



**PUBLIC GOVERNANCE AND TERRITORIAL DEVELOPMENT DIRECTORATE
PUBLIC GOVERNANCE COMMITTEE**

GOV/PGC/REG(2006)1/ANN2
For Official Use

Working Party on Regulatory Management and Reform

Risk and Regulation: Issues for Discussion

Annex 2. Risk and Regulatory Governance

**24 April 2006
OECD Headquarters**

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JT03207384

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SUMMARY

1. The theme of the paper is interconnectedness in respect of risk and risk regulation. The parameters include: joint effects of simultaneous exposure to multiple risks; rapid cross-border transmission of risks; *ex ante* and *ex post* policy impact assessment; analysis of all the effects of risk reduction efforts; and co-ordination of risk policies across agencies and governments.
2. Private institutions are generally not sufficient to deal with large-scale risks. Market failures may undermine the ability of private actors to manage risk efficiently. High transaction costs may impede negotiation, such that the potential victims of an externality cannot reach an effective agreement with those responsible. In addition, the protection of public goods such as clean air may be compromised. There may also be government failures, such as when state-run enterprises respond slowly to signals of scarcity, or may neglect negative externalities. Government regulations may themselves protect polluting industries from competition. In addition, government policies may generate new risks.
3. Government is challenged to overcome the fragmentation of risk assessment and management among a mix of public and private organisations, and within government. A policy cycle for risk regulation calls for several different kinds of expertise. Impact assessments should develop the means to forecast the joint effects of simultaneous exposure to multiple risks (which is not the same as the sum of individual effects). Multiple scenarios may be needed to reflect the mix of variables, potentially weighted by probability judgements (required in the United States since 2003 for policies with impacts exceeding \$1 billion).
4. Benefit/cost analysis is not uniformly required in the United States. It is referenced in different pieces of legislation, some requiring and some prohibiting its use (*e.g.*, for clean air and for hazardous waste treatment and cleanup, for ratifying international treaties, and for selected public works). Benefit-cost analysis also often ignores business compliance costs, making it difficult to consider risk-risk tradeoffs. The prohibition against using benefit-cost analysis reflects the perception that its use would jeopardize the adoption of health and environmental regulations. The tool should be understood as neutral.
5. *Ex ante* assessment runs the risk of false positives, that is, exaggerating a risk that turns out to be of little significance. *Ex post* assessment runs the risk of false negatives, which would happen when waiting too long when a product previously thought to be safe, for example, turns out to be a significant risk. Both *ex ante* and *ex post* assessment are needed to complete a policy cycle. This should promote transparency through reporting of assumptions and methods and comparisons to alternatives, and greater use of economic incentive instruments (*e.g.* taxes, tradable allowances, information disclosure, self-regulation). The actual occurrence of a crisis, or just the lower-level manifestation of a risk, should be used as feedback to help adjust and improve the policy to reduce overall risk.
6. Thus, a crucial component of effective risk governance is monitoring performance. Do policies actually work? Do they achieve results? This component is often neglected. Essentially all countries do some kind of *ex ante* assessment at present, but few carry out an *ex post* review. These are essential to improve policies through a strategy of adaptive management, and to validate and improve *ex ante* methodologies for future decision-making.
7. The real challenge is institutional, not technical: to extend the coverage of benefit-cost analysis to a wider range of issues, and to build oversight capacity for quality control and to monitor the process. An oversight body could be a key Centre-of-Government task: such a unit would need a clear assignment of responsibility, authority and capacity.

RISK AND REGULATION: ISSUES FOR DISCUSSION

ANNEX 2. RISK AND REGULATORY GOVERNANCE

1. The challenge of risk

8. Risk is one of the major challenges facing governments today. Societies are shaken by the heavy burden of diseases such as cancer, heart disease, influenza and malaria; by environmental pollution and climate change; by financial crises; and by sudden accidents, storms and terrorist attacks. They are also vexed by hasty and poorly designed policies to address risk. In May 2005, UK Prime Minister Tony Blair delivered a “Speech on Risk and the State,” emphasizing that risk regulation is absolutely necessary, but criticizing overregulation of small risks in the hopeless effort to reduce risks to zero (often as an overreaction to a recent crisis), thus impeding innovation and inducing perverse effects that “do more damage than was done by the problem itself.” He advocated a program of “Better Regulation” based on a “rigorous risk-based approach” that will employ impact assessments and “regulate only after reflection.”¹

9. In 2005, the OECD adopted Guiding Principles for Regulatory Quality and Performance, including an admonition to governments to “assess risk to the public and to public policy in a changing environment as fully and transparently as possible, thereby contributing to a better understanding of the responsibilities of all stakeholders” (p.8).² OECD has also recently undertaken a major study of future risks.³ This attention to risk represents a major new area for policy as compared with the 1997 OECD Principles for Regulatory Reform, which had focused on reform of economic regulation, via competition, market openness, and deregulation.

10. This paper offers a critical overview of the main issues for policymakers considering risk regulation, and identifies important areas for future improvement. The core theme of this paper is that *interconnectedness*, in several dimensions, creates new challenges and opportunities for dealing with risk.

11. Traditionally, risks have been handled one at a time, by a single government agency acting in isolation, and sometimes based on an *ex ante* impact assessment of the chosen risk policy. Many individual risks have thereby been reduced. But increasing interconnectedness poses new demands:

- Forecasting the joint effects of simultaneous exposure to multiple risks;
- Dealing with the rapid transmission of risks (such as disease or terrorism) across countries and continents, through increasing interconnections among ecological, trade, travel, and telecommunications systems;
- Assessing policy impacts, both *ex ante* and also *ex post*, with effective institutional oversight;
- Analyzing the full portfolio effects, including ancillary and countervailing risks, of any effort to reduce a target risk; and
- Co-ordinating risk policies across agencies and across governments of different countries, especially for transboundary and global risks.

12. At the same time, interconnectedness offers an important opportunity:

- Learning from other countries' experiences and thereby borrowing policy ideas, in a process of transnational diffusion of regulatory innovations.

1.1. Background

13. Risk is not, of course, a new subject for regulatory policy. In a general sense, risk assessment (asking what could happen, and how serious it would be) and risk management (asking what should be done about it) have been undertaken by human beings for millennia, and are essential to the survival and prosperity of human societies.⁴ More formally, governments have been enacting systems of risk regulation for at least the last century (for example, many laws and agencies addressing food, drug, and workplace safety risks were adopted in the early 1900s), and especially since the 1960s and 1970s (when many major environmental laws and agencies were created). The “economic regulation” of industries such as transport, telecoms and banking has waned in favor of privatization and more open competition, and meanwhile the “social regulation” of health, safety and environmental risks has grown.⁵ Thus, risk regulation is now the major regulatory function in many countries.

14. Some argue that the main goal of civilization has shifted from prosperity to risk management.⁶ Others see prosperity as the best antidote to risk, and see the rise of risk regulation as a costly burden on innovation and progress. An intermediate view is that risk regulation is necessary and desirable to protect societies against risks that private markets do not address adequately, but that it is equally desirable to develop a systematic approach to evaluate and oversee risk regulation in order to ensure that it is effective and efficient and does not yield excessive countervailing risks.⁷

15. Risk is generally understood as the combination of the probability and consequences of an adverse outcome. Risk is therefore ubiquitous. It encompasses both highly publicized exotic events such as avian flu, SARS, BSE, terrorist attacks, and global climate change; and more mundane routine events that generate less publicity but that inflict tragically heavy losses, such as cancer, heart disease, diabetes, malaria, and traffic accidents. The term “risk regulation” is typically used to describe health, safety and environmental policies, but banking, insurance, and homeland security regulations also address risk and employ methods of risk analysis.

16. It is commonplace, but arguably incorrect, to assert that risks are more serious today than they were in the past. Overall risks to human health have largely declined over time, and life expectancy at birth has substantially increased (nearly doubling in wealthy countries from about 45 to 80 over the period 1900 to 2000). Increasing wealth has led to longer, healthier lives, reductions in many forms of pollution (the so-called Environmental Kuznets Curve), and increasing attention to environmental conservation. Famine and strategic nuclear war are of less concern today than a few decades ago. Prophecies of doom, from Thomas Malthus two centuries ago to the Limits to Growth models of the 1970s, have turned out to be wrong, largely because they did not take account of the feedbacks, signals of scarcity, and adaptive responses (both by markets and by public institutions) which prevent collapse.

17. On the other hand, other risks might be increasing even as human health is improving. Current life expectancy estimates do not yet reflect inchoate future health risks. Past increase in human longevity might perhaps be temporary – if, say, infectious bacteria soon become widely resistant to antibiotics, or if current technology is sowing the seeds of an abrupt risk in the future. Or, the advance in human longevity might have come at the cost of reduced vitality of non-human ecosystems (such as through deforestation, over fishing, and climate change).

18. And, of course, many people living in poor countries continue to suffer a heavy burden of disease, hunger, armed conflict, and other risks, with life expectancies shorter by two or even three decades. Roughly a billion people lack access to clean drinking water. Even if this is a smaller percentage of the world's population than in prior eras, the absolute magnitude of the problem remains grave. Risks to health and environment in poor countries, such as malaria and desertification, may also contribute to their persistent poverty.

1.2. Looking ahead

19. Even if the more optimistic vision is correct – that human longevity and environmental conservation will both continue to increase worldwide (due to future gains in prosperity) – it may nonetheless be true that increasing global *interconnectedness* – through trade, travel, telecommunications (including the internet), transboundary environmental spillover effects, and armed conflict – may make future risks spread more quickly to yield distant or systemic impacts, may complicate regulatory strategies, and may make risks faster to be reported via news media worldwide (in turn influencing public opinion regarding policy responses). For example, increased travel enables both pathogens and terrorists to spread more quickly. Interconnectedness and greater speed of transmission may thus make new risks more difficult to foresee and prevent.

20. And interconnectedness in a complex multidimensional web of risks also means that risk regulation itself will have complex effects: intervening to regulate one risk will also affect other risks, increasing the potential for unintended side effects.⁸ At the same time, interconnections may also foster better solutions: the capacity of scientific detection and hence advance warning are improving, and greater information sharing among experts and governments helps them to respond to new risks more rapidly and effectively. Interconnectedness offers the opportunity for experience and learning about risks and policy options to be shared across countries, in an adaptive process of borrowing or diffusion.⁹

21. Decreasing human health risks may not portend decreasing need for risk regulation. Over the past several decades, public demand for risk regulation appears to have risen even as health risks have declined. This is not as paradoxical as it might at first seem. Although there are declining marginal returns to reducing ever-smaller risks, three factors support an increasing taste for risk prevention: wealth, aging, and science. First, rising wealth (over time and across countries) implies declining preoccupation with basic survival needs and hence rising concern about the environment and about more remote and more distant risks. Countries appear to devote greater resources to controlling pollution as they grow wealthier. Second, greater longevity – a result of declining risk – implies rising concern about risks that might occur later in life (in one's 80s or 90s, at an advanced age that one could not have counted on reaching when life expectancy was, say, 45). Thus an aging population may care more about the risks of latent illnesses caused by exposure to toxic substances, and about harms to one's great-grandchildren caused by long-term climate change. Third, improvement in scientific methods enables detection of new risks and of risks at ever-smaller levels of exposure. Our very success in reducing risks thus can yield increasing demand for action against remaining risks.

22. But taking action is not simple. Like choosing medical therapies, designing successful risk regulation is a complex and challenging task.¹⁰ Diagnosing a risk does not indicate the right remedy. The wrong remedy could be ineffective, or costly, or counterproductive. Interconnectedness only complicates this challenge. The questions remain: Does risk regulation work? When, where, and how well, with what consequences? Which approaches, tools, and institutional structures yield the best results?

2. Institutions to assess and manage risk

23. The basic social institutions for assessing and managing risks are typically private: individuals, families, firms, markets, and civil society organizations. These private actors share overlapping membership, and they number in the billions. Most choices about risks – anticipating risks, setting priorities, undertaking preventive measures, and dealing with crises – are made by these private actors. For example, most decisions about risks to the next generation (children) are made by parents, along with the physicians, teachers, and caregivers they choose. Most interpersonal risks, to which one or more persons are exposed as the result of others' actions, are handled by self-help (avoidance behavior), negotiation, and insurance. Indeed the insurance industry, including both first-party (*e.g.* health) and third-party (liability) insurance, is one of the most important institutions to assess and manage risks.

24. But private institutions are generally not sufficient to deal with larger-scale risks. First, market failures may undermine the ability of private actors to manage risk efficiently. Firms and other actors may treat risks that they impose on others as “externalities,” *i.e.* outside of the factors that they take into account in their decision making, and therefore generate more risk than is socially desirable.¹¹ For example, a firm that emits pollution may ignore the cost of that pollution to others in society, and therefore produce too much pollution (and too much of the firm's products). Second, high “transaction costs” may impede negotiation between the emitters and receptors, so that private institutions have no effective way to internalize the externality¹²; for example, there may be so many potential victims of an externality, or so many possible sources, or such difficulties in finding and monitoring these sources, that the costs of reaching an effective private bargain exceed the gains from of doing so. Third, a related market failure is that protection of “public goods” such as clean air or biodiversity may go underprovided because the benefits, once provided, will be widely shared (non-excludable) and hence each person has an incentive to let others bear the cost of conserving the resource (*i.e.* to “free ride”), resulting in general underinvestment in the shared objective.¹³ Fourth, information about risks may itself be a public good, so that each individual underinvests in learning about the risks he or she may face. Individuals may make heuristic errors about risks based on incomplete information and analysis, such as focusing on visible recent events rather than on the likelihood of future events.

25. In addition to these market failures, private efforts to address risks may be hampered by government failures.¹⁴ State-run enterprises may be slow to respond to signals of scarcity, and may be heavy polluters because they focus on production goals and neglect externalities. State-run mines, factories and forests are notorious for pollution and clear cutting. Government subsidies to private actors may perpetuate or exacerbate harmful activities such as over fishing and deforestation. Government-erected barriers to trade and market access may shield dirty industries from competition. Government regulations may themselves be adopted to favor or protect one segment of industry against another (so-called “rent-seeking” or “predation by regulation”).

26. Where private institutions are inadequate to deal with risks, there is a *prima facie* case for a public role in risk assessment and management. (It is only a *prima facie* case because the public role can also impose costs or generate new risks, which must be weighed against the reduction in the target risk.) Governments can and do address risks in numerous ways,¹⁵ including public sector provision of:

- Information generation such as scientific research and meteorology;
- Infrastructure construction such as seawalls and levees;
- Crisis response such as disaster relief, fighting forest fires, rescuing victims or reconstructing damaged homes;

- Public defense and security agencies such as the military and the intelligence community;
- Social insurance such as pensions, medical care, deposit insurance, and flood insurance;
- Regulation such as health and safety standards, pollution controls, and bank capital reserve requirements; and
- Tort liability.

27. Regulation is an *ex ante*, prospective strategy to limit the likelihood or severity of future risks, such as by requiring pre-market screening of new drugs or chemicals, requiring installation of pollution control technology, imposing quantity limits on pollutant emissions, taxing emissions, or requiring public disclosure of emissions. Tort liability is an *ex post*, retrospective strategy to provide compensation for harm and thereby to provide deterrence signals that will also influence *ex ante* behavior.

28. Regulatory “governance” may imply a wider array of actors than government alone. Governance is often taken to include the roles of nongovernmental organizations in civil society, and perhaps in business as well.¹⁶ Thus governance includes public-private partnerships to advance public objectives. At the same time, “governance” can also refer to the mode or approach of governing. In this sense, “regulatory governance” means the overall approach to regulating, including the structure of government, interaction between government and nongovernmental entities, policy analysis tools, and policies adopted. The structure of government includes at least two major dimensions:

- A vertical dimension across hierarchical levels of government (international, national, state/province, and local) (and also hierarchies within each level of government, such as executive authority over regulatory agencies), raising questions of federalism, subsidiarity, oversight and pre-emption; and
- A horizontal dimension across government bodies (across agencies with different topical missions, across branches of government such as executive and legislative, and across jurisdictions affected by transboundary or spillover effects), raising questions of co-ordination, competition, co-operation and free riding.

29. In this institutional context, interconnectedness poses a challenge to fragmentation. Fragmentation is the logical result of turf-claiming and specialization in governance: dividing up problems into pieces to be addressed by different entities. Such specialization can be desirable, but it can also yield problems when issues are interconnected. Actions by one government entity can impose spillover effects on others – that is, they can yield “regulatory externalities.” Fragmented institutions have difficulty dealing with interconnected risks: multiple simultaneous risks, risks that are transmitted across or cause impacts in multiple domains, and policies that reduce one risk but increase other risks in other domains. Some version of co-ordination or integration is needed. But some degree of specialization is inevitable because a monolithic government entity could not handle all issues at once (and would raise other concerns about concentration of power). Meanwhile, the interconnections across government entities – such as through transnational networks of official and nongovernmental experts – can foster learning and borrowing of innovative approaches that help address risks more successfully.

3. Risk regulation through the policy cycle

30. Although methods vary across countries, across agencies, over time, and depending on the particular risk being addressed, many governments generally follow (or at least espouse) a “policy cycle” regarding risk.¹⁷ This policy cycle typically involves six major steps or components:

- Forecasting (“risk assessment”)
- Prevention (“risk management”)
- Oversight (“regulatory review”)
- Implementation (including Enforcement)
- Adaptation, Remediation, Crisis Response/Disaster Relief, and Compensation (if Prevention fails and a risk comes to pass)
- Evaluation

31. There can be opportunities for public input throughout the cycle.

32. These several components of the policy cycle invoke different kinds of expertise. Risk analysis is inescapably multidisciplinary, drawing on expertise in toxicology, epidemiology, hydrology, biology, chemistry, physics, engineering, statistics, economics, finance, decision science, psychology, communications, political science, public policy, law, and other disciplines.

33. Compared to alternative approaches, risk-based regulation may require more information in order to make decisions, but may also thereby achieve better decisions. Risk-based regulation sets standards aimed at reducing risk, understood to mean the combination of probability and consequence of adverse outcomes, and also typically (though not necessarily) involves consideration of the benefits and costs of policy options. Statutory language directing agencies to employ risk-based regulation include phrases such as “prevent unreasonable risk” (weighing all risks, benefits and costs) and “reduce overall risk” (weighing all risks). The phrase “as low as reasonably practicable” has been interpreted to require reductions so long as cost is not in gross disproportion to benefit. Statutory phrases such as “protect public health” or “minimize threat” have been interpreted to call for standards to reduce risk to some tolerable or insignificant level, although often without consideration of cost (leaving it unclear where the regulator should stop regulating¹⁸).

34. Alternatives to a risk-based approach, by contrast, typically base decisions on less information and on a less complete assessment of their consequences. Such alternatives include:

- Hazard-based regulation (a ban or limit based on a possible harm having been identified, without respect to dose or actual exposure – thus neglecting Paracelsus’ adage that “the dose makes the poison” – and without respect to benefits or costs)
- Strong versions of the Precautionary Principle (prohibiting activities if there is a chance of serious risk) – unless the PP is revised to include proportionality or benefit-cost analysis
- Command-and-control “best technology” requirements, or “as low as feasible” requirements (without respect to risks or benefits; usually limited by cost)

- Deregulation or non-regulation (to reduce costs, but without respect to benefits)
- Trade measures (protectionism) via risk regulation

3.1. *Forecasting – risk assessment*

35. In principle, risk regulation begins with some forecast of potential future risk. In practice, regulation may react to a recent crisis event. In either case, risk-based regulation attempts to forecast the future likelihood of adverse consequences, through an initial component usually called “risk assessment.” The particular inquiry will differ based on the type of risk. One widely applied form of risk assessment is Environmental Impact Assessment (EIA).¹⁹ In chemicals regulation, a four-part approach to risk assessment has been developed: Hazard Identification, Dose-Response assessment, Exposure assessment, and Risk Characterization. This approach gained widespread use in the United States following the US Supreme Court’s decision in the *Benzene* case in 1980,²⁰ in which the Court held that the regulatory agency must demonstrate “significant risk” before it could regulate. This decision turned on the particular wording of the relevant statute, but it quickly became the impetus for widespread use of quantitative risk assessment across US agencies. This trend was redoubled when the National Academy of Sciences published its “Redbook”²¹ detailing methods to yield consistency across agencies, and to keep risk assessment a scientific endeavor distinct from risk management. The US approach has been viewed as exceptional, but has also been borrowed in Japan and some European countries.²²

36. In the EU, the move toward quantitative risk assessment has been more recent, driven in part by WTO decisions under the Agreement on Sanitary and Phytosanitary Standards (SPS), which requires a scientific risk assessment to support international trade restrictions. The European Commission has espoused scientific risk assessment as a predicate to any invocation of the precautionary principle,²³ and the European Court of Justice held, in a case on mad cow disease (BSE) quite reminiscent of *Benzene*, that Member State governments may not invoke precaution to regulate risks that the Commission has deemed insignificant.²⁴ Still, major risk regulations within the EU sometimes do without risk assessment methods, as in the recent Pfizer and Alpharma cases regarding antibiotics in animal feed,²⁵ in which the court held that a ban could proceed without a risk assessment and even when the relevant scientific advisory committee had recommended against a ban or had not been consulted. The court ruled in the Pfizer case, paras. 139 and 142-144:

“... a risk assessment cannot be required to provide the Community institutions with conclusive scientific evidence of the reality of the risk and the seriousness of the potential adverse effects were that risk to become a reality... [But] a preventive measure cannot properly be based on a purely hypothetical approach to the risk, founded on mere conjecture which has not been scientifically verified . . . a preventive measure may be taken only if the risk, although the reality and extent thereof have not been ‘fully demonstrated by conclusive scientific evidence,’ appears nevertheless to be adequately backed up by the scientific data available at the time when the measure was taken.”

37. This statement is confusing. The court appears to misunderstand the purpose of a risk assessment, which is never to provide “conclusive scientific evidence” (which does not exist) but rather to provide a forecast of inevitably uncertain future risks. The court holds that “purely hypothetical” or “mere conjecture” is inadequate, but that a risk assessment is not required, and it remains unclear what the court means by its alternative of “adequately backed up by the scientific data” – an invitation to further litigation.

38. Risk assessment has been criticised for both overstating and understating risks. Overstatement (false positives) arguably results from the use of conservative default assumptions used to fill data gaps, such as the use of a linear low-dose extrapolation with no thresholds or hormesis, the use of the most sensitive test species, identifying any observed effect as adverse, making animal-to-human extrapolations without accounting for mechanistic differences (“modes of action”), using the maximum exposed individual (MEI) as a hypothetical exposure assumption (*e.g.* dirt-eating children on highway median strips). Risk assessors are driven to supply some assumptions by the high cost of animal bioassays (necessitating smaller samples and higher doses), and by a science policy choice to err on the side of caution – even though over regulating based on conservative risk assessments may itself yield countervailing risks.²⁶

39. Understatement (false negatives) arguably results from neglecting risks until they reach a crisis; studying one-risk-at-a-time instead of assessing the joint effects of the multi-risk “soup” of simultaneous exposures (although some simultaneous exposures could exacerbate each other while others offset each other); inattention to sensitive subgroups, *e.g.* children; and inattention to very low-probability high-consequence (extreme/catastrophic) risks.²⁷

40. To address many of these problems, US EPA has adopted new cancer risk assessment guidelines,²⁸ which require greater use of evidence before resorting to conservative default assumptions, greater attention to modes of action, and more attention to children and other susceptible subgroups. And US OMB issued a proposed Bulletin on Risk Assessment in January 2006,²⁹ seeking to ensure greater transparency and realism, use of central estimates, and consistent criteria for identifying adverse effects. In addition, although few statutes specify the criteria for scientific risk assessment,³⁰ courts have begun to apply general statutory edicts to use the “best available science” to require agencies to conduct high-quality risk assessments.³¹

41. Meanwhile, public perceptions of risk may differ from experts’ risk assessments. The public may be more motivated by perceptions of dread (unfamiliar, mysterious or sinister risks) and the availability heuristic (recent crisis events), and may be inclined toward under reaction to other risks (*e.g.* routine risks even if of great magnitude, and very rare extreme event risks which do not offer available recent crises). Public input may improve some policies, but may distort others. But experts may be susceptible to their own heuristic errors. The result of both public heuristics and the over- and understatements in expert risk assessments may be a pattern of simultaneous paranoia about some risks and neglect of others.³²

42. Risk assessment is also difficult because different risks pose different forecasting problems. Actuarial risks, which have been occurring in large numbers, such as traffic accidents, can be forecast using historical data. Still, past may not be prologue; past patterns may not predict future patterns (*e.g.* if weather conditions, driver characteristics or vehicle technologies change). Risk assessment always involves uncertainty, even for routine well-observed risks: there is no such thing as a “certain” risk. But it can be more difficult to forecast risks with little historical data. Latent risks in which cause and effect are separated by many years may be difficult to foresee. Low-probability extreme events may only occur once in a long time (*e.g.*, an asteroid collision). Strategic agents such as terrorists or pathogens may strike or spread suddenly, and may react or evolve to evade preventive measures.

43. Interconnectedness exacerbates these challenges. Government agencies and scientists typically assess the risk of one chemical or technology at a time.³³ For the most part, agencies regulate one risk at a time.³⁴ Yet the real world is one of interconnection and complexity, in which people and ecosystems are exposed to multiple risks at the same time. Naturalist John Muir famously remarked in 1869 that “when we try to pick out anything by itself, we find it hitched to everything else in the universe.”³⁵ The modern science of ecotoxicology is moving to formalize that insight in models of simultaneous “multiple stressors.”³⁶ Modern legal scholars see the same thing: “It only takes a moment’s reflection to see that

multiple-risk situations are quite common.”³⁷ “Most of today's environmental law violates basic principles of ecology. Nature teaches the connectedness of all activities, but most current-generation law regulates separate pollutants with little consideration of ecosystems as a whole.”³⁸

44. Recognition of interconnectedness suggests at least three innovations in risk assessment. First, risk assessors should develop the means to forecast the joint effects of simultaneous exposure to multiple risks. The joint effect may be synergistic (supralinear), linear (additive), or offsetting (subtractive), but the key point is that it is the joint effect rather than the sum of the individual effects that must be forecast. Second, increasing interconnections may accelerate the transmission of risks (such as disease or terrorism) across countries and continents, through increasingly dense networks among ecological, trade, travel, and telecommunications systems (including the internet). Risk assessment needs to account for these propagation vectors. Third, rather than simply extrapolating single variables (such as exposure to a chemical), risk assessors need to develop multiple scenarios incorporating the mix of multiple variables affecting risk, potentially weighted by probability judgments.³⁹ OMB Circular A-4 (Sept. 2003) now requires a formal probabilistic portfolio of scenarios for policies with impacts exceeding \$1 billion.

45. Options for improving risk assessment include:

- Strengthening capacity through staff expertise and resources.
- Greater accuracy through more reliance on data and on realistic assumptions and methods.
- Greater transparency through reporting of assumptions and methods and comparison to alternatives.
- Assessment of strategic actors, such as terrorists and pathogens, using game theory
- Assessment of low-probability extreme events.
- Assessment of the joint effect of multiple risks in concert.
- Attention to interconnected transmission networks which may foster the rapid propagation of risks.
- Greater use of multiple scenarios for forecasting.
- Conduct an OECD survey of risk assessment methods and innovations across member states.
- Develop OECD guidelines on risk assessment to improve accuracy, consistency and transparency across member states.

3.2. *Prevention – risk management*

46. After forecasting a risk, decision makers must decide what to do about it. This is the task of risk management.⁴⁰ In risk-based regulation, this task is conducted by comparing the consequences of policy alternatives (including the alternative of no action). To compare alternatives, some method of weighing their consequences is needed. Making regulatory choices without considering the consequences does not make the consequences disappear, but may instead invite undesirable unintended consequences.

47. Risk management asks at least two questions: How much prevention is warranted? And, How to accomplish this prevention? The first question addresses the optimal level of regulatory protection, while the second addresses instrument choice.

3.2.1. *How much*

48. The standard approach to assessing “How much” is to compare benefits to costs. Reduction of the target risk (forecast using risk assessment) is the primary benefit. In the United States, every President since Jimmy Carter has required some form of benefit-cost analysis (BCA) of new agency regulations. President Carter issued Executive Order (EO) 12044, requiring economic analysis of regulations. President Reagan issued EO 12291, requiring regulations to yield benefits that “outweigh” their costs, with a goal of maximizing net benefits, and established OMB/OIRA as the White House office with the authority to oversee such regulatory impact analyses (RIAs). President Clinton issued EO 12866,⁴¹ reconfirming the bipartisan commitment to BCA, while also replacing the word “outweigh” with “justify” (a less quantitative term, embracing a broad public judgment about the policy’s merits), adding emphasis on qualitative and distributional impacts, adding an instruction to evaluate the countervailing health and environmental risks induced by regulation of a target risk (risk-risk tradeoffs), and adding new procedures for transparency. The administration of current President Bush is using the Clinton EO; it has issued more “return” letters (saying “No” to deficient regulations), and has also innovated the new device of the “Prompt letters” (using BCA to say “Yes” to desirable regulations such as those requiring trans-fat labels on food and electronic defibrillators in the workplace). OMB/OIRA has also issued new RIA Guidelines⁴² calling for more use of cost-effectiveness analysis, lower discount rates (3% as well as 7%), risk-risk tradeoff analysis, and probabilistic scenarios if impacts exceed \$1b.

49. Based on this bipartisan consensus among Presidents for the last three decades, requiring agencies to use BCA for risk management, one prominent author has heralded the era of the “cost-benefit state.”⁴³ But BCA is still not applied to all risk policies in the US. US federal agencies appear to quantify some benefits or costs most of the time, but to quantify and monetize both benefits and costs only about half the time.⁴⁴ One reason for this incomplete use of BCA is that federal statutes sometime prohibit BCA in agency regulation (and the Presidential EOs do not countermand this prohibition). Congress often requires agencies to use BCA, as in the CPSA (1972) (consumer products), FIFRA (1975) (pesticides), TSCA sec. 6 (1977) (toxic substances), and UMRA (1995) (“unfunded mandates” on states, businesses). Sometimes Congress permits BCA without requiring its use in decision making, *e.g.* in OSHAct 3(8) (1972) (workplace hazards other than toxics), CWA sec. 304 (1977) (water pollution technology standards), and SDWA (1996 amendments) (drinking water contaminants). But some Congressional statutes prohibit agencies’ use of BCA in regulation, such as CAA sec. 109 (1970) (national ambient air quality standards), OSHAct sec. 6(b)(5) (1972) (workplace toxics), ESA sec. 7 (1973) (endangered species), RCRA sec. 3004m (1984) (hazardous waste treatment standards), and CERCLA sec. 121 (1986) (hazardous waste cleanup standards).

50. Moreover, BCA is not required for Congressional legislation (although UMRA (1995) encourages it), nor for international treaties, nor for public works projects such as highways, dams and national forest logging (despite the early history of BCA as developed to evaluate dams in the 1940s, the language in NFMA sec. 6(k) requiring economic suitability for timber cutting, and the early effort to require BCA via environmental impact assessments under NEPA in Judge Skelley Wright’s opinion in *Calvert Cliffs* (1971)), nor for military and counterterrorism operations (despite the early history of BCA and systems analysis being brought to DOD by Secretary McNamara’s “Whiz Kids” in the 1960s).⁴⁵

51. In the European Union, BCA is increasingly required, but less often practiced. The Proportionality Principle, a general principle of European law, has been held to imply some version of BCA (as noted in the *Pfizer* opinion cited above, paras. 410-411, although that opinion later remarked in para. 456 that “health must take precedence over economic considerations”). The Nice Treaty of the EU provides in article 174(4)(3) that an accounting of “the potential benefits and costs of action or lack of action” must be undertaken in environmental policy. The Communication on the Precautionary Principle of Feb. 2000 (cited above) requires precautionary regulations to be *proportional* to the chosen level of protection, *non-discriminatory* in their application, *consistent* with similar measures already taken, *based on an examination of the potential benefits and costs* of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis), *subject to review*, in the light of new scientific data, and *capable of assigning responsibility for producing the scientific evidence* necessary for a more comprehensive risk assessment. In effect, the Communication reclaims the PP as part of decision analysis.

52. Most recently, the new “Better Regulation” initiative has launched Impact Assessment Guidelines (2002, revised 2005).⁴⁶ Of the 70 Extended IAs conducted by the European Commission so far (2003-05), fewer than 40% quantify and monetize either benefits or costs, and only 17% compared net benefits.⁴⁷ Several member states, including notably the UK and the Netherlands, have adopted strong Better Regulation programs with RIA procedures.⁴⁸ But the Better Regulation initiatives (both in the EU and at the member state level) appear to focus on administrative costs (“cutting red tape”) rather than on maximizing net benefits to society. So far, I have not been able to identify a prohibition on BCA in European Union law, although such prohibitions may exist in EU law and in member states’ laws.

53. Different technical parameters in BCA may yield different policy choices across governments, even if the use of these analytic tools were otherwise the same. For example, the valuation of morbidity and mortality may differ across agencies and across country governments. Apparently the US EPA currently uses a value of a statistical life (VSL) of \$6m, whereas the EU’s DG Environment uses \$1.2m (both US\$, for air pollution).⁴⁹ (VSL also differs across US agencies,⁵⁰ but this may not be sensible unless the VSL actually relates to the particular risk being evaluated.) Another important factor is the discount rate on future impacts (*e.g.*, 7% or 3%), which may vary across country governments or agencies.

54. Interconnectedness again poses an important challenge to risk governance. In theory, BCA embraces all effects. But in practice, BCA is often limited to looking only at the reduction in the target risk (TR) versus Industry compliance cost. The problem is that risk-risk tradeoffs are thereby ignored. The focus on TR omits countervailing/ancillary effects. And the focus on industry compliance cost favors options with low-cost substitutes, but these substitutes can pose their own risks. The solution is a full portfolio analysis (“treat the whole patient”) that interprets Maximize net benefits ($\max(B-C)$) more broadly, to maximize overall risk reduction (including Countervailing Risks and Ancillary Benefits) less overall social costs: $\text{Max}(\Delta TR - \Delta CR + \Delta AB - C)$.⁵¹ Thus risk-risk tradeoff analysis needs to be made an explicit part of BCA (or conducted on its own where BCA is prohibited or otherwise not used). Fragmentation into specialized agencies with narrow missions exacerbates the inattention to risk-risk tradeoffs, by causing spillover effects into the domains of other agencies (*e.g.*, EPA asbestos ban yielding weaker brake linings and hence increased highway accidents, or EPA limits on air toxics emissions yielding increased exposures to workers inside factories). It is worth noting that OMB/OIRA’s Circular A-4 (2003) (cited above) contains narrative instructions to perform risk-risk tradeoff analysis, but the table it attaches as a scorecard to guide agency calculations does not contain any line on which risk-risk impacts (countervailing or ancillary effects) can be entered.⁵²

55. BCA is sometimes criticized as biased against health and environmental protection, on the view that costs are overstated *ex ante*, and benefits are understated when they must be quantified. Retrospective analyses of a variety of policies (though not a representative sample) does not support this concern; both benefits and costs appear to be overstated.⁵³ Recall as well (from Part 3.1 above) the debate over whether

risk assessment, which figures importantly in the calculation of policy benefits, may tend to overstate risks (and hence benefits). And critics of contingent valuation (used to value non-market assets such as ecosystems) contend that it overstates benefits.

56. Moreover, even if BCA does yield biased estimates, critics of BCA need to offer an alternative method of decision making that produces socially desirable results. If BCA is seen as an unempathetic form of “cool analysis,” one option is to employ a “warm analysis” that compares pros and cons in a structured decision framework but without insisting on strictly quantified and monetized impacts. This is the “prudential algebra” recommended by Benjamin Franklin, in a letter to Joseph Priestley in 1772:

“In the Affair of so much Importance to you, wherein you ask my Advice, I cannot for want of sufficient Premises, advise you *what* to determine, but if you please I will tell you *how*. When those difficult Cases occur, they are difficult, chiefly because while we have them under Consideration, all the Reasons *pro* and *con* are not present to the Mind at the same time; but sometimes one Set present themselves, and at other times another, the first being out of Sight. . . . “To get over this, my Way is, to divide half a Sheet of Paper by a Line into two Columns; writing over the one Pro, and over the other Con. Then during three or four Days Consideration, I put down under the different heads short Hints of the different Motives, that at different Times occur to me, *for* or *against* the Measure. When I have thus got them all together in one View, I endeavour to estimate their respective Weights . . . and thus proceeding I find at length where the Ballance lies . . . “And, tho’ the Weight of Reasons cannot be taken with the Precision of Algebraic Quantities, yet, when each is thus considered, separately and comparatively, and the whole lies before me, I think I can judge better, and am less liable to make a rash Step; and in fact I have found great Advantage from this kind of Equation, in what may be called *Moral or Prudential Algebra*.”⁵⁴

57. Similarly, John Maynard Keynes remarked that he would “rather be roughly right than precisely wrong.”⁵⁵ This tradeoff between accuracy and precision suggests that on standard BCA criteria, it would do more to improve policy decisions to get the full set of consequences before the decision maker, than to invest in precisely quantifying only a few of those consequences while neglecting others.⁵⁶

58. The real concern about BCA may be institutional rather than technical. That is, the institutional bent toward using BCA to stop costly health and environmental regulations poses it as anti-regulatory, whereas the tool could be understood as neutral if it were applied to a wider array of decisions. Greater use of “Prompt” letters (using BCA to promote desirable new risk regulation), and extension of BCA to a wider array of risk policies such as dams, forest clearing, and counterterrorism (as discussed above), would make it more evenhanded and would apply it as well to promote health and environmental protection.

59. In addition, important factors such as distributional equity (fairness) may need to be included in the analysis, and may be difficult to quantify or aggregate with benefits and costs. The specific references to distributional equity in EO 12866, and the term “justify,” were added to ensure consideration of these effects.

3.2.2. *How to*

60. Regulatory intervention options are numerous. They can be interposed at various points in the sequence from production to outcomes: inputs (materials, fuels), technologies (production methods/processes), activity levels (production level, driving speed), outputs (emissions, disposal, products), ambient levels (concentrations of pollutants), exposure levels, risk levels, injuries, and remediation. The regulator has a choice of regulatory instruments to deploy through these steps of the production sequence:

- Conduct standards, *e.g.*:
 - Requirements or prohibitions on materials inputs or fuels
 - Requirements or prohibitions on technologies or designs (*e.g.* “best technology”)
 - Requirements or prohibitions on outputs, such as product takebacks or waste disposal methods
 - Negligence-based tort liability
- Price instruments, *e.g.*:
 - Taxes, fees
 - Subsidies for abatement
 - Strict tort liability
- Quantity instruments, *e.g.*:
 - Emissions limits
 - Other performance standards
 - Tradable allowances (marketable permits, cap-and-trade)
- Information instruments, *e.g.*:
 - Requirements to disclose materials, ingredients, emissions
 - Labelling
 - Assessment or planning requirements
- Hybrid instruments, *e.g.*:
 - Tradable allowances with a price ceiling (“safety valve”)
 - Deposit-refund, assurance bonding (price linked to conduct)

61. Self-regulation by industry standards (*e.g.* ISO codes) can similarly choose among these steps and instruments. A combined approach uses industry codes subject to government oversight to achieve promised performance, as in the approach of Dutch environmental covenants and Project XL in the United States (setting broad performance standards with subsequent monitoring of results, while leaving industry the choice of methods).

62. The more *ex ante* (prospectively) the policy is interposed in the production sequence, the more preventive or precautionary it can be, but the less information the regulator has about actual cause-and-effect and eventual harm.⁵⁷ Hence earlier interventions run the risk of false positives – crying wolf, such as regulating a product that turns out to be low risk, or incarcerating an innocent person. They may also reduce the ability of the instrument to encourage cost-effective behaviour at subsequent steps in the production cycle.

63. The more *ex post* (retrospectively) the policy is interposed, the more information about actual harm the regulator has, but the more such harm must be tolerated and compensated, or deterred *ex ante* by the threat of the *ex post* remedy. Hence later interventions run the risk of false negatives – waiting too long, such as not regulating a product that turns out to be high risk, or not apprehending a dangerous felon – especially if the harm is irreversible, or more irreversible (more costly to repair) than prevention costs would have been.⁵⁸

64. Options for improving risk management include:

- Strengthening capacity through staff expertise and resources.
- Requiring Impact Assessments based on structured decision analysis, including risk-risk tradeoff analysis.
- Greater transparency through reporting of assumptions and methods and comparison to alternatives.
- Greater use of economic incentive instruments, such as taxes, tradable allowances, and information disclosure.
- Conduct an OECD survey of risk management methods and innovations across member states, including the types of analysis employed and the technical assumptions within such analyses.
- Develop OECD guidelines on risk management to improve societal wellbeing, consistency and transparency across member states.

3.3. *Oversight – regulatory review*

65. A serious system of risk and regulatory governance needs not only the tools of risk assessment and management, but also an institutional structure to guide and oversee these analyses. Justinian asked “*Quis custodiet ipsos custodias*,” and the question remains urgent today. As noted above, in the US, EO 12291 and EO 12866 established OMB/OIRA as the White House office, reporting to the President, with the authority and responsibility (and capacity: a staff of experts in economics and now in sciences as well) to oversee risk regulation. Other countries have also developed versions of oversight, including the UK Better Regulation Executive, the Canadian Privy Council overseeing lifecycle assessments, the Australian Productivity Commission, an independent body in the Netherlands, and others.

66. Such oversight is particularly needed in a world of interconnections. Risk regulations adopted by one agency may induce countervailing risks in other agencies’ domains, requiring some co-ordination and oversight to manage these tradeoffs and if possible overcome them through innovative policies that reduce multiple risks in concert. In addition, the rapid propagation of risks through complex networks may warrant co-ordinated strategies among multiple agencies.

67. Ideally, the oversight body would review integrated IAs that address all relevant issues. One concern is the tendency to proliferate splintered narrow IA requirements, such as separate IAs for Administrative Costs, Federalism, Energy, Environment, Sustainability, Competitiveness, Children, Small Businesses, etc. An integrated approach to full societal net benefits should be the real objective.

68. A second concern is the question of who will serve the oversight role in important institutions such as the European Union. A central oversight office, as in the US and UK, offers a powerful, politically accountable, expert body to review all agencies' regulations. But a lateral approach, with one agency reviewing IAs by other agencies (such as DG Enterprise taking the primary role in reviewing analyses by DG SANCO or Environment), potentially pits factional interests against each other (business versus environment) and loses the opportunity to have the oversight body reflect the shared interests of the institution through its presidency. Thus, regulatory oversight should be a key task for centers-of-government. In the EU, the review function would thus be centralized – perhaps in the General Secretariat — with added expert staff; and also in each EU member state, both for domestic policy and as a pooled resource of experts to support/influence the Council of the EU in its legislative role. The central oversight body needs the:

- Responsibility: to think through, to analyze
- Authority: to influence decisions, to Prevent bad policies (return), to Promote good policies (prompt)
- Capacity: to review – the staff and skills (in economics, sciences, law)

69. In addition, oversight should conduct both *ex ante* and *ex post* analyses, as discussed further under section 3.6 below.

70. Judicial review of agency action is also available in some countries (especially in the US and increasingly also in the EU), as is legislative review (such as under the Congressional Review Act). But these reviews serve legal and political functions; they typically lack the expert capacity of executive branch oversight by professional risk analysts. Indeed, effective executive branch oversight can help obviate the resort to judicial and legislative review.

3.4. Implementation (including enforcement)

71. Effective risk regulation needs implementation and enforcement. Institutions for this component vary widely across countries. This (large) topic is too far afield to address in detail in the present paper.

3.5. Adaptation, remediation, crisis response/disaster relief, compensation

72. Some measures will be needed to respond to the manifestation of a risk, if prevention fails and the risk occurs (*e.g.* hurricane, disease outbreak, terrorist attack), or if residual risks occur after preventive efforts have been made, or if serious side effects (countervailing risks) arise (*e.g.* children killed by airbags, or counterterrorism yields blowback). This topic is not the focus of this paper. But the occurrence of the crisis, or just the lower-level manifestation of the risk or countervailing risks, should be used as feedback to help adjust and improve the policy to reduce overall risk (*e.g.* the development of “smart airbags”). Note that disaster relief poses a possible moral hazard problem (*i.e.*, the problem that subsidized or underpriced insurance may encourage people to incur greater risk) resulting from taxpayer-financed protection, insurance, relief and rebuilding (*e.g.* in the flood plain).

3.6. *Evaluation and updating*

73. A crucial component of effective risk governance is monitoring performance. Do policies actually work? Do they achieve results? This component is often neglected, perhaps because agencies have scarce resources which they prefer to devote to new initiatives. There is a crucial need for *ex post* evaluation. Essentially all countries do some kind of *ex ante* assessment at present (through RIA), but few do *ex post* review.

74. The question is how accurate are the *ex ante* RIA estimates. As noted above, initial retrospective studies by OMB and by Harrington et al.⁵⁹ find both over- and under-estimates in the *ex ante* analyses. *Ex post* analyses are needed in order to improve policies as they evolve (“adaptive management”), and to validate and improve the *ex ante* methodologies for subsequent decision making.

75. *Ex post* validation effort should be done

1. As a representative sample rather than a convenience sample,
2. Quantifying the monetized degree of error rather than just over/under estimated or the ratio factor,
3. As a routine required step for every major rule, 4) also taking account of countervailing risks & ancillary benefits.

4. **The challenge of interconnectedness**

76. As discussed above, traditionally risks have been handled one at a time, by a single government agency acting in isolation, and sometimes based on an *ex ante* impact assessment of the chosen risk policy. Many individual risks have thereby been reduced. But increasing interconnectedness poses new demands:

- Forecasting the joint effects of simultaneous exposure to multiple risks;
- Dealing with the rapid transmission of risks (such as disease or terrorism) across countries and continents, through increasing interconnections among ecological, trade, travel, and telecommunications systems;
- Assessing policy impacts, both *ex ante* and also *ex post*, with effective institutional oversight;
- Analysing the full portfolio effects, including ancillary and countervailing risks, of any effort to reduce a target risk; and
- Co-ordinating risk policies across agencies and across governments of different countries, especially for transboundary and global risks.

77. At the same time, interconnectedness offers an important opportunity:

- Learning from other countries’ experiences and thereby borrowing policy ideas, in a process of transnational diffusion of regulatory innovations.

78. Much current debate over risk regulation concerns conflicts over individual specific risks such as climate change (the Kyoto Protocol), genetically modified (GM) foods, chemicals (the new REACH policy), and counterterrorism (including the war in Iraq). But the larger context is of general transatlantic parity in overall governance of risk, and a need for increasing co-ordination on interconnected systems.

79. Some argue that Europe is now “ahead” in risk regulation, perhaps as the result of underlying culture — European risk-aversion versus American risk-taking — or, by contrast, as the result of a reversal in position from greater U.S. precaution in the 1970s to greater European precaution today. The reversal hypothesis highlights the slowdown in new lawmaking in the U.S. Congress, and the accretion of EU regulatory institutions, since 1990.

80. But this evidence of greater European precaution, drawn from a few visible policies, is not the whole story. Other cases point in the opposite direction, of greater relative U.S. precaution. For example, the U.S. began phasing out CFCs a decade before Europe, and years before observations confirmed the theoretical link to ozone depletion. The U.S. also phased out lead in gasoline before Europe did. Precaution is espoused in key U.S. statutes, including the Clean Air Act and the Endangered Species Act. The U.S. adopted earlier and more stringent restrictions on fine particulate matter and diesel emissions, in both the Clinton and current Bush administrations. In response to the European epidemic of mad cow disease, the U.S. has banned British beef since 1989, whereas the EU did not do so until 1996, and then removed that ban three years later. Further, in 1999 and 2001 the U.S. FDA adopted “Precautionary Measures” banning blood donations by people who have spent a few months in Britain or a few years in Europe since 1980 — earlier and far stricter than in Europe, despite little evidence of mad cow disease transmission via blood, and despite the countervailing risk of hospital blood shortages.

81. Thus the cases point both ways. But these competing cases are not an adequate basis for overall comparisons. Selective examples do not support conclusions about the general pattern. Hasty comparisons are vulnerable to the heuristic errors of disproportionate attention to recent, highly visible events, and exaggerated distinctions between groups that are actually similar.

82. To overcome these limitations, we undertook a multi-year study of a broadly representative sample. We identified the 2,878 risks mentioned in the relevant literature in the U.S. and Europe from 1970-2004. From this universe, we selected a random sample of 100 risks and scored the relative precaution in U.S. and European regulations for each over the past 35 years.⁶⁰ We found less than a 6 percent difference in average relative precaution over the period. Neither the cultural nor the reversal hypothesis was supported by the data.

83. The real pattern, then, is not the precautionary principle, it is precautionary particularity. Our broad analysis reveals that the U.S. and Europe exhibit general transatlantic parity, punctuated by divergences on a few specific risks, with each side acting more aggressively in some cases. The interesting question is not who is ahead, but why the U.S. and EU sometimes select such different worries.

84. Risk regulation is a multifaceted terrain on which no single race is being run. Rather than debating who is ahead, we should be learning from policy experimentation, evaluation, and borrowing. We should be identifying *better* laws, not just more laws. Instead of a race to the top, the United States and the EU should be developing a transatlantic policy laboratory.

85. Recognition of interconnectedness in risks requires a whole-of-government approach to link and co-ordinate among diverse sectors where interdependent risks may arise or impose consequences. It requires assessment of rapid propagation via linked networks, and of the joint effects of multiple exposures to different risks at the same time. And it requires analysis of the full portfolio effects of policy proposals, in order to weigh risk-risk tradeoffs and to adopt comprehensive policies that reduce multiple risks in concert. Efforts toward comprehensive regulation include the multi-gas approach in the climate treaties, and Integrated Pollution Control in the UK and elsewhere. The importance of interconnected risks and risk-risk tradeoffs underscores the need for co-ordinated, central oversight of diverse risk policies, and for *ex post* review of the actual effects of regulation — “evidence-based regulation,” based on outcomes research (as in medicine).

86. Interconnectedness also offers the opportunity for learning, borrowing, and hybridization, in a process of “diffusion of innovations.”⁶¹ Good policies can spread across countries (even without a crisis event in each country). Numerous examples have occurred in risk regulation, including environmental impact assessment, BCA, precaution, emissions trading, environmental covenanting, and others.⁶² A key mechanism of borrowing is the role of epistemic communities of experts who transcend national boundaries and engage in reflective comparative study. Thus the OECD can help facilitate constructive borrowing via sharing ideas across countries, exchange of visiting experts, and comparative studies of policies in practice.

5. Conclusions

87. How best to improve risk governance? This paper has argued that increasing interconnectedness across risks, sectors, and countries will require new approaches and emphases. In particular:

- Forecasting the joint effects of simultaneous exposure to multiple risks;
- Dealing with the rapid transmission of risks (such as disease or terrorism) across countries and continents, through increasing interconnections among ecological, trade, travel, and telecommunications/internet systems;
- Assessing policy impacts, both *ex ante* and also *ex post*, with effective institutional oversight; centralized and expert oversight, and *ex post* outcomes studies;
- Analyzing the full portfolio effects, including ancillary and countervailing risks, of any effort to reduce a target risk; and
- Co-ordinating risk policies across agencies and across governments of different countries, especially for transboundary and global risks.

88. At the same time, interconnectedness offers an important opportunity to learn from other countries’ experiences and thereby borrow policy ideas, in a process of transnational diffusion of regulatory innovations.

89. These institutions require:

- Responsibility – to forecast and to assess policy options; to think through decisions, to improve social wellbeing.
- Authority – to regulate risks effectively and efficiently; to reject bad policies and to prompt good policies, through a central oversight body that can evaluate and influence decisions.
- Accountability: for decisions, reasons, transparency, performance/results.
- Capacity – staff and skills to conduct high-quality analyses and decisions.

Notes

1. Prime Minister Tony Blair, "Speech on Risk and the State," 26 May 2005, available at www.number-10.gov.uk/output/Page7562.asp.
2. The 2005 Guidelines also advocate the use of *ex ante* and *ex post* analyses of regulatory impacts (pp.3-4), and urge that a "good regulation" is one whose benefits justify its costs (including economic, environmental and social effects)) (p.3).
3. *Emerging Risks in the 21st Century* (2003).
4. Peter Bernstein, *Against the Gods: The Remarkable Story of Risk* (John Wiley, 1996).
5. Robert Horowitz, *The Irony of Regulatory Reform* (1989).
6. Ulrich Beck, *Risk Society: Toward a New Modernity* (Mark Ritter tr., Sage 1992).
7. E.g. Stephen G. Breyer, *Breaking the Vicious Circle: Toward Effective Risk Regulation* (Harvard Univ. Press, 1993); John D. Graham & Jonathan B. Wiener, *Risk vs. Risk: Tradeoffs in Protecting Health and the Environment* (Harvard Univ. Press, 1995); Cass R. Sunstein, *Risk and Reason* (2002).
8. Jonathan B. Wiener, "Precaution in a Multirisk World," in Dennis Paustenbach, ed., *Human and Ecological Risk Assessment: Theory and Practice* 1509-1531 (New York: John Wiley & Sons, 2002).
9. Jonathan B. Wiener, *Something Borrowed for Something Blue: Legal Transplants and the Evolution of Global Environmental Law*, 27 *Ecology Law Quarterly* 1295-1371 (2001).
10. Jonathan B. Wiener, "Managing the Iatrogenic Risks of Risk Management," 9 *Risk: Health Safety & Environment* 39-82 (1998).
11. A.C. Pigou, *The Economics of Welfare* (1932).
12. Ronald Coase, "The Problem of Social Cost," 3 *J. Law & Econ.* 1 (1960)
13. On the general problem of free riding impeding the collective provision of public goods, see Mancur Olson, *The Logic of Collective Action* (Harvard Univ. Press, 1965).
14. See Charles Wolf, *Markets or Governments: Choosing Between Imperfect Alternatives* (MIT Press, 1988).
15. For an overview (emphasizing fiscal policies), see David Moss, *When All Else Fails: Government as the Ultimate Risk Manager* (Harvard Univ. Press 2002).
16. See Ortwin Renn, *Risk Governance: Toward an Integrative Approach*, White Paper No. 1, International Risk Governance Council (IRGC), Geneva, Sept. 2005, p.22.
17. For examples, see Peter Graham, Annex A to Ortwin Renn, *Risk Governance: Toward an Integrative Approach*, White Paper No. 1, International Risk Governance Council (IRGC), Geneva, Sept. 2005.
18. The science of health effects is necessary but not sufficient to set regulatory standards; policy analysis is also needed, incorporating valuations of health effects and of the costs, countervailing risks and other sacrifices involved in reducing those health effects. See Gary E. Marchant, Cary Coglianese, Jonathan B. Wiener, *et al.*, "Principled Standard-Setting Requires Consideration of More than Science," Brief 00-02, AEI-Brookings Joint Center on Regulatory Studies (Sept. 2000) (Brief Amici Curiae to the U.S. Supreme

- Court in *Browner v. American Trucking Assns.*), available at www.aei-brookings.org/publications/abstract.php?pid=91.
19. See Peter H. Sand (1990), *Lessons Learned in Global Environmental Governance* 25; Wiener, *Something Borrowed*, supra, at 1306-07, n.35 (noting transnational borrowing of EIA requirements).
 20. *Industrial Union Dept., AFL-CIO v. American Petroleum Institute*, 448 US 607 (1980).
 21. NAS/NRC, *Risk Assessment in the Federal Government: Managing the Process* (1983).
 22. See Sheila Jasanoff, *Risk Management And Political Culture* (1986) (US approach to quantitative risk assessment is exceptional); Ragnar E. Lofstedt, Saburo Ikeda & Kimbrey M. Thompson, *Risk Management Across the Globe: Insights from a Comparative Look at Sweden, Japan and the United States*, 20 *Risk Analysis* 157-161 (2000) (Japan and others have borrowed US approach).
 23. Commission of the European Communities, *Communication from the Commission on the Precautionary Principle*, COM(2000)1, Brussels, Feb. 2, 2000, available at http://europa.eu.int/comm/dgs/health_consumer/library/pub/pub07_en.pdf.
 24. Case 1/00, *Commission of the European Communities v. French Republic (Failure of a Member State to fulfill its obligations – Refusal to end the ban on British beef and veal)*, 2001 E.C.R. I-09989 (European Court of Justice, 2001).
 25. Case T-13/99, *Pfizer Animal Health S.A. v. Council*, 2002 WL 31337 (European Court of First Instance, Sept. 11, 2002); Case T-70/99, *Alpharma Inc. v. Council*, 2002 WL 31338 (European Court of First Instance, Sept. 11, 2002).
 26. For both sides of this debate, see National Research Council, *Science and Judgment in Risk Assessment* (National Academy Press, 1994).
 27. On false negatives, see European Environment Agency, *Late Lessons from Early Warnings* (2001). On extreme event risks, see Richard A. Posner, *Catastrophe* (Oxford Univ. Press, 2005).
 28. U.S. Environmental Protection Agency (2005). *Guidelines for Carcinogen Risk Assessment*. EP/630/P-03/0001F www.epa.gov/cancerguidelines.
 29. US OMB, *Proposed Bulletin on Risk Assessment*, 9 January 2006, available at www.whitehouse.gov/omb/inforeg/infopoltech.html#iq
 30. See Kelsey Stansell, Mark Marvelli & Jonathan B. Wiener, “‘Adverse Effects’ And Similar Terms In U.S. Law,” Report for the Dose Response Specialty Group of the Society for Risk Analysis (SRA) (July 2005), available at www.sra.org/drsg/docs/Adverse_Effects_Report.pdf.
 31. *E.g.*, *Chlorine Chemistry Council v. EPA*, 206 F.3d 1286 (D.C. Cir. 2000) (vacating goal for maximum level of chloroform because agency set goal based on linear low-dose extrapolation when it had just found that a threshold model was superior). See also **Error! Main Document Only.** *Leather Industries v. EPA*, 40 F.3d 392 (D.C. Cir. 1994) (remanding standard for selenium content in sewage sludge because the exposure assumption – children eating sludge on highway median strips – was not credible).
 32. See Breyer, *Breaking the Vicious Circle*, supra; Jonathan B. Wiener, “Risk in the Republic,” 8 *Duke Env’tl Law & Policy Forum* 1-21 (1997) (available at <http://www.law.duke.edu/journals/delpf/>).
 33. International Life Sciences Institute (ILSI), *A Framework for Cumulative Risk Assessment*, ILSI Risk Science Institute Workshop Report 5 (1999), available at <http://rsi.ilsa.org/file/rsiframrpt.pdf> (visited Sept.

- 10, 2003) (“Traditionally, these risk assessments have been conducted on individual chemicals medium by medium; however, humans are exposed to multiple chemicals by multiple routes concurrently in daily life.”).
34. See J. Clarence Davies & Jan Mazurek, *Pollution Control in the United States: Evaluating the System* (1999).
35. John Muir, *My First Summer in the Sierra* 110 (1988) (journal entry for July 27, 1869).
36. See Nico M. Van Straalen, *Ecotoxicology Becomes Stress Ecology*, *Envtl. Sci. & Tech.* 325A (Sept. 1, 2003); J.A. Foran & S.A. Ferenc, eds., *Multiple Stressors in Ecological Risk and Impact Assessment* (Society of Environmental Toxicology and Chemistry (SETAC) Press, 1999); S.A. Ferenc and J.A. Foran (Eds.), *Multiple Stressors in Ecological Risk and Impact Assessment: Approach to Risk Estimation* (SETAC Press, Pensacola, FL, 2000).
37. Mark Grady, Book Review, *Discontinuities and Information Burdens*, reviewing William Landes and Richard Posner, *The Economic Structure of Tort Law* (1987), 56 *Geo. Wash. L. Rev.* 658, 664 (1988).
38. E. Donald Elliot, *Toward Ecological Law and Policy*, in *Thinking Ecologically* (Marion R. Chertow & Daniel C. Esty, eds., 1997).
39. Herman Kahn & Anthony Wiener, *The Year 2000: A Framework for Speculation* (1967); Bertrand de Jouvenel, *L’Art de la Conjecture* (1964). Stephen Schneider, *Can We Estimate The Likelihood Of Climatic Changes At 2100? An Editorial Comment*, *Climatic Change* 52: 441–451 (2002) (criticising single-scenario forecasts and calling for probability-weighted portfolios of scenarios).
40. Separating risk assessment and risk management makes sense conceptually, but not necessarily organizationally. It is often better to have risk assessors and risk managers in the same agency, where they can be responsive to each other in an iterative conversation. This is especially true under conditions of interconnectedness, where risk managers will need to go back to risk assessors to seek forecasts of the countervailing and ancillary risks of their policy options.
41. Executive Order 12866, “Regulatory Planning and Review,” October 4, 1993, available at www.whitehouse.gov/omb/inforeg/eo12866.pdf.
42. OMB/OIRA, Circular A-4, “Regulatory Analysis,” September 17, 2003, available at www.whitehouse.gov/omb/circulars/a004/a-4.pdf.
43. Cass R. Sunstein, *The Cost-Benefit State* (Chicago: American Bar Association, 2002).
44. Hahn & Muething, 55 *Admin. L. Rev.* 608-42 (2003).
45. Analysis of counterterrorism policies (both domestic homeland security and external intelligence and military operations) is particularly urgent, because effective counterterrorism is essential but counterproductive policies can do serious damage to national security as well as to human life. See Barbara Tuchman, *The March of Folly* (1984). Yet these policies are difficult to analyze because information may be classified, because terrorists are strategic agents who respond to preventive measures hence requiring dynamic game theory models, and because some consequences may be hard to quantify (e.g. loss of privacy and freedom). In a recent article, we argue that little serious *ex ante* analysis was done of the Iraq invasion, with the result that serious countervailing risks were neglected, including collateral damage (civilian deaths), blowback, bog-down, distraction, and theft; and we advocate subjecting counterterrorism policies to a joint OIRA-NSC oversight process using analytic tools of BCA and risk-risk tradeoff analysis. See Jessica Stern and Jonathan B. Wiener, *Precaution Against Terrorism*, *J. Risk Research* (forthcoming 2006) and in Paul Bracken *et al.*, eds., *Managing Strategic Surprise* (Cambridge Univ. Press, forthcoming 2006).

46. See Andrea Renda, *Impact Assessment in the EU* (Brussels: Center for European Policy Studies, 2006); Lucas Bergkamp, *European Community Law for the New Economy* (Intersentia, 2004), p.169.
47. A.Renda, *Impact Assessment in the EU* (CEPS, 2006), p.63.
48. For more on RIAs in a variety of countries, see OECD, *RIA Inventory* (2003).
49. There is survey evidence indicating that VSL differs across country populations, e.g. Viscusi & Aldy, 27 *J. Risk & Uncertainty* 5, 27 (2003); Cass R. Sunstein, *Valuing Life: A Plea for Disaggregation*, 54 *Duke L.J.* 385, 415 (2004) (citing studies from \$0.2m to \$19.9m).
50. Sunstein, 54 *Duke L.J.* 385, 396-98 (2004) (\$1.6m to \$6.5m); Lisa Robinson, paper for National Academy of Sciences / Institute of Medicine, *Current Federal Agency Practices for Valuing the Impact of Regulations on Health and Safety* (2004) (\$1m - \$8m).
51. See Graham Wiener (1995), *supra*; Wiener, *Iatrogenic Risks* (1998), *supra*.
52. Other approaches do not achieve this full portfolio analysis. For example, “income-risk” (“health-health”) analysis translates costs into risk units by estimating the amount of household income reduction (due to regulatory cost) associated with a death (due to reduced household expenditures on health). This in effect “riskizes” costs, instead of the standard practice of “monetizing” health risks, to achieve a common numeraire; but it does not address the risk-risk phenomena of CR or AB, which are additional effects apart from regulatory costs. “Precaution” typically looks only at Δ TR and ignores CR and C (although the European Commission’s Communication calls for attention to C). A focus on “Administrative Costs” (“red tape”) is only a subset of C, and reducing Administrative Costs could increase social costs, for example if a good BCA would necessitate some administrative costs, or if requiring industry to do more paperwork for information disclosure would save lives.
53. See OMB, *Validating Regulatory Analysis: 2005 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities* (2005), chapter III, pp.41-49; Winston Harrington, Richard Morgenstern, and Peter Nelson, *Journal of Policy Analysis and Management* 19(2): 297-332 (2000).
54. Benjamin Franklin, “Letter to Joseph Priestley,” London, September 19, 1772, in Benjamin Franklin: *Representative Selections, with Introduction, Bibliography and Notes*, Frank Luther Mott and Chester E. Jorgenson; New York: American Book Company, 1936, pp. 348-349.
55. See also Cass R. Sunstein, *Cognition and Cost-Benefit Analysis*, in Mathew Adler and Eric Posner eds., *Cost-Benefit Analysis* (2001), also in 29 *Journal of Legal Studies* 1059 (2000).
56. This point is akin to the question of how much analysis is optimal. Better analysis yields fewer policy errors, but also incurs costs in money and time (delay). So one must compare the Value of Information (VOI) vs. the Cost of Information. The EU therefore calls for “proportionate analysis,” see EU Impact Assessment Guidelines (2005) p.8; Andrea Renda, *Impact Assessment in the EU* (2006), p. 92.
57. *Ex ante* regulation is ordinarily based on forecasts of subsequent results (with and without the policy), such as future emissions, ambient levels, exposures, risk, and harm. Each of these forecasts of future variables is uncertain.
58. Even *ex post* liability often requires a forecast of subsequent harm, e.g. liability for natural resource damages after an oil spill, when the harm will persist for decades (compared to a counterfactual forecast of what the site would have been like absent the oil spill).
59. See OMB, *Validating Regulatory Analysis: 2005 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities* (2005), chapter III, pp.41-49;

Winston Harrington, Richard Morgenstern, and Peter Nelson, *Journal of Policy Analysis and Management* 19(2): 297-332 (2000).

60. James K. Hammitt, Jonathan B. Wiener, Brendon Swedlow, Denise Kall, & Zheng Zhou, "Precautionary Regulation in Europe and the United States: A Quantitative Comparison," 25 *Risk Analysis* 1215-1228 (2005).
61. See Everett Rogers, *Diffusion of Innovations* (Free Press, 5th ed. 2003).
62. See Wiener, *Something Borrowed*, supra; Jonathan B. Wiener, "Whose Precaution After All?" 13 *Duke J. Comparative & International Law* 207, 258-261 (2003).