Foundations of Risk Regulation: Science, Decision-Making, Policy Learning and Institutional Reform

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I. From substantive to procedural rationality

The long subtitle of this paper, appearing in the first issue of the EJRR – a publication which fills a serious gap in the scholarly literature of the old continent – identifies what I take to be the key terms of the current debate on risk regulation. It is impossible to understand the evolution of risk regulation over the last three decades in Europe and the United States without having a good grasp of how these concepts, and their corresponding practices, interact. How, for example, does a particular institutional design affect the way scientific uncertainties are resolved? What decision rules are appropriate in situations of high scientific uncertainty? Which constitutional principles facilitate policy learning and accountability in the regulation of risk?

By definition, uncertainty is pervasive in risk regulation. What is less well understood, however, is that in many cases scientific uncertainty cannot be significantly reduced. In controversies over the analysis and management of risk, the issues over which the experts disagree most vehemently are those that are, in Alvin Weinberg's terminology, trans-scientific rather than strictly scientific or technical. 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.[1] One of Weinberg's examples is the determination of the effects on health of low-level radiation. It has been calculated that, in order to determine by direct experimentation at the 95 % confidence level whether a level of X-ray radiation of 150 millirems would increase spontaneous mutation in mice by half of one per cent, about 8 billion mice would be required. Time and resource constraints make experiments on such a scale virtually impossible.

Similarly, the choice of a particular dose-response function must be treated at present as a trans-scientific question. A dose-response model establishes a relationship between different dose levels of a substance and the probability of a lifetime response. But the relationship can be represented by many different functions, and a firm scientific basis for choosing a particular functional representation is usually lacking. However, such a choice can have a major effect on the determination of the virtually safe dose – more than a 100,000-fold effect, according to a study conducted some years ago by the Committee on Safety Evaluation of the U.S. Food and Drug Administration. Analogous conceptual and technical difficulties attend calculations that attempt to determine the probability of extremely unlikely events (such as catastrophic reactor accidents) as far as any direct verification of the calculations is concerned, or to settle the issue of when animal data alone will form a sufficient basis for standard-setting.

Since the level of scientific (or trans-scientific) uncertainty is so high, concepts like "acceptable risk doses", "virtual safety", and "no observed effect level" (NOEL) – commonly used by risk regulators, especially with reference to potentially toxic substances – leave ample room for discretionary choices and rules of thumb. The words that a distinguished statistician wrote in the 1970s remain largely true today: "All present safety evaluation procedures, whether involving the use of NOELs, or of some favoured non-threshold dose-response function with a "virtually safe" level, must be regarded as mathematical formalisms whose correspondence with the realities of low-dose effect is, and may long remain,

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1 Weinberg, A. M., "Science and Trans-science", *Minerva*, Vol. 10 (April 1972), pp. 209–222.

largely conjectural."[2] Thus, the first – and arguably most important – question facing political leaders, citizens, and experts is how to limit regulatory discretion and enforce accountability in policy areas characterised by high uncertainty and cognitive complexity and that are also politically very sensitive. I shall argue that the solution to this apparently intractable problem depends in a large part on the distinction between "substantive" and "procedural" rationality.

The preoccupation with methods of analysis and evaluation that emphasise outcome rather than process, and the interest in what decisions are made rather than in how they are made, are both typical of situations where certainty is assumed. Indifference towards procedures and the formal layout of arguments is understandable if one assumes that in a given situation there exists a unique best decision. If the correctness of the outcome can be determined unambiguously, the manner in which the decision is made is largely immaterial; only results count. That is the reason why the key concept in the theory of decision-making under certainty, whether in economics or in management science, is optimization. But "optimization" has no well-defined meaning when the consequences of each feasible course of action are uncertain. (One should not, for example, maximize the *expected* return without considering also its variance). Hence, the key concept in the theory of decision- making under uncertainty is not optimization but, as we shall see, *consistency*, a characteristically procedural notion. Indeed, if the factual or value premises of a decision are moot, if no generally accepted criterion for the correctness of a solution exists, then the procedure of decision making acquires special significance. This is the basic insight on which the classical theories of judicial and legislative procedures are based; the reason why procedures play such an important legitimating function in the decisions of courts and legislatures.[3] In general terms, the more complex a system, the greater the reliance on procedural rationality, for, as Talcott Parsons writes: "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."[4] In the following pages I shall work out in some detail what "procedural rationality" means and what this implies for risk regulation. I begin by considering the important topic of procedural harmonization.

II. Procedural harmonization

The purpose of harmonization (using the term in the present context) is to make the regulatory requirements or public policies of different jurisdictions more similar, if not identical. Regulatory regimes, and the political and institutional systems in which they are embedded, can differ in numerous aspects. Hence, several broad types of harmonization may be usefully distinguished.[5] First, specific rules or standards that prescribe the desired characteristics of the outputs of production processes, institutions or transactions may be harmonized. For example, the emission limits for polluting factories located in different countries may be brought into closer alignment. We may call this "output harmonization" since the goal is to reduce pre-existing differences in certain characteristics of the relevant outputs or outcomes. Second, international regulatory harmonization may relate to certain governmental policy objectives – for example, the central banks of a group of countries may attempt to keep inflation within agreed limits – or to general policy principles such as the "polluter pays" and the precautionary principles.

Finally, harmonization of institutional structures, procedures or methodologies is often sought. Thus, some of the provisions of the North American Free Trade Agreement (NAFTA – here referring to the NAFTA "side agreement" on the environment) require that certain procedures for enforcement of domestic laws, including appellate review, be harmonized.

Procedural harmonization usually serves to reinforce other types of harmonization. When the aim is to harmonize decisional outcomes, both substantive criteria and decisional processes are implicated. Rules, policies and principles will generally not be truly harmonized unless the procedures and institutions for implementing them are brought to similar

2 Cornfield, J., "Carcinogenic Risk Assessment", *Science*, 194 (October 1977), pp. 693–699, at p. 698.

3 Luhmann, N., *Legitimation durch Verfahren*, (Neuwied: Luchterhand 1975), pp. 27–37.

4 Parsons, T., *Societies: Evolutionary and Comparative Perspectives*, (Englewood Cliffs, N. J.: Prentice Hall 1966), p. 27.

5 Leebron, D. W., "Lying down with Procustes: An Analysis of Harmonization Claims", in Bhagwati, J. N. and Hudec, R. E. (eds), *Fair Trade and Harmonization*, Vol. 1 (Cambridge, MA.: MIT Press 1996), pp. 41–118.

levels of efficiency, and in so doing they may become more aligned.[6] This, incidentally, is the reason why EU-level harmonization (e.g. in the environmental field) fails to produce identical, or at least very similar, results across the Union. EU measures are typically implemented by national administrations, but the Community is not competent to harmonize national administrative procedures and processes. This problem has been recognized for some time, and certain directives attempt to harmonize not only national laws and policy objectives, but also the institutional design of the "competent authorities" at national level (e.g. with respect to their independence in the case of telecommunications). The results so far have been rather disappointing.[7]

There are, however, situations where procedural harmonization is not meant to reinforce other types of harmonization, but is the only type which is politically, economically or technically feasible. Thus, in the case of the NAFTA environmental side-agreement it would have been impossible to impose on Mexico the same environmental standards as those used in Canada or the United States. Hence, Article 3 of the agreement recognizes "the right of each Party to establish its own levels of domestic environmental protection ... ", while Article 5 requires that "each Party shall effectively enforce its environmental laws and regulations through appropriate government action ... "; and Article 6 requires that "interested persons" be able to request a Party's regulatory authorities to investigate possible violations of *domestic* environmental laws and regulations.

An important example of purely procedural harmonization is provided by the WTO Agreement on Sanitary and Phytosanitary Measures (SPMs). Harmonization is discussed in Article 3, which states, in part, 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 Article is noteworthy in several respects. First, nothing substantive is said about the level of the international standards, not even of a qualitative nature. By way of comparison, the NAFTA Agreement on Environmental Cooperation 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". At the same time, the Agreement recognizes "the right of each Party to establish its own levels of domestic environmental protection". Thus, at least 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 (see also Article 95(3) TEC, according to which "The Commission, in its proposals ... concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection ...").

By contrast, the approach of the WTO SPS Agreement is purely procedural, as also shown by the requirement that the Member States play an active role in the activities of the international standardization bodies. The requirement that a country should provide "scientific justification" if it wishes to adopt a higher level of protection than that 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. This interpretation seems to be supported by Article 5 (on *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;

6 *Ibid*, at p. 46.

7 Majone, G., "The Credibility Crisis of Community Regulation", *Journal of Common Market Studies*, Vol. 38, No.2, 2000, pp. 273–303.

- 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.

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 and trans-scientific issues, the only way to promote international regulatory cooperation is through the harmonization of procedures. This, at any rate, is how progress has been achieved in the international harmonization of testing procedures for new medical drugs (known as the "ICH process"), in which the European Agency for the Evaluation of Medicinal Products (EMEA) has played a leading role.[8] Precisely for this reason, it is essential that the procedural requirements of the SPS Agreement, and all other requirements of the same nature, be respected and, if possible, improved upon, rather than weakened or circumvented, allegedly in the name of risk prevention, but in fact for short-term political or economic advantages.[9]

III. Consistency in decision-making

It has already been suggested that our intuitive notions of means-end (goal-oriented) rationality and optimality have to be revised when decisions are made under uncertainty. (Strictly speaking, all human decisions are uncertain in their outcomes, but here we are considering situations where it is impossible to rely on some simple "certainty equivalent" such as an average value.) Probabilistic thinking does not come naturally, even to scientists or to intellectually sophisticated people, but it is essential for a logically defensible regulation of risk. It seems more natural to think of decisions and institutions in teleological terms. According to this conception, as formulated by John Rawls in his critique of utilitarianism, "those institutions and actions are right which of the available alternatives produce the most good, or at least as much good as any of the other institutions and acts open as real possibilities." Rawls adds: "Teleological theories have a deep intuitive appeal since they seem to embody the idea of rationality. It is natural to think that rationality is maximizing something ... Indeed, it is tempting to suppose that it is self-evident that things should be arranged as to lead to the most good."[10]

Modern decision theory also prescribes the maximization of something, namely expected utility, but this decision rule has procedural, not substantive, significance: it "only" guarantees consistent decision-making. Here I can do no more than sketch the argument, starting with the key assumptions of the theory: that there is only one form of uncertainty, and that all uncertainties can be compared.

Thus decision theory does away with all old-fashioned and theoretically untenable distinctions such as that between statistical and non-statistical events, or Frank Knight's (1971) distinction between risk and uncertainty[11]. By saying that there is only one kind of uncertainty, and that therefore all uncertainties can be compared, that means that if E and F are any two uncertain events then either E is more likely than F, or 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.

The comparability and consistency requirements are then used to define the probability of any uncertain event E. This can be done in several ways that are equivalent. 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 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

8 Majone, G., "Managing Europeanization: The European Agencies", in Peterson, J. and Shackleton, M. (eds), *The Institutions of the European Union*, 2nd ed. (Oxford: Oxford University Press 2006), pp. 190–209.

9 Majone, G., *Dilemmas of European Integration* (Oxford: Oxford University Press 2005), pp. 124–138.

10 Rawls, J., *A Theory of Justice* (New York: Oxford University Press 1973), pp. 24–25.

11 Knight, F.H., *Risk, Uncertainty and Profit* (Chicago, ILL.: University of Chicago Press 1971 [1921]).

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.[12] In addition to a numerical measure of probabilities, we need a numerical measure for the consequences of our decisions. We proceed as follows.

Let c_{ij} be the consequence if we choose alternative A_i and event E_j occurs, $i = 1, 2, ...n$; $j = 1, 2$, up to 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.

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 keep in mind is that all these utilities are probabilities and hence obey the rules of the probability calculus.

12 Lindley, D., *Making Decisions* (New York and London: Wiley-Interscience 1971), pp. 18–26.

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 average (more precisely, the "expected") value of the utilities of all the consequences corresponding to A_i : $u(A_i) = u(c_{i1})p_1 + u(c_{i2})p_2 + ... u(c_{im})p_m$. 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 maximizes the probability of getting C. This is the principle of 'maximization 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 on the rules of probability and hence can be applied to any decision situation, whether repetitive or unique.

The discussion so far may be summarized as follows:

A decision problem can be expressed as a list of alternatives and a list of possible events. 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. A few more comments on the general approach follow.

First, the consistency argument is essentially one that hinges on how separate assessments – probabilities of events, utilities of individual consequences and of alternatives – are going to fit together and make a consistent whole. Second, the rule of maximization of expected utility does not guarantee better actual results 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. Third, consistency is important not only logically but also practically: it facilitates communication among experts, between experts and policy makers, and with the general public; by showing how to break down the whole decision problem into separate but coherent components, it also facilitates accountability; moreover, as mentioned in the following section on learning, the method provides a way of consistently updat-

ing one's beliefs in light of new information. The type of decision analysis outlined here may even facilitate risk taking. Thus, 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.

One final point: Any decision under uncertainty, even one which does not make explicit use of probabilities, will in fact imply 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.[13] 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

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, our decision maker chooses alternative A_2.

This choice suggests that she 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 of the two alternatives are:

$$M(A_1) = 10p + (1\text{-}p) = 9p + 1$$
$$M(A_2) = 3p + 2(1\text{-}p) = p + 2$$

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.

IV. Policy learning

One serious limitation of the decision-theory approach outlined above is that, in principle, it applies only to the decisions of an individual. Decision theory does not provide unambiguous advice for group decisions if the different members of the group have different attitudes toward risk. Even in this situation, however, the methodology can help, though without providing a complete solution. As already noted, the process of breaking down the decision problem into its main components – alternatives, uncertain events, consequences, numerical measures of probabilities and consequences – and hence identifying the particular sources of disagreement, can facilitate interpersonal communication and the emergence of a common position. Moreover, an important, if elementary, result known as Bayes' theorem, enables probabilities to be modified, in a consistent manner, by incorporating the information provided by new data. This means that the pooling of information among the members of a group (e.g. a committee) may serve as a device for bringing the probability assessments of the members 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 mutually exclusive.

In the remainder of this section I am going to discuss policy learning in the area of risk regulation, in a broader but less rigorous sense than that of decision theory and Bayesian statistics.

However, the fundamental lesson of the preceding discussion must always be kept in mind: namely, 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. To a large extent, policy learning means learning this lesson, as we try to show by considering 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;

13 See, for example, Morrow, James D., *Game Theory for Political Scientists* (Princeton, N.J.: Princeton University Press 1994), pp. 170–180.

- elimination of significant risk;
- balancing the costs and benefits of risk reduction.

While this is not a linearly progressing sequence – since different principles coexist even in the same area, such as food safety – we shall argue that a trend can be detected in the direction of a broader inclusion of relevant factors, and of greater consistency in putting together the various elements of the regulatory problem.

1. Prohibitions

Prohibitions represent one of the earliest and least sophisticated approaches to risk regulation. This does not deny that in some cases an outright ban may be the most appropriate regulatory response, but only indicates that the appropriateness of such a radical measure 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 so-called Delaney Clause in the Federal Food, Drug and Cosmetic Act. The Clause appears in the provision of the Act that empowers the Food and Drug Administration (FDA) to license food additives. The Food Additives Amendment was added to the law in 1958, and it directs the FDA to refuse approval of any food additive not shown to be safe. To this general instruction the Delaney Clause adds the proviso that:

"No additive shall be deemed to be 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 the safety of food additives, to induce cancer in man or animals."

According to FDA officials, this proviso authorizes the agency to exercise scientific judgment in determining whether a test is an appropriate one, and whether the results demonstrate induction of cancer. Once the agency has established its findings on these two matters, however, no further inquiry is permitted. For example, the agency may not establish a maximum level of safe use, or authorize further use of an additive based on a judgment that the benefits of continued use would outweigh the risks involved.[14] For nearly twenty years the Delaney Clause had little influence on FDA's actions, since only a very small number of additives had been shown to cause cancer in animal experiments. On 9 March 1977, however, the FDA announced its intention to ban the use of the artificial sweetener saccharin because of a recent Canadian study showing that saccharin (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. Representatives of health organizations testified at congressional hearings, that saccharin provides enormous health benefits to persons, such as diabetics, who must restrict their intake of sugar.

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.

The proposals did not lead to any radical amendment of the legislation, but the FDA found other means of avoiding a ban if a food additive presented only slight risks, or offered substantial benefits. Thus, the agency has sometimes concluded that a substance is not a "food additive", and hence subject to the Delaney Clause, even though it occurs in food,

14 Mashaw, J.L./Merrill, R.A./Shane, P.M., *Administrative Law*, 4th ed. (St. Paul, MINN.: West Group 1998), p. 132.

arguably through human agency.[15] 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.

In retrospect, we can see that the drafters of this Clause believed that while only a few additives caused cancer, those that did 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 authorized substances allowed them to be approved. The result is less rather than more safety.[16]

2. Least feasible risk

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 Occupational Safety and Health Act directs the U.S. 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."[17] The meaning of "feasibility" is crucial in the present context. A body of analysis and case law has thus emerged to clarify this term.

According to some court decisions, a standard may be considered technologically feasible even if no existing devices allowed industry to comply with the standard, as long as evidence exists that companies "acting vigorously and in good faith", are able to develop the technology. This "technology-forcing" approach implies that regulatory agencies are not limited to setting 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 regulators 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 unfeasible. Although some firms may find safety standards particularly expensive or even financially prohibitive, courts have not exempted 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."[18] Thus, economic feasibility has been interpreted quite strictly: a standard is to be considered "unfeasible" only if it would cripple or bankrupt an entire industry, rather than some technologically backward firms.

It is clear that the least-feasible-risk approach is very 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 cannot be considered comparatively. As the above-cited opinion of Justice Brennan makes clear, health benefits have to be considered "above

15 *Ibid*, pp. 129–134.

16 Sunstein, C.R., *After the Rights Revolution* (Cambridge, MA: Harvard University Press 1990), p. 198.

17 Graham, J.D./Green, L.C./Roberts, M.J., *In Search of Safety* (Cambridge, MA.: Harvard University Press 1988), p. 97.

18 *Ibid*, p. 99.

all other considerations". Even if one accepts this value judgment, however, some 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 leaves out 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.[19] 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 instance of over-regulation leading 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.

3. The significant-risk doctrine

As mentioned above, in general the federal courts uphold OSHA standards. The striking exception was the benzene standard, which reduced the occupational exposure to this carcinogen from 10 parts per million (ppm) to 1 ppm. In the case *American Petroleum Institute v. OSHA* (1978), the Fifth Circuit Court of Appeals held the regulation invalid on the ground that the agency had not shown that the new exposure limit was "reasonably necessary and appropriate to provide safe or healthful employment" as required by the 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."[20]

What the court required was some kind of quantification of benefits as a necessary step for carrying 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. Unlike other agencies such as the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA), OSHA had always maintained that quantitative risk analysis is meaningless. Thus, in the preamble to the benzene standard it stated that it was "impossible to derive any conclusions regarding dose-response relationships". As Mendeloff notes, OSHA's reluctance to follow the example of the EPA and the FDA reflected trade union pressures, combined with staff preferences for protection to override any interest in the use of more analytic approaches. It was feared that if the agency performed quantitative risk assessments (QRAs), these might be used as a weapon by those who opposed strict standards. On the other hand, an agency like EPA with a much broader mandate, was aware that not every risk could be reduced to the lowest feasible level.

The Fifth Circuit Court's decision stunned OSHA's leaders, who viewed it as a total challenge to their regulatory philosophy and to their idea of the agency's mission.[21] They decided to appeal the decision. In *Industrial Union Department (AFL-CIO) v. American Petroleum Institute* (1980), a badly split Supreme Court – the nine justices issued five separate opinions! – upheld the Fifth Circuit's decision, but not all parts of its argument; in particular, it expressed no opinion about the requirement of a cost-benefit assessment. Justice Powell, concurring in part and concurring in the judgment, did however note 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

19 Mendeloff, J.M., *The Dilemma of Toxic Substance Regulation* (Cambridge, MA.: MIT Press 1988), pp. 100–102.

20 *Ibid*, pp. 116–117.

21 *Ibid*, p. 117.

at a lower cost."[22] 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 lowest-feasible-risk approach: "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."[23]

In other words, zero risk cannot be the goal of risk regulation. 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 risk from a toxic substance must be quantified sufficiently to enable the agency to characterize it as significant "in an understandable way". Conceding the difficulty of quantifying risks, the plurality opinion emphasized the scientific elements of the significant-risk determination. 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, the agency is free to use conservative assumptions in interpreting the data, risking error on the side of overprotection.

The problem with the proposed regulation was procedural rather than substantive: the question was not whether the standard of 1 ppm was "correct", but whether sufficient justification for this determination had been provided. According to the plurality opinion, this had not been done, hence the standard-setting process was flawed. Thus, OSHA did not ask for comments as to whether or not benzene presented a significant health risk at exposures of 10 ppm or less. Rather, it asked for comments as to whether 1 ppm was the minimum feasible exposure limit. Also, the evidence of adverse health effects of benzene exposure at 10 ppm was sketchy at best. OSHA had not attempted to make any estimate, based on the available scientific studies, of how significant the risk would be at exposure of 10 ppm or less. Rather, it stated that because of a lack of data it was impossible to construct a dose-response curve at this time, even rejecting an industry witness' testimony that a dose-response curve could be constructed on the basis of the reported epidemiological studies. In short, the agency had simply concluded – from the government's generic carcinogen policy – 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."[24]

Since the government's generic carcinogen policy provides no guidance as to which substances should be regulated first, an important merit of the significant-risk doctrine is to raise the crucial issue of regulatory priorities. Most risks are regulated in response to petitions or pressures from labour 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, perhaps more significant, risks. By requiring OSHA 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.

In conclusion, the significant-risk doctrine places a higher analytical burden on regulators than the lowest-feasible-risk approach. Not all potential risks are treated equally; only those substances shown to pose a significant risk of cancer will be regulated, thus limited agency resources are focused on the most important health risks. In addition, while not requiring a formal marginal analysis of benefits and costs, the doctrine 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.[25] *Industrial Union Department (AFL-CIO) v. American Petroleum Institute* is a landmark

22 Mashaw *et al.*, p. 815.

23 Graham *et al.*, p. 100, (emphasis added).

24 Mashaw *et al.*, p. 813.

25 Graham *et al.*, pp. 103–105.

case also from the point of view of the methodology of risk analysis. The U.S. Supreme Court not only confirmed the legitimacy of quantitative risk assessment; it effectively placed reliance on the methodology obligatory for all American agencies engaged in risk regulation. In most subsequent disputes over regulatory decisions for the protection human health, the question has not been whether a risk assessment was required but whether the assessment offered by the agency was plausible.[26] This historical background may explain the American advocacy of science-based risk assessment at international level, as well as that country's opposition to the precautionary principle as interpreted by the European Commission.

4. Balancing costs and benefits

Until the 1970s, judicial review was the only effective control on the quality of the decision-making process of American regulatory agencies. Congress can, of course, pass legislation requiring an agency to take a particular type of action. However, congressional oversight is output- rather than process-oriented. At any rate, routine regulatory measures seldom receive congressional scrutiny. 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 also suffers from serious shortcomings. First, it is only exercised *ex post* – though it is true 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 taken in judicial decision-making and the hectic pace of agency rule-making, while placing heavy reliance on judicial review creates, according to many observers, an adversarial atmosphere which does not always facilitate the achievement of regulatory objectives.

From the point of view of policy learning, however, the most serious limitation of judicial review is the unpredictability of court decisions. In the benzene case, for example, the Supreme Court criticized the logic of the least-feasible-risk decision rule, and effectively mandated the use of quantitative risk assessment, while it took no position on the issue whether or not an agency should undertake a formal cost-benefit analysis (CBA) to justify its decisions. More precisely, the question that was not answered in the benzene 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, in the cotton-dust case (*American Textile Mfrs. v. Donovan,* 1981), the Court explicitly held 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 criticized by students of the regulatory process. Yet no judicial decision could conceal the growing economic impact of risk regulation.

With the great expansion of environmental, health, and risk regulation in the 1970s, the need became increasingly evident for more precise calculation of both the costs of the proliferating regulations and also their corresponding benefits. According to many advocates of regulatory reform, only the executive could provide a continuous and systematic oversight of the regulatory process. Important steps to improve the quality of federal regulation were taken under President Carter, when the notion of a "regulatory budget" 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 rule-making process. Instead of simply imposing a cost-effectiveness requirement, as previous presidents had done, Reagan moved to a fully fledged cost-benefit test with his Executive Order No. 12291 of 1981: regulatory action was not to be undertaken unless the potential benefits to society outweighed the potential costs; among alternative approaches to any given regulatory objective, the alternative involving the least net costs to society had to be chosen; finally, agencies were required to

26 Mashaw *et al.*, pp. 823–825.

set regulatory priorities with the aim of maximizing 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. If the cost-benefit test conflicted with the agency's legislative mandate – as it did at that time for most risk and environmental regulations – the test was not binding, in the sense that the standard need not be based on the result of the cost-benefit calculations; but a complete analysis had be submitted to the OMB nevertheless.

Executive Order No. 12498 of 1985 added to the oversight process (the OMB review of the regulation proposed by an agency and of the analysis supporting it) the development of a formal planning process whereby the agencies would have to clear a regulatory agenda (a "regulatory calendar") with OMB. The exercise was meant to alert administration officials and the public at large about the future of regulatory policy. In practical terms, however, the regulatory calendar has not had as much impact on policy outcomes as the formal review process, coupled with a cost-benefit test. Although OMB has often been unable to enforce the test completely (due to conflicts with the agency's legislative mandate), the quality of rule-making has improved significantly over the last two decades. The usefulness of the regulatory oversight process designed by the Reagan administration explains why subsequent administrations, Democrat and Republican, have continued to use it in a form that has not substantially changed from the original model. In the meantime, the Congress was also undergoing a learning process, resulting in a more balanced appreciation of the many dimensions of risk regulation. In 1995, regulatory legislation was passed. Its net effect is to strengthen the test that must be passed by new regulations. The key congressional concerns were that regulations be based on an accurate 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.[27]

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. Compared to these developments, risk regulation in Europe, especially perhaps at EU level, is still at a rather primitive stage. Indeed, in comparative terms, some recent episodes – such as the strenuous advocacy of the precautionary principle – appear to be manifestations of an infantile disorder of risk regulation rather than progressive moves.[28] As we have seen, policy learning in America has been made possible by the interaction among different, partly cooperating, partly competing institutions. A more detailed study would have also revealed the importance of a style of policy discourse that puts a high premium on reliable quantitative information and on sophistication in analysis. While American institutions and political culture cannot be replicated on this side of the Atlantic, a discussion of the foundations of risk regulation would be seriously incomplete without mentioning at least some of the institutional issues that still await a satisfactory solution at European level.

V. Institutional reform

A serious problem of EU regulation in general, and of risk regulation in particular, is the mismatch between the growing complexity of the tasks and the inadequacy of the existing regulatory institutions. The root cause of this problem is to be found in the non-delegation doctrine promoted since the 1950s by the European Court of Justice and enthusiastically supported by the European Commission. Incidentally, it is interesting to note that in the United States a corresponding non-delegation doctrine – prohibiting the delegation of rule-making powers by Congress to regulatory agencies – has not been applied by the federal courts since the 1930s, despite the centralisation of separation-of-powers in the federal constitution. The ECJ's "Meroni doctrine", dating from 1958 (case 9/56, *Meroni v. High Authority*) and relating specifically to the European Coal and

27 Viscusi, W.K./Vernon, J. M./Harrington, J. E. Jr., *Economics of Regulation and Antitrust* (Cambridge, MA.: MIT Press 1996), pp. 27–28.

28 Majone, 2005, pp. 124–142.

Steel Community Treaty, remains "good law", and is supposed to apply to all European treaties. It still acts as a barrier to the delegation of tasks to institutions not mentioned as such within the European treaties – even when the scientific or technical complexity of the tasks exceed the expertise of a generalist administration like the European Commission. In the Court's reasoning, the Commission could, in fact, delegate tasks to bodies not named in the treaty, but such delegation was subject to strict constraints:

- delegation must relate to the preparation and performance of executive acts only;
- as a consequence of this, independent bodies may not be granted any discretionary powers;
- thus, the Commission must retain oversight over the delegated competence and will be held responsible for the manner in which it is performed;
- finally (and this is the crucial point) such a delegation must not disturb the "institutional balance" embedded within the Community method.

Such a narrow reading of Article 4 of the Treaty of Rome (Article 7 EC Treaty), is reflected in the structure and *modus operandi* of the European agencies, which are subject to direct Commission oversight and largely engage only in preparatory executive acts (or in what the Commission chooses to define as "preparatory" acts).

Of the ten European agencies created in the 1990s ("second generation" agencies) only two have been delegated authority to make final determinations in narrow technical fields: the Office for Harmonisation in the Internal Market, and the Community Plant Variety Office. The rationale for this delegation, according to the Commission's Legal Service, is that in both cases the task is simply to verify that individual applications satisfy certain conditions precisely defined by the relevant EC regulations. Hence, agency decisions do not entail any use of regulatory discretion beyond a purely technical evaluation of the applications against fixed criteria. On the other hand, the most important of the second generation agencies – the European Agency for the Evaluation of Medicinal Products (EMEA) – has not been granted the power to authorise the marketing of new products: under present rules such authorisations can be given only by the Commission, on the recommendation by the agency, and subject to the usual comitology controls.

This pragmatic solution can perhaps be defended as a reasonable compromise between the rigidity of the official non-delegation doctrine and the need for regulatory discretion in highly technical matters. However, such a compromise entails costs which a clearer delegation of authority would avoid. First, as the agency itself laments, the need to wait for the Commission's formal decision means that precious time is lost before a new – and possibly life-saving – product reaches the market. Moreover, the present situation blurs the line of accountability and also, because of its ambiguity, presents risks for the Commission, which some day might be called upon to bear the responsibility of decisions in whose formation it did not play any substantive role.

In the case of the European Food Safety Authority, the tension between the desire to improve the credibility of EU regulation, by appealing to independent scientific expertise, and the refusal to delegate regulatory powers to the agency, has been temporarily resolved by the doubtful expedient of institutional separation of risk assessment (the task assigned to the Authority) and risk management (which remains the responsibility of the Commission). Such institutional separation has been tried in several countries, usually with disappointing results. For example, the already mentioned U.S. Occupational Safety and Health Act of 1970 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. 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 writes: "... 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."[29]

The institutional separation of risk assessment and risk management is counterproductive, because while the two functions are conceptually distinct, in practice they are closely intertwined.

Thus, the setting of rational regulatory priorities entails scientific, economic, and political judgments 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. For example, it is often impossible to know whether a dose-response function follows a linear or a non-linear (threshold) model, yet the scientists' choice of one or the other model is crucially important for the determination of the acceptable level of safety. If risk assessment and risk management are not separable in practice, then it follows that accountability and efficiency are best achieved when an expert agency, rather than a collegial body of political executives like the Commission, is solely responsible for the entire regulatory process. As in the case of pharmaceuticals, for food safety too the refusal to delegate powers to independent bodies is creating a serious accountability deficit as well as a growing credibility problem.

Both theory and experience suggest that regulatory powers should be delegated to independent European agencies. However, because of the above-mentioned Meroni doctrine, such a solution appears not to be feasible without a new treaty. However, for the powerful anti-delegation faction within the Commission (led by the Legal Service) an *ad hoc* change of the treaty would not be sufficient to overcome the doubts about the legality of delegating rule-making powers to independent agencies. An isolated modification of the treaty in order to enable the delegation of such powers to bodies other than the Council, the European Parliament, and the Commission would necessarily, it is argued, upset the institutional balance within the EC/EU.

Moreover, the argument continues, even a partial limitation of the regulatory competencies of the Commission could compromise the technical capacities of its departments, thus affecting the exercise of other essential competencies, in particular the monopoly of legislative initiative. Such an amendment would undermine the very foundations of the Community method, and thus could not be contemplated without a prior constitutional debate on the future of the Community institutions.

The obvious counter-argument is that the balance of powers between the policymaking institutions has changed continuously since the creation of the European Communities; in fact, the rate of change has increased since the Maastricht Treaty introduced the pillar structure of the Union.

In addition the delegation of rule-making powers to agencies could actually strengthen the Commission by allowing it to concentrate its limited resources on policy initiation and on the other treaty-based powers, as well as on the new managerial and political tasks entailed by enlargement.

The crucial point, however, is that the growing complexity of the EU policy-making system should be matched by greater functional differentiation, in particular, by the explicit assignment of an autonomous role to a "European regulatory estate" – the extended network of national, sub-national, and supranational, organisations operating in the various areas of regulatory policy making

The lack of a European administrative infrastructure means that between the supranational level of rule-making and the national, or sub-national, levels of enforcement an institutional vacuum exists which is supposed to be filled by the loyal cooperation of all the competent authorities.

Unfortunately, in many cases such cooperation is not forthcoming, while significant differences in the resources, expertise, and political independence of the various regulators – differences which can only increase in a greatly enlarged EU – impede a uniform application of the common rules. One important function of a European regulatory estate would be to fill this institutional vacuum by straddling the line that still separates the supranational from the national (or sub-national) levels of regulatory governance. This would send a clear signal to the various economic and social interests whose plans depend on a reasonably consistent enforcement of EU regulations, that henceforth they will be able to operate in a predictable environment.

In a globalizing world, managing international regulatory interdependence is almost as important as filling the institutional vacuum separating the European and the national levels of regulation. The EU's

29 Greenwood, T., *Knowledge and Discretion in Government Regulation* (New York: Praeger 1984), p. 118.

commitment to, and application of, the precautionary principle has been repeatedly challenged by the WTO, the United States, and by many other developed and developing countries. The proposals presented to the Codex Alimentarius Committee on General Principles in April 2000 were opposed by the U.S. and other third countries, fearing that the principle might be too easily misused for protectionist purposes. Such fears are fed by episodes like the proposed aflatoxin standards – which would seriously affect the agricultural exports of the poorest African countries for negligible health benefits to Europeans – and the beef hormones dispute which has for years brought the EU into opposition with its major trading partners. In this dispute the Commission found itself in the same position vis-à-vis the WTO bodies as that in which various Member States have found themselves vis-à-vis the Community: they have been sanctioned for introducing a public health and consumer protection measure which has not been sufficiently supported by scientific evidence.[30]

VI. Conclusion

Problems of accountability and credibility arise in all areas of European regulation, but are particularly severe in risk regulation. The stubborn refusal to delegate rule-making powers to independent agencies can only aggravate these problems in the future. In fact, the controversy about the use and abuse of the precautionary principle may be interpreted as the sign of a widening gap between the political objectives of European integration and the correct setting of regulatory objectives and priorities. In the past it was generally assumed that the two sets of objectives largely coincided or were at least compatible. The assumption was justified as long as the overriding priority was the establishment of the single European market. Today, now that this objective has been achieved in most sectors of the economy, Europeans are entitled to demand that regulatory decisions in sensitive areas like food safety should be taken, not for political reasons, however noble, but to pursue health and safety objectives in the most efficient and effective way possible. As long as there is no functional and institutional separation of regulatory and executive powers at European level (thus allowing the Commission to retain the monopoly of policy initiation in all areas of Community competence), so long it will be difficult to dispel the suspicion that regulatory objectives and priorities may be distorted for the sake of integration or, more cynically, in order to augment the power and competencies of the Brussels bureaucracy. What is needed are full-fledged European regulatory agencies that are not only independent from both the national governments and the European executive, but also subject to a stringent system of accountability and control.

30 de Búrca, G./Scott, J., "The Impact of the WTO on EU Decision-making". *Harvard Jean Monnet Working Paper 6/00.*