What Price Safety?
The Precautionary Principle and its Policy Implications

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Abstract

The European Commission is actively promoting the precautionary principle as a "key tenet" of Community policy as well as a general principle of international law. This paper explains why this promotional effort is likely to fail or to produce unanticipated and undesirable consequences. The principle has a legitimate but limited role to play in risk management, for example whenever there is an imminent danger of irreversible damage. As a general approach to risk regulation, however, it suffers from a number of shortcomings: it lacks a sound logical foundation; it may distort regulatory priorities; it can be misused to justify protectionist measures; it undermines international regulatory cooperation; and it may have undesirable distributive consequences. What is perhaps even more worrisome, the principle, as interpreted by the Commission, tends to favour a double standard for what is permissible internationally and in intra-Community relations. Thus the Commission seems willing to risk international isolation and the segmentation of the European market for the sake of an ambiguous and poorly understood principle. This paper suggests some possible explanations of this puzzle, but its main focus is on the conceptual problems and policy implications of the principle itself.

I. Introduction

Like the English constitution according to Walter Bagehot, the precautionary approach includes 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 approach 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 "globalisation 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 which can be used for a variety of purposes: to meet legitimate public concerns, but also to practice protectionism, or to reclaim national autonomy in politically sensitive areas of public policy. Even the Commission, which considers the precautionary principle a "key tenet" of its policy, admits that the principle may be used as a disguised form of protectionism (Commission, 2000, p. 3 and *passim*).

In sum, the precautionary approach is deeply ambiguous, and as we shall see in the following pages, this ambiguity is abetted by a lack of clear definitions and sound logical foundations. In the EC Treaty the precautionary principle appears only in the Title on the environment. It is not defined there or anywhere else in the Treaty. Nonetheless, the Commission, pushed by the Council and the European Parliament (see section V), is presently engaged in a sustained effort to promote the principle to the status of a "central plank" of Community policy and, more ambitiously, to the status of a general principle of international economic and environmental law.

However, given the conceptual deficiencies and disturbing policy implications discussed at some length in this paper, it seems unlikely that the other members of the World Trade Organization (WTO) will accept the precautionary principle, at least in the permissive interpretation advocated by the Commission. In the end the major beneficiaries of this promotional campaign may well be the member states of the EC/EU, which can use the approach to reclaim significant portions of their regulatory autonomy in the management of environmental and health risks.

There are, in fact, indications that the member states are quickly learning to rely on the principle of precaution as an argument to justify stricter national regulations. In theory, the Commission allows member states to rely on the precautionary principle only when the Community's scientific committees consider that the scientific evidence presented by the member states is justified in light of new evidence, or by a particular national situation. The problem is that member states seem to be increasingly suspicious of the findings of the Community's scientific committees, and increasingly inclined to rely on the determinations of their own regulatory bodies (Scott and Vos, 2001). For example, the precautionary principle has recently been invoked by Denmark as an argument for the annulment of the Commission's refusal to grant that country's derogation request for its stricter national regulations on the use of certain food additives (ib., p. 22).

The politically significant question is why the Commission is willing to risk international isolation and the segmentation of the European market for the sake of a controversial and ill-understood principle. This paper offers some suggestions which may help to explain this puzzle, but

its focus is on the conceptual problems and policy implications of the principle itself. A full discussion of the politics and the political economy of the precautionary approach would require a separate treatment. At any rate, a useful discussion along such lines presupposes some knowledge of the substantive issues analysed in the following pages.

II. Regulatory Science and Free Trade

Increasingly, science is playing a significant role in the regulation of international trade. In particular, the WTO *Agreement on the Application of Sanitary and Phytosanitary Measures* introduces a new science-based regime for disciplining health regulations which may affect international trade in agricultural products and foodstuffs. Annex A to the Agreement defines a sanitary or phytosanitary (SPS) measure as any measure applied to protect animal or plant life or health from a variety of risks, including "risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs".

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". Article 5 deals with risk assessment as a method for determining the appropriate level of health protection. Risk assessment is the standard by which SPS measures are to be judged as necessary and justified. In other words, for such measures to be necessary, based on scientific principles and not maintained without sufficient scientific evidence, they must be supported by a risk assessment conducted according to the criteria, and taking into account the factors, mentioned in Article 5. As interpreted by the WTO Appellate Body in the beef hormones case (see Section IV), this article says that there must be a rational relationship between the SPS measure and the risk assessment.

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).

Article 5(7) is the only reference to a precautionary approach in the entire Agreement, and we shall come back to it in a later section. The aim of the immediately following pages is simply to introduce the reader to some of the conceptual and technical complexities surrounding the notions of "scientific justification" and "risk assessment" as they apply to regulatory measures.

The process of standard setting is at the core of risk regulation. If we understand the extent of scientific uncertainty in standard setting, we are in a good position to appreciate the problems of regulatory science. Extrapolation is a key element in the establishment of environmental and health standards, hence a good part of the uncertainty inherent in standard setting originates in various types of extrapolation processes.

There is, first, the problem of extrapolating from animal experiments. A major issue in regulatory science is the determination of the animal species that best predicts the response in humans. There is little hope that one species could provide the broad range of predictive potential needed to assess the responses of a highly heterogeneous human population to different types of toxic substances. The heterogeneity of human populations leaves the public authorities with an almost impossible regulatory task. In an effort to find a way out of this dilemma, scientists have developed several mathematical models expressing the probability of a lifetime response, P, as a function of dosage D: P = f (D). This is the dose-response function. Different choices of f lead to different models.

Regardless of the choice of model, however, one has always to extrapolate from data points at high doses (the type of data provided by animal experiments) to the low levels relevant to the regulation of risk to humans. However, the same data points are compatible with a variety of extrapolating functions (Calabrese, 1978). Thus, under a threshold (non-linear) dose-response model it would be possible to establish a "virtually safe" level of exposure, at the numerical value of the threshold, even though high doses produce adverse health effects. Instead, if one uses a linear dose-response relationship, adverse health effects are predicted at every level of exposure, so that there is no obvious point at which a reasonable standard could be set.

It may be argued – as do many advocates of the precautionary principle – that if there is no firm scientific basis for choosing among different dose-response models, then one should prefer the safest or most conservative procedure. One problem with the conservatism argument is that it is not clear where one should stop. A no-threshold model is more conservative than one that admits the existence of thresholds for carcinogenic effects. But within the large class of no-threshold models many degrees of conservatism are possible. Again, in designing a toxicological experiment one could use the most sensitive species, the most sensitive strain within the species, and so on down to the level of the most sensitive animal. In short, it is difficult to be conservative in a consistent manner unless one is prepared to propose a zero level of exposure in each case. This, in a nutshell, is the main conceptual problem with the precautionary principle.

Now, extrapolating from the high doses shown to cause harm in animal experiments or in epidemiological studies, to the much lower exposures normally faced by humans is the essence of

quantitative risk assessments. From what has been said above it follows that uncertainty is a pervasive characteristic of regulatory risk assessments. But the technique has been accepted and continues to be used because there are no better alternatives. Thus the United States Supreme Court in *AFL-CIO v. American Petroleum Institute* (448 U.S. 607 (1980)) – the landmark benzene case – not only confirmed the legitimacy of quantitative risk assessment; it effectively made reliance on the methodology obligatory for all American agencies engaged in health 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 (Mashaw *et al.*, 1998, pp. 823-825). This historical background may explain U.S. advocacy of science-based risk assessment at the international level, as well as that country's opposition to the precautionary principle as interpreted by the EU. Today the methodology of risk assessment is used by regulators in all developed countries. Moreover, as mentioned above, risk assessment is the standard by which trade-restricting health regulations are evaluated as necessary and justified. As such, it plays a crucial role in the debate about the application of the precautionary principle at the international level.

III. An Idea in Search of a Definition

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

The German approach was taken up by other policy elites in Europe, including those which drafted the EC's *Fourth Environmental Action Programme*, who sought to develop an approach to environmental policy that was preventive rather than reactive (Weale, 1992, p. 80). In the EC Treaty the principle appears only in the Title on environment. Article 174 EC (ex Article 130(r)) provides that Community environmental policy "shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at the source and that the polluter should pay". No definition of the

precautionary principle is provided in this article or anywhere else in the Treaty. In spite of this, it is argued by the Commission and by some legal scholars that the principle applies beyond EC environmental policy. This is because Article 6 EC provides that the environmental protection requirements be integrated into the definition and implementation of Community policies and activities referred to in Article 3 EC. In so far as the precautionary principle is one of the core principles of EC environmental policy, it is concluded that it should be integrated, as appropriate, into other Community policies (Scott and Vos, 2001, p. 4).

As mentioned in Section II, there is an indirect reference to a precautionary approach (again undefined) in Article 5(7) of the WTO SPS Agreement. WTO member states are allowed to take measures unsupported by a risk assessment when the relevant scientific evidence is insufficient, but only provisionally. Perhaps the best known statement of the precautionary principle is provided by Principle 15 of the Declaration of the 1992 UN Conference on Environment and Development (Rio Declaration):

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

It is important to notice that the similarity of some statements of the principle is often more apparent than real. Even when such statements refer more or less explicitly to a situation where the probability and extent of damage are poorly understood, they often differ in the conditions which precautionary measures must satisfy. Thus, according to the SPS Agreement such measures must be provisional, but the European Commission chooses to interpret this condition not in terms of clock time, but of the time necessary to achieve a sufficient level of scientific certainty – a very flexible standard, given the limitations of regulatory science!

Again, the Commission quotes with approval Principle 15 of the Rio Declaration, even though the standards set by the drafters of the Declaration (a threat of serious and irreversible damage, measures must be cost-effective) are a good deal stricter than the ones the Commission advocates. For example, according to the Commission a precautionary measure may be justified if there are "reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal or plant health may be *inconsistent with the chosen level of protection*" (Commission, 2000, p. 10; emphasis added) – a significantly more permissive standard than the threat of serious and irreversible damage.

Since the precautionary principle lends itself to a wide range of interpretations, it would be instructive to see how the European Court of Justice (ECJ) and the Court of First Instance have dealt with it. A detailed discussion of relevant cases is of course beyond the scope of the present paper – a good survey may be found in Scott and Vos (2001). A general inference from major

decisions appears to be that in cases of scientific uncertainty, member states have considerable discretion in deciding to err on the side of caution. They must however provide some evidence of scientific uncertainty. They must adduce evidence of a specific, concrete risk and not merely of potential risks based on a general precautionary approach (Scott and Vos, p. 15). Thus in the famous *German Beer* case (Case 178/84 [1987]), the ECJ refused to allow a ban on additives in beer, based on a generic principle of prevention. The national authorities must come up with more specific scientific evidence than a mere reference to the potential risks posed by the ingestion of additives in general.

IV. The Precautionary Principle and the WTO: The Beef Hormones Case

As already mentioned, the EU is currently engaged in a major effort to have the precautionary principle adopted as a "key tenet" of Community policy and as a "full-fledged and general principle" of international law (Commission, 2000). While some progress has been made in the field of international environmental law, the EU's commitment to, and application of, the principle has been repeatedly questioned or opposed by the WTO, the United States, and by other developed and developing countries. Thus, the proposals on the precautionary principle presented by the EU to the Codex Alimentarius Committee on General Principles in April 2000 were opposed by the U.S. and many other third countries, which fear that the principle may be too easily misused for protectionist purposes. Such fears are fed by episodes like the proposed aflatoxin standards, to be briefly discussed in Section VI, and the beef hormones dispute which for years has opposed the EU to some of its major trading partners. In this dispute the European Commission found itself in the position vis-à-vis the WTO bodies which various EC member states have found themselves vis-à-vis the Community, being sanctioned for introducing a public health and consumer protection measure which was not sufficiently supported by scientific evidence (de Búrca and Scott, 2000, p. 6).

The Commission argued that the precautionary principle applies across the whole of the SPS Agreement as a general principle of international law. The WTO's Appellate Body specifically rejected this argument and stated that the principle must receive authoritative formulation before it can be raised to the status sought for it by the EU. The same body also observed that the precautionary principle has not been written into Article 5(7) of the SPS Agreement as a ground for justifying measures that are otherwise inconsistent with the obligations of the WTO set out in particular provisions of the Agreement.

The controversy over the use of growth hormones in cattle raising, which has opposed the EU to the U.S. and Canada in the framework of the WTO's dispute resolution mechanism, has been discussed many times and from a variety of disciplinary and policy perspectives. The historical background of the controversy is not widely known, however. Because of its relevance to the present discussion it will be briefly reviewed here. The immediately following pages rely heavily on recent work by Christian Joerges (1997, 2001).

The hormones regime in the EC stems from Directive 81/602 on the prohibition of "certain substances having a hormonal action and of any substances having a thyrostatic action". This directive was amended in 1985 by Directive 85/358, extended in 1988 and consolidated by Directive 96/22. The 1985 directive – which was adopted by qualified majority on the basis of Article 43 EEC (now Article 37 EC) dealing with the common agricultural policy – prohibited the use of hormones in livestock farming. Even then the prohibition was controversial. The United Kingdom brought suit against the directive, arguing *inter alia* that in view of its health objectives the directive should have been based on Article 100 (now Article 94) on the approximation of laws. This article requires unanimity and hence would have allowed the UK government to veto the prohibition of growth hormones in cattle raising and meat products.

The effect of the 1985 directive was also to prohibit the importation of American and Canadian beef into the Community, although this point was not addressed in the legal controversy between the UK and the Community. Instead, the UK asserted that in enacting the directive the Council should have taken into consideration the scientific report which had been prepared in accordance with Article 8 of Directive 81/602. According to this report, risk assessment had shown that growth hormones used according to good veterinary practice would result in no significant harm. This conclusion of its own scientific experts led the Commission to reconsider the strict prohibition imposed by Community law.

However, both the European Parliament and the Economic and Social Council strongly opposed any such policy change. Because of this opposition the Commission cancelled further meetings of the group of scientific experts (Joerges, 2001, p. 10). At the same time the European Court of Justice rejected the complaint of the UK government with the flimsy argument that Article 8 of Directive 81/602 imposed an obligation on the Commission only, so that the Council was under no obligation to take the scientific report into consideration.

Opposition to the Commission's willingness to accept the result of the risk assessment and to reconsider the Community's hormones policy accordingly, led to change the rationale of that policy from health safety to "the interests of the consumers in general". As Advocate General Lenz put it, this type of consumer protection need not be supported by scientific evidence. Once its

legitimacy as an objective of agricultural policy in general, and of the hormones directive in particular, is accepted, there is "really no reason to examine the health problem… and so the fact that in the preamble to the contested directive the Council did not go into the partial findings of the scientific group… cannot be regarded as a failure to give reasons" (cited in Joerges, 1997, pp. 309-310). Without citing any empirical evidence, the Advocate General added that "it could be seen that meat from animals treated with hormones is widely rejected".

Some years later the Commission was to take a similar position, and even use some of the same language, at the WTO level. In 1997 the U.S. and Canada filed complaints with the WTO against the EC ban of meat products containing growth hormones, submitting that this measure violates the SPS Agreement. This agreement, it will be remembered, allows WTO members to adopt health standards that are stricter than international standards, provided the stricter standards are supported by risk assessment. Unfortunately, the risk assessment conducted by the EC scientific experts had shown that the use of growth hormones according to good veterinary practice posed no significant health risk .Hence the Commission was forced to meet the WTO challenge with arguments similar to those used by the Advocate General in rejecting the UK's complaint against Directive 85/358. In particular, it pointed to various incidents since the early 1980s, when hormones that entered the European food market had allegedly made European consumers wary of beef. The Commission concluded that a ban of beef containing growth hormones was necessary to restore consumer confidence.

The WTO's Dispute Resolution Panel decided against the EC. The Panel raised three objections: first, more permissive international standards existed for five of the hormones; second, the EC measure was not based on a risk assessment, as required by Article 5(1) of the SPS Agreement; finally, the EC policy was not consistent, hence in violation of the no-discrimination requirement of Article 5(5). The WTO's Appellate Body agreed with the panel that the EC had failed to base its measure on a risk assessment and decided against the EC essentially for two reasons. First because the scientific evidence of harm produced by the Commission was not "sufficiently specific to the case at hand" – it took the form of general studies, but did not "address the particular kind of risk here at stake". Second, the Appellate Body endorsed the finding of the Dispute Resolution Panel that "theoretical uncertainty" arising because "science can never provide absolute certainty that a given substance will never have adverse health effects" is not the kind of risk to be assessed under Article 5(1) of the SPS Agreement. The similarity with some of the older jurisprudence of the ECJ, particularly the *German Beer* case, is remarkable.

V. The Commission's Communication

As the preceding pages have shown, "[t]he issue of when and how to use the precautionary principle, both within the European Union and internationally, is giving rise to much debate, and to mixed, and sometimes contradictory views" (Commission, 2000, p. 3). With its Communication on the precautionary principle of 2 February 2000, the Commission intends to contribute to the ongoing debate by: outlining its own understanding of the principle; establishing guidelines for applying it; building a common understanding of how to assess and manage risks under conditions of scientific uncertainty; avoiding recourse to the precautionary principle as a disguised form of protectionism.

The document also serves political aims, being a response to pressures originating from the European Parliament and the Council. In its Resolution of 10 March 1998 on the Green Paper on the General Principles of Food Law, the 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".

On 13 April 1999, the Council 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" (both citations in Commission, 2000, p. 25).

These political pressures are at least partly responsible for the ambiguity which pervades the document, undermining its intellectual coherence. On the one hand, the Commission is well aware of the danger that the member states of the EU may use the precautionary principle in order to extend their own regulatory autonomy vis-à-vis the Community. Hence the exhortation to "avoid unwarranted recourse to the precautionary principle as a disguised form of protection" (p. 3); the insistence that "the precautionary principle can under no circumstances be used to justify the adoption of arbitrary decisions" (p. 13); the warning that "reliance on the precautionary principle is no excuse for derogating from the general principles of risk management" (p. 18).

On the other hand, there is a strong temptation to use the principle to maximize the EU's regulatory discretion at the international level. Thus on page 3 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".

The same demand for maximum regulatory discretion is repeated, in various forms, throughout the Communication: "a member [of the WTO] may apply measures, including measures based on the precautionary principle, which lead to a higher level of protection than that provided for in the relevant international standards or recommendations" (p. 11); "the Community is entitled to prescribe the level of protection, notably as regards the environment and human, animal and plant health, which it considers appropriate" (p. 12); "application of the precautionary principle is part of risk management, when scientific uncertainty precludes a full assessment of the risk and *when decision-makers consider that the chosen level of environmental protection or of human, animal and plant health may be in jeopardy*" (p. 13; emphasis added).

While it strives to achieve broad regulatory discretion at the international level, the Commission insists that the envisioned use of the precautionary principle, "far from being a way of evading obligations arising from the WTO Agreements", in fact complies with these obligations. Now, it is true that under the WTO SPS Agreement, if a health measure has a scientific basis, there is little other countries can do to challenge it. However, if a measure lacks an adequate scientific justification, it will be subject to attack. The requirement of a scientific justification, and of risk assessment as a prelude to standard setting, may be seen as a limit on regulatory arbitrariness. But for the requirement to have meaning, there must be the possibility of a dispute panel finding the absence of a scientific justification and the inadequacy of a risk assessment (Atik, 1996-97).

As discussed in the preceding section, both the WTO's Dispute Resolution Panel and the Appellate Body determined that the EC's ban on the importation of American beef was unsupported by scientific evidence and by an adequate risk assessment. One of the undeclared aims of the Communication is to prevent similar embarrassments in the future by proposing very elastic interpretations of the requirements of the SPS Agreement.

Thus, Article 5(7) of the Agreement concedes that when scientific evidence is insufficient, a country may adopt measures on the basis of the available pertinent information, but only provisionally. Moreover, the country must obtain the additional information necessary for a more objective risk assessment, and review the measure accordingly *within a reasonable period of time*. The Communication interprets these requirements as follows: "The measures, although provisional, shall be maintained as long as the scientific data remain incomplete, imprecise or inconclusive *and as long as the risk is considered too high to be imposed on society*" (Commission, 2000, p. 21; emphasis added). It is difficult to see how a dispute resolution panel could apply such subjective standards.

Again, according to the Communication, the concept of risk assessment in the SPS Agreement "leaves leeway for interpretation of what could be used as a basis for a precautionary

approach". It need not be confined to purely quantitative scientific data, but could include "non-quantifiable data of a factual or qualitative nature" (p. 12). This interpretation, the Commission claims, has been confirmed by the WTO's Appellate Body which, in the hormones case, rejected the panel's initial interpretation that the risk assessment had to be quantitative and had to establish a minimum degree of risk. However, the opinion of the Appellate Body does not necessarily coincide with the Commission's permissive interpretation. Between this interpretation and a quantitative risk analysis of the traditional type, there is a wide range of possible analytic approaches. One such approach is *comparative* risk assessment. Even though scientists may be unable to make exact quantitative statements about the low-dose risks of particular substances, they can often rank the risks of various substances at currently experienced doses. For example, scientists might say that a lifetime exposure to x parts per million (ppm) of substance A presents in their judgment a larger risk of cancer to a worker than a lifetime exposure to y ppm of substance B (Graham *et al*., 1988, p. 200). It is not necessary to evaluate precisely the risks posed by both substances in order to have a reasonable basis for such a comparison.

The Communication insists that the precautionary principle offers no excuse for derogating from the general principles of risk management, including an examination of the benefits and costs of action and inaction. However, cost-benefit analysis should include not only evaluation of the costs "to the Community", but also non-economic considerations such as acceptability to the public. Who should determine public acceptability remains unclear, unless this determination is seen as part of the right of the Community to establish the level of protection that it deems appropriate at any particular time. An adjustable peg can justify any measure, making cost-benefit or risk analysis superfluous.

We have here another manifestation of the deep ambiguity of the Communication. This document is also a public relations exercise "designed to calm the fears of those who perceive that the precautionary principle serves, in the case of the EU, to legitimate decisions which are irrational other than in terms of their capacity to serve protectionist goals" (Scott and Vos, 2001, p. 31). Hence the emphasis on the centrality of scientific evaluation and on the generally accepted principles of risk management. However, the exercise is ultimately unpersuasive because all the substantive and procedural constraints on regulatory arbitrariness are relaxed to the point of becoming non-binding.

So far the Commission's Communication has been criticized for what it says. In the following pages it will be criticized for what it fails to consider.

VI. The Precautionary Principle and the Logic of Decision-Making

A glaring shortcoming of the Communication is the failure to consider the overall implications of adopting the precautionary principle, not as an exceptional temporary measure but as a "key tenet" of Community policy, a "guide in preparing proposals for legislation", a "full-fledged and general principle of international law". In the present section we examine the principle's implications for the logic of decision-making. In the following section political and social consequences will be discussed.

One important factor the Communication does not consider is the opportunity cost of precautionary measures. The attempt to control poorly understood, low-level risks necessarily uses up resources that in many cases could be directed more effectively towards the reduction of well-known, large-scale risks. Thus, one of the unanticipated consequences of the precautionary principle is to raise the issue of a rational setting of regulatory priorities at national and European levels. Since resources are always limited it is impossible to control all actual and potential risks. Even if a society is willing "to pay a higher cost to protect an interest, such as the environment or health, to which it attaches priority" (Commission, 2000, p. 20), it is still the case that some environmental or risks regulations might be too expensive. Hence the choice of which risks to regulate and when to regulate them are crucially important for a rational allocation of resources and for consistency in policymaking. Precautionary measures – taken on an ad hoc basis, often in response to political pressures – may distort priorities and compromise the consistency of regulatory policies.

More generally, the precautionary principle appears to be seriously flawed as an aid to rational decision-making under uncertainty. Although lack of precise definitions makes it difficult to develop a formal critique, the following considerations may help to grasp the principle's main theoretical shortcomings.

To begin with, recall that risk is a compound measure (more precisely, a product) of the probability of harm and its severity. Now, according to the fundamental theorem of decision theory, the only consistent rule for decision-making under uncertainty is to choose the alternative which minimizes the expected loss (or maximizes the expected utility). Consider a situation where there are various possible events (or "states of nature") E_1, E_2, …, E_n, with probabilities p_1, p_2, …, p_n, alternative actions A_1, A_2, …, A_m, and losses l_{ij} for each combination of alternative A_i and event E_j, i = 1, 2, …, m; j = 1, 2, …, n. The optimal decision consists in choosing the alternative which minimizes the expected loss, i.e., the sum of the products of the losses by the corresponding probabilities (formally: the alternative which minimizes $\Sigma_j p_j l_{ij}$).

Any good textbook on decision theory (e.g., Lindley, 1971) provides the proof that any other decision rule – and in particular any rule which does not use both the losses and the corresponding probabilities – can lead to inconsistent decisions. One such decision rule is the minimax principle, which in some respects is quite similar to the precautionary principle. The minimax approach to decision-making under uncertainty uses losses but not probabilities, either denying the existence of the latter, or claiming that the method is to be used when they are unknown (here is an important similarity with the precautionary principle). This approach makes sense in special situations – zero-sum games where the uncertainty is "strategic", i.e. part of the strategy of a rational opponent – but not in the general case, as may be seen from the following examples. Consider first the decision problem described in Table 1, where the entries indicate losses, e.g. extra deaths due to exposure to a toxic substance:

	E_1 (p_1)	E_2 (p_2)
A_1	10	0
A_2	1	1

TABLE 1

Following the minimax rule, for each row (i.e., alternative) we select the maximum loss (10 for A_1 and 1 for A_2), and choose that alternative having the minimum of these values. This is A_2 with value 1. Hence the minimax rule says: always choose A_2. The principle of expected loss would assign probabilities p_1 and p_2 to the uncertain events and choose A_2 if $1 < 10\ p_1$, i.e. $p_1 > 1/10$, otherwise A_1 should be selected. To see which of the two rules is more reasonable, suppose that p_1 is quite small (say, $p_1 = 0.01$ or 0.001) so that $10\ p_1$ is much less than 1. The minimax rule would still choose A_2, even though it is almost sure that no extra deaths would occur under A_1.

The result is even more striking in Table 2, where only the loss corresponding to the pair (A_1, E_1) has been changed:

	E_1 (p_1)	E_2 (p_2)
A_1	1.1	0
A_2	1	1

TABLE 2

The minimax rule would still choose A_2, even though the expected loss for A_1 is much smaller for all values of p_1 less than, say, 0.8. In short, the problem with the minimax rule is that it does not take account of all the information available to the decision-maker. The advantage of the expected-loss rule is that it takes account of both losses and probabilities.

As noted above, one defense of the minimax is that it is to be used when probabilities are unknown (and perhaps unknowable). This argument is strongly reminiscent of the distinction made by the American economist Frank Knight in the 1920s between "risk" (when the events are uncertain, but their probabilities are known) and "uncertainty" (where the probabilities are unknown). Knight attached great theoretical importance to this distinction, but modern analysis no longer views the two classes of events as different in kind. Probabilities may be known more or less precisely, they may be more or less subjective, but there are some logical difficulties involved in giving meaning to the statement that the probabilities are unknown. If we insist that we are "completely ignorant" as to which of the events E_1, …, E_n will occur, it is hard to escape the conclusion that all the events are equally likely to occur. But this implies that the probabilities are in fact known, and that $P(E_i) = 1/n$ for all i: the well-known uniform distribution!

The point of this digression on decision theory is to identify with more precision than would otherwise be possible the logical problems raised by the application of the precautionary principle. Like the minimax principle, the principle of precaution tends to focus the attention of regulators on some particular events and corresponding losses, rather than on the entire range of possibilities. As a consequence, regulators will base their determinations on worst cases, rather than on the weighted average of all potential losses, i.e. on the expected overall loss. The Commission's Communication provides a good example. On page 19 we read that in examining the benefits and costs of different alternatives, "[a] comparison must be made between the *most likely* positive and negative consequences of the envisaged actions and those of inaction…" (emphasis added). Consistent decision-making under uncertainty requires consideration of all consequences, not just the most (or, for that matter, least) likely ones. Note, too, that if we are truly ignorant of the probability distribution of consequences – a condition which is sometimes invoked in order to justify recourse to the precautionary principle – then it is logically impossible to speak of "most likely" consequences. The phrase implies a ranking of probabilities, and hence at least an approximate knowledge of the relevant distribution.

The most serious conceptual flaw, however, is the artificial distinction between situations where scientific information is sufficient to permit a formal risk assessment, and those where "scientific information is insufficient, inconclusive or uncertain". In reality, these are two points on a knowledge-ignorance continuum rather than two qualitatively distinct situations. The same logic

which leads to the rejection of Knight's distinction between risk and uncertainty, applies also here. As we saw, by its very nature regulatory science deals with uncertainties. For example, for most toxic substances it is still unknown whether the relevant model for standard setting is a threshold or a linear one. Most scientists favour the latter model, but this only complicates the regulator's problem, since it is unclear where a standard should be set above the zero level. Moreover, the continuous progress of science and technology produces increasingly precise measurements of toxicity (e.g., parts per billion) so that the search of safety becomes ever more elusive.

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

The prescriptions of decision theory break down only in one case, namely when losses (or utilities) are unbounded. In such a case it is clearly impossible to calculate expected values. An example of potential unbounded loss is the threat of serious and irreversible damage – the situation envisaged by Principle 15 of the Rio Declaration (see Section III). In this and similar situations, the precautionary principle may be a useful tool of risk management. But to acknowledge such possibilities is to recognize that the principle has a legitimate but quite limited role in risk management.

VII. Political and Social Consequences

Under the political conditions prevailing today, the sustainability of a regime of free trade and market integration depends crucially on international regulatory cooperation and, at least in some areas, on the gradual approximation of national rules and regulations. This dual process of trade liberalization and harmonization has gone furthest in Europe, and for this reason the Community has been able to play a key role in fostering international regulatory cooperation. This is especially evident in the area of technical standardization. While the United States has very few standards based on world standards, the EC has pursued a policy of close cooperation with international standardization bodies. For example, today more than 70% of European electrotechnical standards are based on world standards. Given this tight cooperation between the European and the international levels, it is quite likely that a world standard will automatically provide access to the large EC market. This provides a very strong incentive for producers from third countries to adopt

world standards. The success of the European strategy has convinced the United States that reliance on world standards may be critical to the international competitiveness of American industry (Pelkmans, 1995).

Unfortunately, the situation is quite different in the area of health and safety standards. As we saw above, the Commission would like to interpret the entire SPS Agreement in the light of the precautionary principle, in order to be able to conclude that the EC is free to adopt the level of safety that it deems appropriate, regardless of the objections other countries may raise. Thus, just as the U.S. is beginning to appreciate the importance of international regulatory cooperation, the Community seems to be switching to an isolationist stance. By rejecting international risk standards in the name of the precautionary principle, it jeopardizes its role of pioneer in regulatory cooperation.

Finally, we should mention the distributive consequences of measures inspired by this principle. The search of higher and higher levels of safety leads to promulgate standards so stringent that the regulatory action ultimately imposes high costs without achieving significant additional safety benefits. Perhaps we should not be too concerned if such costs were felt only by exporters in rich countries like the United States and Canada, and by affluent European consumers. But what if the cost is borne by some of the poorest countries in the world?

The EU and all its member states are deeply committed to assist, financially and otherwise, developing countries, especially African ones. However, World Bank economists have recently estimated the impact on some of the poorest African countries of new and very strict standards for aflatoxins (carcinogens present in peanuts and other farm products) proposed by the Commission in the late 1990s in the name of the precautionary principle. The proposed standards are significantly more stringent than those adopted by the U.S., Canada and Australia, and also stricter than the international standards established by the Codex Alimentarius Commission, a body advising the Food and Agriculture Organization and the World Health Organization. Using trade and regulatory survey data for the member states of the EU and nine African countries between 1989 and 1998, the World Bank economists estimate that the new standards would decrease African exports of cereals, dried fruits and nuts to the EU by 64 percent, relative to regulation set at the international standards (Otsuki *et al.*, 2000).This reduction in agricultural exports is equivalent to a loss of about USD 700 million a year. Notice that African countries cannot shift their export to other parts of the world because as former colonies they are heavily dependent on European markets. Again, while middle-income developing countries, such as Brazil, can evade the impact of the precautionary measures by shifting to the export of processed food, poor countries do not have this option.

At about the same time the World Bank report was published, the Commission, through its president, was advertising its intention of eliminating all tariffs and quantitative restrictions on imports from the poorest countries. Of course, the practical significance of this apparently generous offer is greatly reduced by the fact that some of the major obstacles to international trade today are not tariffs or quantitative restrictions, but non-tariff barriers such as the aflatoxin standards and similar measures inspired by the precautionary principle.

Are the additional costs imposed on African countries justified by the health benefits for EU citizens? According to studies conducted by the Joint FAO/WHO Expert Committee on Food Additives, the Community standard of 2 parts per billion (ppb) for B_1 aflatoxin would reduce deaths from liver cancer by 1.4 deaths per billion, i.e. by less than one death per year in the EU. For the purpose of this calculation the Community standard is compared to a standard that follows the international (Codex) guideline of 9 ppb. Since about 33,000 people die from liver cancer every year in the EU, one can see that the health gain produced by the precautionary standard is indeed minuscule. Is saving less than two lives in a billion in Europe worth the misery imposed on African farmers? It is true that, according to the Commission, in examining the potential costs and benefits of action or inaction only the "overall cost to the Community" need be examined (Commission, 2000, p. 5). But given the international commitments of the EU – not least in the areas of development aid and environmental protection – this sort of Euro-centrism is, at best, un-diplomatic.

VIII. Conclusions

To repeat: the precautionary principle has a legitimate but limited role to play in risk regulation – whenever there is an imminent danger of irreversible damage, and/or knowledge of causal processes is too limited to bring about a consensus of scientific opinion. As I have tried to show in the preceding pages, however, the principle lacks a firm logical foundation; it may be misused for protectionist ends; it tends to undermine international regulatory cooperation; and it may have highly undesirable distributive consequences. What is perhaps even more serious, the principle, as interpreted by the Commission, raises the possibility of a double standard for what is permissible internationally and in intra-Community relations. Indeed, in the area of risk regulation member states are beginning to claim, in their relations with each other and with the EC, the same autonomy which the Commission claims in relation to the international community.

Given so many disturbing implications of a broad use of the precautionary principle, how can we explain the Commission's determination in attributing to it the status of "a central plank of Community policy"? Part of the explanation has to do with inter-institutional politics. As we saw, the Council and the EP urged the Commission "to be… ever more determined to be guided by the precautionary principle in preparing proposals for legislation", and "to anticipate possible challenges to Community food law by the World Trade Organization and by third countries". These two European institutions were responding to domestic political pressures, as well as to diffuse concerns about the "globalisation" of risk. In turn, a weakened and demoralised Commission is tempted to see in the promulgation of the internationally strictest safety standards a promising way of improving its legitimacy.

Related to this search for legitimacy is the search for credibility. In other words, the "dignified parts" of the precautionary principle may also serve to conceal a general reluctance to establish credible regulatory institutions at European level. Many observers have commented on the striking difference in the attitudes of Americans and Europeans concerning technological, environmental and health risks. Cultural factors are often mentioned as explanatory variables, but I believe that the explanation is simpler, having to do with the different credibility of regulatory institutions on the two sides of the Atlantic. From the thalidomide disaster of the 1960s to the recent food scares, Europeans have experienced a series of regulatory failures, largely unknown to Americans. Hence it is not surprising that Americans trust their risk regulators while Europeans do not. To re-establish consumers' and producers' confidence it would be necessary to create independent bodies – European agencies or more likely networks of national and European regulators – not just to conduct scientific studies, but with powers of rule-making and enforcement (Majone, 2000). For different reasons, however, neither the Council nor the Commission or the Parliament presently favour such a solution. Hence the recent emphasis on the precautionary principle could be interpreted as a strategy to avoid or at least delay difficult institutional choices.

Each of these hypotheses probably contains more than a grain of truth. To test them, however, would require a separate treatment. What the present paper does attempt to do, is to raise reasoned doubts about the general applicability of the precautionary principle. The Commission's Communication does not pretend to be the last word on the subject. Rather, it is meant to be "a point of departure for a broader study of the conditions in which risks should be assessed, appraised, managed and communicated" (Commission, 2000, p. 22). This paper is offered as a contribution to such a study.

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