. They were in fact asked to make a false choice. Instead the question should have been framed around which areas should people and governments make decisions and which should be delegated to experts.

In the end there are few certain and enduring truths in the ecological and biological sciences, nor in the economics, psychologies, sociologies and politics that we use to govern them. One, however,

comes from the work of Elinor Ostrom, a late and widely missed colleague, who showed from her work on managing fisheries and ecosystems that complex problems can be solved if communication is transparent and open, visions are shared, trust is high and communities are activated to work from the bottom-up as well as from the top down.

As we navigate the Anthropocene, the epoch named in recognition of our impact on the planet, we will need to encourage more people to become involved in solving the wicked problems of our times. Whether through gathering local information or becoming more aware of the many uncertainties and unpredictabilities in our surroundings, the power structures of knowledge will need to change. And if we are to respond more responsibly to the early warning signals of change, we will need to re-design our style of governance to one which reflects a future defined by the local and specific rather than only the global and the average. We hope that Volume 2 of *Late lessons from early warnings* with its many lessons and insights can help us all meet such a challenge.



Professor Jacqueline McGlade,
Executive Director

1 Introduction

Why further late lessons from early warnings?

The 2013 *Late lessons from early warnings* report is the second of its type produced by the European Environment Agency (EEA) in collaboration with a broad range of external authors and peer reviewers.

Volume 1 of *Late lessons from early warnings: the precautionary principle 1896–2000* published in 2001, looked at the history of a selection of occupational, public health and environmental hazards and asked whether we could have been better at taking action early enough to prevent harm. Twelve key lessons for better decision-making were drawn from cases where public policy was formulated against a background of scientific uncertainty and 'surprises' — and where clear evidence of hazards to people and the environment was often ignored (see box on page 11).

The 14 case studies and 12 key lessons from the 2001 report remain highly pertinent today, and underline four main reasons for a second report. The first relates to expanding the late lessons approach to consider long-known, important additional issues with broad societal implications such as lead in petrol, mercury, environmental tobacco smoke and DDT, as well as issues from which lessons have emerged more recently such as the effects of the contraceptive pill on feminisation of fish and the impacts of insecticides on honeybees.

The second concerns filling an acknowledged gap in the 2001 report, by analysing the issue of false positives where government regulation was undertaken based on precaution but later turned out to be unnecessary. Most of the cases examined in the *Late lessons from early warnings* reports are 'false negatives' — instances where early warnings existed but no preventive actions were taken.

The third reason is to address the rapid emergence of new society-wide challenges such as radiation from mobile phones, genetically-modified products, nanotechnologies and invasive alien species as well as if, how and where precautionary actions can play a role.

The final reason relates to how precautionary approaches can help manage the fast-changing, multiple, systemic challenges the world faces today, what new insights can be drawn in this context and how these can underpin opportunities for sustainable innovations and, supported by information technologies, greater public participation in their selection.

Overall approach

As for Volume 1, the approach in Volume 2 has been to include a wide range of relevant case studies produced by external authors along with chapters written by members of the report's editorial team (see acknowledgements section for details). The relevant topics for case study treatment were selected on the basis of advice from the editor, in collaboration with the editorial team and an advisory board, members of the EEA Scientific Committee and the Collegium Ramazzini ⁽¹⁾.

The chapters in Volume 2 are grouped into five parts: A. Lessons from health hazards; B. Emerging lessons from ecosystems; C. Emerging issues; D. Costs, justice and innovation; and E. Implications for science and governance.

The chapters have been written by authors who, to varying degrees, have had substantial involvement in the subject area being addressed. Indeed they would not have been approached if

⁽¹⁾ The Collegium Ramazzini is an independent, international academy founded in 1982 by Irving J. Selikoff, Cesare Maltoni and other eminent scientists. Its mission is to advance the study of occupational and environmental health issues and to be a bridge between the world of scientific discovery and the social and political centers, which must act on the discoveries of science to protect public health.

they had not already extensively studied the case that they were asked to write about. All of them, as respected experts in their fields and in line with their professional scientific training, were expected to be as objective as possible in answering the questions put to them by EEA. To support this, and to develop consistency between chapters, the authors were provided with seven structuring questions to be followed when building their chapter.

The case studies have been peer-reviewed by recognised experts in the respective fields who gave of their time freely and provided their feedback within a set of editorial guidelines provided by the EEA.

Scope

The report has been designed, structured and written in order to, inter alia, help politicians, policymakers and the public to:

- i understand better the ways in which **scientific knowledge** is financed, created, evaluated, ignored, used and misused in taking timely and precautionary decisions about how to reduce harms, whilst stimulating benign innovations and generating useful employment;
- ii learn from some **very expensive 'mistakes' in the past** so as to help societies make fewer mistakes now, and in the future, especially with some of the relatively new, largely unknown, yet already widespread technologies like nanotechnology and mobile phones;
- iii be aware of less visible, important factors such as the skewed ways in which the **costs of actions and inactions** for hazardous technologies have been estimated, and the role that **some businesses** have played in ignoring early warnings and in manufacturing doubt about the science supporting such warnings;
- iv consider how the law, or administrative arrangements, could be better used to deliver **justice, to those people (and ecosystems) that have been, or could be, harmed** by poorly designed, or badly deployed, innovations;
- v explore how best to **engage the public** in helping to make **strategic choices over innovations**, and their technological and social pathways, as well as their involvement in **ecosystems management** and in long term monitoring through **citizen science**.

Part A of the report commences with an analysis of 'false positives' showing that these are few and far between as compared to false negatives and that carefully designed precautionary actions can stimulate innovation, even if the risk turns out not to be real or as serious as initially feared. The remaining nine chapters address false negatives — lead in petrol, perchlorethylene contaminated water, Minamata disease, occupational beryllium disease, environmental tobacco smoke, vinyl chloride, dibromochloropropane (DBCP), Bisphenol A and dichlorodiphenyltrichlorethane (DDT) — from which three common themes emerge: there was more than sufficient evidence for much earlier action; slow and sometimes obstructive behaviour by businesses whose products endangered workers, the public and the environment; and the value of independent scientific research and risk assessments.

Part B focuses on emerging lessons from the degradation of natural systems and their wider implications for society — booster biocides, the pill and the feminisation of fish, climate change, floods, insecticides and honeybees as well as ecosystem resilience more broadly. It considers, like its predecessor, the issues of scientific evidence as the basis for action/inaction, the multiple, often complex factors and feedback loops in play, many of which are not fully understood, as well as the interfaces between science, policy and society and how all actors can move together towards necessary actions in the context of heightened systemic risks, and substantial unknowns.

Part C analyses some newly emerging and large-scale products, technologies and trends, which potentially offer many benefits but also potentially much harm to people and ecosystems and thereby ultimately economic development. Cases addressed include the Chernobyl and Fukushima nuclear accidents; genetically modified agricultural crops and agroecology; the growing threat of invasive alien species; mobile phones and the risk of brain tumours; and nanotechnologies. There is often little science, and very little direct hindsight, to assist in the management of these emerging technologies but the lessons from the historical case studies need to be applied if hazards are to be avoided.

The evidence from the chapters in Part C is that, by and large, societies are not making the most use of the costly lessons that can be gleaned from their histories. A key question is how this can be improved given the many reasons identified from the case studies why taking actions have been delayed including: the novel

and challenging nature of the issues themselves; poorly or inconsistently evaluated information; strong opposition by the corporate and scientific establishments of the day; and the tendency by the decision making institutions, practices and cultures to favour the status quo and the short term perspective. This section also illustrates the value of bottom up as well as top down approaches to innovations in ensuring that the directions of technological pathways, the equitable distributions of benefits, costs and knowledge ownership, and the diversity of locally sensitive technological options are relevant to the food, energy and ecosystems crises.

The historical chapters illustrate numerous harms which for the most part have been caused by irresponsible corporations. This fact, coupled with shortcomings in how decisions are made by governments on when to act on early warnings, and in the law when it comes to compensating victims of harm, are analysed in three chapters in Part D of the report. Each chapter analyses the reasons behind prevailing practice and then goes on to offer insights, for example, on how cost

calculation methods can be improved; on how insurance schemes could be used to compensate future victims of harm; and on the reasons why businesses frequently ignore early warnings.

The cases in Parts A–D form the basis for considering in Part E the governance implications for science, public policy and public engagement, and how current practices could be improved to enable society to maximise the benefits of innovations while minimising harms. The main insights are that science could be more relevant for precautionary decision-making; that the wider use of the precautionary principle can avert harm and stimulate innovation; and that the late lessons of history and precautionary approaches are highly pertinent to today's multiple and inter-connected crises — such as those arising from finance, economics, the use of ecosystems, climate change, and the use and supply of energy and food.

Finally, many of the historical and recent case studies illustrate the value of engaging the public in broadening the knowledge base and stimulating robust innovations.

Twelve late lessons

Based on the case studies of Volume 1 of *Late lessons from early warnings* (EEA, 2001), twelve key lessons for better decision-making were drawn:

- 1 Acknowledge and respond to ignorance, as well as uncertainty and risk, in technology appraisal and public policymaking
- 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

Source: EEA, 2001, *Late lessons from early warnings: the precautionary principle 1986–2000*, Environmental issues report No 22, European Environment Agency.

2 The precautionary principle and false alarms — lessons learned

Steffen Foss Hansen and Joel A. Tickner

Most of the cases examined in the *Late lessons from early warnings* reports are 'false negatives' — instances where early warnings existed but no preventive actions were taken. In debates surrounding the precautionary principle it is often claimed that widespread application of the principle will lead to a large number of regulatory false positives — over-regulation of minor risks and regulation of non-existent risks, often due to unwarranted public 'fears'. Understanding and learning from past false positives as well as false negatives is essential for improving decision-making about public health and the environment.

This chapter reviews incidents of 'false positives', where government regulation was undertaken based on precaution but later turned out to be unnecessary. In total 88 cases were identified to be alleged false positives, however, following a detailed analysis most of them turned out to be either real risks, or cases where 'the jury is still out', or unregulated alarms, or risk-risk trade-offs, rather than false positives.

The analysis revealed four regulatory false positives: US swine flu, saccharin, food irradiation, and Southern leaf corn blight. Numerous important lessons can be learned from each, although there are few parallels between them in terms of when and why each risk was falsely believed to be real. This is a lesson in itself: each risk is unique, as is the science and politics behind it and hence a flexible approach is therefore needed, adapted to the nature of the problem. The costs of the false positives identified were mainly economic, although the actions taken to address swine flu

in 1976 did lead to some unintended deaths and human suffering, and diverted resources from other potentially serious health risks. Determining the net costs of mistaken regulatory action, however, requires a complete assessment of the impacts of the regulation, including the costs and benefits of using alternative technologies and approaches.

Overall, the analysis shows that fear of false positives is misplaced and should not be a rationale for avoiding precautionary actions where warranted. False positives are few and far between as compared to false negatives and carefully designed precautionary actions can stimulate innovation, even if the risk turns out not to be real or as serious as initially feared. There is a need for new approaches to characterising and preventing complex risks that move debate from the 'problem' sphere to the 'solutions' sphere. By learning from the lessons in this chapter, more effective preventive decisions can be made in the future.

The scarcity of genuine false positives compared to the large number of 'mistaken false positives' could partly be the result of a deliberate strategy in risk communication. Several references and leaked documents have shown that some regulated parties have consciously recruited reputable scientists, media experts and politicians to call on if their products are linked to a possible hazard. Manufacturing doubt, disregarding scientific evidence of risks and claiming over-regulation appear to be a deliberate strategy for some industry groups and think tanks to undermine precautionary decision-making.

3 Lead in petrol 'makes the mind give way'

Herbert Needleman and David Gee

This chapter addresses the widespread use of lead in petrol. It focuses on the period 1925–2005, when leaded petrol was first widely marketed in the US and then spread to the rest of the world before being gradually phased out from the 1970s. In Europe, the Aarhus Protocol (www.unece.org/env/pp/treatytext.html) initiated the phase-out of leaded petrol in the period 1998–2005.

The neurotoxic effects of lead were recognised as far back as Roman times. And in 1925, at the 'one day trial' of leaded petrol in the US, many experts warned of the likely health impacts of adding lead to petrol. Yet, despite the availability of an equally effective alcohol additive which was assessed by experts to be cleaner, the leaded route to fuel efficiency was chosen in the US and then exported to the rest of the world.

For several decades after the introduction of leaded petrol, virtually no independent research was carried out and the main source of information was industry and industry-sponsored researchers. Not until the 1960s and 1970s did independent scientists from outside this group show, for example, that

body burdens of lead arising from human activities were not 'normal', as industry claimed, but were hundreds of times higher than before the industrial revolution and were therefore likely to be harmful.

At its peak in the mid-1970s, leaded petrol released about 200 000 tonnes of lead into the atmosphere annually in both the US and Europe. Following the subsequent phase-out, blood lead levels in children (the most sensitive group exposed) quickly fell, in line with the decrease in air concentrations. The lessons nevertheless remain relevant globally today. Although nearly all countries worldwide had phased out leaded petrol by 2012, lead concentrations in soils and sediments remain high. Meanwhile, electronic wastes containing lead and other contaminants also cause elevated blood lead levels.

Supplementary panel texts focus on the events leading up to the US choice of leaded petrol as the primary fuel source in 1925 and more recent accounts of EU policymaking on lead in petrol and the road to phase-outs in Germany and the United Kingdom.

4 Too much to swallow: PCE contamination of mains water

David Ozonoff

PCE (perchloroethylene, also known as 'perc' or tetrachloroethylene), was used in the production of plastic linings for drinking water distribution pipes in the late 1960s and 1970s. This new and relatively untested type of distribution pipe was used in over 700 miles of New England's water distribution systems. Not until 1976 was it discovered that PCE had been leaching into the water from the pipe lining, causing widespread contamination of water supplies that still today require continuous remediation.

Before the pipes were put into production there was a substantial amount of scientific information available about the potential hazards of PCE. This did not include current concerns about PCE's carcinogenicity, teratogenicity and other health consequences of relatively low-level exposure upper most among today's concerns, but many early warnings suggested the need for caution in introducing PCE-based mains pipe linings.

PCE had been used to treat hookworm and data on side effects were in the literature, while later a variety of occupational users were studied, including aircraft workers, small companies in countries where biological monitoring was required, and dry-cleaning firms. Several environmental studies were also conducted to see if drinking water contaminated with PCE or its close relative, TCE (trichloroethylene), was associated with

cancer. Results were mixed and the chemical industry consistently denied that PCE was a human carcinogen.

This case study explores the early (pre 1970) history researching the toxicity of the chemical. It also focuses on the failure of one manufacturer, Johns-Manville Corporation, to recognise the warning signals about using a suspected toxic substance. It examines why a new product was deployed without thought to the public health consequences and why evidence of the potential hazard was ignored.

The science has not been hidden. It has been ineffective in guiding and catalysing action. Whether the problem is a failed duty of care or a lack of clarity about what evidence will trigger action, the contemporary argument over how to interpret the scientific evidence is irresolvable within science itself. There are no overarching criteria from the philosophy of science that can dictate a solution.

This chapter also includes two supplementary texts. A panel that analyses the differences between the conclusions of risk assessments based on the same data, focusing in particular on assessments of PCE and TCE. A further panel describes the opportunities to switch to wet-cleaning technologies to reduce the current use of PCE in dry cleaning.

5 Minamata disease: a challenge for democracy and justice

Takashi Yorifuji, Toshihide Tsuda and Masazumi Harada

Minamata disease, which can induce lethal or severely debilitating mental and physical effects, was caused by methylmercury-contaminated effluent released into Minamata Bay by Chisso, Japan's largest chemical manufacturer. It resulted in widespread suffering among those who unknowingly ate the contaminated fish. This chapter documents the story in three phases.

The disease first came to prominence in the 1950s. It was officially identified in 1956 and attributed to factory effluent but the government took no action to stop contamination or prohibit fish consumption. Chisso knew it was discharging methylmercury and could have known that it was the likely active factor but it chose not to collaborate and actively hindered research. The government concurred, prioritising industrial growth over public health. In 1968 Chisso stopped using the process that caused methylmercury pollution and the Japanese government then conceded that methylmercury was the etiologic agent of Minamata disease.

The second part of the story addresses the discovery that methylmercury is transferred across the placenta to affect the development of unborn children, resulting in serious mental and physical problems in later life. Experts missed this at first because of a medical consensus that such transfer across the placenta was impossible.

The third phase focuses on the battle for compensation. Initially, Chisso gave token

'sympathy money' under very limited criteria. In 1971 the Japanese government adopted a more generous approach but after claims and costs soared a more restrictive definition was introduced in 1977, justified by controversial 'expert opinions'. Legal victories for the victims subsequently made the government's position untenable and a political solution was reached in 1995–1996. In 2003, the 'expert opinions' were shown to be flawed and the Supreme Court declared the definition invalid in 2004.

In September 2011 there were 2 273 officially recognised patients. Still, the continuing failure to investigate which areas and communities were affected means that the financial settlement's geographic and temporal scope is still not properly determined. Alongside deep-seated issues with respect to transparency in decision-making and information sharing, this indicates that Japan still faces a fundamental democratic deficit in its handling of manmade disasters.

This chapter is followed by three short updates on the effects of mercury poisoning since Minamata; on attempts to contain it, including the 2009 global agreement to phase mercury out of economic activity; and on the need for better information about contaminant exposures to enable policymakers to make informed choices that balance the benefits of fish consumption against the assumed adverse effects of low-level methylmercury exposures.

6 Beryllium's 'public relations problem'

David Michaels and Celeste Monforton

Scores of workers employed in nuclear weapons production have been diagnosed with chronic beryllium disease (CBD), a progressive and irreversible inflammatory lung disease. This chapter presents a history of knowledge and public policy about preventing beryllium-related disease, focusing primarily on the United States beryllium industry's role in shaping US regulatory policy.

Over several decades increasingly compelling evidence accumulated that CBD was associated with beryllium exposure at levels below the existing regulatory standard. The beryllium industry had a strong financial incentive to challenge the data and decided to be proactive in shaping interpretation of scientific literature on beryllium's health effects. It hired public relations and 'product defence' consulting firms to refute evidence that the standard was inadequate. When the scientific evidence became so great that it was no longer credible to deny that workers developed CBD at permitted exposure levels, the beryllium industry responded with a new rationale to delay promulgation of a new, more protective exposure limit.

This case study underscores the importance of considering the hazards from toxic materials

throughout the entire product life cycle. While primary producers of beryllium products may be able to control exposures in their own facilities, it is unlikely that many secondary users and recyclers have the expertise, resources and knowledge necessary to prevent beryllium disease in exposed workers and residents in nearby communities.

The primary lessons of this chapter are widely applicable to many environmental health controversies. In particular, it illustrates the practice of 'manufacturing uncertainty' — a strategy used by some polluters and manufacturers of hazardous products to prevent or delay regulation or victim compensation.

This chapter is followed by an analysis of the rationale for corporate behaviour in the regulation of beryllium. It is argued that the availability of occasional and limited opportunities for companies to change course without suffering onerous consequences would encourage them to rethink their position and create an obligation on shareholders to take the responsible course. Although this may be perceived as letting them 'get away with it', the end result may be better public policy and corporate responsibility.

7 Tobacco industry manipulation of research

Lisa A. Bero

This chapter differs in some ways from the others in Volume 2 of *Late lessons from early warnings*. The history of 'second hand', 'passive' or 'environmental tobacco smoke' (ETS), to which non-smokers are exposed overlaps with the history of active smoking. Those affected include the partners and children of smokers, and the bartenders and other workers who have to work in smoky environments.

The focus in this chapter is on the strategies used by the tobacco industry to deny, downplay, distort and dismiss the growing evidence that, like active smoking, ETS causes lung cancer and other effects in non-smokers. It does not address the history of scientific knowledge about tobacco and how it was used or not used to reduce lung cancer and other harmful effects of tobacco smoke. There is much literature on this and a table at the end of the chapter summarises the main dates in the evolution of knowledge in this area.

The chapter concentrates on the 'argumentation' that was used to accept, or reject, the growing scientific evidence of harm. Who generated and financed the science used to refute data on adverse health effects? What were the motivations?

What kind of science and information, tools and assumptions were used to refute data on the adverse health of tobacco?

The release of millions of internal tobacco industry documents due to law suits in the US has given insights into the inner workings of the tobacco industry and revealed their previously hidden involvement in manipulating research. However, this insight is not available for most corporate sectors. The chapter discusses the possibilities of 'full disclosure' of funding sources and special interests in research and risk assessment in order to secure independence and prevent bias towards particular viewpoints.

While smoking bans are now being introduced in more and more countries, other industries are drawing inspiration from tobacco company strategies, seeking to maintain doubt about harm in order to keep hazardous products in the marketplace.

The chapter also includes a summary of the tobacco industry's role in shaping risk assessment in the US and Europe to serve its own interests.

8 Vinyl chloride: a saga of secrecy

Morando Soffritti, Jennifer Beth Sass, Barry Castleman and David Gee

This chapter is about how early warnings in the 1950s and 1960s concerning the short-term harm of vinyl chloride (VC) to the skin and bones of workers, and to the livers of laboratory animals, were initially hidden from other workers and regulators. This was despite some early misgivings by company experts whose advice was initially ignored by their employers. This pattern was repeated when the later, more devastating news of a rare liver cancer in workers was revealed by long-term animal studies and by an attentive and concerned company physician.

Unlike many other histories, however, this story features a very prompt response from the global chemical industry to the publication of the liver cancer evidence, a response that included funding cancer testing and later compliance with a large reduction in the permissible exposure limits. The case also provides early evidence of reproductive effects of vinyl chloride monomer (VCM).

Other features of this story presage the later and common responses of the corporate world to heightened public awareness and pressure from non-governmental organisations (NGOs) and trade unions, including greatly exaggerated estimates of

the likely costs of complying with tighter pollution controls; a frequent mismatch between the position of the trade association and that of many, more progressive companies within the association; but also some relatively quick corporate responses to public, NGO and regulatory pressure.

The chapter also features two legal aspects, which, though more common in the US, are also valuable for Europeans. First, the potentially positive role that judicial review of regulatory proposals can play in providing a societal judgement about the behaviour of corporations. This can embrace not just moral judgements but also judgements about the state of the science and what society should do with it.

Second, the role that document discovery in legal compensation cases can play in revealing the real and until then secret activities of corporations. Any proposals to promote justice for victims of environmental and health harms via no fault administrative arrangements need to be accompanied by other measures to extract information about corporate behaviour.

The chapter is followed by a panel analysing the value of animal testing for identifying carcinogens.

9 The pesticide DBCP and male infertility

Eula Bingham and Celeste Monforton

Dibromochloropropane (DBCP) is a pesticide used against nematodes (roundworms or threadworms) that damage pineapples, bananas and other tropical fruits. It was introduced into US agriculture in 1955 and approved for use as a fumigant in 1964. By 1961 laboratory experiments had shown that it made the testicles of rodents shrink and significantly reduced the quantity and quality of sperm. Nonetheless, the compound was widely marketed and became a commercial success.

In 1977, workers at a production plant became worried that they were unable to father children. An emergency study by a US government agency discovered that in many cases the workers were suffering from deficient or absent sperm. While controls were improved at US facilities, the product continued to be marketed and sprayed in Latin America, the Philippines, some African countries, and elsewhere.

By the 1990s, tens of thousands of plantation workers in these countries had allegedly suffered adverse reproductive effects from DBCP use.

The story continues today with contentious legal claims for compensation, contamination of drinking water and industry attempts to prevent a Swedish documentary on the issue from being screened.

This chapter looks at the knowledge available about the hazards and the actions taken, or not taken, to avert them. The DBCP story is significant as it is the first clear example of reproductive damage to workers who manufactured and used a synthetic chemical. This is one of many examples supporting the growing concerns about increasing rates of reproductive and developmental disease, and about the endocrine disrupting chemicals that seem to be playing a role in these disorders.

Protecting production workers, users, consumers and the environment from chemicals that may damage reproduction demands closer integration of scientific disciplines, as well as government action. The lessons of DBCP may help in ensuring timely protection from harm, based on precautionary approaches to scientific evidence.

10 Bisphenol A: contested science, divergent safety evaluations

Andreas Gies and Ana M. Soto

Bisphenol A (BPA) is currently one of the world's best-selling chemicals and primarily used to make polycarbonate plastics. It is widely used in common products such as baby bottles, household electronics, medical devices and coatings on food containers. BPA is known to mimic the female hormone oestrogen and has been found to leach from the materials where it is used.

Studies have suggested that even exposure to low doses of BPA may cause endocrine disrupting effects. As with other hormones, it appears that an organism is most sensitive during development but that effects are often not observed until much later in the lifecycle. This means that at the time when the effects become detectable, the chemical exposure has vanished. This makes it extremely difficult to link exposure to effects in humans.

This chapter maps some of the findings in studies of rodents and humans. It also discusses the challenges of evaluating scientific findings in a field where industry-sponsored studies and independent scientific research seem to deviate strongly. The authors offer suggestions for ways to uncouple financial interests from scientific research and testing.

A widely used and dispersed industrial chemical like Bisphenol A is a controversial example

of an endocrine disrupting substance that has implications for policymakers. Different approaches to risk assessment for BPA by US and European authorities are presented. It throws light on the ways in which similar evidence is evaluated differently in different risk assessments and presents challenges for applying the precautionary principle.

The intense discussion and scientific work on BPA have slowly contributed to a process of improving test strategies. While traditional toxicology has relied on a monotonic increasing dose-response relationship as evidence that the effect is caused by the test agent, studies on BPA and other endocrine disruptor chemicals (EDCs) have demonstrated the limitations of this approach and adjustments have been made in some cases.

It has also been widely accepted that effects cannot be predicted by simply thinking of BPA as a weak oestrogen and extrapolating from what is observed for more potent endogenous oestrogens. This lesson is particularly evident in the intense pharmaceutical interest in selective oestrogen response modifiers (SERMs).

The chapter is followed by a panel analysing the value of animal testing for identifying carcinogens.

11 DDT: fifty years since *Silent Spring*

Henk Bouwman, Riana Bornman, Henk van den Berg and Henrik Kylin

'There was a strange stillness. The birds for example — where had they gone? Many people spoke about them, puzzled and disturbed. The feeding stations in the backyards were deserted. The few birds seen anywhere were moribund: they trembled violently and could not fly. It was a spring without voices ... only silence lay over the fields and woods and marsh.'

The book *Silent Spring* by Rachel Carson is mainly about the impacts of chemicals (in particular dichlorodiphenyltrichlorethane also known as DDT) on the environment and human health. Indeed, the close association between humans and birds remains very apt. Representing the only two warm-blooded groups of life on Earth, mammals and birds share the same environments and threats.

Carson's claim that she lived in 'an era dominated by industry, in which the right to make a dollar at whatever cost is seldom challenged' still resonates strongly with the problems that societies face all over the world. One chapter heading, 'The obligation to endure', derived from the French biologist and philosopher Jean Rostand's famous observation that, 'the obligation to endure gives us the right to know'. United States President John F. Kennedy responded to the challenge posed by Carson by investigating DDT, leading to its complete ban in the US. The ban was followed by a range of institutions and regulations concerned with environmental issues in

the US and elsewhere, driven by public demand for knowledge and protection.

DDT was the primary tool used in the first global malaria eradication programme during the 1950s and 1960s. The insecticide is sprayed on the inner walls and ceilings of houses. Malaria has been successfully eliminated from many regions but remains endemic in large parts of the world. DDT remains one of the 12 insecticides — and the only organochlorine compound — currently recommended by the World Health Organization (WHO), and under the Stockholm Convention on Persistent Organic Pollutants, countries may continue to use DDT. Global annual use of DDT for disease vector control is estimated at more than 5 000 tonnes.

It is clear that the social conscience awakened by Rachel Carson 50 years ago gave momentum to a groundswell of actions and interventions that are slowly but steadily making inroads at myriad levels. Chapter 17 of her book, 'The other road' reminds the reader of the opportunities that should have been seized much earlier. With more than 10 % of bird species worldwide now threatened in one way or another, it is clear that we missed early warnings or failed to act on them. Will we continue to miss signposts to 'other roads'? Are our obligations to endure met by our rights to know? As Carson said 50 years ago: 'The choice, after all, is ours to make.'

12 Booster biocide antifoulants: is history repeating itself?

Andrew R. G. Price and James W. Readman

Tributyltin (TBT) was widely used as an effective antifouling agent in paints for ships and boats until the European Community restricted its use in 1989 because of its proven harm to the environment and shellfisheries. Thereafter, booster biocides were introduced to enhance the performance of antifouling paints. They were believed to be less damaging to aquatic life than TBT. Subsequently, however, it has been established that booster biocides can also create significant environmental risks.

This chapter outlines the background to booster biocide use, the early warnings about their potential physiological and ecological impacts on non-target species, and the actions taken in response. The science that set some alarm bells ringing is described, along with lessons that could influence the future of an industry still searching for less environmentally invasive solutions.

Booster biocide antifouling agents threaten a variety of habitats — from coral reefs and seagrass beds to open moorings — within the EU and globally. Their primarily herbicidal properties mean that coral zooxanthellae, phytoplankton and periphyton are particularly vulnerable. Compared to TBT, an antifouling agent with a quite specific action, booster

biocides have more broad-spectrum impacts. The wider ecological effect of shifting to booster biocides remain poorly understood but of considerable concern because they may affect the base of marine food chains.

From a toxicological viewpoint, booster biocides do not threaten to have endocrine disrupting properties similar to TBTs. At current environmental concentrations, however, some can damage primary producers and some are persistent. While legislation has been introduced to control their use, the rigour of regulations varies between countries. These geographical disparities need to be addressed, and future biocidal products and novel approaches to antifouling should be better appraised.

For policymakers, the challenge is to protect non-target biological communities from selective change resulting from booster biocide use. Persistence, bioaccumulative and toxic (PBT) criteria can be used to evaluate the relative potential impact from the available biocides, and consequently target appropriate legislation. Nevertheless, lateral thinking, aiming to identify novel materials and strategies to address antifouling, could pay dividends in the future.

13 Ethinyl oestradiol in the aquatic environment

Susan Jobling and Richard Owen

Many decades of research have shown that when released to the environment, a group of hormones known as oestrogens, both synthetic and naturally occurring, can have serious impacts on wildlife. This includes the development of intersex characteristics in male fish, which diminishes fertility and fecundity. Although often sublethal, such impacts may be permanent and irreversible.

This chapter describes the scientific evidence and regulatory debates concerning one of these oestrogens, ethinylloestradiol (EE2), an active ingredient in the birth control pill. First developed in 1938, it is released to the aquatic environment via wastewater treatment plants. Although it is now clear that wildlife species are exposed to and impacted by a cocktail of endocrine disrupting chemicals, there is also reasonable scientific certainty that EE2 plays a significant role, and at vanishingly low levels in the environment.

In 2004 the Environment Agency of England and Wales accepted this, judging the evidence sufficient to warrant consideration of risk management. In 2012, nearly 75 years after its synthesis, the

European Commission proposed to regulate EE2 as a EU-wide 'priority substance' under the Water Framework Directive (the primary legislation for protecting and conserving European water bodies). This proposal was subsequently amended, delaying any decision on a regulatory 'environmental quality standard' until at least 2016.

This is in part because control of EE2 will come at a significant price. Complying with proposed regulatory limits in the environment means removing very low (part per trillion) levels of EE2 from wastewater effluents at considerable expense.

Is this a price we are willing to pay? Or will the price of precautionary action be simply too high — a pill too bitter to swallow? To what extent is society, which has enjoyed decades of flexible fertility and will also ultimately pay for the control and management of its unintended consequences, involved in this decision? And what could this mean for the many thousands of other pharmaceuticals that ubiquitously infiltrate our environment and which could have sublethal effects on aquatic animals at similarly low levels?

14 Climate change: science and the precautionary principle

Hartmut Grassl and Bert Metz

The first scientifically credible early warning about the possible dangers of climate change due to carbon dioxide (CO₂) emissions from burning fossil fuels came in 1897. While the basic physical principles of global warming are simple, however, the more detailed science of climate change is exceedingly complicated. Even now, more than a hundred years since the first early warning, many important details of climate change cannot be predicted with certainty. It is therefore unsurprising that the science of climate change and questions about the true value of burning fossil fuels have fostered sustained scientific and political controversy.

When the first volume of *Late lessons from early warnings* was drafted there appeared to be too much legitimate controversy about climate change for the issue to be included. A case study could have led to arguments that distracted attention from the valuable and robust lessons from more established issues such as asbestos, polychlorinated biphenyls (PCBs), chlorofluorocarbons (CFCs) and the ozone-hole, X-rays and acid rain. This decision was taken despite the then widespread acceptance that 'the balance of evidence suggests a discernible human influence on global climate' (*Contribution of Working Group I to the Second Assessment Report of the Intergovernmental Panel on Climate Change, IPCC, 1995*).

Over a decade later and after two more reviews by the Intergovernmental Panel on Climate Change (IPCC) of a much greater volume of climate change science it seemed appropriate to include climate change in this volume, despite some continuing controversy. The evidence that human activities are having a dangerous impact on the climate has strengthened since 1995. By 2007, the IPCC was able to conclude with 'very high confidence that the global net effect of human activities since 1750 has been one of warming'. Given the size and irreversibility (on human time scales) of many of the harmful effects of human-induced climate change, there is an urgent need for action to reduce CO₂ emissions and other greenhouse gases. Some contrarian views persist, however, as the authors illustrate.

This chapter summarises the history of growing knowledge about human-induced climate change and of the main actions, or inactions that accompanied it. Like many other chapters, it reflects the lifelong commitment of both authors to trying to understand and mitigate the effects of human-induced climate change. It concludes with some lessons and insights that are relevant to many other environmental and health issues.

Also included is a panel text describing how the IPCC's approach to assessing uncertainty evolved between its first to its fifth assessment reports.

15 Floods: lessons about early warning systems

Zbigniew W. Kundzewicz

Floods are an increasingly acute problem. Intense precipitation has become more frequent and more intense, growing manmade pressure has increased the magnitude of floods that result from any level of precipitation, and flawed decisions about the location of human infrastructure have increased the flood loss potential.

Unlike most other case studies presented in this report, this chapter focuses on flooding as a phenomenon and the requirements for effective early warning systems, rather than addressing a particular event and the lessons that can be learned.

Flooding cannot be wholly prevented. The occurrence of a flood need not be considered a 'failure' and, conversely, minimisation of losses may constitute a 'success'. There are lessons to be learned from every flood and it is important to use them in preparing for the next flood. Once we accept that no flood protection measures can guarantee complete safety, a general change of paradigm is needed to reduce human vulnerability to floods. The attitude of 'living with floods' and accommodating them in planning seems more sustainable than hopelessly striving to eradicate them.

Flood forecasting and warning systems fail because links in the chain perform poorly or fail completely. A single weak point in a system that otherwise contains excellent components may render the overall system performance unsatisfactory. A successful system requires sufficient integration of components and collaboration and coordination between multiple institutions.

The chapter deals primarily with the challenges of fluvial (river) floods. It is complemented by three short supplementary texts. The first highlights the complex, dynamic and diverse ecosystems of river floodplains, which are often degraded during construction of flood defences. Despite their huge economic value, near-natural floodplains are among the most threatened ecosystems globally.

The second discusses uncertainties in anticipating rainfall patterns and intensity, and their relationship to flood levels during extreme flows. Such uncertainties present challenges for scientists and decision-makers alike.

The third addresses the increasing risks of coastal flooding due to factors such as climate change and sea-level rise, and reviews European experience with precautionary action.

16 Seed-dressing systemic insecticides and honeybees

Laura Maxim and Jeroen van der Sluijs

In 1994 French beekeepers began to report alarming signs. During summer, many honeybees did not return to the hives. Honeybees gathered close together in small groups on the ground or hovered, disoriented, in front of the hive and displayed abnormal foraging behaviour. These signs were accompanied by winter losses.

Evidence pointed to Bayer's seed-dressing systemic insecticide Gaucho[®], which contains the active substance imidacloprid. This chapter presents the historical evolution of evidence on the risks of Gaucho[®] to honeybees in sunflower and maize seed-dressing in France, and analyses the actions in response to the accumulating evidence regarding these risks.

The social processes that ultimately lead to application of the precautionary principle for the ban of Gaucho[®] in sunflower and maize seed-dressing are described, with a focus on the ways in which scientific findings were used by stakeholders and decision-makers to influence policy during the controversy.

Public scientists were in a difficult position in this case. The results of their work were central to a

social debate with high economic and political stakes. In certain cases their work was not judged according to its scientific merit but based on whether or not it supported the positions of some stakeholders. This situation tested the ability and courage of researchers to withstand pressure and continue working on imidacloprid.

Other European countries also suspended neonicotinoid seed-dressing insecticides. Evidence of the toxicity of neonicotinoids present in the dust emitted during sowing of coated seeds supported such decisions. Most important, the French case highlighted the major weaknesses of regulatory risk assessment and marketing authorisation of pesticides, and particularly neonicotinoids. These insights were recently confirmed by work by the European Food Safety Authority.

From this case study eight lessons are drawn about governance of controversies related to chemical risks. The study is followed by two additional texts. A first panel presents Bayer Crop Science's comments on the analysis in this chapter. A second contains the authors' response to the Bayer comments.

17 Ecosystems and managing the dynamics of change

Jacqueline McGlade and Sybille van den Hove

A decade after Rachel Carson's *Silent Spring* was published, describing the toxic legacy of the twentieth century, Annie Dillard in her Pulitzer prize winning book *Pilgrim at Tinker Creek*, opened up a different way of looking at the world. It presaged a twenty first century in which the global economy would be based on a more thorough understanding of nature, its functioning and material wealth. Wholly descriptive, yet increasingly relevant, her book captured the very essence of what this chapter is about: that amongst the observations which routinely help to predict the evolution of the natural world are the seeds of surprise — surprise of the unusual and surprise as a portent of future change. Our systemic failure to anticipate such surprises forms the core of this chapter. A series of case studies from fisheries, forests, savannah and aquatic systems are used to underline how early warnings about changes in these natural systems emerged but were not used.

The chapter highlights how the division of knowledge into political, disciplinary and geographic silos has led to the 'recurring nightmares' of short-term interests outcompeting

long-term vision; situations where competition replaces co-operation; fragmentation of values and interest; fragmentation of authority and responsibility; and fragmentation of information and knowledge leading to inadequate solutions or even additional problems. In addition, the lack of institutional fit has often confounded the effectiveness of the stewardship of ecosystem services, and led to unexpected surprises, excessive rent seeking and high transaction costs.

Using counterfactual thinking (i.e. the dependence of *whether*, *when* and *how* one event occurs on *whether*, *when* and *how* another event occurs and the possible alteration of events), built around the four interconnected concepts of *planetary boundaries*, *tipping points*, *panarchy* and *resilience*, the chapter provides an analytical lens through which to explore why many of the warning signals were not seen. The chapter concludes by suggesting why ecosystems are likely to be even more at risk in the future and why we will need to observe and interpret the dynamics of both nature and institutions ever more closely if we are to avoid sudden irreversible ecological changes.

18 Late lessons from Chernobyl, early warnings from Fukushima

Paul Dorfman, Aleksandra Fucic and Stephen Thomas

The nuclear accident at Fukushima in Japan occurred almost exactly 25 years after the Chernobyl nuclear accident in 1986. Analysis of each provides valuable late and early lessons that could prove helpful to decision-makers and the public as plans are made to meet the energy demands of the coming decades while responding to the growing environmental costs of climate change and the need to ensure energy security in a politically unstable world.

This chapter explores some key aspects of the Chernobyl and Fukushima accidents, the radiation releases, their effects and their implications for any construction of new nuclear plants in Europe. There are also lessons to be learned about nuclear construction costs, liabilities, future investments and risk assessment of foreseeable and unexpected events that affect people and the environment.

Since health consequences may start to arise from the Fukushima accident and be documented over the next 5–40 years, a key lesson to be learned concerns the multifactorial nature of the event. In planning future radiation protection, preventive measures and bio-monitoring of exposed populations, it will be of great importance to integrate the available data on both cancer and non-cancer diseases following overexposure to ionising radiation; adopt a complex approach to interpreting data, considering the impacts of age,

gender and geographical dispersion of affected individuals; and integrate the evaluation of latency periods between exposure and disease diagnosis development for each cancer type.

Given the degree of uncertainty and complexity attached to even the most tightly framed and rigorous nuclear risk assessment, attempts to weight the magnitude of accident by the expected probability of occurrence have proven problematic, since these essentially theoretical calculations can only be based on sets of pre-conditioning assumptions. This is not an arcane philosophical point but rather a very practical issue with significant implications for the proper management of nuclear risk. With its failure to plan for the cascade of unexpected beyond design-base accidents, the regulatory emphasis on risk-based probabilistic assessment has proven very limited. An urgent reappraisal of this approach and its real-life application seems overdue.

Whatever one's view of the risks and benefits of nuclear energy, it is clear that the possibility of catastrophic accidents and consequent economic liabilities must be factored into the policy and regulatory decision-making process. In the context of current collective knowledge on nuclear risks, planned pan-European liability regimes will need significant re-evaluation.

19 Hungry for innovation: from GM crops to agroecology

David A. Quist, Jack A. Heinemann, Anne I. Myhr, Iulie Aslaksen and Silvio Funtowicz

Innovation's potential to deliver food security and solve other agriculture-related problems is high on the agenda of virtually all nations. This chapter looks at two different examples of food and agricultural innovation: genetically modified (GM) crops and agroecological methods, which illustrate how different innovation strategies affect future agricultural and social options.

GM crops are well suited to high-input monoculture agricultural systems that are highly productive but largely unsustainable in their reliance on external, non-renewable inputs. Intellectual property rights granted for GM crops often close down, rather than open up further innovation potential, and stifle investment into a broader diversity of innovations allowing a greater distribution of their benefits.

Science-based agroecological methods are participatory in nature and designed to fit within the dynamics underpinning the multifunctional role of agriculture in producing food, enhancing biodiversity and ecosystem services, and providing security to communities. They are better suited to agricultural systems that aim to deliver sustainable food security than high external input approaches. They do, however, require a broader range of incentives and supportive frameworks to succeed. Both approaches raise the issue of the governance

of innovation within agriculture and more generally within societies.

The chapter explores the consequences of a 'top-down transfer of technology' approach in addressing the needs of poor farmers. Here innovation is often framed in terms of economic growth in a competitive global economy, a focus that may conflict with efforts to reduce or reverse environmental damage caused by existing models of agriculture, or even deter investment into socially responsible innovation.

Another option explored is a 'bottom-up' approach, using and building upon resources already available: local people, their knowledge, needs, aspirations and indigenous natural resources. The bottom-up approach may also involve the public as a key actor in decisions about the design of food systems, particularly as it relates to food quality, health, and social and environmental sustainability.

Options are presented for how best to answer consumer calls for food quality, sustainability and social equity in a wide sense, while responding to health and environmental concerns and securing livelihoods in local small-scale agriculture. If we fail to address the governance of innovation in food, fibre and fuel production now, then current indications are that we will design agriculture to fail.

20 Invasive alien species: a growing but neglected threat?

Sarah Brunel, Eladio Fernández-Galiano, Piero Genovesi, Vernon H. Heywood, Christoph Kueffer and David M. Richardson

Biological invasions are one of the five major causes of biodiversity loss as global human travel and trade have moved, and continue to move, thousands of species between and across continents. Some species of alien origin have a high probability of unrestrained growth which can ultimately lead to environmental damage.

An alien species — animal, plant or microorganism — is one that has been introduced, as a result of human activity, either accidentally or deliberately, to an area it could not have reached on its own. A common definition of the term 'invasive' focuses on its (negative) impact, while other definitions consider only rate of spread and exclude considerations of impact.

Despite the growing amount of legislation being adopted at the global scale, biological invasions continue to grow at a rapid rate, with no indication yet of any saturation effect. Decision-making in this area is very challenging. The overall complexity of the problem, its interdisciplinarity, the scientific uncertainties and the large number of stakeholders that need to be informed and involved, together demand governance actions that are difficult to see emerging at the regional scale (as in the EU), let alone globally.

It is widely agreed that preventing biological invasions or tackling them at a very early stage is the most efficient and cost-effective approach. Harmless species can be confused with harmful invasive species, however, leading to a waste of resources. Even more seriously, harmful invaders can be mistaken for innocuous species — so-called 'invaders in disguise' — and no appropriate action may be taken to counter the threats they pose.

Even with a very good risk assessment system, new outbreaks of invasive alien species could still occur, necessitating a system of rapid early warning and effective eradication response. The decision on where to draw the line on the acceptable environmental risks versus the introduction of new species or new communities that may carry invasive alien species then becomes a value judgement.

There is lively debate within the scientific community regarding the most appropriate strategies for managing invasive alien species. Governments and institutions charged with making decisions have access to considerable knowledge on the topic, but the lack of rules of interactions between multiple parties regularly thwarts effective decision-making.

21 Mobile phones and brain tumour risk: early warnings, early actions?

Lennart Hardell, Michael Carlberg and David Gee

In 2011 the World Health Organization's International Agency for Research on Cancer (IARC) categorised the radiation fields from mobile phones and other devices that emit similar non-ionizing electromagnetic fields (EMFs), as a Group 2B i.e. 'possible' human carcinogen. Nine years earlier IARC gave the same classification to the magnetic fields from overhead electric power lines.

The IARC decision on mobile phones was principally based on two sets of case-control human studies of possible links between mobile phone use and brain tumours: the IARC Interphone study and the Hardell group studies from Sweden. Both provided complementary and generally mutually supportive results. This chapter gives an account of the studies by these two groups — and others coming to different conclusions — as well as reviews and discussions leading up to the IARC decision in 2011. The chapter also describes how different groups have interpreted the authoritative IARC evaluation very differently.

There are by now several meta-analyses and reviews on mobile phones and brain tumours, which describe the challenges of doing epidemiology on this issue, the methodological limitations of the major studies published so far and the difficulties of interpreting their results.

It has been suggested that national incidence data on brain tumours could be used to qualify or disqualify the association between mobile phones and brain tumours observed in the case-control studies. However, in addition to methodological shortcomings, there might be other factors that influence the overall incidence rate such as changes

in exposure to other risk factors for brain tumours that are unknown in descriptive studies. Cancer incidence depends on initiation, promotion and progression of the disease. As the mechanism for radiofrequency electromagnetic fields carcinogenesis is unclear, it supports the view that descriptive data on brain tumour incidence is of limited value.

The chapter points to mobile phone industry inertia in considering the various studies and taking the IARC carcinogenic classification into account and a failings from the media in providing the public with robust and consistent information on potential health risks. The IARC carcinogenic classification also appears not to have had any significant impact on governments' perceptions of their responsibilities to protect public health from this widespread source of radiation.

The benefits of mobile telecommunications are many but such benefits need to be accompanied by consideration of the possibility of widespread harms. Precautionary actions now to reduce head exposures would limit the size and seriousness of any brain tumour risk that may exist. Reducing exposures may also help to reduce the other possible harms that are not considered in this case study.

Evidence is increasing that workers with heavy long-term use of wireless phones who develop glioma or acoustic neuroma should be compensated. The first case in the world was established on 12 October 2012. The Italian Supreme Court affirmed a previous ruling that the Insurance Body for Work (INAIL) must grant worker's compensation to a businessman who had used wireless phones for 12 years and developed a neuroma in the brain.

22 Nanotechnology — early lessons from early warnings

Steffen Foss Hansen, Andrew Maynard, Anders Baun, Joel A. Tickner and Diana M. Bowman

Nanotechnology is the latest in a long series of technologies heralded as ushering in a new era of technology-driven prosperity. Current and future applications of nanotechnology are expected to lead to substantial societal and environmental benefits, increasing economic development and employment, generating better materials at lower environmental costs, and offering new ways to diagnose and treat medical conditions. Nevertheless, as new materials based on nanoscale engineering move from the lab to the marketplace, have we learnt the lessons of past 'wonder technologies' or are we destined to repeat past mistakes?

This chapter first introduces nanotechnology, clarifies the terminology of nanomaterials and describes current uses of these unique materials. Some of the early warning signs of possible adverse impacts of some nanomaterials are summarised, along with regulatory responses of some governments. Inspired by the EEA's first volume of *Late lessons from early warnings*, the chapter looks critically at what lessons can already be learned, notwithstanding nanotechnology's immaturity.

Nanotechnology development has occurred in the absence of clear design rules for chemists and materials developers on how to integrate health, safety and environmental concerns into design. The emerging area of 'green nanotechnology' offers promise for the future with its focus on preventive design. To gain traction, however, it is important that research on the sustainability of materials is funded at levels significant enough to identify early warnings, and that regulatory systems provide incentives for safer and sustainable materials.

Political decision-makers have yet to address many of the shortcomings in legislation, research and development, and limitations in risk assessment, management and governance of nanotechnologies and other emerging technologies. As a result, there remains a developmental environment that hinders the adoption of precautionary yet socially and economically responsive strategies in the field of nanotechnology. If left unresolved, this could hamper society's ability to ensure responsible development of nanotechnologies.

23 Understanding and accounting for the costs of inaction

Mikael Skou Andersen and David Owain Clubb

In political decision-making processes, the burden of proof is often distributed such that policymakers only respond to early warning signals from environmental hazards once the costs of inaction have been estimated.

This chapter revisits some key environmental issues for which estimates of costs of inaction have been carefully developed over many years of research. The aim is to consider the methodological challenges involved in producing estimates that are credible and appropriate rather than present specific estimates for these costs.

The case studies also provide insights into how early warning signals might provide a basis for estimating the costs of inaction, when the science base is less consolidated. For example, the case of nitrates in drinking water illustrates that a precautionary approach to the costs of inaction is quite conceivable. The phase-out of ozone-depleting substances, where early-warning scientists successfully alerted the world to the damaging effects of chlorofluorocarbons (CFCs), provides another important case because additional impacts for global warming actually cause the costs of inaction to be considerably higher than

initially believed. This is a reminder that figures for the costs of inaction have often been grossly underestimated.

Finally, in the case of air pollution, making use of different estimates for mortality risk avoidance will help decision-makers to see that there are higher- and lower-bound estimates for the costs of inaction. Even if the lower-bound estimates are perhaps too conservative, with a bias towards health effects, they will in many situations encourage more rather than less abatement effort. Reducing emission loads will also tend to bring relief for the intangible assets of biodiversity and nature.

Making the best use of environmental science and modelling helps to make environmental protection and precaution a priority. Producing cost estimates should not be left to economists alone, but should rather be seen as a starting point for a broader discussion, featuring also the relevant expertise in health, ecology, demography, modelling and science. Well researched estimates, based on interdisciplinary collaboration, can strengthen some of those scattered and diffuse interests, which during the ordinary processes of policy-making have difficulty making their voices heard.

24 Protecting early warners and late victims

Carl Cranor

Many *Late lessons from early warnings* chapters provide examples of early warning scientists who were harassed for bringing inconvenient truths about impending harm to the attention of the public and regulators. There is also some evidence that young scientists are being discouraged from entering controversial fields for fear of such harassment. In addition, where warnings have been ignored and damage has ensued, it has often proven difficult in the past to achieve prompt and fair compensation for the victims. Some ideas for reform, building on some current institutional models are explored here.

This chapter first explores the idea of extending whistleblowing laws to help encourage and protect early-warning scientists and others who identify evidence of impending harm. Complementary measures, such as greater involvement of professional societies and the use of recognition awards, as for example in Germany, could also be helpful.

Next, the chapter explores improved mechanisms for compensating victims of pollution and contamination. The chapter on the Minamata Bay disaster provides an extreme example of long delays in getting adequate compensation for the victims of methylmercury poisoning. It was almost fifty years, between 1956 and 2004, before the

victims attained equitable levels of compensation and legal recognition of responsibility. Other case studies illustrate similar examples of long delays in receiving adequate compensation.

Options are examined for providing justice to any future victims of those emerging technologies such as nanotechnology, genetically modified crops and mobile phone use, which currently can provide broad public benefits but potentially at a cost to small groups of victims. The potential for widespread exposure and uncertain science could justify 'no-fault' administrative schemes that provide more efficient and equitable redress in situations where the benefit of scientific doubt would be given to victims. The use of anticipatory assurance bonds to help minimise and meet the costs of future environmental damage from large scale technologies is also explored.

A supplementary panel text describes cases of asbestos and mesothelioma, where the senior courts in the United Kingdom have developed innovative ways of dealing with both joint and several liability, and the foreseeability of subsequent asbestos cancers, after the initial recognition of the respiratory disease, asbestosis. Such legal developments in the field of personal injury could illustrate the future direction of long-tail liability in both environmental damage and personal injury.

25 Why did business not react with precaution to early warnings?

Marc Le Menestrel and Julian Rode

In the past, companies have frequently neglected early warning signals about potential hazards for human health or the environment associated with their products or operations. This chapter reviews and analyses relevant interdisciplinary literature and prominent case studies — in particular those documented in both volumes of *Late lessons from early warnings* — and identifies main factors responsible for the disregard of early warning signals.

The chapter shows how economic motives often drive non-precautionary business decisions. In virtually all reviewed cases it was perceived to be profitable for industries to continue using potentially harmful products or operations. However, decisions are also influenced by a complex mix of epistemological, regulatory, cultural and psychological aspects. For instance, characteristics of the research environment and the regulatory context can provide business actors with opportunities to enter into 'political actions' to deny or even suppress early warning signals. Also, business decision-makers face psychological barriers to awareness and acceptance of the conflicts of values and interests entailed by early warning signals. Cultural business context may further contribute to the denial of conflicts of values.

The chapter concludes with a set of reflections on how to support more precautionary business decision making. A prominent policy response to the conflicting interests of business and society

is introducing regulations that attempt to steer business rationality towards internalising external effects. Innovative solutions such as assurance bonding should be considered.

There is a need to better understand and expose why business actors do not respond voluntarily to early warning signals with precautionary actions. Blaming business, in particular with hindsight, tends to be common reaction that may not always be constructive. It often misses the complex or even contradictory set of motives and drivers that business actors face.

Public institutions could support progressive business by analysing and publically disclosing the dilemmas and temptations entailed by early warning signals, for example for different industries and for the specific societal and regulatory context of decisions. Rigorous and explicit exposition of the dilemmas will create further incentives for responsible actors to share and communicate their precautionary responses.

An additional reflection centres on the role of political actions of business actors, in particular those actions aimed at suppressing early warning signals. Regulatory efforts that make the political actions of business more transparent can help to sustain a sound balance of power, thereby maintaining our ability to benefit from early warning signals and reducing the likelihood of health and environmental hazards.

26 Science for precautionary decision-making

Philippe Grandjean

The goals of academic researchers may differ from those of regulatory agencies responsible for protecting the environment. Thus, research must take into account issues such as feasibility, merit and institutional agendas, which may lead to inflexibility and inertia.

A large proportion of academic research on environmental hazards therefore seems to focus on a small number of well studied environmental chemicals, such as metals. Research on environmental hazards should therefore to a greater extent consider poorly known problems, especially the potential hazards about which new information is in particular need.

Misinterpretation may occur when results published in scientific journals are expressed in hedged language. For example, a study that fails to document with statistical significance the presence of a hazard is often said to be negative, and the results may be misinterpreted as evidence that a hazard is absent. Such erroneous conclusions are inspired by science traditions, which demand meticulous and repeated examination before a hypothesis can be said to be substantiated.

For prioritising needs for action, research should instead focus on identifying the possible magnitude of potential hazards. Research is always affected by uncertainties and many of them can blur a real association between an environmental hazard and its adverse effects, thereby resulting in an underestimated risk. Environmental health research therefore needs to address the following question: are we sufficiently confident that this exposure to a potential hazard leads to adverse effects serious enough to initiate transparent and democratic procedures to decide on appropriate intervention?

The choice of research topics must consider societal needs for information on poorly known and potentially dangerous risks. The research should be complementary and extend current knowledge, rather than being repetitive for verification purposes, as required by the traditional science paradigm. Research findings should be openly available and reported so that they inform judgments concerning the possible magnitude of suspected environmental hazards, thereby facilitating precautionary and timely decision-making.

27 More or less precaution?

David Gee

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

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

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

A working definition of the precautionary principle is presented that aims to overcome some of the

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

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

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

28 In conclusion

The first volume of *Late lessons from early warnings* highlighted the difficulties of balancing precaution with technological innovation and ended with a call to action for policymakers. How much progress has been made since then?

First, there is growing evidence that precautionary measures do not stifle innovation, but instead can encourage it, in particular when supported by smart regulation or well-designed tax changes. Not only has the body of knowledge become richer since 2001, but also the number of stakeholders involved in decision-making has become larger and more diverse. There has also been increasing attention to communicating scientific uncertainty, especially in the fields of climate change, food safety, and emerging risks.

However, there has been less progress in other areas: for example, many of the political and scientific 'bureaucratic silos' still remain, despite frequent calls for policy integration and inter-departmental coordination. This has led to the unintended destruction of stocks of natural capital in some parts of the world and in other instances, the global spread of technologies, despite warnings of impending hazards. The result has been widespread damage, with most polluters still not paying the full costs of pollution.

Yet, more encouragingly, new transformative approaches are emerging to manage the systemic and interconnected challenges the world faces e.g. economic/financial, climate/energy, ecosystems/food. These relate, inter alia, to the increasing use of digital communications and networking by consumers, citizens and shareholders to demand and foster increased participation, more social responsibility, greater levels of accountability and higher transparency, especially in determining future pathways for energy and food production. There is a greater understanding of the complexity of the environment, of scientific ignorance and uncertainties, the irreversibility of many harmful impacts and on the broader risks to the long term interests of society if political and financial institutions remain unchanged. Also

some corporations are fundamentally embracing sustainable development objectives in their business models and activities.

The case studies across both volumes of *Late lessons from early warnings* cover a diverse range of chemical and technological innovations, and highlight a number of systemic problems. These include a lack of institutional and other mechanisms to respond to early warning signals; a lack of ways to correct market failures either caused by misleading market prices or where costs and risks to society and nature are not properly internalised; and the fact that key decisions on innovation pathways are made by those with vested interests and/or by a limited number of people on behalf of many. The insights and lessons drawn from the case histories certainly provide the seeds for some of the answers. They also provide knowledge for a series of key actions that are outlined below.

Of course, many questions remain. For example: how can the precautionary principle be used further to support decision-making in the face of uncertainties and the inevitable surprises that come from complex systems?; how can societies avoid a lack of 'perfect' knowledge being used as a justification for inaction in the face of 'plausible' evidence of serious harm?; how can conflicting interests be balanced during the phases of development and use?; and how can the benefits of products and technologies be more equitably distributed?

Reduce delays between early warnings and actions

The majority of the case studies in *Late lessons from early warnings* Volumes 1 and 2 illustrate that if the precautionary principle had been applied on the basis of early warnings, justified by 'reasonable grounds for concern' many lives would have been saved and much damage to ecosystems avoided. It is therefore very important that large scale emerging technologies, such as biotechnologies, nanotechnologies and information

and communication technologies, apply the precautionary principle based on the experiences and lessons learned from these and other case studies.

Precautionary actions can be seen to stimulate rather than hinder innovation; they certainly do not lead to excessive false alarms. As the analysis in Volume 2 shows, of 88 cases of claimed 'false positives', where hazards were wrongly regulated as potential risks, only four were genuine false alarms. The frequency and scale of harm from the mainly 'false negative' case studies indicate that shifting public policy towards avoiding harm, even at the cost of some false alarms, would seem to be worthwhile, given the asymmetrical costs of being wrong in terms of acting or not acting based on credible early warnings.

However, the speed and scale of today's technological innovations can inhibit timely action. This is often because by the time clear evidence of harm has been established, the technology has been modified, thereby allowing claims of safety to be subsequently re-asserted. Even where the technological change has been marginal, the large, often global, scale of investment can lead to widespread technological lock-in, which is then difficult and expensive to alter.

These features of current technological innovation strengthen the case for taking early warning signals more seriously and acting on lower strengths of evidence than those normally used to reach 'scientific causality'. Most of the historical case studies show that by the time such strong evidence of causality becomes available, the harm to people and ecosystems has become more diverse and widespread than when first identified, and may even have been caused by much lower exposures than those initially considered dangerous.

The case studies have also shown that there are many barriers to precautionary action, including: the short-term nature of most political and financial horizons; the existence of technological monopolies; the conservative nature of the sciences involved, including the separate 'silos' within which they operate; the power of some stakeholders; and the cultural and institutional circumstances of public policymaking that often favour the status quo.

Acknowledge complexity when dealing with multiple effects and thresholds

Increasing scientific knowledge has shown that the causal links between stressors and harm are more complex than was previously thought and this has

practical consequences for minimising harm. Much of the harm described in Volumes 1 and 2, such as cancers or species decline, is caused by several co-causal factors acting either independently or together. For example, the reduction of intelligence in children can be linked to lead in petrol, mercury and polychlorinated biphenyls (PCBs) as well as to socio-economic factors; bee colony collapse can be linked to viruses, climate change and nicotinoid pesticides; and climate change itself is caused by many complex and inter-linked chemical and physical processes.

In some cases, such as foetal or fish exposures, it is the timing of the exposure to a stressor that causes the harm, not necessarily the amount; the harm may also be caused or exacerbated by other stressors acting in a particular timed sequence. In other cases, such as radiation and some chemicals such as bisphenol A (BPA), low exposures can be more harmful than high exposures; and in others, such as asbestos with tobacco, and some endocrine disrupting substances, the harmful effects of mixtures can be greater than from each separate stressor. There are also varying susceptibilities to the same stressors in different people, species and ecosystems, depending on pre-existing stress levels, genetics and epigenetics. This variation can lead to differences in thresholds or tipping point exposures, above which harm becomes apparent in some exposed groups or ecosystems but not others. Indeed there are some harmful effects which occur only at the level of the system, such as a bee colony, which cannot be predicted from analysing a single part of the system, such as an individual bee.

Our increased knowledge of complex biological and ecological systems has also revealed that certain harmful substances, such as polychlorinated biphenyls (PCBs) and dichlorodiphenyltrichlorethane (DDT) can move around the world via a range of biogeochemical and physical processes and then accumulate in organisms and ecosystems many thousands of kilometres away.

The practical implications of these observations are threefold. First, it is very difficult to establish very strong evidence that a single substance or stressor 'causes' harm to justify timely actions to avoid harm; in many cases only reasonable evidence of co-causality will be available. Second, a lack of consistency between research results is not a strong reason for dismissing possible causal links: inconsistency is to be expected from complexity. Third, while reducing harmful exposure to one co-causal factor may not necessarily lead to a large reduction in the overall harm caused by many other

factors, in some cases the removal of just one link in the chain of multi-causality could reduce much harm.

A more holistic and multi-disciplinary systems science is needed to analyse and manage the causal complexity of the systems in which we live.

Rethink and enrich environment and health research

Environment and health research overly focuses on well-known rather than unknown hazards at the expense of emerging issues and their potential impacts. For example the ten most well-known substances, such as lead and mercury, account for about half of all articles on chemical substances published in the main environmental journals over the last decade. Over the past decade, public research funding in the European Union on nanotechnology, biotechnology as well as Information and Communications Technology (ICT) is heavily biased towards product development with about 1 % being spent on their potential hazards. A more equal division of funding between known and emerging issues, and between products and their hazards, would enrich science and help avoid future harm to people and ecosystems and to the long term economic success of those technologies.

Funding more holistic systems science would also help achieve a greater integration among the different branches of science and counteract problems such as: peer review predominantly within and not across disciplines; short-term interests outcompeting long-term vision; competition replacing cooperation because of conflicts of interest; contradictions amongst paradigms; fragmentation of values and authority; as well as fragmentation of information and knowledge. These can all lead to inferior solutions and provide increased opportunities for those with vested interests to manufacture doubt.

Scientific methods can also be improved. For example, much higher strengths of evidence are required overall before causality is accepted, compared to the evidence being used to assert safety. The assertion that there is *no evidence of harm* is then often assumed to be *evidence of no harm*, even though the relevant research is missing. Historically there has been an over-reliance on the statistical significance of point estimates compared to confidence limits based on multiple sampling. There has also been a bias towards using models

that grossly simplify reality rather than using long-term observations and trend data of biological and ecological systems. These approaches have sometimes led to the production of false positives. More importantly the governance of scientific ignorance and unknown unknowns has been neglected.

Finally, many case studies highlight the problems faced by early warning scientists who have been harassed for their pioneering work, including bans on speaking out or publishing, loss of funding, legal or other threats, and demotion. One obvious conclusion is that scientists in these situations should receive better protection either via an extension of 'whistle blowing' and discrimination laws, or by independent acknowledgement of the value of their work.

Improve the quality and value of risk assessments

The majority of the case studies in *Late lessons from early warnings* indicate that risk assessment approaches need to better embrace the realities of causal and systems complexity (rather than use a narrow conception of 'risk') with the inevitable features of ignorance, indeterminacy and contingency. In a number of case studies, for example BPA, where low doses are more harmful than high doses, or tributyltin antifoulants (TBT) and synthetic oestrogen diethylstilboestrol (DES) where the timing of the dose is what makes it harmful, simplistic assumptions are inadequate. Variability in exposures and varying susceptibilities in populations and species exposed also need to be more realistically factored into risk assessments.

This is equally true for technological risk assessments. As the Fukushima Investigation Committee concluded in 2011:

'...the accidents present us with crucial lessons on how we should be prepared for 'incidents beyond assumptions'. With its failure to plan for the cascade effects beyond design-base accidents 'the regulatory emphasis on risk based probabilistic risk assessment has proven very limited'.

In other words, narrow risk assessment approaches are now outstripped by the realities which they cannot address, recognise and communicate. Too often this contributes to the effective denial of those risks that do not fit the risk assessment frame. It is therefore urgent that risk assessment practices

be transformed to make them broader-based, more inclusive, transparent and accountable. There should also be more communication on the diversity of scientific views, especially on emerging issues where ignorance and uncertainties are high and genuine differences of scientific interpretations are likely, desirable, and defensible. In this sense, recognising the pedigree of knowledge, i.e. the consistency of views amongst peers and the level of convergence coming from different branches of research, is essential for effective decision making and action to support the wellbeing of people and the environment.

The case studies show that evaluations of evidence in risk assessments can be improved by including a wide range of stakeholders when framing the risks and options agenda; broadening the scope and membership of evaluation committees; increasing the transparency of committee approaches and methods, particularly in identifying uncertainties and ignorance; and ensuring their independence from undue influence through using appropriate funding sources and applying robust policies on conflicts of interest.

Public confidence would be increased if all the evidence used in risk assessments was made publicly accessible and open to independent verification, including data submitted by industries to authorities.

As experiences from mercury, nuclear accidents, leaded petrol, mobile phones, BPA, and bees show, there can be a significant divergence in the evaluations of the same, or very similar, scientific evidence by different risk assessment committees. In such instances, differences in the choice of paradigm, assumptions, criteria for accepting evidence, weights placed on different types of evidence, and how uncertainties were handled, all need to be explained. Risk assessors and decision makers also need to be aware that complexity and uncertainty have sometimes been misused to shift the focus away from precautionary actions by 'manufacturing doubt' and by waiting for 'sound science' approaches that were originally developed by the tobacco industry to delay action.

Foster cooperation between business, government and citizens

Policy formulation should start from a broad concept of technological innovation to include non-technological, social, institutional, organisational and behavioural innovation. In

this framework, governments have at least three roles: providing direction by putting in place smart regulations and consistent market signals; ensuring that the distributional consequences of innovations are balanced between risks and rewards across society, fostering a diversity of innovations so that the wider interests of society; and take precedence over narrower interests.

Numerous case studies show that decisions to act without precaution often come from businesses. There are, however, several impediments to businesses acting in a precautionary manner, including a focus on short-term economic value for shareholders alongside psychological factors that lead to a so-called 'ethical blindness' or a 'self-serving bias' whereby people largely interpret ambiguous situations in their own interests. Governments and businesses could collaborate more with citizens on publicly disclosing the potential value conflicts entailed in acting on early warning signals. A culture of transparency can in turn promote positive business attitudes and innovations.

Involving the public can also help in choosing between those innovation pathways to the future; on prioritising relevant public research; on providing data and information in support of monitoring and early warnings; improving risk assessments; on striking appropriate trade-offs between innovations and plausible health and environmental harms; and, making decisions about risk-risk trade-offs.

Correcting market failures using the polluter pays and prevention principles

When evidence of initial harm emerges, the costs should be internalised retroactively into the prices of polluting products, via taxes and charges, in line with the polluter pays principle and emerging practice across the world. The revenues could then be devoted partly to stimulating research into less hazardous alternatives, and partly to reform tax systems by reducing taxes and charges on 'societal goods' like employment.

The pollution taxes/charges would rise or fall in line with new scientific knowledge about increasing/decreasing harm, and this would help to level the playing field for less-polluting alternative products. Tax shifts from employment to pollution and the inefficient use of resources can bring multiple benefits such as increased employment, a stimulus to innovation, a more stable tax base in the light of expected demographic changes, and a more efficient tax collection system.

More broadly, firms and governments need to extend their economic accounting systems to incorporate the full impacts of their activities on people's health and on ecosystems. Governments need to anticipate this in their policies, by providing the right blend of fiscal instruments to both protect the public and ensure that firms internalise the true costs of potential harm.

A number of case studies also demonstrate the long time lags between evidence of harm and the additional injustice and time of forcing victims to pursue their cases through civil compensation claims. Prompt and anticipatory no-fault compensation schemes and assurance bonds, could be set up and financed in advance of potential harm by the industries that are producing novel and large-scale technologies, thereby helping to offset any potential market failure. Such schemes can also be designed to increase the incentives for innovating companies to carry out more *a priori* research into the identification and elimination of hazards.

Governance of innovation and innovation in governance

The *Late lessons from early warnings* reports demonstrate the complexities of developing not only the right kind of science and knowledge but also handling the interactions between the many actors and institutions involved — governments, policymakers, businesses, entrepreneurs, scientists, civil society representatives, citizens and the media.

Alongside many other analyses produced across the world today, the reports also stress the need to

act to transform our ways of thinking and of doing, and urgently so in the face of unprecedented global changes, challenges and opportunities. Many lessons have been learnt, yet have not been acted upon. Any calls for action will need to reflect on today's global socio-economic setting and support, among other things, the drive to:

- rebalance the prioritisation of economic and financial capital over social, human and natural capitals through the broader application of the policy principles of precaution, prevention and polluter-pays, and environmental accounting;
- broaden the nature of evidence and public engagement in choices about key innovation pathways by directing scientific efforts more towards dealing with complex, systemic challenges and unknowns and complementing this with professional, lay, local and traditional knowledge; and,
- build greater adaptability and resilience in governance systems to deal with multiple systemic threats and surprises, through strengthening institutional structures and deploying information technologies in support of the concept of responsible information and dialogues.

The governance of innovation will remain at the level of good intentions unless it is translated into innovations in science practices, institutional arrangements and public engagements as well as transformations in prevailing business attitudes, practice and influence. These are the tasks that lie ahead.

In memory of Masazumi Harada, 1935–2012



Masazumi Harada, a physician involved for many years in the study of the mercury poisoning Minamata disease, died in June 2012 of acute myelocytic leukemia at his home in Kumamoto City. He was 77.

Harada conducted medical examinations on the disease's sufferers for the first time in the summer of 1961 in Minamata city in Kumamoto Prefecture while he was a student at Kumamoto University's graduate school.

Shocked by their miserable lives, Harada devoted himself to the study of the disease from that time. Harada published a thesis on congenital Minamata disease in 1964. The work had a significant impact as it disproved the conventional belief at the time that the placenta does not pass poisons. He received an award from the Japanese Society of Psychiatry and Neurology for the thesis in 1965.

He then established the Open Research Center for Minamata Studies at the university in 2005, becoming the center's head. He continued to lead the disease's research from non-medical perspectives as well. Harada visited Brazil, China and native Indian communities in Canada to discover those suspected of suffering from the disease.

Author of many books, Harada wrote 'Minamata Byo' (Minamata Disease), which raised awareness on the issue around the world.

Dr. Masazumi Harada first came to Asubpeeschoseewagong (Grassy Narrows) and Wabaseemoong (White Dog) First Nations in Canada in the early 1970s. Harada's death comes at the end of River Run 2012, five days of actions by members and supporters of Grassy Narrows in Toronto, who are seeking to have Minamata disease recognized in Canada and Ontario. Harada's final report for the Grassy Narrows community was released on 4 June 2012 after 30 years of research, showing mercury deposited in the river by the Dryden paper mill in the 1970s is impacting those who were not yet born when the dumping ceased.

In memory of Poul Harremoës, 1934–2003



Poul Harremoës was a key player in environmental issues in Denmark and internationally for more than 30 years until his death, at 69, in 2003. In that time, those who worked closely with him benefited from a continuous, almost daily flow of excellent ideas for new research projects.

He was a member of the Danish Pollution Council, which prepared the first framework national law on environmental protection and advised on the establishment of a Ministry of Environment from

1971. He was a key participant in numerous settings, including the first Scientific Committee of the European Environment Agency from 1995.

He had a civil engineering degree from the Technical University of Denmark. He specialised early on in geo-technics and constructed dams on the Faroe Islands. While teaching geo-technics he wrote a textbook that was used for more than 40 years. However, he was able to quickly change his research direction and develop new areas of excellence. So, for example, he got a grant to study at Berkeley, California, from where he received a M.Sc. degree in environmental engineering.

In 1972, he became professor in environmental engineering at the Technical University of Denmark where he originally worked with wastewater discharge to the sea and the biological processes of wastewater treatment. He became a world leading scientist in the theories of biofilms for removal of organics and nitrogen from wastewater before turning to sewer design and modelling. In 2000, Poul was awarded the *Heineken prize for Environmental Sciences* for his contributions to the theory of biofilm kinetics in relation to biological waste water treatment and for his successful organisation of the international scientific community in water pollution research and control.

As a result of his work with sewers and storm water he went into the area of risk analysis and the role of the precautionary principle. In a short time he became an international expert in this field and was highly demanded for lectures in all parts of the world. A key outcome of his interest was his contributions as chairman of the editorial team for the first volume of *Late lessons from early warnings* published in 2001.

European Environment Agency

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