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Working Party on Regulatory Management and Reform

Risk and Regulation: Issues for Discussion

Annex 1: Strategic Issues in Risk Regulation and Risk Management

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This paper was prepared by Giandomenico Majone, Professor Emeritus, European University Institute, Florence, to discuss strategic and analytical issues in risk regulation and risk management and to draw their implications for regulatory management and policy.

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SUMMARY

Main messages

1. Absolute safety cannot be a sensible regulatory goal. Uncertainty is irreducible in many cases. A zero-risk approach is untenable practically and conceptually. Regulators must move away from ad-hoc rules and towards more inclusive principles. This assumes a significant capacity for policy learning, to learn from past mistakes.

2. There are two key challenges: what to do about public misperceptions of certain risks in governance arrangements which value transparency and participation; and how to achieve a more coherent approach to risk regulation, with what that implies for institutional arrangements and accountability. The fragmentation of risk regulation must be overcome.

3. People are prepared to trade off risks and benefits as long as both sides of the benefit/cost equation are honestly presented. But popular perceptions may be moving in the direction of a "risk society" where problems of "risk distribution" replace those of income distribution which characterised industrial society. In any case, the public has a tendency to over-estimate lo-probability events. The result is random agenda-setting, leading to over- and under-regulation.

4. The two steps of risk regulation – analysis and management – although conceptually distinct, are not separable in practice, and hence should not be separated analytically. They are closely intertwined in practice. Regulatory mistakes are always possible. For the credibility of the risk regulators, lines of accountability must be defined unambiguously. The institutional separation of risk analysis and risk management does not help in this respect.

Supporting evidence

5. If the correctness of the outcome can be determined unambiguously, the manner in which the decision is made is largely immaterial: only results count. By contrast, the key concept in the theory of decision-making under uncertainty is consistency, a characteristically procedural notion. The international harmonisation of procedures may be the only way to promote regulatory co-operation in politically sensitive areas which are also areas of great scientific uncertainty. The only consistent rule when deciding under uncertainty is to choose the alternative which minimises the expected loss (or maximises the expected utility), and to take account of the probabilities of all possible events. Decisions based one either consequences or on probabilities are unsatisfactory. In a holistic approach, all the parts of the decision-making process must fit together in a consistent and transparent manner, and be open to revision in the light of new information. Decision-making should use all available information, weighted by its reliability in terms of subjective probabilities, instead of privileging some particular risk.

6. The minimax decision rule and precautionary principle instead focus on particular probabilities, and not on a range. The precautionary principle is ill-defined, and may direct resources toward attempts to control poorly understood, low-level risks using resources that could be more effectively directed toward the reduction of well-known, large-scale risks. The precautionary principle is inherently ambiguous, making it ill-suited as a guide in preparing legislation or as a principle in international law. Its most basic flaw is the artificial distinction between situations where the level of scientific information is sufficient to permit a formal risk assessment, and where it is not. In reality these are two points on a knowledge-ignorance continuum, rather than two qualitatively distinct situations. The opportunity costs of precautionary measures are seldom, if ever, considered. They include potentially negative consequences for scientific and technological development or for product innovation, its use as a protectionist device, and perverse distributional consequences.

7. Improving the practice of risk management depends on the consideration of ideas and information in a consistent manner, not in isolation. This is illustrated by the steady improvement in the conceptual foundations of risk regulation in the United States, where over time efforts have been made to put the various elements of the regulatory problem together in a consistent regulatory management system. The paper shows this progression from consideration of least feasible risk to that of significant risk as criteria. Policy learning was greatly facilitated by the interaction among different institutions, partly cooperating, partly competing, and by the high premium placed on reliable quantitative information and sophisticated analysis.

Proposals for the future

- Well-defined procedures for electorally accountable policymakers to over-ride an agency's decision if he is convinced that social welfare is thereby promoted;

- Education of the public Consideration of a centralised agency to overcome institutional fragmentation

- Education of risk regulators, including use of electronic media to help decision makers perform sensitivity analysis of complex decisions under a great variety of probability and utility assumptions International harmonisation of regulatory procedures.

RISK AND REGULATION: ISSUES FOR DISCUSSION

ANNEX 1. STRATEGIC ISSUES IN RISK REGULATION AND RISK MANAGEMENT

Introduction

8. Defining an appropriate analytical framework is of critical importance for effective risk policies. Public officials are increasingly facing the need to make decisions about policies where future uncertainties are economically significant and unavoidable. Today the issue of risk, in its multifarious forms, looms so large in public discourse and in popular perceptions that some observers speak of a "risk society", where problems of "risk distribution" replace those of income distribution which characterised industrial society.

9. In such a situation the need of clear and consistent principles for dealing with uncertainty is as urgent in the public sector as it was in the private sector a few decades ago. Perhaps the most convincing way of demonstrating this need is to provide concrete examples of the practical consequences of confused thinking about the principles of decision-making under uncertainty.

10. This report will present numerous examples of such confused thinking. A number of such examples are in fact scattered throughout the present report. Sections 6 and 7, in particular, point out the shortcomings of the precautionary principle as a general decision rule, while Section 8 shows how, in the United States, early approaches to risk regulation have been progressively refined along the lines suggested by modern decision theory. This introduction considers an old, but still instructive, episode from the early history of risk regulation. (Box 1)

Box 1. An early example: the Saccharin case

Moving away from full certainty towards rational decisions under uncertainty

This early episode refers to the Saccharin Ban imposed by the US Food and Drug Administration (FDA) in 1977, after a study sponsored by the Canadian government showed a significant increase in bladder tumors among male (especially second-generation) rats exposed to high levels of saccharin consumption. According to the agency, the ban was made necessary by the wording of the so-called Delaney anti-cancer clause to the 1958 Food Additives Amendment. The Delaney clause reads, in part: "No additive shall be deemed safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of food additives, to induce cancer in animal or man".

According to FDA officials, this proviso authorises the agency to exercise scientific judgment in determining whether a test is an appropriate one, and whether the results demonstrate induction of cancer. But once the agency has made its determinations concerning these two matters, no further inquiry is allowed. For example, the agency may not establish a maximum level of safe use, or authorise further use of an additive based on a judgment that the benefits of continued use outweigh the risks involved. The proposed saccharin ban was very controversial, particularly since an acceptable saccharin substitute did not exist at that time, and the possibility of developing a non-nutritive sweetener that was safe and economic, was judged to be remote. Actually, the evidence against saccharin was less than overwhelming. Laboratory studies of rats repeatedly showed a weak carcinogenic effect, but retrospective human studies failed to reveal a consistent link between saccharin consumption and bladder cancer. The weight of medical testimony before congressional subcommittees was that: (a) saccharin is probably a weak carcinogen that could have substantial adverse effects on human health if consumed in large quantities over prolonged periods; but (b) a ban on saccharin could also pose risks, especially if saccharin users responded by substantially increasing their consumption of sugar or other high-calorie foods. Despite congressional awareness of the fact that saccharin might provide consumers with benefits as well as posing health risks, congressional hearings failed to produce any definite conclusion. The only outcome was continuing postponement of the ban, coupled with labelling requirements. The Food and Drug Administration did try, however, to modify in practice a conceptually flawed, but legally binding, decision rule. Thus, the agency has sometimes concluded that a substance is not a "food additive", and hence is not subject to the Delaney clause, even though it occurs in food, arguably through human agency. For example, FDA has refused to regulate compounds such as PCBs and aflatoxin. Proceeding in this fashion, by the mid-1980s the agency had effectively narrowed the application of the Delaney clause to direct food additives.

11. Several lessons can be drawn:

- First it is obvious that risk regulators operate on the basis of great, and in many cases irreducible, uncertainty, see Sections 1 and 2 below. Such uncertainty is too important to be treated in a purely intuitive and qualitative way; rather, it should be expressed in terms of numerical probabilities. These probability estimates are necessarily subjective, but they are explicit, hence open to scrutiny by third parties, and can be revised in a logically consistent way when new information becomes available. The reluctance of medical doctors and health scientists to think in probabilistic terms, and to express subjective estimates has already been noted some time ago.[1] Since then, the situation has not greatly improved in this respect, while the idea of making net benefit assessments, rather than consistently favoring worst-case scenarios, if anything, has gained greater acceptance.

- A second important lesson is that a zero-risk approach is untenable practically as well as conceptually (such as is implied by the Delaney clause, but also by some versions of the precautionary principle). Since the FDA's saccharin ban the capacity to detect chemicals in foods in quantities as small as parts per trillion has been perfected. These scientific advances further complicate the regulatory task since the significance of such tiny amounts in carcinogenesis is generally unknown. What is clear, however, is that absolute safety cannot be a sensible regulatory goal.

- Third, a good decision rule must take into consideration all the important elements of the risk problem: the level of uncertainty, the health and other risks, as well as the potential benefits of alternative measures. As is shown in Section 5, a decision rule that fails to consider all such elements tends to distort regulatory priorities. One of the most important issues facing legislators and risk regulators today is to move away from the ad hoc rules of the past (for example, uncritical use of "safety factors"), towards more inclusive and logically defensible principles. This presupposes a significant capacity for policy learning, and it is encouraging to observe that some countries have indeed been able to correct past mistakes in their approach to risk regulation, see Section 8.

12. Before concluding these introductory remarks it may be worthwhile to mention a fourth lesson: *this case suggests that people are quite prepared to trade off, at the margin, risks and benefits, as long as both sides of the benefit/cost equation are honestly and convincingly presented to them*. As already mentioned, the proposed saccharin ban was very controversial, particularly since an acceptable substitute did not exist. Congressmen reportedly received more mail on saccharin than on any other issue since the Vietnam war. Representatives of health organisations testified at congressional hearings that saccharin provides enormous health benefits to persons, such as diabetics, who must restrict the intake of sugar. In response to widespread opposition to a regulatory decision which took the remote risk posed by a product, but not its benefits, into account, Public Law 95-203 was passed, providing for a moratorium during which period the National Academy of Sciences was asked to review federal food safety policy, with special emphasis on saccharin.

13. A gap often separates the public's risk perception from the assessment of the experts. According to a number of empirical studies, there is a tendency to overestimate events associated with lower-probability events, while ignoring potential benefits. But in the case of the saccharin ban we have, in a sense, the reverse situation: a public acceptance of some risk for the sake of well-understood benefits. This leads one to suspect that the exclusive concentration of some decision rules on (often negligible) risks, regardless of foregone benefits, may be politically inspired—for example, in the shape of "position taking" in parliament, or protecting special interests – rather than a reflection of genuine popular preferences.

14. Managing risks from a regulatory management perspective requires not only appropriate analytical foundations and institutional set-up, but also an appropriate communication strategy that will enable all individuals as well as society to accept the best rational trade-offs, with a clear and honest presentation of both sides of the benefit/cost equation.

1. The implications of regulatory science for risk management

15. Managing risks in a regulatory framework requires addressing a mix of analytical and institutional aspects. From the analytical perspective, significant aspects may have complex, and often unintended consequences, as rational decisions have to be taken in an *uncertain* world, where uncertainty cannot be eliminated. Uncertainty is pervasive in risk regulation, by definition. What seems to be less well understood is that in many cases, uncertainty is not only pervasive but also irreducible, as is illustrated by the example of potential chemical carcinogens. The heterogeneity of human populations, as well as the difficulty in finding the best close animal specie for tests leaves public authorities with an almost impossible regulatory task in terms of managing and fully securing the risks associated for potential carcinogens for the overall population, including high risk groups. The difficulty to produce solutions that are entirely and totally logical to the various problems of risk assessment leaves regulators dealing with scientific uncertainty, and with the need to search for various “safety factors” or conservative assumptions, which are nothing else than empirical rules of thumb, which is one reason that explains the origin of the so called "*precautionary principle"*.

16. Typical regulation of carcinogens is based on laboratory tests involving animals. A major issue is the determination of the animal species that best predicts the response of humans. Would the same species be equally predictive for all carcinogens being tested? Do species differ in the degree to which they can predict toxicity for specific organ systems—kidney, liver, lungs, and so on? Which “animal model” best simulates the pregnant woman, the new-born child, or individuals with inadequate diet or genetic deficiencies? There are no unequivocal answers to such questions. Thus, many researchers have criticised the excessive use of rodents as predictive models because rodents are phylogenetically further removed from humans than other species, such as the dog or the monkey. Yet, some years ago a scientific panel of the Unites States Food and Drug Administration on carcinogenesis did not recommend the general use of the dog in the testing of chemical carcinogenesis because of its large size and relatively long life span.

17. Several scientific as well as practical aspects have to be considered. There is, in fact, little hope that one species could provide the broad range of predictive potential needed to assess the responses of a highly heterogeneous human population to different types of pollutants. Predictions could be improved by using multiple species in toxicological experiments. But heterogeneity in human populations is often social in origin, and social conditions cannot be reproduced in the toxicologist’s laboratory. The issue of human heterogeneity also arises in connection with the prediction of adverse health effects on individuals who are (or may be) at high risk with respect to certain pollutants.

18. Once the toxic dose for the “normal healthy” population has been derived, consideration must be given to high-risk groups: children and adults with vitamin C deficiency are hypersensitive to ozone and to a number of heavy metals; pregnant women, to lead and carbon monoxide; people with asthmatic and chronic respiratory diseases, to respiratory irritants such as nitrogen dioxide, ozone, and sulfur dioxide, etc. Standards developed for statistically “normal” individuals should be adjusted in order to protect the sections of the population at high risk. Unfortunately, for a variety of reasons such as lack of detailed exposure information, high-risk groups are seldom considered specifically and separately in setting environmental and health standards, except perhaps through the dubious device of “safety factors”, see below.

19. Strictly speaking, each individual has a unique genetic composition and life history, and thus a unique response to carcinogens and environmental pollutants. This heterogeneity of human populations leaves public authorities with an almost impossible regulatory task, in securing a guaranteed "life time" response for specific products, using specific formal mathematical models, and facing the need to find the safest of all mathematical assumptions (Box 2).

Box 2. Links between life time response and dose levels

In an effort to find a way out of these uncertainties toxicologists and statisticians have developed several mathematical models expressing the probability of a lifetime response, P, as a function of dose levels, D: P=f(D). This is the dose-response function, and different choices of functional form—*i.e.*, different choices of f – generate different models, such as: the traditional threshold (non-linear) dose-respose model; or the linear (non-threshold) model, according to which adverse health effects occur at every level of exposure, and there is no obvious point at which a reasonable standard could be set; or again, a dose-response relationship could be expressed by a curve which is linear at high or moderate dose levels, but at low doses it could indicate more serious health effects than the linear model would have predicted. But how is the functional form f chosen? The usual procedure consists in fitting a curve (by one of several available methods) to the observations in the observable range, and then extrapolating downward to a "virtually safe dose" (VSD). A VSD is defined as a dose level such that the probability of a lifetime response at that level is less than some *preassigned* small probability such as 10(exp-8), the value favored by many toxicologists, or 10(exp-6), the value used for example by the US FDA.

There are three major problems with such procedures for determining the shape of the function f. First, the choice of functional form has a major effect on the value of the VSD. Thus, under a threshold model it is possible to establish a "virtually safe" level of exposure (even though high doses produce adverse health effects) whereas, as we saw, this is impossible if one uses a linear model. Second, the different extrapolating functions often cannot be distinguished from each other in the range of the observable responses. Finally, no firm scientific basis exists for choosing among the different possibilities.

20. What a distinguished statistician wrote in the late 1970s is still largely true today: "All present safety evaluation procedures... must be regarded as mathematical formalisms whose correspondence with the realities of low-dose effect is, and may long remain, largely conjectural" (Cornfield 1977: 698). (See Box 2.) It might be argued that if there is no firm scientific basis for choosing among different dose-response models, then one should prefer the *safest* or *most "precautionary*" procedure. One problem with this argument is that it is not clear where one should stop. A no-threshold model is more conservative than one that admits the existence of thresholds for carcinogenic effects. But within the large class of no-threshold models many degrees of precaution are possible. Again, in designing a toxicological experiment one could use the most sensitive species, the most sensitive strain within the species, and so on down to the level of the most sensitive animal. In short, it is difficult to be precautionary in a consistent manner, unless one is prepared to propose a zero level of exposure in each case. This dilemma, which Jerome Cornfield stated so clearly some thirty years ago, has not yet been resolved by the advocates of such decision rules as the *precautionary principle.*

21. Unable to produce logically defensible solutions to the various problems of *risk assessment,* regulators deal with scientific uncertainty by means of various "safety factors" or conservative assumptions, which are nothing else than empirical rules of thumb. Often a safety factor of 100 is used, meaning that test animals should show no adverse health effects from a given pollutant or potential carcinogen when exposed to doses at least 100 times greater than the likely human dose. This particular rule of thumb is sometimes justified by the reasoning that humans may be ten times more sensitive than the experimental animals used, and that there may be in addition a tenfold variation in sensitivity among individuals. But then, how does one justify safety factors of 50 or 500 which are also in use? The consequences of such unsatisfactory methods of dealing with uncertainty are far-reaching, as will be discussed later on in the present report. At this point it suffices to point out that reliance on such subjective – but often practically unavoidable – judgments as "virtually safe doses", "acceptable risk doses", "virtual safety", and numerical safety factors, blurs the distinction between risk analysis and risk

management. To anticipate a later conclusion: *although the two stages of risk regulation—analysis and management – are conceptually distinct, they are not separable in practice and, hence, should not be separated institutionally.*

22. The examples mentioned above only begin to give an idea of how pervasive is the uncertainty which faces the risk regulator. Thus, risks posed by drinking water regulated by the US Environmental Protection Agency could be ten times greater or ten times less than the mean estimate of the risk. Similarly, the risks posed by air pollution could be twenty times less than the mean estimate (Viscusi *et al.*1996: 673, Table 19.6). What is perhaps less well known is that for some problems, such as global warming, the main uncertainty is with respect to the potential increase in the benefits of controls above current levels. Although temperature seems certain to increase by several degrees in the near future, for northern regions this may be a benefit, while for southern regions it will generally be a disadvantage. Again, the warming in the winter will be beneficial and will occur to a larger extent than warming in the summer, which will have an adverse effect, etc.

23. The analysis in this section illustrates the intractable aspects of risk analysis, and the pervasive nature of uncertainty. Given this pervasive nature, it may be difficult to draw a clear distinction between risk analysis and risk management, with significant implications in terms of institutional design of regulatory management systems, notably with regards to the need for an *integrated approach of risk analysis and management.*

2. Regulatory science and trans-science: scientific analysis versus popular perception

24. Uncertainty in risk regulation is not only pervasive but also irreducible. Careful analysis of old and new controversies about the analysis and management of risk shows a number of “trans-scientific” issues. This shows the boundary between science and "trans-science", for issues over which expert disagreement is most serious, and for which the gap between the available scientific evidence and popular perceptions of risk. “Trans-scientific” issues are beyond strictly scientific or technical issues. In Alvin Weinberg’s terminology, trans-scientific issues are questions of fact that can be stated in the language of science but are, in principle or in practice, unanswerable by science (Weinberg, 1972). For both cognitive and practical reasons, intrinsic, irreducible uncertainty is a key feature of regulatory science. The gap between risk assessment and actual risk perception may have significant implications as well in terms of risk management as well as communication over risks. The difficulty in dealing with irreducible uncertainty often lead to a proliferation of such ad hoc methods, and to the reference to the so called “precautionary principle”, which reveal a lack of understanding of the logic of decision-making under uncertainty.

Irreducible uncertainty

25. For example, at present the choice of a particular dose-response function must be treated as a trans-scientific question since, as we saw, the relationship can be represented by many different functions, but with the experimental data usually available there is no firm scientific basis for choosing a particular functional representation. However, the choice can have a major effect on risk management. Also mentioned was the unreliability of extrapolations outside the experimental range, in particular downward extrapolation from the very high dose levels used in animal experiments. But why are test animals exposed to levels of toxic substances far in excess of those to which humans would be exposed under normal circumstances, thus making downward extrapolation necessary? The answer is that this is done in order to compensate for the small number of animals usually tested.

26. Thus, if we assume that a chemical agent will cause cancer in 1 out of 10 000 people who are exposed to it, and that humans and test animals do not differ significantly in sensitivity with respect to the given agent, it would be necessary to test 10 000 animals (but preferably something like 30 000 animals) in order to detect one case of cancer. With 1 000 test animals and an unacceptably low confidence level of 90%, the upper confidence limit for a negative experiment (no cancer induced at the given dose level) is 2.3 cancers per 1 000 tests. It has been calculated that to reduce the upper limit of risk to 2 cancers per one million at a confidence level of 99.9 per cent would require a negative result in somewhat more than three million test animals. In practice, no more than 50 or so animals are usually available per dose level, and this explains the use of high doses on small samples of animals. "Megamouse" experiments with extremely large number of animals have been proposed. Such experiments would allow reducing the experimental doses and hence the unreliability of downward extrapolations; but the costs would be prohibitive and the validity of the conclusions still doubtful because of the problems connected with human heterogeneity and extrapolations from animal test to humans. Analogous issues arise in the regulation of the risks of nuclear radiation—the area where the notion of trans-science originated. Thus, one of Weinberg's examples is the determination of the health effects of low-level radiation. He calculated that in order to determine by direct experimentation, at the 95 per cent confidence level, whether a level of X-rays radiation of 150 millirems would increase the spontaneous mutation in mice by ½ per cent, would require about 8 billion mice.

The time frame for decision-making

27. Another defining feature is the necessity of reaching a decision within a reasonable time. Unlike the academic scientist, the regulatory scientist cannot refuse to decide, or postpone a decision while waiting for better evidence: s/he must come to some definite conclusion, however large the area of *subjective* uncertainty. How to deal rationally and consistently with *such irreducible uncertainty* in a limited time frame is the most basic problem of risk regulation.

28. Safety factors, risk classification ("similar risks should be treated similarly"), worst-case scenarios, least-feasible-risk rule, and the precautionary principle, are all attempts to come to grips with this basic problem. Unfortunately, these and similar attempts are not only *ad hoc*, but logically flawed, practically misleading (since they create a false sense of security), and prone to be misused for protectionist or other purposes having nothing to do with risk abatement. The very proliferation of such *ad hoc* methods of dealing with probabilistic events shows how widespread, even among scientists and regulators, is the ignorance of the logic of decision-making under uncertainty.

How to formulate a coherent approach for risk analysis and management?

29. The rest of this report will try to go back to basic principles to see how they may help in formulating a coherent approach to the analysis and management of risk. The aim is not to provide ready-made solutions, but rather to demonstrate the usefulness of a clear understanding of a few fundamental ideas. General ideas must always be adapted to a multiform reality, but the adaptation should be made having in mind, that an approximate answer to the real question, which is often vague, is much to be preferred to a precise answer to the wrong question, in the spirit of John Tukey's.

3. Towards procedural rationality when facing uncertainty

30. Before introducing the basic ideas of probabilistic decision theory, it is useful to draw attention to the important, but often overlooked distinction, between *procedural* and *substantive rationality* (See Appendix 1). *Substantive rationality* tends to consider the final outcomes of the decisions themselves, and will be applied in cases of certainty. Uncertainty and more complex cases will lead to *procedural rationality*, with an emphasis on process, and how decisions are made. This distinction will serve as a means of demonstrating the plausibility of certain key results of the theory, as well as making sense of certain practices in risk regulation, especially at the international level.

31. Generally speaking, the more complex a system, the greater the reliance on procedural rationality, for, as Talcott Parsons wrote: "Only on the basis of procedural primacy can the system cope with a wide variety of changing circumstances and types of cases without prior commitment to specific solutions" (Parsons 1966: 27). Relatively simple situations – in particular, situations where certainty is assumed, involve an emphasis on emphasise on substantive outcomes rather than processes. Both the focus on substantive results and indifference toward procedures are understandable if one assumes that there exists an objectively best decision in a given situation. If the correctness of the outcome can be determined unambiguously, the manner in which the decision is made is largely immaterial: only results count. This is the reason why the key concept in the traditional theory of choice, whether in microeconomics or in management science, is *optimisation*.

32. The conditions for choice will differ in an uncertain context, with an increased emphasis on *consistency*, and *procedural rationality*. Optimisation has no well defined meaning when the consequences of a course of action are uncertain – one should not, for example, maximise expected profit without considering, at a minimum, also its variance. By contrast, the key concept in the theory of decision-making under uncertainty is not optimisation but *consistency*, a characteristically procedural notion.

33. *Procedural harmonisation* provides a good illustration of the importance of procedures in the international regulation of risk. The purpose of harmonisation is to make the regulatory requirements of different jurisdictions more similar, if not identical. Regulatory regimes can differ in numerous aspects, and at least three main types of harmonisation may be usefully distinguished (Leebron, 1996):

- *Specific rules or standards could be harmonised.* These rules prescribe the desired characteristics of the outputs of production processes, institutions, or transactions could be harmonised. For example, emission limits for polluting factories located in different countries may be made more similar. We may call this substantive, or output-, harmonisation since the goal is to reduce pre-existing differences in certain characteristics of the relevant outputs.

- *Regulatory harmonisation may relate to certain governmental policy objectives*—for example, the central banks of the G-7 countries attempt to keep inflation within agreed limits—or to general policy principles such as the OECD's polluter-pays principle, or the precautionary principle advocated by the European Commission.

- *Harmonisation of institutional structures, procedures or methodologies is often sought*—the kind of harmonisation which interests us here. Thus, some of the provisions of the North American Free Trade Agreement (NAFTA; the reference here is to the NAFTA "side agreement" on the environment) require that certain procedures for enforcement of domestic laws, including appellate review, be harmonised.

34. Procedural harmonisation usually serves to reinforce other types of harmonisation. Thus, if the aim is to harmonise decisional outcomes, both substantive criteria and decisional processes are implicated. *Rules, policies, and principles will generally not be truly harmonised unless the procedures and institutions for implementing them are made more similarly effective,* and doing so may mean making them more similar. There are, however, situations where procedural harmonisation is not meant to reinforce other types of harmonisation, but is the only type which is politically, economically, or technically feasible, which different countries have too different standards and too different levels of domestic protection. Another important example of procedural harmonisation is provided by the WTO Agreement on Sanitary and Phytosanitary Measures (SPMs).[2] Harmonisation is discussed in Article 3 of the Agreement, which refers to international standards.[3] This Article is noteworthy in several respects. Nothing substantive is said about the level of the international standards, not even of a qualitative nature. By contrast, the approach of the WTO SPMs Agreement is purely procedural. The requirement that a country provide "scientific justification" if it wishes to adopt a higher level of protection than what is provided by international standards, goes in the same procedural direction: given the uncertainty surrounding the scientific basis of risk regulation, "scientific justification" can only mean that the relevant arguments should satisfy generally accepted rules of scientific methodology.[4]

35. It seems clear that in an area as politically sensitive as the protection of health and life, and where at the same time regulators face great scientific uncertainty, the only way to promote international regulatory cooperation is through *the harmonisation of procedures*. This, at any rate, is how progress has been achieved in the international harmonisation of testing procedures for new medical drugs – the so-called ICH process – in which the European Agency for the Evaluation of Medicinal Products (EMEA) has played a leading role (Majone, 2002).

4. The core concepts of risk analysis and management: risk, uncertainty, and probability

36. Risk is defined as the probability of an unfavorable event multiplied by the severity of harm, if the event occurs. The connection between risk and probability is clear: risk is simply an *expected* loss, which can be calculated once we know the probability distribution of all possible events. Given this definition of risk, it is clear that probability and utility (or loss=negative utility) are the key concepts of risk regulation.

37. These two concepts are so intimately related that the modern view of probability was developed in an attempt to understand the logic of decision-making in the face of incomplete knowledge. According to this view an individual, when faced with the necessity of making a decision that may have different consequences depending on events about which she has incomplete knowledge, can express her preferences and uncertainties in a way consistent with some basic principles of rational behavior.

38. It can then be deduced that the individual has a "*utility function"* – which measures the value to her of each course of action when each of the uncertain possibilities is assumed to be the true one – and a "subjective probability distribution", which expresses quantitatively her beliefs about the uncertain events. The individual's optimal decision is the one that maximises expected utility (or minimises expected loss) with respect to this probability distribution.

39. A basic, if often unrecognised, *reason for the inability of the advocates of ad hoc decision criteria, such as the precautionary principle, to deal consistently with risk and scientific uncertainty is an outdated understanding of the very notion of probability*. The modern view of probability as expressing the strength of our knowledge or beliefs, is much broader than the old ("objective") view of probability, which only applies to phenomena or experiments that can be indefinitely repeated under essentially the same conditions. But each political, managerial, or regulatory decision is essentially *unique*—it can never be repeated under the same conditions – and hence may be analysed only by means of the *subjective notion of probability*.

40. From this viewpoint, "objective" probabilities represent only a special case, but as in all good generalisations in science, the same principles ("axioms") apply to both kinds of probability. *What is really important about subjective probabilities is the procedure* (known as Bayes theorem) by which they can be revised in the light of new information. Hence "subjective" in this context, is not at all equivalent to "arbitrary". Both subjective probabilities and utilities are derived according to precisely defined rules that guarantee their internal consistency (see again the Appendix), and also learning—in the sense of transforming "prior" into "posterior" probabilities in the light of new evidence—follows a well-defined procedure, as just noted.

41. The *consistency* argument is essentially one that hinges on how separate assessments (of probabilities and utilities) are going to fit together and make a consistent whole. It should be clearly understood that the *rule of maximisation of expected utility* (or minimisation of expected loss) does not guarantee better outcomes than other decision rules – including decisions made in purely intuitive fashion. It does, however, guarantee consistency *in decision-making*, and no other known decision rule can claim the same.

42. *Consistency is important also from a practical point of view: it facilitates communication* among experts, between experts and policy makers, and with the general public; *it also facilitates accountability* by showing how to break down the whole decision problem into separate but coherent components. Moreover, the method provides a way of consistently updating one's beliefs in light of new information. Such a formalised approach to decision-making may even facilitate risk taking. For instance, if managers are evaluated exclusively on outcomes, they will naturally be reluctant to engage themselves in very risky undertakings. A more sophisticated method of evaluation, which in addition to results also includes the quality of the decision process, can reduce the cost of failure by distinguishing between foresight and outcomes due to chance (Williamson 1975). Similarly, risk regulators would have less incentives to take refuge in safety factors and other *ad hoc* methods of dealing with uncertainty if they knew that their decisions are going to be evaluated according to more sophisticated procedural standards than the ones currently used.

43. What about *uncertainty*? In an otherwise remarkable book published in 1921, the American economist Frank Knight asserted that "a *measurable* uncertainty, or "risk" proper, is so far different from an *unmeasurable* one that it is not in effect an uncertainty at all"[5]. In other words, we should talk about *risk* only *when the events are uncertain but their probabilities are known*, reserving the term *"uncertainty" for the case where the probabilities are unknown*. Knight attached great theoretical importance to this distinction – which is still used by some risk analysts – but contemporary probability theory no longer views the two classes of events as different in kind. Probabilities may be known more or less precisely, they may be more or less subjective, but it is logically difficult to give precise meaning to the statement that certain probabilities are completely unknown. For instance, if we insist that we are 'completely ignorant' as to which of the possible events $E_1, \ldots, E_n$ will occur, it is hard to escape the conclusion that they are all equally likely to occur. But this implies that the probabilities are in fact known, and that $p(E_j) = 1/n$ for all j: the so-called uniform distribution, well known to first-year students of probability and statistics! From a practical point of view it should also be noted that for some decision problems, it is not necessary to know the entire probability distribution of events: more aggregate information may be sufficient to find a sensible solution. Thus, even though toxicologists may be unable to make exact quantitative statements about the low-dose risk of particular substances, they can often rank the risks of various substances at currently experienced doses. For example, they might say that a lifetime exposure to x part per million (ppm) of substance A presents in their judgment a larger risk of cancer to a worker than a lifetime exposure to y ppm of substance B. It is not necessary to evaluate precisely the risks posed by both substances in order to have a reasonable basis for a *comparative risk assessment* (Graham *et al.,* 1988).

5. Decision rules when deciding under uncertainty

44. *The only consistent rule* when deciding under uncertainty is *to choose the alternative which minimises the expected loss* (or maximises the expected utility) of the decision-maker. Any other decision rule – and in particular any rule which does not take into account both the losses and the probabilities of *all* possible events – can lead to inconsistent decisions. One such potentially inconsistent decision rule is the *minimax*, which formalises the worst-case approach often used in risk analysis and risk management: The minimax decision rule uses losses but not probabilities, either denying the existence of the latter, or claiming that the method is to be used when they are "unknown" (and perhaps unknowable, as Frank Knight would have it). (See Box 3.) This particular decision rule makes sense in special situations, such as zero-sum games where the uncertainty is 'strategic', *i.e.* part of the strategy of a rational opponent, but not in the general case. A formal proof that the rule can produce inconsistent decisions is beyond the scope of the present discussion.[6]

Box 3. Concrete examples

The basic problem may be understood with the help of simple examples. Consider first the following decision problem, where the entries in the 2x2 table indicate losses, *e.g*. extra deaths due to exposure to a toxic substance:

EX1	E_1	E_2
A_1	10	0
A_2	1	1

EX2	E_1	E_2
A_1	1.1	0
A_2	1	1

In example 1 (EX1), following the minimax rule, for each row (*i.e.*, each alternative) we select the maximum loss (10 for A_1 and 1 for A_2), and choose that alternative having the minimum of these values. This is A_2 with value 1. Hence the minimax rule says: always choose A_2. The principle of minimum expected loss would assign probabilities p_1 and p_2 to the uncertain events E_1 and E_2, and choose A_2 if $1 < 10p_1$, *i.e.* $p_1 > 1/10$, otherwise A_1 should be selected. To see which of the two rules is more reasonable, suppose that p_1 is quite small (say, $p_1 = 0.001$ or 0.0001) so that $10p_1$ is much less than 1. The minimax rule would still choose A_2, even though it is almost sure that no extra deaths would occur if A_1 is chosen.

The conclusion is even more striking in a second example (EX 2), where only the loss corresponding to the pair (A_1, E_1) has been changed: The minimax rule would still choose A2, even though the expected loss for A1 is much smaller for all values of p1 less than, say, 0.8.

45. In short, *the problem with the minimax rule is that it does not take into account all the information available to the decision-maker*, by considering only the worst possible case and disregarding probabilities. *The advantage of the expected-loss (or expected-utility) rule is that it takes account of both losses/utilities and probabilitie*s.

46. As just noted, the minimax rule is unsatisfactory because it takes into account only the consequences, ignoring their probabilities. *Equally unsatisfactory are decision rules based only on probabilities.* An example of a probability-only approach is the risk-classification method already mentioned in Section 2. The method, which has been proposed by some toxicologists, in particular for dealing with food safety, consists in classifying risks into high, moderate, and low risk categories. For example, based on linear extrapolation from animal experiments, a risk higher than 1 in a 100 should be banned, a risk lower than 1 in 100 000 should be regarded as trivial (*de minimis* rule), while a risk between these two levels should be subject to some form of regulation.

47. This approach is problematic for two main reasons (Williamson, 1981):

- First, a classification based strictly on probabilities implicitly assumes that losses are constant both within and across risk categories. Since risk is defined as an expected loss, to omit the loss in the calculations is equivalent to assuming that it is constant for all items. If the loss is not constant, however, the method could lead to the banning of items that produce trivial losses and to the consumption of items that result in significant losses.

- A second problematic aspect of the method is that it ignores benefits. Again, ignoring benefits would be acceptable only if all benefits were identical, but this is certainly not true in general. Thus, a medical drug that has a high probability of producing severe side effects, but which is also life-saving, would presumably be considered by both patients and doctors to pose an acceptable risk (recall the case of the saccharin ban).

- A third aspect is that the risk-classification method tends to generate a false sense of security, and to favor a rigid bureaucratic approach to risk regulation. It is similar here to the use of safety factors

48. *The great advantage of the decision-theoretic approach consists in forcing the risk regulator to analyse all the relevant dimensions of the decision problem.* This holistic approach differs markedly from the ad hoc methods discussed above. It then shows how the different pieces can be put together in a consistent way. The method openly acknowledges that most risk assessments are subjective, but it also provides a way of consistently revising and updating such assessments in light of new information. The fact that the assessments are basically subjective, increases the importance of coherence – all parts of the decision-making process must fit together in a consistent and transparent manner.

49. However, the approach has been criticised for being normative rather than positive or descriptive. For instance, it is said that laboratory experiments, as well as casual observation, prove that people do not choose under uncertainty, nor update their beliefs, in the manner prescribed by the theory (see Section 10). However, this criticism overlooks the complex interdependence between normative and positive viewpoints in social life. Grammar, logic, arithmetic, and legal codes are all examples of normative systems that are often violated in practice, but are not discarded as a consequence – society could not function without them. What is true is that social practice, including policymaking, is guided by norms, which in turn develop under the influence of social practice. For example, normative principles of decision-making have been quite influential in directing the attention of American courts and policymakers to the importance of opportunity costs and the rational setting of regulatory priorities. In turn, this learning process has changed the practice of the regulatory agencies (see Section 8).

50. A very important function of normative models is to provide standards by which old practices and new proposals may be assessed. Thus, anybody familiar with the decision-theoretic approach will immediately see that the Precautionary Principle (PP), like the minimax decision rule, tends to focus the attention of regulators on some particular events and corresponding losses, rather than on the entire range of possibilities. As a consequence, regulators will base their determinations on worst cases, rather than on the weighted average (expected value) of all potential losses and benefits. To mention only one example taken from an official document, it has been argued that in examining the benefits and costs of different alternatives '[a] comparison must be made between the *most likely* positive and negative consequences of the envisaged actions and those of inaction ...' (Commission of the European Communities 2000: 19; emphasis added). In fact, we know that rational decision-making under uncertainty requires consideration of *all* consequences, not just the most (or, for that matter, least) likely ones.

51. In recent years the PP has been debated intensely, not only in Europe but also internationally. It has even been suggested that it should be granted the status of a key tenet of international economic law—even though the real meaning and implications of the PP are far from being clear. Hence it seems appropriate to devote two sections of the present report to a critical analysis of the principle.

6. The precautionary approach: an idea in search of a definition

52. This section will offer a critical attempt of the precautionary principle, as an ill defined principle, that may lead to attempts to control poorly understood, low-level risks, using up resources that in many cases could be directed more effectively towards the reduction of well-known, large-scale risks. Therefore, the use of the Precautionary Principle entails significant opportunity costs, which ought to be considered, as part of full impact assessment under uncertainty. A rational allocation of resources and consistency in policymaking requires identifying which risks to regulate, and when to regulate them. Precautionary measures—taken on an ad hoc basis, often in response to political pressures—tend to distort priorities and compromise the consistency of regulatory policies.

53. The precautionary principle is an idea (perhaps a state of mind) rather than a clearly defined concept, much less a decision rule or a guide to consistent policymaking. In fact, there are logical reasons for its intrinsic vagueness. Not surprisingly, an authoritative and generally accepted definition is nowhere to be found. The principle is of German origin (*Vorsorge Prinzip*) and has been used in that country since the 1980s in order to justify a number of important developments in environmental law. However, an eminent legal scholar has distinguished no fewer than 11 different meanings assigned to the PP within German policy discourse (Rehbinder 1991).

54. The German approach was taken up by other senior decision-makers in Europe, including the drafters of the European Community's Fourth Environmental Action Programme who thus sought to develop an approach to environmental policy that was preventive rather than reactive. In the Treaty establishing the European Community, (EC Treaty, 1997) the principle is mentioned only in the title on the environment: Article 174(2) provides that Community environmental policy "shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at the source and that the polluter should pay". No definition of the precautionary principle is offered in this article or anywhere else in the Treaty. In spite of this, some legal scholars argue that the principle applies beyond EC environmental policy. The reason given is that Article 6 EC provides that the environmental protection requirements be integrated into the definition and implementation of Community policies and activities referred to in Article 3 EC – in practice, all policies, activities and measures undertaken at EU level. Insofar as the PP is one of the core principles of EC environmental policy, it is concluded that it should be integrated, as appropriate, into other Community policies. European institutions have proceeded on this assumption.

55. The WTO Agreement on sanitary and phytosanitary measures has already been mentioned in Section 3. There is an indirect reference to a precautionary approach (again undefined) in Article 5(7) of this Agreement. WTO member states are allowed to take measures unsupported by a risk assessment when the relevant scientific evidence is insufficient, *but only provisionally*.

56. Perhaps the best known statement of the precautionary approach is provided by Principle 15 of the declaration of the 1992 UN Conference on Environment and Development (Rio Declaration):

> *In order to protect the environment, the precautionary approach shall be widely used by States according to their capabilities. Where there are threats of serious and irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.*

57. It should be noted that apparently similar statements of the principle may conceal quite different approaches. Even when such statements refer more or less explicitly to a situation where the probability and extent of damage are said to be poorly understood, and thus to justify precaution, they often differ in the conditions which precautionary measures should satisfy. Thus, according to the SPS Agreement, such

measures must be provisional, but some European governments chose to interpret this condition not in terms of clock time, but of the time necessary to achieve a sufficient level of scientific certainty—a very flexible standard, given the pervasive, and often irreducible, uncertainty of regulatory science!

58. The same governments claim to support Principle 15 of the Rio Declaration, even though the conditions envisaged by the declaration—a threat of serious and irreversible damage, measures must be cost-effective—are considerably stricter than the ones these same governments advocate. Even within the European Union interpretations of the principle vary considerably. Thus, a general inference from major decisions of the European Court of Justice (ECJ) appears to be that in cases of scientific uncertainty member states have considerable discretion in deciding to err on the side of caution. However, they must adduce evidence of specific, concrete risk and not merely of potential risks based on a general precautionary approach. In the well known *German Beer* case (Case 178/84 [1987]), for instance, the ECJ refused to allow a ban on additives in beer, based on a generic principle of precaution or prevention. The national authorities, the Court said, must come up with more scientific evidence than a mere reference to the potential risks posed by the ingestion of additives in general. On the other hand, according to the European Commission's *Communication on the Precautionary Principle* of the year 2000 a precautionary measure may be justified if there are reasonable grounds for concern that the potentially dangerous effects on human, animal, or plant health may be inconsistent with the chosen level of protection—a more flexible standard than the one used by the ECJ in *German Beer* and in other cases. In the famous dispute about hormones in beef, the EU found itself in the same position *vis-à-vis* the WTO bodies that various member states have found themselves in *vis-à-vis* the EU: the Union was sanctioned for introducing a public health and consumer protection measure which was not sufficiently supported by scientific evidence or risk analysis.

59. In sum, *the PP is invoked by the member states of the EU against the European institutions as a sword*; at the same time, these same institutions use the principle at the international level as a shield to justify measures that are viewed as thinly disguised forms of protectionism by the EU's trading partners (De Bùrca and Scott, 2000; Scott and Vos, 2002). This dual use of the PP—as a sword and as a shield—is made possible by the profound ambiguity of the principle. The consequences of this ambiguity are particularly serious if the precautionary approach—however defined – is considered, not as an exceptional measure, but as a guide in preparing proposals for legislation, or even as a "full-fledged and general principle of international law".

60. *The attempt to control poorly understood, low-level risks necessarily uses up resources that in many cases could be directed more effectively towards the reduction of well-known, large-scale risks.* Unfortunately, the opportunity costs of precautionary measures are seldom, if ever, considered. Hence one of the unanticipated consequences of the advocacy of the PP is to *raise the issue of a rational setting of regulatory priorities* (see also Section 8). Since resources are always limited it is impossible to control all actual and potential risks. Even if a society is willing to pay a higher cost to protect an interest, such as the environment or health, to which it attaches a priority, it is still the case that some environmental or risk regulations might be too expensive. Therefore, a rational decision needs to assess both the costs and the benefits of dealing with risks, as well as the need to prioritise public policy efforts.

61. More generally, the PP appears to be seriously flawed as an aid to rational decision-making under uncertainty. The critique of the minimax rule presented in Section 5, applies *a fortiori* to the PP, which does not even have the advantage of being a clear-cut decision rule. Like the minimax rule, the PP tends to focus the attention of regulators on some particular events and corresponding losses, rather than on the entire range of possibilities. As a consequence, regulators will base their determinations on worst cases, rather than on the weighted average of all potential losses and benefits. *The most basic conceptual flaw, however, is the artificial distinction between situations where the level of scientific information is sufficient to permit a formal risk assessment, and those where "scientific information is insufficient, inconclusive or*

uncertain". In reality, these are two points on a knowledge-ignorance continuum rather than two qualitatively distinct situations. The same logic which leads to the rejection of Knight's distinction between risk and uncertainty also applies here. As we repeatedly stressed, by its very nature regulatory science deals with uncertainties. Recall that for most toxic substances it is still unknown whether the relevant model for standard setting is a threshold or a linear one. Most scientists today favor the latter model, but this only complicates the regulator's problem since it is unclear where a standard should be set above the zero level. Moreover, the continuous progress of technology produces increasingly precise measurements of toxicity (*e.g*., parts per billion or even per trillion) so that the search for safety becomes ever more elusive.

62. In sum, regulatory problems are not solved but only complicated by appealing to different logics of decision-making, according to the available level of information. Especially in risk regulation, the normal state of affairs is neither scientific certainty nor complete ignorance. For this reason a sensible principle of decision-making is one that uses all the available information, weighted by its reliability in terms of subjective probabilities, instead of privileging some particular risk.

7. The precautionary principle: policy implications

63. The previous section identified and discussed some major conceptual flaws of the *precautionary principle.* This principle violates basic principles of the logic of decision-making under uncertainty; it disregards the opportunity cost of precautionary measures; it fails to take the potential benefits, as well as the potential losses, into consideration; not least, it greatly complicates the already difficult problem of setting rational regulatory priorities.

64. The current section (see also Box 4) will discuss the policy implications of the PP:

- Potentially negative consequences for scientific research and technological development, or for product innovation;
- Recurrent temptations to use the principle as a protectionist device;
- Perverse distributional consequences of some precautionary measures.

65. The discussion is complicated by the ambiguity and vague definition of the PP. The meanings attached to the PP, and *a fortiori* to a more generic precautionary approach, vary so widely—from the obvious to the obnoxious—that any critique is bound to be inappropriate for at least some of the possible variants of the concept. For this reason the following analysis will focus on official documents, specific decisions, and actual or proposed policies, rather than on general considerations.

Box 4. The policy principle through concrete examples

The Rio Declaration

Principle 15 of the above-mentioned Rio Declaration provides a good example of an unobjectionable, but also unhelpful, interpretation of the precautionary approach. It is certainly correct to say that "lack of full scientific certainty" should not be used as an excuse for regulatory inertia; but since risk regulators seldom, if ever, can rely on scientific certainty, the statement does not provide any useful guidance.

The EC Communication on the PP

Much more worrisome is the claim that the PP entails the principle of *reversal of the burden of proof*, according to which it is up to the developer of a new product or process to prove that the product or process poses no health or environmental risk. Thus, according to the European Commission's Communication on the PP: "Community rules ... enshrine the principle of prior approval (positive list) before the placing on the market of certain products, such as drugs, pesticides or food additives. This is one way of applying the precautionary principle ... In this case the legislator, by way of precaution, has clearly reversed the burden of proof by requiring that the substances be deemed hazardous until proven otherwise.' It is important to note that reliance on the principle of reversal of the burden of proof is not an exclusive feature of Community legislation.

It is difficult, if not actually impossible, to apply the PP in a consistent way as illustrated through the EU example. In conformity with the reversal-of-the-burden-of-proof interpretation of the principle, Article 3.1 of the 1997 EC ‘Novel Food’ Regulation (Regulation 258/97) states that genetically modified food can be authorised only if ‘it does not present a danger to the consumer’. Since no such proof is, strictly speaking, possible, acceptance of this interpretation is equivalent to advocating *a zero-risk approach* which would effectively stop scientific and technical innovation. But here the European policymakers are caught in a serious dilemma: on the one hand, they have officially espoused the PP, in the hope of enhancing their regulatory credibility and political legitimacy in the eyes of a sceptical public opinion; on the other hand, they want to increase the international competitiveness of Europe’s biotech industries. Biotechnology is one of the priorities of the EU’s sixth research framework program, and significant budgetary resources have been allocated to this area of research. The European Commission has sought a way out of the dilemma of precaution versus innovation by softening the rigorous standard of the Novel Food Regulation. A new regulation lowers the threshold by stating that genetically modified food may be authorised if it does not present an *unacceptable* risk for human health or the environment. Moreover, traces of unauthorised GMOs are now acceptable, under certain conditions, whereas previously they were not allowed to circulate in the market under any condition (Majone 2005).

The shift from “no risk” to “acceptable risk” represents a significant weakening of the precautionary philosophy in the direction of a more reasonable ‘balancing approach’ which takes the potential benefits, as well as the risks, of a new technology into account (see Section 8). In sum, the principle of reversal of the burden of proof, if consistently applied, would lead to a prohibition of potentially beneficial activities, including scientific research and technological innovation.

The case of the US Clean Air Act

The case of the US Clean Air Act Amendments provides further evidence of this danger. The US Clean Air Act distinguishes two types of outdoor pollutants: those for which there is clear evidence of harm, and everything else lumped under the label of hazardous air pollutants (HAP). Before 1990, HAP regulation was a two-step process (Goldstein and Carruth, 2003). First, the US Environmental Protection Agency (EPA) determined that a compound was likely to be hazardous at ambient levels. Once this determination was made and survived a rigorous hearing process, the second step was to choose which emission sources of this pollutant were to be regulated, using a variety of criteria which included risk reduction and abatement costs. Impatience with this careful process, which had succeeded in regulating only a handful of pollutants, led to the 1990 Amendments. Although these amendments of the Clean Air Act made no explicit reference to the PP, they are perfectly compatible with it. In essence, the new HAP provisions switched the burden of proof to industry. If before 1990 the EPA had to show that a compound required regulation, now it is up to industry to show that a compound on the list of some 185 compounds specified by Congress is harmless—a hopeless task. Moreover, Congress required that maximum available control technology (MACT) be installed on all sources, regardless of toxicity. At the same time risk assessment, which used to play a primary role under the old procedure, has been significantly downgraded since 1990. One casualty of the new approach has been research into the health effects of HAPs. EPA’s budget for such studies has decreased, while industry has no incentive to invest resources in the impossible task of proving that a chemical is harmless. As a consequence, some *American experts warn that the precautionary approach enshrined in the HAPs amendments may induce a shift from compounds for which there is ample evidence of apparent lack of toxicity at ambient levels, to compounds for which there is little toxicological information and thus a greater likelihood of unwanted health or environmental consequences* (Goldstein and Carruth, 2003; Goldstein, 2004).

The controversy over the use of growth hormones in cattle raising

Equally serious are the potential consequences of relying on the PP, rather than on methodologically defensible risk assessments, in international economic relations. The standard example here is the controversy over the use of growth hormones in cattle raising, which for years has opposed the European Union to some of its major trading partners. In 1997 the US and Canada filed complaints with the WTO against the European ban of meat products containing growth hormones, submitting that this measure violates the Sanitary and Phytosanitary (SPS) Agreement. As we saw, this Agreement allows WTO members to adopt health standards that are stricter than international standards, provided the stricter standards are supported by risk assessment. Unfortunately, the risk assessment conducted by the Community’s scientific experts had not established any significant health risk the (Majone, 2005: 126-128). Hence the Commission was forced to meet the WTO challenge with various *ad hoc* arguments. In particular, it pointed to various incidents since the early 1980s, when hormones that entered the European food market had allegedly made European consumers wary of beef. The Commission concluded that a ban of beef containing growth hormones, even if it did not pose a demonstrable health risk, was necessary to restore consumer confidence.

The WTO's Dispute Resolution Panel did not accept this argument, and decided against the EC. The Panel raised three objections: first, more permissive international standards existed for five of the hormones; second, the EC measure was not based on a risk assessment, as required by Article 5(1) of the SPS Agreement; finally, the EC policy was not consistent, hence in violation of the no-discrimination requirement of Article 5(5). The Appellate Body agreed with the panel that the EC had failed to base its measure on a risk assessment and decided against the EC essentially for two reasons: because the scientific evidence of harm produced by the Commission was not 'sufficiently specific to the case at hand'; and, second, because 'theoretical uncertainty' arising because 'science can never provide absolute certainty that a given substance will never have adverse health effects' is not the kind of risk to be assessed under Article 5(1) of the SPS Agreement. A key finding that persuaded the Appellate Body was that the carcinogenic risk from banned hormone-treated beef was no greater than the carcinogenic risk from anti-biotic treated pork, grown in Europe, which was not banned. This finding seemed to support the contention of the United States and Canada that the EC ban was in fact a disguised restriction on trade aimed at reducing beef surpluses in the EC member states.

One of the objectives of the Commission *Communication on the Precautionary Principle* of 2 February 2000 was to *respond to the objections raised by the WTO bodies*, and to the accusations of its trading partners. Hence *the exhortations—presumably directed to the member states – to "avoid unwarranted recourse to the precautionary principle as a disguised form of protection" (p.3); the insistence that "the precautionary principle can under no circumstances be used to justify the adoption of arbitrary decisions" (p.13); the warning that "reliance on the precautionary principle is no excuse for derogating from the general principles of risk management" (p.18).* This document also insists that the envisioned use of the PP "far from being a way of evading obligations arising from the WTO Agreements" in fact complies with these obligations. Unfortunately, this is not the opinion still prevailing in the WTO.

It has already been noted that under the WTO SPS Agreement, if a health measure has a scientific basis, there is little other countries can do to challenge this. The Beef Hormones case proves this *a contrario,* and also confirms what was already pointed out in Section 3, namely that the approach of the WTO dispute resolution bodies to questions of scientific uncertainty is procedural or methodological—requiring a risk assessment meeting internationally recognised scientific standards – rather than substantive.

The case of Asbestos

The *Asbestos Case*, in which the dispute-resolution bodies of WTO upheld the position of France and the European Community, proves that a ban supported by a competent risk assessment will be upheld, not only under the SPS Agreement, but even under the old GATT rules. In 1996 France adopted a decree banning, with few exceptions, the importation of asbestos and asbestos-containing products, for the stated purpose of halting the spread of asbestos-related death and disease. As an exporter of chrysotile asbestos Canada challenged the French ban, invoking, *inter alia*, Article III(4) of the General Agreement on Tariffs and Trade (GATT, the precursor of WTO) which prohibits discrimination against "like products" of another GATT member. Canada argued that chrysotile asbestos and cellulose and other substitute fibers (which were not banned) constitute "like products" within the meaning of Article III(4). Therefore banning one and not the others was a violation of the anti-discrimination rule. In defense of the French position, the European Community responded that the ban was not discriminatory because, due to the significant difference in health risk, chrysotile asbestos and the substitute fibers were not really "like products". At any rate, even if the French ban violated the anti-discrimination rule, it was still permissible under Article XX(b) of the GATT, which allows derogations from GATT obligations where "necessary to protect human...life or health". According to the EC experts, the scientific literature establishing the adverse health effects of asbestos was applicable to chrysotile asbestos; in fact, chrysotile asbestos was a known carcinogen. To Canada's argument that there is no detectable risk from modern chrysotile cement products since the fibers are bound in a compact matrix, the EC replied that cement-bound products often had to be cut during construction or repair, thus freeing fibers and creating inhalation exposures.

In reaching its decision the WTO *Asbestos* Panel made clear that in situations where scientists disagree, it is not the Panel's role to decide which among competing scientific views is the correct one. Rather, its task is to determine whether there is sufficient analysis and scientific evidence to justify a reasonable public health official in adopting a particular measure for the protection of public health (Carruth and Goldstein 2004). After reviewing the scientific data presented by the parties and the input from its appointed experts, the Panel found that there was sufficient evidence that chrysotile asbestos is a carcinogen that causes both mesothelioma and lung cancer. Moreover, there is no known threshold below which chrysotile has been shown not to be carcinogenic, and in the absence of data the appropriate approach to extrapolating risk from high doses is a linear, no-threshold dose-response curve (see Section 1 above). The panel was also convinced by the argument of the EC experts that there is inhalation exposure to chrysotile asbestos fibers even with modern cement-bound products, because those products often have to be cut during construction, or for maintenance, repairs, or remodelling. The Panel concluded that the French ban qualified for the exception under Article XX(b) as legitimate health measure. Comparing the beef hormones and the asbestos cases, the crucial difference was the procedural requirement of a risk analysis meeting international standards of quality.

The case of the Aflatoxines and distributional consequences

Finally, let us consider some of the distributional implications which a systematic use of the PP may entail; specifically, the impact of precautionary health standards on the welfare of developing countries. The European Commission's Communication on the PP maintains that in considering the positive and negative consequences of alternative risk strategies, one should take into consideration '*the overall cost to the Community*, both in the long- and short-term' (Commission 2000: 19; emphasis added). Such strict focus on Community's interest could perhaps be justified if the cost of precautionary measures was felt only by exporters in rich countries, but what if the cost is borne by very poor countries? World Bank economists have estimated the impact on some of the poorest African countries of precautionary standards for aflatoxins proposed by the European Commission in 1997. Aflatoxins are a group of related toxic compounds that contaminate certain foods and have been associated with acute liver cancer in humans. Aflatoxin B_1 – the most common and toxic of these compounds – is generally present in corn and corn products, and various types of nuts. The proposed Community standards were significantly more stringent than those adopted by the US, Canada, and Australia, and also stricter than the international standards established by the FAO/WHO Codex Alimentarius Commission. Brazil, Bolivia, India, Mexico, Uruguay, Australia, Argentina, Pakistan, and other countries, in opposing the proposed measures, demanded to know in detail which risk assessments the EC had used in setting the new standards. As a consequence of consultations with the trading partners about these concerns, the Commission relaxed the standard for cereals, dried foods, and nuts. Even after this relaxation, however, aflatoxin standards for products intended for direct human consumption remain quite stringent: 4 parts per billion (ppb), and 2 ppb for B_1 aflatoxin, against an overall Codex standard of approximately 9 ppb.

Using trade and regulatory survey data for the member states of the EU and nine African countries between 1989 and 1998, the World Bank economists estimated that the new standards would decrease African exports of cereals, dried fruits, and nuts to the EU by 64 percent, relative to regulation set at the international standards (Otsuki *et al.* 2000). The total loss of export revenue for the nine African countries amounted to US$ 400 million under EC standards, compared to a gain of US$ 670 million if standards were adopted according to Codex guidelines. Were these costs, imposed on some of the poorest countries in the world, justified by the health benefits to Europeans? According to studies conducted by the Joint Expert Committee on Food Additives of the Food and Agriculture Organisation and World Health Organisation, the Community standard of 2 ppb for B_1 aflatoxin would reduce deaths from liver cancer by 1.4 deaths per billion, *i.e. by less than one death per year in the EU.* For the purpose of this calculation the Community standard was again compared to a standard that follows the international (Codex) guideline of 9 ppb. *Since about 33 000 people die from liver cancer every year in the EU, one can see that the health gain promised by the precautionary standard was indeed minuscule, certainly out of proportion to the cost imposed on the countries of Sub-Saharan Africa.*

66. These examples complete our analysis of the precautionary principle. The overall assessment is negative. The PP is too ill-defined to serve as a general principle of international economic law, as some had hoped, while any known attempt to give it a precise meaning turns out to be either logically flawed or trite. This lack of a reasonably precise definition invites abuses, and breeds policy incoherence. Even the apparently innocuous statement that lack of scientific certainty does not justify regulatory inertia, reveals a poor understanding of the nature of science in general, and of regulatory science in particular. If science grows through a series of conjectures and refutations, to use Karl Popper's well-known characterisation, then it follows that scientific certainty can never be reached. What is objective in science is the process (the method) rather than the output—the knowledge, which is always conjectural and hence ultimately probabilistic. This is the reason why learning is so important, in science but also in the analysis and management of risk.

8. The lessons for risk analysis and management

67. This section will discuss the lessons the area of risk regulation and management, in a broader, but less rigorous, sense than that of formal decision theory. One of the key elements of the present report is that the theory of decision-making under uncertainty, as sketched in Section 5 and in the Appendix, provides the appropriate conceptual framework for thinking about uncertain events and their consequences, and thus also for thinking about risk. One limitation of this theory, however, is that it has been developed for structuring the choice problems of an individual decision-maker – it does not provide unambiguous advice for group decisions when the members of the group, *e.g.*, different stakeholders, have different attitudes toward risk. But even in this situation the methodology can help, without providing formal solutions.

68. As already noted, the process of breaking down the decision problem into its main components—feasible alternatives, uncertain events, consequences, numerical measures of probabilities and utilities/losses—helps to identify the actual sources of disagreement, and thus facilitates interpersonal communication and the emergence of a common position.

69. Moreover, the theory shows how to assess the value of additional information, and how the new information is to be processed in order to update probabilities in a consistent manner. This means that the pooling of information available to the different stakeholders may serve as a device for bringing their probability assessments into reasonable agreement. Even more is true: it has been shown (*Blackwell-Dubins Theorem*) that with increasing information the probability assessments of different individuals tend to converge, provided the initial assessments are not directly opposite ("mutually orthogonal").

70. However, the fundamental conclusion of the discussion in Section 5 – that *ideas should not be considered in isolation, but should be related to other relevant ideas to see how they fit together in a coherent manner*—must always be kept in mind, for the broad analysis of risk regulation. To a large extent, improving the practice of risk management depends on learning this lesson.

The trends towards greater consistency in decision making in the United States

71. This will be illustrated by the slow but steady improvement in the conceptual foundations of risk regulation in the United States. It is convenient to trace this development through a sequence of four regulatory principles: prohibitions; lowest feasible risk; elimination of significant risk; balancing the costs and benefits of risk reduction. Regulatory practice in the US has not moved along this sequence in a continuous, linear fashion. For example, in the previous Section 7 we saw how the 1990 Amendments of the Clean Air Act introduced a principle of reversal of the burden of proof which, from our perspective, represents a regressive move. In spite of this and other lapses, however, a trend is clearly discernible in the direction of a broader inclusion of relevant factors, and of greater consistency in putting together the various elements of the regulatory problem in a consistent regulatory management system.

Prohibitions

72. Bans represent one of the earliest and least sophisticated approaches to risk regulation. To say this is not to deny that in some cases an outright ban may be the most appropriate regulatory response. For example, the ban on the use of freon in refrigeration was a cost-effective way of reducing chlorofluorocarbon emissions. Generally speaking, however, the appropriateness of such radical measures has to be proved rather than simply assumed. One of the best-known illustrations of the problems raised by an apparently clear-cut prohibition is provided by the already mentioned Delaney clause (see Box 1). For nearly twenty years this clause had little influence on FDA's actions, since only very few additives had been shown to cause cancer in animal experiments. On March 9, 1977, however, the FDA announced its

intention to ban the use of saccharin because of a recent Canadian study showing that this artificial sweetener (in doses equivalent to 800 cans of diet soft drinks a day!) induced cancer in test animals. At the time no other non-nutritive sweetener was approved for use in the United States. Hence the FDA announcement threatened the marketing of all artificially sweetened foods and beverages and, consequently, precipitated intensive public controversy, see the introductory section.

73. Responding to these concerns, Congress, through the Department of Health and Human Services, commissioned two studies by the National Academy of Sciences, one to assess the scientific evidence concerning saccharin's safety; the other to evaluate the law's current food safety standards and suggest alternative approaches. The Academy's assessment of the scientific evidence confirmed that saccharin was a carcinogen in laboratory animals, although a weak one. It found no reliable evidence that saccharin caused cancer in humans, but it stressed that epidemiological methods were not capable of detecting increases in the incidence of bladder cancer of the magnitude the animal data suggested saccharin could cause. The second Academy study found that the standards for regulating food additives were inadequate. One proposal was to amend the law to allow FDA to rank additives in three risk categories: those so serious as to merit prohibition; those so trivial as to warrant no regulatory action; and those whose acceptability should depend on an assessment of benefits and on the availability of alternatives (see Section 5). The proposals did not lead to any radical amendment of the legislation, but the FDA found other means to avoid a ban if a food additive presented only slight risks, or offered substantial benefits.

74. In retrospect, we can see that the drafters of the Delaney clause believed that only a few additives caused cancer, but that they were extremely dangerous. By the 1980s it was clear that many substances are carcinogenic, but many of them create exceptionally minor risks. The new information severely undermined the assumptions of the clause, suggesting that it may well cause more deaths than it prevents. This is because vastly improved detection techniques prevent basically safe, but weakly carcinogenic, substances from coming on the market, whereas cruder and older technology used to test previously authorised substances allowed them to be approved. The result is less rather than more safety (Sunstein, 1990).

Least feasible risk

75. According to this principle, human exposure to health risks should be reduced to the lowest possible level. This is a sort of second-best rule. The first-best regulatory policy would be one that ensures a risk-free working and living environment, but because of technical and economic constraints a risk-free environment is unattainable; hence the need of a second-best rule. Thus, Section 6(b)(5) of the 1970 US Occupational Safety and Health Act directs the Occupational Safety and Health Administration (OSHA), in regulating worker exposure to toxic substances, to set standards that "most adequately assure, *to the extent feasible*,…that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard…for the period of his working life" (emphasis added). Trade union representatives claimed that this instruction obliged OSHA to mandate the use of whatever available technology an industry could afford without bankrupting itself. Justice Brennan of the U.S. Supreme Court expressed a similar view: "Congress itself defined the basic relationship between costs and benefits, by placing the "benefits" of worker health above all other considerations save those making attainment of the "benefit" unachievable" (cited in Graham *et al.*,1988: 97). The meaning of "feasibility" is crucial in the present context. A body of analysis and case law has thus emerged to clarify this term.

76. According to some court decisions, a standard may be considered technologically feasible even if no existing devices would allow industry to comply with the standard, as long as there is evidence that companies "acting vigorously and in good faith", can develop the technology. This "technology forcing" approach implies that regulatory agencies are not limited to set standards based on existing devices, but may require improvements in existing technology, or even the development of new technology. This may

be quite expensive, so the issue of technical feasibility is inseparable from the issue of economic feasibility. It is clear that risk managers estimate the costs of proposed standards, but it is less clear which criteria they use to judge whether a given standard is "affordable". At least as far as the Occupational Safety and Health Act is concerned, American courts have ruled that an expensive standard is not necessarily economically infeasible. Although some firms may find safety standards particularly expensive or even financially prohibitive, courts have not excused individual firms from such standards. As one court put it in a 1978 case: "It would appear to be consistent with the purposes of the [OSH] Act to envisage the economic demise of an employer who has lagged behind the industry in protecting the health and safety of employees and is consequentially financially unable to comply with new standards as quickly as other employers" (cited in Graham *et al*., 1988: 99). Thus, economic feasibility has been interpreted quite strictly: a standard is to be considered "infeasible" only if it would cripple or bankrupt an entire industry, rather than some technologically backward firms.

77. It is clear that the least-feasible-risk approach is far from any sort of balancing of marginal costs and benefits. In fact, marginal considerations are rejected on the ground that the two sides of the basic relationship are incommensurable. As the above-mentioned opinion of Justice Brennan makes clear, health benefits have to be considered "above all other considerations". Even if one accepts this value judgment, however, serious conceptual problems remain. First, the approach fails to consider possible alternatives to standards, such as information disclosure or greater reliance on liability rules. It also omits any consideration of probabilities of possible events, so that standards are set without any knowledge of the expected number of deaths or accidents prevented. Second, setting standards strictly is a significant cause of the slow pace of the standard-setting process. This means that relatively few standards can be set, so that many hazards remain unregulated; hence, *over-regulation leads to under-regulation* (Mendeloff, 1988). Third, the emphasis on industry viability means that very dangerous occupations in marginally profitable industries may be unregulated, while other jobs may be made so safe at such high cost that employment levels and wages shrink—another way in which over-regulation may lead to under-regulation. Finally by ignoring one of the key lessons of economics and policy analysis—that decisions should be based on marginal costs and benefits—the approach wastes resources that could have been used to control more risks.

The significant-risk doctrine

78. In *American Petroleum Institute v. OSHA* (1978), the Fifth Circuit Court of Appeals invalidated a regulation which reduced the occupational exposure to benzene, a carcinogen, from 10 ppm to 1 ppm. The court found that the competent regulatory agency, the Occupational Safety and Health Administration (OSHA), had not shown that the new exposure limit was 'reasonably necessary and appropriate to provide safe or healthful employment' as required by the relevant statute. Specifically, the court argued that OSHA had failed to provide substantial evidence that the benefits to be achieved by the stricter standard bore a reasonable relationship to the costs it imposed. The court added: 'This does not mean that OSHA must wait until deaths occur as a result of exposure levels below 10 ppm before it may validly promulgate a standard reducing the permissible exposure limit. Nevertheless, OSHA must have some factual basis for an estimate of expected benefits before it can determine that a one-half billion dollar standard is reasonably necessary' (cited in Mendeloff, 1988: 116-17).

79. What the court required was some sort of quantification of benefits as a necessary step to carry out a benefit-cost test of the new standard. Without a quantification of risk, and hence of the expected number of lives saved by the regulation, it is clearly impossible to weigh the benefits against the costs. OSHA, unlike other American agencies involved in risk regulation, had always maintained that quantitative risk analysis is meaningless. Hence, the agency's leaders decided to appeal the Fifth Circuit Court's decision. In *Industrial Union Department (AFL-CIO) v. American Petroleum Institute* (1980), the US Supreme Court upheld the Fifth Circuit's decision. Justice Powell noted that 'a standard-setting process

that ignored economic considerations would result in a serious misallocation of resources and a lower effective level of safety than could be achieved under standards set with reference to the comparative benefits available at a lower cost' (cited in Mashaw *et al.*, 1998: 815). Expressing the view of a four-judge plurality (in a separate opinion, Justice Rehnquist provided the fifth vote for overturning the standard) Justice Stevens explicitly rejected the precautionary, lowest-feasible-risk approach followed by the agency: 'We think it is clear that the statute was not designed to require employers to provide absolute risk-free workplaces whenever it is technologically feasible to do so, so long as the cost is not great enough to destroy an entire industry. Rather, both the language and structure of the Act, as well as its legislative history, indicate that it was intended to require the elimination, as far as feasible, of *significant* risks of harm' (cited in Graham *et al.* 1988: 100; emphasis added).

80. Thus was born the significant-risk doctrine, a crucial step in the process of learning how to deal with societal risks in a rational manner. Justice Stevens insisted that 'safe' is not the same as risk-free, pointing to a variety of risks in daily life – ranging from driving a car to 'breathing city air' – that people find acceptable. Hence, before taking any decision, the relevant risk must be quantified sufficiently to enable the agency to characterise it as significant 'in an understandable way'. In fact, OSHA was not required to support its finding that a significant risk exists with anything approaching "scientific certainty". So long as the determination is supported by a body of reputable scientific thought (again, a procedural standard!), the agency is free to use conservative assumptions in interpreting the data, risking error on the side of over-protection. From the government's generic carcinogen policy the agency had concluded that in the absence of definitive proof of a safe level, it must be assumed that *any* level above zero presents *some* increased risk of cancer. But, as the justices pointed out: 'In view of the fact that there are literally thousands of substances used in the workplace that have been identified as carcinogens or suspect carcinogens, the Government's theory would give OSHA power to impose enormous costs that might produce little, if any, discernible benefit' (cited in Mashaw *et. al.*, 1998: 813). The great merit of the significant-risk doctrine is to have raised the crucial issue of regulatory priorities. Most risks are regulated in response to petitions or pressures from labor unions, public-health groups, environmentalists, and other political activists, with little analysis by the agency of other possible regulatory targets. Given that resources are always limited, the real (opportunity) cost of a regulation is the number of lives that could be saved by using the same resources to control other, more significant, risks. By requiring the agency to show significant risk as a prelude to standard setting, the justices were insisting on some analysis in priority setting: regulatory priorities should be directed toward the most important risks – which are not necessarily those that are politically most salient.

81. The significant-risk doctrine places a higher analytical burden on regulators than the lowest-feasible-risk approach, or the precautionary principle. Not all potential risks are treated equally; only those substances shown to pose a significant risk of cancer will be regulated, focusing limited regulatory resources on the most important health risks. In addition, the doctrine, without requiring a formal analysis of benefits and costs, does place a constraint on the stringency of standards. If exposure to a carcinogen is reduced to the point that the residual risk is insignificant, then no further tightening of the standard is appropriate. *Industrial Union Department (AFL-CIO) v. American Petroleum Institute* is a landmark case also from the point of view of the methodology of risk analysis. The US Supreme Court not only confirmed the legitimacy of quantitative risk assessment; it effectively made reliance on the methodology obligatory for all American agencies engaged in risk regulation. In most subsequent disputes over regulatory decisions to protect human health, the question has not been whether a risk assessment was required but whether the assessment offered by the agency was plausible. This historical background probably explains American advocacy of science-based risk assessment at the international level, as well as that country's opposition to the precautionary principle advocated by the EU. Today, risk assessment is also the standard by which trade-restricting risk regulations are evaluated as necessary and compatible with the rule of the WTO, see Sections 3 and 7.

Balancing costs and benefits

82. Until the 1970s judicial review was the only effective control on the quality of the decision-making process of US regulatory agencies. Congress can, of course, pass legislation requiring that an agency take a particular type of action. However, congressional oversight is output- rather than process-oriented. At any rate, in the US as in all other OECD countries, routine regulatory measures seldom receive legislative scrutiny. What is most important, there is no need for congressional approval for a regulatory agency to take action, provided that it can survive judicial review. By contrast, the courts have been important agents of policy learning, as we just saw in the *Benzene* case. Nevertheless, judicial oversight, too, suffers from serious shortcomings. First, it is only exercised *ex post* – though it should be noted that a judicial doctrine like the significant-risk doctrine, will influence a stream of future agency decisions. Also, the principle of separation of powers prevents any sustained interaction between courts and agencies before proceedings are formally initiated. Again, there is a serious mismatch between the leisurely time of judicial decision-making and the hectic pace of agency rule-making, while heavy reliance on judicial review creates, according to some observers, an adversarial atmosphere which does not always facilitate the achievement of regulatory objectives.

83. From the point of view of policy learning, the most serious limitation of judicial review, however, is the unpredictability of court decisions. In the *Benzene* case, for example, the Supreme Court criticised the logic of the least-feasible-risk decision rule, and effectively mandated the use of quantitative risk assessment, while taking no position on the issue whether an agency should undertake a formal cost-benefit analysis (CBA) to justify its decisions. More precisely, the question that was not answered in this case was: is the use of CBA by OSHA required, permitted, or outlawed? At any rate, Justice Stevens' opinion, strongly suggests that the plurality shared the belief that the benzene standard imposed high costs with limited benefits. But only a year later the Court—in the *Cotton-Dust* case (*American Textile Mfrs. v. Donovan,* 1981) – held explicitly that OSHA standards need not show a positive cost-benefit ratio; they must only be shown to be technologically achievable and "affordable". Clearly, unpredictable court decisions do not help systematic policy learning. The decision on the cotton-dust standard seemed to interrupt an ongoing learning process, and for this reason it has been severely criticised by students of the regulatory process. No judicial decision, however, could conceal the growing economic impact of risk regulation.

84. With the great expansion of environmental, health, and risk regulation in the 1970s, the need to calculate more precisely the benefits and costs of the proliferating regulations became increasingly evident. Important steps to improve the quality of federal regulation were taken under President Carter, when the notion of a 'regulatory budget' – the attempt to assess an acceptable level of regulatory costs for the entire economy – was first introduced. The oversight mechanism was perfected in the late 1980s, during the second term of the Reagan administration. The Office of Management and Budget (OMB), in the president's executive office, was given responsibility for setting the budgets of all regulatory agencies, and for monitoring the rulemaking process. Instead of simply imposing a cost-effectiveness requirement, as previous presidents had done, Reagan moved to a full-fledged cost-benefit test with his Executive Order No. 12291 of 1981:

- Regulatory action is not to be undertaken unless the potential benefits to society outweigh the potential costs;

- Among alternative approaches to any given regulatory objective, the alternative involving the least net cost to society has to be chosen;

- Finally, agencies are required to set regulatory priorities with the aim of maximising the aggregate net benefits, taking into account the condition of the particular industries affected by regulations, the condition of the national economy, and other regulatory measures contemplated for the future.

85. As a result of this and subsequent reforms, the quality of rulemaking has improved significantly over the last two decades. The usefulness of the regulatory oversight process designed by the Reagan administration explains why subsequent administrations, democratic as well as republican, have continued to use it in a form that has not substantially changed from the original model. In the meantime also Congress was undergoing a learning process, resulting in a better appreciation of the opportunity costs of risk regulation. In 1995, new regulatory legislation was passed, whose net effect was to strengthen the test that must be passed by new regulations. The key congressional concerns were that regulations be based on an accurate and comprehensive assessment of the risks involved, rather than on worst-case scenarios, and that regulatory agencies proceed with regulations only if the benefits exceed the costs (Viscusi *et al*., 1995).

86. This brief survey of policy and institutional developments in the United States reveals a steady improvement in the understanding of the various dimensions of risk regulation—scientific, economic, legal, and political—and of the methodologies for fitting together these partial analyses in a coherent manner. The progress from the early reliance on outright bans or simple "feasibility" tests to the applications of key principles of decision theory not only to agency rule-making but also to the enabling legislation, is an outstanding, and in many respects unique, example of policy learning. This was also linked to the development of a proper regulatory impact analysis management system.

87. Compared to these developments, risk regulation in many other OECD countries, is still at a rather early stage. Indeed, some recent episodes, such as the strenuous advocacy of the precautionary principle, suggest an unwillingness to learn from international experience. As illustrated above, policy learning in the United States has been greatly facilitated by the interaction among different, partly cooperating, partly competing institutions. A more detailed study would have revealed also the importance of a style of policy discourse that puts a high premium on reliable quantitative information and on analytic sophistication.

9. Institutional Implications: avoiding separating risk assessment and risk management

88. This section of the report will show that, while a conceptual distinction can be made in risk regulation between risk assessment and risk regulation, the analytical distinction should not imply the need for an institutional separation.

89. *Risk assessment* is the process used to describe and estimate the likelihood of adverse health or environmental effects. *Risk management* is the process of analysing, selecting implementing and evaluating actions to reduce risk—has become standard in discussions of risk regulation. The distinction is clear, and useful for some purposes. Thus, the four main steps of risk assessment—*hazard identification*, *dose-response assessment*, *exposure assessment*, and *risk characterisation*—involve processes that are conceptually distinct from those used in risk management.

90. The error is to derive from such analytic distinctions the need or at least the usefulness of an *institutional separation* of risk management from risk assessment. Such institutional separation has been tried in several countries, usually with disappointing results. For example, the 1970 U.S. Occupational Safety and Health Act created the National Institute for Occupational Safety and Health (NIOSH), directing it to perform research and risk assessments for the newly established regulatory agency, the Occupational Safety and Health Administration (OSHA). While NIOSH is an independent agency within

the Department of Health and Human Services, OSHA has been placed within the Department of Labor—an institutional design largely dictated by political reasons. This organisational separation, however, yielded functional separation to only a limited extent. On the one hand, NIOSH's "criteria documents" not only provided risk assessments, but also recommended occupational standards. On the other, OSHA tended to take on more of the risk assessment function itself. NIOSH continued to assist OSHA in the preparation of risk assessments, but gradually OSHA asserted control over the entire standard-setting process. As the author of a detailed case study concludes: "despite its separation from OSHA, or indeed perhaps because of it, NIOSH's criteria documents were often found to be deficient as bases for issuing standards. OSHA regulators found them to be little beyond compendium summaries of the literature, with little effort to evaluate the quality of relevant studies or to resolve scientific disputes. The lesson appears to be that such complete organisational separation of functions is counterproductive" (Greenwood, 1984: 118).

91. Complete organisational separation of risk assessment and risk management has been tried also in other jurisdictions, notably in the European Union. Thus, in the case of the European Food Safety Authority (EFSA) – established in 2002 and based in Parma, Italy – the tension between the desire to improve the credibility of EU regulation by appealing to independent scientific expertise, and the European Commission's refusal to delegate rulemaking powers to the agency, has been temporarily resolved by the expedient of separating institutionally risk assessment (the task assigned to the Authority) and risk management (which remains the responsibility of the Commission). There are already some indications that also in this case the organisational and geographical separation of risk analysis and risk management is complicating rather than facilitating the overall regulatory task.

92. The institutional separation of risk assessment and risk management is counterproductive because while the two functions are conceptually distinct, they are closely intertwined in practice. Thus, the setting of rational regulatory priorities entails scientific, economic, and political judgements that are not easily separable. Again, under conditions of scientific uncertainty the determinations of the risk analysts can effectively pre-empt the decisions of the risk managers. It is often impossible to know whether a dose-response function follows a linear or a non-linear (threshold) model, yet the analysts' choice of one or the other model is crucially important for the determination of the acceptable level of safety. Also the ubiquitous use of "safety factors" (see Section 1) blurs the distinction between the assessment and the management aspects of risk regulation. Even though it is easy to prove that such factors lack a logically defensible basis, both risk analysts and risk managers will continue to use them, at least in the foreseeable future, because they seem to provide some protection against "Type II" errors—accepting the hypothesis that a product or process is safe when it is not. In this connection it is useful to recall an observation made earlier (see Section 4) to the effect that a more sophisticated method of evaluating decision-makers—a method which in addition to results also includes the quality of the decision process – can reduce the cost of failure by distinguishing between foresight and outcomes due to chance. It follows that risk regulators would have less incentives to take refuge in safety factors and other *ad hoc* methods of dealing with uncertainty if they knew that their determinations are evaluated according to standards capable of distinguishing between procedural and substantive rationality.

93. In sum, if risk assessment and risk management are not separable in practice, if all risk determinations necessarily include a host of subjective judgments, then it follows that accountability and efficiency are best achieved when *somebody—typically the head of an expert agency – takes responsibility for the entire process. Regulatory mistakes are always possible, and in such cases it is important for the credibility of the risk regulators that the lines of accountability be unambiguously defined. The institutional, as distinct from the mere functional, separation of risk analysis and risk management certainly does not help in this respect.*

10. Differences in risk perceptions and in regulatory regimes

94. The issue of the appropriate standards of accountability is related to another problem facing risk regulators in all countries. The problem is the huge gap which often separates the public's risk perceptions from the assessments of the experts. Studies by Paul Slovic, Baruch Fischoff and other cognitive psychologists have demonstrated that there is a tendency to overestimate events associated with lower-probability events such as botulism and floods, and to underestimate the risks associated with higher-probability events, such as the risk of being killed in a car accident, or risks of cancer, heart disease and stroke. Also risks associated with toxic waste dumps and nuclear power appear near the bottom of most experts' lists, while in many countries they appear near the top of the public's list of concerns.

95. Notoriously, risk perceptions can vary greatly even among neighbouring countries: cyclamates are permitted and saccharin is banned in Canada, while cyclamates are banned and saccharin was effectively permitted in the USA until acceptable substitutes were available. During the BSE ("mad cow" disease) crisis the European Union imposed a ban on exports of beef from the United Kingdom, while the product was permitted for sale within the UK. Other well-known examples of international differences in risk regulation regimes have been mentioned in preceding sections: the EU's precautionary ban on imports of milk and beef containing growth hormones—products that are consumed daily by millions of Americans and Canadians; and the ban by France and other EU countries on the importation of chrysotile asbestos from Canada—which most experts believe to be virtually harmless if left in place. At least, in cases directly affecting international trade, the differences are openly debated in the WTO, in international standards organisations, and in other international fora; and it often happens that within particular risk domains, such as chemicals and air and sea transport, there is a strong international exchange of knowledge and views.

96. Paradoxically, there seems to be very little cross-domain exchange within countries. The result, it has been observed, "is a policy and intellectual "archipelago" of risk domains isolated from one another, with very different policy stances across the various domains. For some hazards, governments adopt heavy-duty, anticipative, and intrusive regulatory arrangements...For other hazards, such as smoking, much lighter and more reactive approaches are adopted" (Hood *et al.* 2001: 6-7). Such within-country differences in regulatory regimes are due to a variety of historical, cultural, and institutional factors: among others, differences in regulatory philosophies, in standard-setting practices, or in organisational setups – as when one agency monopolises an entire risk domain, while in others the domain is divided up among a multiplicity of public and private players.

The risk from overestimation of low-probability events: distorting the public policy agenda and the public policy responses

97. Now, these conflicts in risk perceptions and in regulatory regimes raise some of the most intractable problems of risk regulation. In particular, the overestimation of low-probability events has substantial implications for public policy. Scientific uncertainties and worst-case scenarios produce public pressure which, in turn, may encourage legislators to closely supervise agencies by encouraging strong action in respect to those substances or activities that catch the public eye.

98. The result is random agenda setting. An important policy question, therefore, is how governments should respond, if at all, to public (mis)perceptions of risk. According to many advocates of the precautionary principle, and many of those who would like to see democracy at work at all levels and in all areas of policymaking, public perceptions of risk should be considered together with "harder" scientific and economic data.

99. On the other hand, Justice Stephen Breyer of the United States Supreme Court has argued that not every risk-related matter "need become a public issue. A depoliticised regulatory process might produce better results, hence increased confidence, leading to more favorable public and Congressional reactions" (Breyer, 1993: 55-6). Even assuming that public perceptions should be taken into account by risk managers, the crucial, but unanswered, question is which weight should be attached to such social data relative to scientific, technical, and economic data. Some fundamentalists go as far as suggesting that regulatory priorities should follow public perceptions of risk. But there seems to be an odd asymmetry in such an extreme position. If the general public underestimates a certain risk, one presumably would not expect the government to remain idle and let citizens incur risk unknowingly. But if other risks are overestimated, why should the government be guided or influenced by biased perceptions, rather than by the best available estimates of the true risk levels?

100. Be that as it may, biased public perceptions create what Justice Breyer has called a "vicious circle"—public perceptions influence Congress, Congress (in particular, through media reports of its activities) helps to shape public perceptions, and both influence the response of regulatory agencies, distorting regulatory priorities. He suggests breaking this vicious circle by institutional changes, such as creating a mission-oriented, independent agency commanding significant prestige and authority. This superagency would have "the mission of building an improved, coherent risk-regulating system adaptable for use in several different risk-related programs; the mission of helping to create priorities within as well as among programs; and the mission of comparing programs to determine how better to allocate resources to reduce risks" (Breyer, 1993: 60). Breyer envisages a centralised administrative group that "could usefully try to make explicit, and more uniform, controversial assumptions that agencies now, implicitly and often inconsistently, use in reaching their decisions". This group could also help develop models that aim to achieve higher quality analysis and better results, and "might create a "risk agenda" that helps to prioritise different programs, and different activities within programs, and that looks for tradeoffs among programs that will lead overall to improved health or safety" (*ib*.: 65-67). This centralised, elite group of experts would not directly regulate, but presumably accomplish its ambitious tasks primarily by argument and persuasion. It is, however, hard to see how such a group, with no rulemaking power and thus taking no responsibility for the final regulatory outcomes, could acquire sufficient prestige and legitimacy to change public perceptions and reform the decision-making processes of existing agencies.

101. A detailed analysis of Justice Breyer's proposal is beyond the scope of the present report, but the two key issues he raises – what to do about public misperceptions of certain risks; and how to achieve a more coherent approach to risk regulation across programs and agencies—deserve some additional comments. Biased public perceptions would be irrelevant if risk regulation could be taken out of politics. A depoliticised regulatory process is indeed the basic rationale for delegating rulemaking powers to independent agencies, but in a democracy depoliticisation can only be carried so far, especially in sensitive areas like health and environmental risk.

Addressing political trade-offs

102. We are faced with a real dilemma: on the one hand, risk regulation, like any other public policy, should be responsive to the preferences of the citizens; on the other hand, the regulator's task is to issue regulations that are needed to control the "real" risk levels, as indicated by the best available scientific evidence, not to respond to biased perceptions. Even less is it the regulator's responsibility to balance conflicting societal values, such as safety and economic efficiency, or a precautionary approach and the rate of technological innovation. Such balancing is, or should be, the exclusive responsibility of electorally accountable policymakers. Hence, the dilemma can be resolved only by acknowledging that both the regulator and the elected politician have important, but distinct, roles to play in risk regulation. The electorally accountable policymaker should have the right to override an agency's decision if s/he is convinced that societal welfare is thereby promoted. But such interventions into the regulatory process

ought to be completely transparent, and follow well-defined and publicly known procedures. Generally speaking, overriding agency decisions should be neither too easy – for in this case agency independence would be an empty concept – nor too difficult—so that basic principles of democratic accountability may not be sacrificed in favor of narrow regulatory principles. An example taken from the area of antitrust regulation may help to clarify this important point.

103. Suppose an antitrust regulator has disapproved a merger because it violates the competition rules she is supposed to enforce. The government, on the other hand, thinks that in this particular case competition principles are too narrow from the point of view of aggregate welfare, and that the merger should be approved in the interest of the national economy. Here we have a clear situation of conflict of values which, as we said, can only be resolved by electorally accountable policymakers. From the democratic point of view, therefore, the government is justified if it decides to overrule the regulator, as long as it follows certain strict procedures and assumes full responsibility for its decision. In Germany, for example, the procedures which the government must follow when it wishes to overrule a decision of the antitrust regulator (the Federal Cartel Office) are such that they entail high political costs and make the interference plain for all to see. If the Cartel Office refuses to authorise a merger on the grounds that the merger is likely to lead to the creation or strengthening of a dominant position, the interested firms may apply to the Economics Minister for an authorisation. The Minister will evaluate both the advantages and disadvantages of the merger. This evaluation is based on the judgment of the Cartel Office, set against the advantages for the entire economy. In addition, the minister must obtain the opinion of another independent body, the Monopoly Commission. Because of these strict procedural requirements—which are meant to make it politically costly for the Minister to interfere in the decisions of the Cartel Office for party-political reasons – the Minister has overridden the Cartel Office only on rare occasions.

104. It is submitted that this example provides a relevant model also for risk regulation. In particular, the procedural approach exemplified by the German case seems to be more realistic than the depoliticisation proposed by Justice Breyer as a way of breaking the vicious circle created by biased public perceptions of risk. Public education may be another effective way of correcting misperceptions. After all, the case of the saccharin ban, discussed in the introductory section, suggests that people are willing to trade off risks and benefits, at the margin, if provided with sound and credible information. Incidentally, it is even possible that underestimation of risks associated with higher-probability events may be a way for the respondents to include benefits in an implicit risk-benefit analysis of certain products or processes. Thus, the observed underestimation of the risk of being killed in a car accident may simply tell us that people value private transportation so highly that they are willing to run certain risks in order to continue enjoying the benefits of this mode of transportation.

Towards a more coherent approach to risk regulation and management: international cooperation, regulatory impact assessment and education and training

105. This leads to the second issue: how to achieve a more coherent approach to risk regulation across programs and agencies. Indeed, the fragmentation of risk regulation among a variety of national, supranational, and international agencies, using different criteria and methodologies, and responding to different constituencies, is becoming one of the most serious regulatory problems facing the governments of all OECD countries. At the national level, one possible solution is the establishment of coordinating groups or task forces. In the US, the Environmental Protection Agency (EPA) has pioneered this approach, and its experience deserves to be studied carefully.

106. Another promising approach is to use the framework of regulatory impact assessment by adding a facility responsible for analysing the consistency of risk priorities and actual risk measures, both across and within agencies. Justice Breyer's proposed solution – a mission-oriented, independent superagency commanding significant prestige and authority—is more ambitious. As noted above, however, it remains unclear how this elite organisation could acquire prestige and legitimacy. At any rate, Breyer is aware that his proposal is not entirely new. Aside from more or less convincing European examples, such as the French *Conseil d'État*, he points out that the Executive Branch of the US government already contains groups that seek to harmonise the activities of different agencies. Thus, the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and the Budget (OMB), reviews regulatory agendas and major regulations that the different federal agencies intend to propose. The purpose of the review is precisely to bring about greater coherence within and across agencies, and to enforce a more rational setting of regulatory priorities. However, OIRA is understaffed and its perspective tends to be more economic.

107. Finally, training and education offer interesting policy options. Education could be the most promising, as well as practical, solution. Here I am referring to the education of risk regulators, who should be required to add to their scientific and technical expertise a solid training in the logic of decision-making under uncertainty. Appendix 1 discusses the introduction of decision theory in the curriculum of all leading business schools during the 1960s and 1970s. Major corporations complemented university education by in-house courses, introducing senior managers to the key concepts of probability and utility analysis. For instance, the highly diversified du Pont Company discovered that its executives used different, even inconsistent, criteria when assessing the level of risk and expected profits of proposed investments. An intensive course in decision-making under uncertainty, supported by graphical displays of various types of utility functions, reportedly helped to harmonise the decision rules used by du Pont executives. Since the 1970s sophisticated software has been developed allowing to perform sensitivity analysis of complex decision problems under a great variety of probability and utility assumptions. In the age of eGovernment, the development of analogous technology to support the decisions of risk regulators would be a significant contribution to a policy area of growing significance in all OECD countries.

APPENDIX 1. RECENT TRENDS IN THE THEORY OF DECISION MAKING: TOWARDS PROCEDURAL RATIONALITY

108. During the 1960s and 1970s the theory of decision-making under uncertainty became part of the standard curriculum in all leading Business Schools and Economics Departments. Now, pervasive uncertainty has always been the most obvious feature of decision processes in business and in economic policymaking. Why did it take so long to develop a general theory of such processes, and what is the contribution of this theory to a more rational approach to real decision problems? The answer to the first part of the question is that no general conceptual approach to decision-making under uncertainty was possible until the twin concepts of subjective (or personal) probability and of probabilistic utility were introduced in a clear and logically consistent way, and this did not happen until the late 1940s. Once these concepts were well understood it became possible to develop a theory based on three simple principles. First, the uncertainties present in the situation must be quantified in terms of values called probabilities. Secondly, the various consequences of the feasible courses of action must be similarly described in terms of utilities. Thirdly, that decision must be taken which is expected, on the basis of the calculated probabilities, to give the greatest utility: any deviation from this rule is liable to lead the decision-maker into procedures which are inconsistent.

109. As for the practical contribution to better decision-making in business and in government: the theory allows us to open up the black box inside which the various ingredients of a decision problem are mixed and synthesised. It may be true, as President J.F. Kennedy once observed, that the essence of decision remains impenetrable to the observer, often even to the decider himself. But in a world where transparency and accountability are viewed as necessary conditions of legitimacy, decision-makers in business, and even more those in government, are under an obligation to be as explicit as possible about the steps which led them to their final determination. In turn, this requires a conceptual framework within which the different components of the decision problem can be separately analysed, and then put together in a consistent way. In the language of Section 3 below, modern decision theory adds to the notion of "substantive rationality"—which applies to situations where uncertainty can be assumed away—that of "procedural rationality", which is especially relevant when uncertainty is too important to be disregarded. Whereas substantive rationality refers to the extent to which the chosen course of action leads to what, ex post, appears to be the optimal outcome, procedural rationality deals with how complex policy issues are structured.

APPENDIX 2.

110. A decision problem can be expressed as a list of alternatives and a list of possible events with the corresponding consequences. On the assumption of consistent comparison of events and of consequences, probabilities can be assigned to events, and utilities to consequences. Each alternative can also be assigned a utility, calculated as the expected value of the corresponding consequences. The best alternative is the one with the highest utility. Thus, the key assumption of the theory is that there is only one form of uncertainty and that all uncertainties can be compared. By saying that there is only one kind of uncertainty, and that therefore all uncertainties can be compared, it is meant that if E and F are any two uncertain events then either E is more likely than F, F is more likely than E, or E and F are equally likely. Moreover, if G is a third uncertain event, and if E is more likely than F, and F is more likely than G, then E is more likely than G. The first requirement expresses the *comparability* of any two events; the second expresses a *consistency* in this comparison.

111. The comparability and consistency requirements are then used to define the probability of any uncertain event E. This can be done in several, but equivalent, ways. For example, the probability of E can be obtained by comparing it with the probability of a point falling at random within a set S contained in the unit square. Because S is a subset of the unit square, its area is a probability, *i.e.*, it is a positive number between 0 and 1, which satisfies all the rules of the probability calculus. Now, consistent comparability implies a unique value for the uncertainty of E, *i.e.*, the probability of S (its area), is judged to be as likely as the uncertain event E, in the sense that a prize awarded on the basis of E occurring could be replaced by an equal prize dependent on a random point falling within S. The interested reader can find the details in any good textbook on decision theory, such as the one by Dennis Lindley (1971: 18-26). In addition to a numerical measure of probabilities, we need a numerical measure for the consequences of our decisions.

112. We proceed as follows. Let c_{ij} be the consequence if we choose alternative A_i and event E_j occurs, i=1, 2,…n; j=1, 2,…m. Note that the consequences may be qualitative as well as quantitative. Denote by c and C two consequences such that all possible consequences in the decision problem are better than c and less desirable than C (it can be shown that the precise choice of c and C does not matter, as long as the condition of inclusion is satisfied; thus, we could choose as c the worst possible outcome in the payoff table, and C as the best outcome). Now take any consequence c_{ij} and fix on that. Consider a set S of area u in the unit square (the reason for using "u" will be clear in a moment; also, keep in mind that the area of S is a probability). Suppose that if a random point falls in S, consequence C will occur, while c will occur if the random point falls elsewhere in the unit square. In other words, C occurs with probability u and c with probability 1-u. We proceed to compare c_{ij} with a "lottery" in which you receive C with probability u and c with probability 1-u. Thus, if u=1, "C with probability u" is better than (or at least as good as) c_{ij}, while if u=0 then "C with probability u" is worse than c_{ij} . Furthermore, the greater the value of u the more desirable the chance consequence "C with probability u" becomes.

113. Using again the principle of consistent comparisons it can be shown that there exists a unique value of u such that the two consequences, c_{ij} and "C with probability u", are equally desirable in that you would not mind which of the two occurred. The argument consists in changing the value of u, any increase making the "lottery" more desirable, any decrease, less desirable, until "C with probability u" is as desirable as c_{ij}. We indicate this value with u and call it the *utility* of c_{ij}: $u_{ij}=u(c_{ij})$. We repeat the process for each of the possible consequences in the payoff table, replacing each consequence by its utility. The crucial point to remember is that all these utilities are probabilities and hence obey the rules of the probability calculus.

114. The final step consists in calculating the (expected) utility of each of the alternatives: $u(A_1)$, $u(A_2)$,…$u(A_n)$. Using the basic rules of probability, it is easy to show that $u(A_i)$ is simply the expected value of the utilities of all the consequences corresponding to A_i :$u(A_i)=u(c_{i1})p_1+u(c_{i2})p_2+\dots u(c_{im})p_m$. A moment's reflection will show that the expected utility of A_i is simply the probability of obtaining C, when this particular alternative is chosen. It follows that the best alternative is the one with the highest utility, being the one which maximises the probability of getting C. This is the principle of maximisation of expected utility, the major result of decision theory. Note that this principle, or decision rule, has nothing to do with the notion of an indefinite repetition of the same decision, as in some interpretations of expected gain in repeated games of chance. The principle follows directly from the rules of probability and hence can be applied to any decision situation, whether repetitive or unique.

115. One final point. Any decision under uncertainty, even one which does *not* make explicit use of probabilities, in fact implies at least a partial probability assessment. There is nothing mysterious in this statement, which is only a straightforward application of a line of reasoning frequently used also in elementary game theory (see for example Morrow 1994). Suppose a decision maker has to choose between two alternatives with the consequences indicated below:

	E_1	E_2
A_1	10	1
A_2	3	2

116. Without attempting to estimate the probabilities of the uncertain events E_1 and E_2, but only taking the consequences in the payoff table into account, she chooses alternative A_2. This choice suggests that our decision maker is very risk-averse. In fact, she has used the "maximin" decision rule, according to which one should take the worst consequence for each alternative, and then select the alternative which offers the maximum of these minima; hence the name of the decision rule. Although the maximin does not use probabilities, the choice of A_2 indicates that the decision was taken *as if* the probability of E_1 was less than 1/8. In fact, letting p be the unknown probability of E_1, hence 1-p the probability of E_2, the expected values M of the two alternatives are:

$$M(A_1)= 10p+1(1-p)=9p+1$$

$$M(A_2)= 3p+2(1-p)=p+2$$

117. Thus, our decision maker is indifferent between the two alternatives if $9p+1=p+2$, i. e., if $p=1/8$. Any value less than 1/8 makes A_2 preferable to A_1. Since A_2 was chosen we infer that the decision maker implicitly assumed that the probability of E_1 is less than 1/8, q. e. d.

NOTES

1. For example by Richard Neustadt and Harvey Fineberg in their study The Swine Flu Affair, published in 1978.

2. This will be further discussed in a later section of the present report, in connection with a critical evaluation of the precautionary principle.

3. The article states that a) In order to harmonize SPMs on as wide a basis as possible, member states shall base their measures on international standards, guidelines or recommendations, where they exist; b) SPMs that conform to international standards shall be deemed to be necessary to protect human, animal or plant life or health; c) Member states may, however, introduce or maintain SPMs which result in a higher level of protection than would be achieved by measures based on the relevant international standards, provided there is "scientific justification" for the stricter measures; d) Member states are required to "play a full part, within the limits of their resources, in the relevant international organizations and their subsidiary bodies", such as the Codex Alimentarius Commission.

   This WTO SPM Agreement can be compared with the NAFTA agreement on environmental cooperation, which stipulates that "each Party shall ensure that its laws and regulations provide for high levels of environmental protection and shall strive to continue to improve those laws and regulations". The NAFTA agreement recognizes "the right of each Party to establish its own levels of domestic environmental protection". Thus, according to a widely accepted interpretation, a member of NAFTA is permitted to set its own levels of protection, as long as those levels are "high" by some more or less objective standard. (This was also the case in Article 95(3) of the European Community Treaty, dealing with the harmonization of national laws, prescribes: "The Commission, in its proposals…concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection…".)

4. This interpretation seems to be supported by Article 5 of the same WTO Agreement (an article dealing with "Assessment of Risk and Determination of the Appropriate Level of Sanitary and Phytosanitary Protection"), which imposes purely methodological constraints on the freedom of each member state to choose its own levels of safety: risk assessments based on the available scientific evidence and on relevant inspection, sampling, and testing methods; consideration of relevant economic factors and of the relative cost-effectiveness of alternative approaches to limiting risks; consistency in the application of the concept of the appropriate level of protection, and so on.

5. Knight 1971 [1921]: 20; italics in the original.

6. The interested reader may consult Lindley 1971:172-7, or any other good book on decision analysis).

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