The US roots of the regulatory state

All modern states engage in redistribution, in macro-economic stabilization, and in regulation, the latter understood as “control exercised by a public agency, on the basis of a legislative mandate, over activities that are generally regarded as desirable to society” (Selznick, 1985: 364). The relative importance of these functions, however, has varied from country to country and, for the same country, in different historical periods. Until fairly recently, most European countries attached greater political significance to redistribution and economic stabilization than to economic and social regulation. These priorities are reflected in labels like “welfare state,” which emphasizes the redistributive function, and “Keynesian state,” which emphasizes the stabilization function. On the other hand, US scholars often refer to the federal government as a “regulatory state.” The difference in terminology suggests that in the US the regulatory function has been historically more important than the other two functions. In fact, prior to F.D. Roosevelt’s New Deal, the US Government played a modest role in both macro-economic stabilization and in redistribution. Even after the New Deal, the US remained a “welfare laggard” by the standards of the European welfare states.

Passage of the Sherman Act in the US in 1890 may be taken as the birth date of the US regulatory state. The Act set the stage for more than a century of jurisprudence regarding monopoly, cartels, and oligopoly, and even today it is considered to be unequalled in its generality among US statutes that regulate commerce. Indeed, the Sherman Act outlawed “every contract, combination or conspiracy in restraint of trade” and treated violations as crimes. The quasi-constitutional status of the Act was recognized by the US Supreme Court when in Sugar Institute, Inc. vs. United States (297 US 553 [1936]) it wrote: “We have said that the Sherman Anti-Trust Act, as a charter of freedom, has a generality and adaptability comparable to that found to be desirable in constitutional provisions” (cited in Kovacic and Shapiro, 2000: 58). Indeed, the US has played a pioneering role in economic as well as in social regulation. If the Sherman Act served, in part, as a model for the competition articles of the 1957 Rome Treaty establishing the European Economic Community, the Clayton Act of 1914 anticipated by some 75 years the first European provisions in the area of mergers. Also in the 1960s and 1970s the US served as a model for European regulators in new fields...
The evolution of the regulatory state

of social regulation such as environmental protection, nuclear safety, consumer product safety, and the regulation of new technologies.

The growth of statutory regulation in Europe

The founders of communitarian Europe came from countries where public ownership of key industries, national planning, aggregate-demand management, and large-scale income redistribution were considered perfectly legitimate forms of state intervention in the economy. This ideological background is evident in the 1951 Treaty of Paris, which established the European Coal and Steel Community (ECSC). Although the declared objective of the Treaty was the elimination of trade barriers and the encouragement of “normal” competition (rather than competition \textit{per se}) in the sectors of coal and steel, many specific provisions were hardly compatible with economic liberalism. Thus the High Authority, the supranational executive of the ECSC, was given extensive powers of intervention, including the right to levy taxes, to influence investment decisions, and even in some cases to impose minimum prices and production quotas. Given the limited scope of the Coal and Steel Community, the 1951 Treaty of Paris could largely avoid questions of general economic philosophy. Such questions played a much larger role in the preparatory work for the establishment of the European Economic Community (EEC), when it was realized that the integration of highly regulated national markets would have been impossible without a serious effort to liberalize the economies of the member states.

The well-known fact that monopolies and cartels have an inherent tendency to carve up markets was the main motivation for introducing fairly strict competition rules. It would indeed be useless to bring down trade barriers between the member states if the national governments or private industry remained free to use subsidies or cartel-like arrangements to divide markets, or to reserve them for home producers. This explains the quasi-constitutional status of the rules on competition and state aid in the EU. It should also be noted that these rules take the place of WTO-authorized countervailing duties to offset the damage caused by export subsidies to the industries of importing nations. The member states of the EU have surrendered their policy autonomy in matters relating to intra-EU trade, but only because of the existence of a European competition policy.

Still, one can detect traces of the traditional interventionist philosophy of the member states even in the “neo-liberal” core of the Rome Treaty. Thus, Article 85 deemed inconsistent with the common market “all agreements between firms . . . and all concerted practices likely to affected practices between Member States.” As Harvard economist F.M. Scherer observed, the reference to “all agreements” has the ring of the \textit{per se} prohibition embodied in judicial interpretations of America’s Sherman Act. However, Scherer continues, Article 85 went on to permit exceptions for agreements and concerted practices that contributed “towards improving the production or distribution of goods or promoting technical or economic progress while reserv- ing the users a fair share in the [resulting] profit . . . Thus a complex balancing process – what US jurists call a 'rule of reason' approach – was instituted” (Scherer, 1994: 35).

Some supranational regulation in the areas of competition, mergers, state aid to industry and free movement of the factors of production is necessary for the proper functioning of the single European market, but the same cannot be said of most social regulation. In fact, of the three oldest fields of social regulation – environment, consumer protection, and health and safety at the workplace – only the last one is explicitly mentioned in the 1957 Treaty of Rome, and then only as an area where the European Commission should promote close coordination among the member states. Despite the absence of a clear legal basis, in the two decades from 1967 to 1987,
when the Single European Act formally recognized the competence of the EC to legislate in the area of environmental policy, well over 100 directives, regulations and decisions were introduced by the Commission and approved by the Council of Ministers. Already by 1992 the British House of Lords could point out that in many member states the corpus of environmental law of Community origin outweighed that of purely domestic origin. Moreover, although the first environmental directives were for the most part concerned with product regulation, and hence could be justified by the need to prevent that national standards would create non-tariff barriers to the free movement of goods, later directives increasingly stressed process regulation – emission and ambient quality standards, regulation of waste disposal, environmental impact assessment, and so on – aiming at strictly environmental rather than free-trade objectives.

Why independent agencies?

“Agency” is not a technical term, but rather an omnibus label to describe a variety of organizations that perform functions of a governmental nature, and which often exist outside the normal departmental framework of government. The most comprehensive definition is probably the one provided by the US Administrative Procedure Act (APA). According to this important statute, which regulates the decision-making processes of all agencies of the federal government, an agency is a part of government that is generally independent in the exercise of its functions and that by law has authority to take a final and binding action affecting the rights and obligations of individuals, particularly by the characteristic procedures of rulemaking and adjudication. It should be noted that agency status does not require that an agency exercise its power with complete independence, either vertically (in terms of being subject to administrative review) or horizontally (in terms of being required to act in concert with others). If an authority is in complete charge of a program, it is an agency with regards to that program, despite its subordinate position in other respects.

To exemplify, the US independent regulatory commissions (IRCs), such as the Interstate Commerce Commission and the Securities and Exchange Commission, are certainly agencies in the sense of the APA, but so are the Occupational Safety and Health Administration (located within the Department of Labor) and the Environmental Protection Agency (which depends directly on the President). In the EU, most European “agencies” are not, strictly speaking, agencies because the “final and binding action” is usually taken by the European Commission. The European Central Bank, on the other hand, is definitely an independent agency. In the member states the situation varies somewhat from country to country, but by now most national regulatory agencies satisfy the APA criterion. Moreover, regulatory agencies are almost always based on statute, hence “statutory regulation,” see earlier. In the UK, for example, the empowering legislation for bodies such as the Civil Aviation Authority, the Monopolies and Mergers Commission or the regulatory offices created to oversee the privatized utilities, state in some detail the composition and powers of such bodies, as well as the role of the Minister within that regulatory area. Any legal action for judicial review will normally be brought against the agency in its own name, unless the applicant is seeking to impugn a particular decision taken by the Minister. In contrast, in the EU, legal actions for judicial review have to be taken against the Commission rather than against the agency, which presumably did all the technical/scientific work preparatory to the Commission’s decision.

In parliamentary systems, assignment of quasi-legislative (rulemaking) functions to government departments used to be the normal mode of delegation. In the areas of economic and social regulation, however, it is today generally admitted that direct ministerial oversight seldom represents a satisfactory solution. The case in favor of delegation to agencies rather than to
existing departments of government usually includes the following elements: the need for
textbook and the independence from government that experts require; the need of constant
fine-tuning of the rules to adapt them to scientific and technical progress; often ministers cannot
justifying devoting sufficient time to highly technical tasks; the opportunity for consultations
through public hearings is considerably greater for agencies (public hearings are often, in fact,
a statutory obligation) than for departments – bureaucratic anonymity being a corollary of min-
terestial accountability; and the greater possibility of attracting high-level experts without the
restrictions of civil service rules. These are important, but not decisive, advantages of the agency
model. The really crucial factor is the insulation of the agency from direct political influence,
and it is this political independence that needs to be justified. The question “why independent
agencies?” is best understood in the context of a broader question about the role and justifica-
tion of nonmajoritarian institutions in democratic polities, where public policy is supposed to be
made by politically accountable policymakers. By definition, nonmajoritarian institutions, such
as independent regulatory agencies and independent central banks, are not accountable to the
voters or to their elected representatives, and hence do not enjoy direct democratic legitimacy.
However, such institutions can increase the credibility of long-term policy commitments made
by elected politicians by subtracting certain important decisions to the uncertain influence of
the electoral cycle. In turn, this possibility of achieving credible commitments to long-term
policy objectives – despite the fact that democracy is a system of government pro tempore where
the policies of the current majority can be subverted by a new majority – enhances the quality
democracy, just as independent courts of law make constitutional democracy possible.

In an integrating world economy, moreover, domestic and foreign investors are extremely
sensitive to the risk that changing parliamentary majorities may cause significant and unpredict-
able changes in public policy. Independent regulatory agencies have also been established in
order to protect the regulatory process from such political uncertainty. In this perspective, the
independent regulator may be viewed as an impartial referee administering a regulatory contract in
the interest of all the stakeholders. Thus, the challenge facing legislators is to design a framework
where independence and accountability are complementary and mutually supportive, rather
than mutually exclusive, values. I come back to the institutional-design issue after a brief review
of recent trends in regulatory governance. Agency independence is not an end in itself; rather, it
is a means for achieving higher-level objectives such as policy coherence, credibility, and
accountability. In political terms an independent regulatory agency provides assurance both to
the current majority and to future ones that their policies will be implemented impartially, as
well as in a technically and economically competent way. The assumption that the agency oper-
ates at arm’s length from government is of course essential. The agency’s insulation from govern-
ment means, inter alia, that if the new majority wants to change policy priorities, it must do so
in an explicit way, rather than by subterfuge as it often happens with bureaucracies under direct
ministerial control.

Equally crucial is the role of the courts, which must decide whether a particular agency
decision is justified in terms of the explicit statutory goals. The procedural requirements dis-
cussed in a later section are another important feature of an agency, which is accountable as well
as independent – or, rather, that is accountable because it is independent. Such requirements are
best formulated in general legislation, such as the US Administrative Procedure Act, which, as
already mentioned, applies to the decision-making processes of all federal agencies. In countries
where such procedural controls of general applicability are missing, regulation is often perceived
as being too discretionary and hence unaccountable. Actually, general and indirect (procedural)
controls are even more important in parliamentary systems where the partial fusion of executive
and legislative powers requires a sort of double independence of the agencies.
Transnational regulatory networks

There was a time when any difference in national approaches to economic and social regulation was considered a non-tariff barrier, and as such a serious obstacle to market integration. Up to the mid-1970s the tendency in the European Community (as the European Union was then called) was to remove such obstacles by means of “total harmonization.” Under total harmonization, once European rules have been put in place, a member state’s capacity to apply stricter rules by appealing to the values referred to in Article 36 of the Treaty of Rome – such as the protection of the health and life of humans, animals, and plants – is excluded. By the mid-1970s, however, the limits of the approach had become clear, although mounting opposition to what some member states considered excessive centralization convinced the European Commission that this instrument had to be used so as not to interfere too much with the regulatory autonomy of the national governments. The emphasis shifted from total to optional and minimum harmonization – and to mutual recognition. Optional harmonization aims to guarantee the free movement of goods whilst permitting the member states to retain their traditional forms of regulation for goods produced for the domestic market. Under minimum harmonization, the national governments must secure the level of regulation set out in a directive, but are permitted to set higher standards – provided that the stricter national rules do not violate Community law. Finally, the mutual recognition of national regulations does not involve the transfer of regulatory powers to the supranational institutions, but nevertheless restricts the freedom of action of national governments, which cannot prevent the marketing within their borders of a product lawfully manufactured and marketed in another member state.

Harmonization is one of three legal techniques the Rome Treaty made available to the Commission for establishing and maintaining a common European market – the other two techniques being liberalization and the control of anti-competitive behavior. A fact that has been too often overlooked in the past, however, is that each enlargement of the EU necessarily changes the calculus of the benefits and the costs of harmonization – the reduction in transaction costs made possible by harmonized regulations, on the one hand, and the welfare losses entailed by rules that are less precisely tailored to the resources and preferences of each member state, on the other. As long as resources and preferences are fairly similar across countries, the advantages of harmonization are likely to exceed the welfare losses, but when heterogeneity exceeds a certain threshold, the reverse will be true. There are several indications in the present EU that this threshold has already been exceeded: centralized, top-down harmonization, even of the minimum type, is increasingly resented. Mutual recognition of national regulations – as long as they satisfy essential requirements of safety and health – used to be considered a viable alternative to harmonization; however, mutual recognition presupposes a good deal of mutual trust and a certain homogeneity of regulatory institutions and approaches. In the 1980s and 1990s, when the EU consisted of twelve and then fifteen fairly homogeneous West European states, it proved possible to pass important pieces of legislation based on mutual recognition, such as Council Directive 89/48EEC on “a general system for the recognition of higher education diplomas awarded on completion of vocational courses of at least three years’ duration.” The system introduced by this Directive is general, in the sense that it applies to all regulated professions and to employed professionals as well as to the self-employed; and that it deals with both entry into and exercise of a profession. Unlike the older, sectorial directives dealing with individual professions, this one does not attempt to harmonize the length and subject matters of professional education, or even the range of activities in which professionals can engage. Instead, it introduces a system by which the states can compensate for eventual differences in the length of the
training or in the contents of the professional curriculum without restricting the freedom of movement. In the latter case, for example, the host country can demand that the applicant take a test or alternatively acquire practical experience for a period not exceeding three years. The applicant is free to choose between these two “compensation methods,” whilst the competent authority of the host country bears the burden of showing in detail the deficiencies in the requirements for the diploma submitted by the said applicant. The procedure is to be concluded within four months, ending with a reasoned decision that may be appealed in the courts of the host member state. Directive 89/48 created, for the first time in Europe, a single market for the regulated professions. A member state can no longer deny access to, or the exercise of, a regulated profession on its territory to EU citizens who already exercise, or could legitimately exercise, the same profession in another member state.

After the “big bang” enlargement to the East, however, public opinion in Western Europe became particularly sensitive to the distributional consequences of the principle of mutual recognition. Fears of regulatory competition and “social dumping,” which in the past had not prevented the application of this principle to important sectors of the economy, now led to a political veto of the original (Bolkestein) draft of the Services Directive (Majone, 2009). The decline of both centralized harmonization and mutual recognition does not, however, imply the impossibility of regulatory coordination and cooperation within the EU and internationally. What can no longer be achieved in a centralized fashion may be achieved in a more decentralized way, in particular by means of transnational regulatory networks. As already mentioned, networking is a key feature of the new governance, and it is to be expected that transnational networks will also play an increasingly significant role in international regulatory governance. We saw in a previous section that an important, if not the main, justification for the delegation of important regulatory powers to a central institution like the European Commission is to increase the credibility of long-term commitments. It may seem that a transnational network of regulatory agencies (which typically cannot enact legally binding regulations) cannot ensure credible long-term commitments, but this is not necessarily the case. In an earlier section I have argued that under some conditions the provision of information can be more effective than legally binding rules. Similarly, in the case of networks, the lack of formal legal powers may be compensated by the importance of reputation in repeated transactions.

To see how reputation works, let us start with the observation that teamwork can help to achieve credible commitment. As social psychologists have shown, although people may be weak on their own, they can build resolve by forming a group: any member of the group is open to peer pressure and thus places himself in a situation where pride and self-respect are lost when commitments are broken. The success of organizations such as Alcoholics Anonymous and Weight Watchers is said to be based on this insight. Now, what is true of individuals in a group can also apply to organizations in a network. An agency that sees itself as part of a transnational network of institutions pursuing similar objectives and facing similar problems is motivated to defend its policy commitments and/or professional standards against external influences. This is because the agency executives have an incentive to maintain their reputation in the eyes of other members of the network. Unprofessional or politically motivated behavior would compromise their international reputation and make cooperation more difficult to achieve in the future.

In other words, the function of a network is not only to permit an efficient division of labor and the exchange of information, but also to facilitate the development of behavioral standards and working practices that create shared expectations and enhance the effectiveness of social mechanisms of reputational enforcement. In this sense, it has been suggested that a network may be viewed as a “bearer of reputation.”
Dilemmas of risk regulation

The approach to risk regulation advocated by the European institutions has considerable popular appeal, but when it is critically examined and compared with the best international practice, it shows that risk regulation in the EU is still at an early stage of development. As is shown later, the consequences of this situation are serious, not only in terms of allocative efficiency, but also of equity, and of the risk of international isolation. It is, therefore, important to examine critically the logical foundations of the official doctrine. The Commission has been promoting the precautionary principle (PP) as a key tenet of EU risk regulation, and even as a general principle of international economic and environmental law (Commission of the European Communities, 2000). As a general regulatory approach, however, the PP suffers from a number of serious shortcomings: it lacks a sound logical foundation; it distorts regulatory priorities; it can have undesirable distributive consequences; not least, it undermines international regulatory cooperation. Above all, the principle is deeply ambiguous. Like the English constitution according to Walter Bagehot, the philosophy behind the PP is composed of two distinct sets of elements: the “dignified” parts (“those which bring it force”) and the “efficient” parts (“those by which it, in fact, works”). In its “dignified” aspect the precautionary philosophy purports to provide a legitimate basis for taking protective regulatory measures even when reliable scientific evidence of the causes and/or the scale of potential damage is lacking. Thus it appeals to many Europeans who are increasingly concerned about the “globalization of risk” – the transmission of environmental and health risks through the channels of free trade. In its “efficient” aspect, however, the approach tends to expand regulatory discretion at national and international level – a discretion that can be used for a variety of purposes, for example to meet legitimate public concerns, but also to practice protectionism, or to reclaim national autonomy in politically sensitive areas of public policy.

Indeed, the member states of the EU are quickly learning to rely on the precautionary principle as an argument to justify stricter national regulations than those agreed at European level. In theory, the Commission allows member states to rely on the PP only when the Community scientific committees consider that the evidence presented by a member state is justified in light of new data, or by a particular national situation. In practice, the member states seem to be increasingly suspicious of the findings of the European committees and more inclined to rely on the determinations of their own regulatory bodies. Thus, the French Government refused to abide by the decision of the Commission to lift, as of 1 August 1999, the ban on exports of British beef, which had been imposed at the height of the first BSE (“mad cow” disease) crisis. The government turned to the newly established French agency for food safety (AFSSA) to justify its refusal. In an Advice of 30 September 1999, AFSSA concluded that the risks associated with beef from Britain were still significant. The Commission requested the opinion of its own Scientific Steering Committee, which concluded that the precautionary position taken by the French agency was unfounded. After AFSSA had once more confirmed its determination, the French Government on December 8 1999 officially declared that it would not lift its ban. At that point, the Commission had no alternative but to submit a complaint to the European Court of Justice, without, however, pushing the case with much conviction. The Commission is well aware that in cases involving genuine scientific doubts, the Court tends to respect the regulatory autonomy of the member states. This episode shows that the PP may be invoked by the national governments 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 (Scott and Vos, 2002).
The precautionary principle and the World Trade Organization: the beef hormones case

The effort to have the precautionary principle adopted not only as a “key tenet” of Community policy, but also as a “full-fledged and general principle” of international law (Commission of the European Communities, 2000) has met some limited success in the field of international environmental law. However, the World Trade Organization (WTO), the US, and many other developed and developing countries have repeatedly criticized the EU’s commitment to and the application of the principle. What international organizations and third countries fear is that something as poorly defined as the PP may be too easily misused for protectionist purposes. Such fears are fed by episodes like the aflatoxin standards and the beef hormones dispute, which for years has opposed the EU to some of its major trade partners. In this dispute the European Commission found itself in the position vis-à-vis the WTO which various EU member states have found themselves vis-à-vis the Community, being sanctioned for introducing a public health and consumer protection measure that was not sufficiently supported by scientific evidence (de Búrca and Scott, 2000).

One of the objectives of the Commission Communication on the Precautionary Principle of February 2 2000 was to respond to the objections raised by WTO. This Communication also served internal political aims, which were a response to pressures originating from the European Parliament and the Council. In a Resolution of March 10 1998 the European Parliament (EP) had invited the Commission “to anticipate possible challenges to Community food law by WTO bodies by requesting the scientific committees to present a full set of arguments based on the precautionary principle” (Commission of the European Communities, 2000: 25). On April 13 1999, the Council of Ministers adopted a Resolution urging the Commission, inter alia,

> to be in the future ever more determined to be guided by the precautionary principle in preparing proposals for legislation and in its other consumer-related activities and develop as a priority clear and effective guidelines for the application of this principle.

(Commission of the European Communities, 2000: 25)

These political pressures are at least partly responsible for the ambiguity that pervades the document. On the one hand, the Commission is well aware of the danger that the member states may use the PP in order to extend their own regulatory autonomy vis-à-vis the EU, and hence the exhortation to “avoid unwarranted recourse to the precautionary principle as a disguised form of protection” (2000: 3); the insistence that “the precautionary principle can under no circumstances be used to justify the adoption of arbitrary decisions” (2000: 13); the warning that “reliance on the precautionary principle is no excuse for derogating from the general principles of risk management” (2000: 18). On the other hand, there is the desire to accommodate the Council and the EP by using the principle as a means to maximize the EU’s regulatory discretion at the international level. Thus on page 3 of the document, we read:

> The Commission considers that the Community, like other WTO members, has the right to establish the level of protection . . . that it deems appropriate. Applying the precautionary principle is a key tenet of its policy, and the choices it makes to this end will continue to affect the views it defends internationally, on how this principle should be applied.

(Commission of the European Communities, 2000: 3)
The same demand for maximum regulatory discretion is repeated, in various forms, throughout the Communication. At the same time, the Commission 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.

This is not the opinion prevailing in the WTO, however. It is true that under the WTO Sanitary and Phytosanitary (SPS) Agreement, if a health measure has a scientific basis, there is little other countries can do to challenge it. However, Article 2(2) of the Agreement states, *inter alia*, that members of WTO shall ensure that any SPS measure “is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.” The exception provided by Article 5(7) applies to cases where relevant scientific evidence is insufficient, in which case a member state may *provisionally* adopt a measure “on the basis of available pertinent information . . . Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time” (emphasis added). The requirement of a scientific justification, and of risk assessment as a prelude to standard setting, sets a limit on regulatory discretion. But for the requirement to have meaning, there must be the possibility of a panel finding the absence of a scientific justification or the inadequacy of a risk assessment.

Such is the flexibility of the PP that it may be stretched to include 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/process poses no health or environmental risk. To quote again the Commission:

> 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.  

(*Commission of the European Communities, 2000: 21*)

In conformity with this strict interpretation of the PP, Article 3.1 of the “Novel Food” Regulation (Regulation 258/97) states that genetically modified food can be authorized only if “it does not present a danger to the consumer.” Since no such proof is, strictly speaking, possible, this interpretation of the PP is equivalent to advocating a zero-risk approach which, if consistently applied, would effectively stop scientific and technical innovation.

But here the Commission is caught in a serious dilemma: on the one hand, it has officially espoused the PP, in the hope of enhancing its regulatory credibility and political legitimacy in the eyes of a skeptical public opinion; on the other hand, it is committed to finding means for increasing 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 Commission has sought a way out of the dilemma of precaution versus innovation – which at the institutional level is reflected in severe turf conflicts among several of its Directorates General – by softening the rigorous standard of the Novel Food Regulation. The new regulation for genetically modified food being proposed at the time of the writing lowers the threshold: genetically modified food may be authorized if it does not present an *unacceptable* risk for human health or the environment. Moreover, traces of unauthorized GMOs are now acceptable, under certain conditions, whereas previously they were not allowed to circulate in the market under any condition (Poli, 2004). As the following section makes clear, 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 benefits, as well as the risks, of the new technology into account. The Communication on the PP admits that risk regulation cannot be based on a zero-risk approach, but fails to provide an alternative, logically defensible, concept. By contrast, US courts and regulators have been able to move beyond early simplistic approaches to the determination of safety.

By focusing the attention of policymakers and the general public on one specific, perhaps only hypothetical, risk the PP ignores the possibility that a different allocation of the same resources might save more lives. Any 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, as shown by the following example. In the late 1990s the risks connected with electromagnetic fields (EMFs, “electrosmog”) and towers/masts became a topic of intense political controversy in Italy, even involving the Vatican, because of certain radio transmitters located near Rome. Explicitly appealing to the precautionary principle, the then minister of the environment forced the government to approve what were believed to be the most stringent EMF exposure standards in the world. The minister of health of the same government, a highly respected cancer specialist, argued that with the resources needed to implement the new standards it would have been possible to save thousands of cancer patients – rather than the one death from leukemia per year that the new standards for electromagnetic exposure are supposed to prevent – but to no avail.

The opportunity costs of precautionary measures

The Commission Communication on the PP makes no reference to the opportunity cost of precautionary measures, so that the issue of a rational setting of regulatory priorities is not even raised in a document, which pretends to clarify a “key tenet” of risk regulation in the EU. But as risks multiply whilst resources remain limited, the necessity of deciding which risks to regulate can no longer be evaded. Hence, it is instructive to see how the question of regulatory priorities was raised in the US as part of a slow but steady improvement in the conceptual foundations of risk regulation. This learning process may be traced through a sequence of three regulatory principles: lowest feasible risk; elimination of significant risk; and balancing costs and benefits (for a fuller discussion, see Majone, 2003). Although this is not a linear sequence – different principles coexist even in the same area of regulation – a trend can be clearly detected towards a broader inclusion of relevant considerations, including the opportunity costs of individual measures.

Least feasible risk

According to this principle – the US equivalent of the precautionary approach – human exposure to health risks should be reduced to the lowest possible level. This principle is a sort of second-best rule. The best 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. For instance, Section 6(b)(5) of the 1970 Occupational Safety and Health Act directs the Occupational Safety and Health Administration (OSHA) 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. In the 1981 case *American Textile Manufacturers Institute, Inc. vs. Donovan*, Justice Brennan of the US Supreme Court agreed that “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). In the EU, the Court of First Instance was still holding a similar opinion in 1999, when in *Alpharma* (Case T-70/99R) it emphasized that the requirements of public health must take precedence over economic considerations. Like the precautionary approach, the least-feasible-risk approach rejects any sort of balancing of costs and benefits, presumably on the ground that the two sides of the basic relationship are incommensurable. In the 1980s and 1990s, however, US courts, regulators, and eventually also legislators, went through a learning process that convinced them that in the presence of multiplying risks and limited resources, a rational setting of regulatory priorities is impossible without a more sophisticated balancing approach to risk regulation.

**The significant-risk doctrine**

In *American Petroleum Institute vs. OSHA* (1978), the Fifth Circuit Court of Appeals invalidated a regulation that reduced the occupational exposure to benzene, a carcinogen, from 10 parts per million (ppm) to 1 ppm. The court found that the competent regulatory agency, 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)*

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 US 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) vs. 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)*

Thus was born the “significant-risk doctrine,” a crucial step in the process of learning how to deal with risk regulation 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 characterize 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. As 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. 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.

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) vs. 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 US 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 US advocacy of science-based risk assessment at the international level, as well as the country’s opposition to the precautionary principle advocated by the European institutions.
References