Risk Regulation in the European Union: Between Enlargement and Internationalization

Edited by

Giandomenico Majone

EUROPEAN UNIVERSITY INSTITUTE

Robert Schuman Centre for Advanced Studies

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The European Forum

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The Forum examined three major themes: 'Explaining International Regulatory Competition', 'Risk Regulation in Comparative Perspective', and 'Multi-level Governance and Regulation: The choice of governance level'. The European Forum Fellows' projects covered several policy areas, such as financial regulation, regulation of the public utilities, health and safety regulation, foodstuff regulation, international taxation, international trade, interplay between labour market regulation and product regulation, company law, and competition policy.

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The Robert Schuman Centre for Advanced Studies

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Introduction

Giandomenico Majone

The 2002-3 European Forum organized by the Robert Schuman Centre for Advanced Studies of the EUI dealt with regulatory cooperation and regulatory competition in an integrating world economy. Within this broad theme, a series of six seminars on risk regulation were held in the period January-March 2003. Although six seminars are hardly sufficient to cover a fast expanding field like risk regulation, I hope the reader will find the texts collected in this publication useful as an introduction to some of the key issues and concepts in this increasingly important area of EU regulation and international harmonization. Like few other policy areas, risk regulation requires a clear understanding of basic principles of decision-making under uncertainty—principles which cannot be ignored even by those who are interested in the legal, political or psychological aspects of risk rather than in technical risk analysis. Indeed, it could be argued that many current debates would be easily settled—or at least reduced to their ultimate political dimension—if only the participants understood the most elementary principles of coherent decision-making under uncertainty. These principles, and some of their policy and institutional implications, are the topic of the three first chapters of the present publication.

Risk is commonly defined as the product of the probability of an adverse event times the severity of the loss if the event occurs; it is, in other words, a numerical value of the expected loss. Thus, probability and utility (or loss = negative utility) are the key concepts of risk regulation. These two concepts are so intimately related that the modern view of probability developed in an attempt to understand decision making in the face of incomplete knowledge. It is assumed that an individual, when

faced with the necessity to make a decision that may have different consequences depending on events about which she has incomplete knowledge, can express her preferences and uncertainties in a way consistent with some basic principles of rational behavior. It can then be deduced that the individual has a 'utility function'—which measures the value to her of each course of action when each of the uncertain possibilities is assumed to be the true one—and a 'subjective probability distribution', which expresses quantitatively her beliefs about the uncertain events. The individual's optimal decision is the one that maximizes her expected utility with respect to her subjective probability.

Before briefly indicating the relevance of these theoretical principles to the practice of risk regulation, a few additional observations may be helpful. First, note that the modern view of probability as expressing the strength of our knowledge or beliefs, is much broader than the old ('objective') view of probability, which only applies to phenomena or experiments that can be indefinitely repeated under essentially the same conditions. But each political, managerial, or regulatory decision is essentially unique—it can never be repeated under the same conditions—and hence may be analyzed only by means of the modern, subjective, notion of probability. From this modern viewpoint, 'objective' probabilities represent only special cases, but as in all good generalizations in science, the same principles ('axioms') apply to both kinds of probability. Second, what is really important about subjective probabilities is the procedure (known as Bayes theorem) by which they can be revised in the light of new information. Hence, and this is my third observation, 'subjective' in this context, is not at all equivalent to 'arbitrary'. Both subjective probabilities and utilities are derived according to precisely defined rules that guarantee their internal consistency, and also learning—in the sense of transforming prior into posterior probabilities in the light of new evidence—follows a well-defined procedure, as just noted.

Again, the theoretical framework sketched here has being criticized for being normative rather than positive or descriptive. It is said that laboratory experiments, as well as casual observation, prove that people do not choose under uncertainty, nor update their beliefs, in the manner prescribed by the theory. It can be shown, however, that this criticism is naïve, primarily because it overlooks the complex interdependence between the normative and the positive in social life. Grammar, logic, arithmetic, and legal codes are all examples of normative systems that are often violated in practice, but are not discarded as a consequence—society could not function without them. What is true is that social practice is guided by norms, which in turn develop under the influence of social practice. Thus, the normative theory of decision-making under uncertainty needs some modifications when applied to group, rather than individual, decisions; but this does not mean that the basic principles are no longer relevant. A final point. Most contemporary philosophers of science agree that scientific knowledge grows through a series of conjectures and refutations; there is no definitive scientific truth, but a scientific

method by which scientists are able to eliminate conjectures that are unsupported by sufficient empirical evidence. This means that also in the field of natural science, and *a fortiori* in regulatory science, probabilistic statements about the occurrence or non-occurrence of certain events are essentially subjective (which, to repeat, does not mean 'arbitrary').

Chapters 1-3 spell out in somewhat greater detail the ideas briefly sketched here, and discuss their implications for risk regulation in the European Union. In particular, it is argued that the recent attempts by the European Commission to promote the precautionary principle as a 'key tenet' of Community policy, and as a general principle of international law, deserve critical attention not only from a political-economy, but also from a methodological perspective. Even an elementary understanding of basic principles suggests that this effort is likely to founder on the logical inadequacies—not to mention the political problems mentioned in chapter 2—of the principle being promoted. For example, in the absence of any generally accepted definition, the principle is often taken to mean that incomplete scientific knowledge is not a valid excuse for regulatory inertia or, more explicitly, that 'taking regulatory measures to prevent possible risks may be legitimate, even when strong scientific evidence on causal relationships or the extent of damage is lacking'. Thus interpreted, the precautionary principle is said to provide 'the philosophical authority to take decisions in the face of uncertainty,' when in fact it simply restates the obvious, namely that *all* regulatory decisions are taken under conditions of (greater or lesser) uncertainty. Equally empty is the distinction, allegedly drawn by the European Court of Justice in its jurisprudence on food safety, between certain and uncertain levels of evidence ('*sichere und unsichere Erkenntnislagen')*—where 'uncertain level of evidence' is supposed to mean that no level of safety can be definitely established on the basis of the current state of research. Again, this is the normal state of affairs in regulatory science, as shown in chapter 1, so that the distinction is hardly helpful for identifying situations where the precautionary principle could be used as an alternative decision rule.

The difficulty of using the precautionary principle as a consistent rule for decision making under uncertainty is also revealed by Sara Poli's analysis of the emerging EU regulatory framework on genetically modified organisms in chapter 4. According to a widespread interpretation, one of the important implications of the precautionary principle is a reversal of the burden of proof: before an authorization is granted, it is up to the developer of a new product to prove that the product poses no health or environmental risk. Since no such proof is, strictly speaking, possible, the reversal of the burden of proof implies a zero-risk approach to regulation. In conformity with this strict interpretation of the principle, 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'. However, a zero-risk approach, besides being logically untenable, effectively impedes scientific and technical innovation. The Commission has

officially espoused the precautionary principle, but it also wants to favor the development of biotechnology research in Europe. Caught in this dilemma, it has sought a way out by softening the rigorous standard of the Novel Food Regulation. The new regulation for genetically modified food now being proposed, 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. In sum, the shift from 'no danger' to 'acceptable risk' represents a significant weakening of the precautionary philosophy in the direction of a more reasonable 'balancing approach' (see chapter 1). At the very least, as Sara Poli points, the new emphasis on acceptable risk should prevent recourse to outright bans, since under the new regulation, the Commission would be bound to take measures that are proportional to the chosen level of protection.

Among the many other important issues discussed in chapter 4, two will be mentioned here since they relate directly to questions raised in other parts of the present volume. Chapter 3 criticizes the institutional design chosen for the new European Food Safety Authority (EFSA). The tension between the desire to improve the credibility of EU risk regulation by appealing to independent expertise, and the Commission's refusal to delegate regulatory powers to the agency, has been temporarily resolved by the doubtful expedient of separating institutionally risk assessment (the task assigned to the authority) and risk management, which remains the responsibility of the Commission. This institutional separation is likely to be unsatisfactory because while risk analysis and risk management are conceptually distinct functions, they are closely intertwined in practice. The consequences of this institutional separation are even more serious if, in fact, the role of the expert agency in the regulatory process is kept to a minimum. Poli points out that the Authority is not consulted systematically on all issues pertaining to the safety of genetically modified food/feed and products. In some cases, decisions are taken by the Commission, in the framework of the comitology committees, without consulting EFSA at all. It is even possible for the member states and the Commission to decide on an application to market GM food and feed disregarding the scientific opinion of the Authority—provided only that they state the reasons for doing so. The author concludes that the broad discretion of the European institutions in taking risk management measures—a discretion which has been upheld by the European courts in recent decisions—appears to distinguish the European approach from the American one.

The problems raised by too broad executive discretion are compounded when the accountability structure is poorly defined. One of the advantages of the American model of independent regulatory agencies is that the agency head, having been given the authority to take final decisions, is also held responsible for the outcomes of those decisions. By contrast, in the EU it is unclear who is politically

accountable in case of regulatory failure. Should there be a food scandal involving the use of GMOs, Poli asks, who will be held responsible? The executive director of the EFSA? The Commissioner responsible for health and consumer protection or the college of Commissioners? Unfortunately, such questions are not answered, or even mentioned, in the draft regulations or elsewhere. From a strictly legal viewpoint responsibility should lie with the Commission, which takes the final risk management decisions. However, the Commission has no scientific expertise and hence is dependent on the opinion of the expert agency—unless it chooses to disregard it for political reasons. In the American model, the head of the agency—often a former expert—is responsible for the entire regulatory process and thus cannot use the separation of risk assessment and risk management to evade the accountability problem. Precisely because all risk determinations are ultimately 'subjective', it is essential that all stages of the rule-making process be explicit and open to public scrutiny, and that somebody be given final responsibility for putting together in a coherent way the separate components of the process. The practice of American agencies, as shaped by the Administrative Procedure Act and later statutes, and by court-imposed procedural requirements, is a good illustration of the notion of 'procedural rationality' discussed in chapter 1. By contrast, risk regulation in the EU is still far from satisfying the test of procedural rationality.

Chapter 5, also by Sara Poli, adds a very important international dimension to the debate on food safety regulation in the EU. The chapter draws attention to the growing importance, within the WTO and in the EU legal system, of the food safety standards set by the Codex Alimentarius Commission—an intergovernmental body set up in 1962 under the auspices of the Food and Agriculture Organization and the World Health Organization. The growing role of the Codex Commission in international economic law explains the interest of the EC to become full member of the organization, along with its member states. The political and legal complications raised by the accession of the Community are clearly explained in the text. It seems likely that in the future the EU will eventually become a full member of the Codex Commission, but only under fairly restrictive conditions. At present, the Community appears to be rather isolated on many important issues, as shown by the contrasting views on the role of the precautionary principle within the Codex Commission. The position of the EC in favor of including the precautionary principle among the general principles of risk management, is opposed not only by the United States, Canada, and other major trading partners of the EU, but also by many Latin American and other developing countries. Chapter 5 provides a very useful summary of the different positions. The opponents of the European position stress the lack of a precise definition, which facilitates the use of the precautionary principle for protectionist purposes. It is also pointed out, particularly by the United States, that a precautionary approach is already built into risk assessment, since any competent analysis must consider all the uncertainties present in a situation, together with the consequences for each possible course of action. In this sense,

rational decision-making under uncertainty is always 'precautionary', but the idea of precaution should not be used by risk managers to overrule risk assessments. Also, Article 5.7 of the SPS Agreement already addresses the issue of insufficient scientific evidence (see chapter 2 in this volume).

The attentive reader will note the different implications of scientific uncertainty at the national and international level. At the national, and to some extent also at the European level, risk regulators—who always operate under conditions of uncertainty—cannot refuse to decide simply because the evidence at their disposal is incomplete. The situation is different for international organizations like the Codex Commission or the International Standards Organization. The standards set by such bodies are not legally binding—although they provide increasingly important guidelines for national regulators—and generally are reached by consensus. Hence, when the scientific evidence is not sufficient to produce a convergence of opinions, it makes perfect sense for an international organization not to proceed to elaborate a standard, but to limit itself to adopt a code of practice or other recommendations directed to the national regulators, leaving to the latter the responsibility for standard setting.

Among the other topics discussed in chapter 5 are the debates in various Codex committees concerning conditions for the marketing of food derived from biotechnology, especially the issue of 'traceability'. Unsurprisingly, given the preceding discussion, also on this and related issues the positions of the EU and of its major trading partners are still quite distant. Another issue of great contemporary interest is the role of factors other than science (*other legitimate factors* or OLFs) in Codex decision making. This debate is closely related to, indeed is an offshoot of, the controversy on the precautionary principle, and is equally divisive. The fear is, again, that too flexible a definition of such OLFs as economic factors or consumers' concerns, could open the door to all kind of protectionist measures. The author succeeds in summarizing in a few pages all the key points of a complex debate which is bound to continue into future.

While chapter 5 considers the international context of EU food regulation, chapter 6, written by Aleksander Surdej, analyzes the impact of EU food safety requirements on a candidate country like Poland. He does this first by sketching the main trends in the development of EU food safety regulation, and then, discussing the factors which have influenced the transposition of EU food law into domestic laws and regulations, and which might influence the implementation of such regulations in the near future. The main thesis is that the lack of controversy over the transposition of EU food safety regulations seems to be a result of the low salience of food safety issues in the perception of Polish consumers—who tend to believe that domestic food is safe, or even safer than imported food stuffs—and also a result of the fact that the democratic alternation of governments tends to de-couple the act of committing a country to international agreements from the responsibility for implementing the rules and delivering expected regulatory outcomes.

Surdej points out that the EU is changing its strategy to assure a reasonable food safety level across member states by putting an increasingly stronger emphasis on monitoring the national, as well as the company, control systems. This change, although in tune with theoretical developments in the area of risk regulation, creates special difficulties in a candidate country such as Poland whose agriculture and foodstuffs sector is highly fragmented, and whose institutional setup for food safety control is still evolving. The author predicts problems with implementing EU food safety rules in candidate countries, although the consequences of possible violations of such rules are attenuated by the fact that food trade between Poland and the present EU member states is at a relatively low level. He also reminds us that food safety is not only an internal issue of the EU, but a broader problem of how to create a regime for international trade in foodstuffs, which would respect the rules of free trade, while paying attention to the concerns for food safety. This brief summary of chapter 6 does not do justice to the wealth of empirical material presented there, much of it not easily available elsewhere, nor to the many interesting theoretical insights scattered throughout the text.

As was said at the beginning of this introduction, the six seminars whose texts are collected here, cover only a relatively small range of issues arising in risk regulation in the EU, in the candidate countries, and internationally. The focus is on logical foundations, legal principles, and substantive policy problems. For example, nothing is said about the political economy of food safety in general, or of the regulation of GMOs, in particular. At a deeper level, one could investigate the correlation between electoral systems and the emergence of particular topics in the public debate on risk regulation. It is rather striking, for example, that in majoritarian, winner-takes-all electoral systems, like the United States or the United Kingdom, the precautionary principle never became a serious topic of political discussion, whereas in continental Europe, where more or less pure forms of proportional representation prevail, it has moved toward the top of the political agenda during the 1990s, and in some cases even before. Intuitively, this seems to be due to the prevalence of coalition governments under PR, and the possibility of small, single-issue parties playing a pivotal role in such coalitions. At any rate, the influence of the electoral system on the shape and agenda of risk regulation seems to deserve much more attention than it has received by political scientists so far. Again, the importance of policy learning in situations of great cognitive complexity like risk regulation, is emphasized in chapter 1. The examples given there suggest that a separation-of-powers system has certain advantages in this respect. The question is, how to improve the policy-learning capacity of parliamentary governments, or of a polity like the EU, which is neither a separation-of-powers nor a parliamentary system.

The regulation of risk raises a wealth of interesting problems for the political economist, the psychologist, the political analyst, and the lawyer. It is, however, impossible to reach significant conclusions using any of these valuable approaches

without a clear understanding of the basic principles of the logic of decision-making under uncertainty. If this small volume succeeds in conveying this message, it will have achieved its main objective.

Chapter 1

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

Giandomenico Majone

1. From Substantive to Procedural Rationality

The long subtitle of this introductory chapter identifies what I take to be the key terms of the current debate on risk regulation. It is impossible to understand the evolution of risk regulation during the last three decades, in Europe and the United States, without a good grasp of how these concepts, and the corresponding practices, interact. How, for example, does a particular institutional design affect the way scientific uncertainties are resolved? Which are the appropriate decision rules in situations of high scientific uncertainty? Which institutions can facilitate policy learning and the achievement of credibility in the area of risk?

By definition, uncertainty is pervasive in risk regulation, but what is less well understood, is that in many cases scientific uncertainty cannot be significantly reduced. Closer analysis of recent controversies about the analysis and management of risk shows that the issues over which expert disagreement is most serious are, in Alvin Weinberg's terminology, trans-scientific rather than strictly scientific or technical. Trans-scientific issues are questions of fact that can be stated in the language of science but are, in principle or in practice, unanswerable by science (Weinberg 1972). One of Weinberg's examples is the determination of the health effects of low-level radiation. It has been calculated that in order to determine by direct experimentation, at the 95 per cent confidence level, whether a level of X-rays radiation of 150 millirems would increase the spontaneous mutation in mice

by 50 per cent, would require about 8 billion mice. Time and resource constraints make such an experiment all but impossible. Similarly, the choice of a particular dose-response function must be treated at present as a trans-scientific question. A dose-response model establishes a relationship between different dose levels of a substance and the probability of a lifetime response. But the relationship can be represented by many different functions and a firm scientific basis for choosing a particular functional representation is usually lacking. However, such a choice can have a major effect on the determination of the virtually safe dose—more than a 100,000-fold effect, according to a study conducted some years ago by the Committee on Safety Evaluation of the U.S. Food and Drug Administration. Analogous conceptual and technical difficulties attend calculations attempting to determine the probability of extremely unlikely events like catastrophic reactors accident—as far as any direct verification of the calculations is concerned—or the issue of when animal data alone form a sufficient basis for standard-setting.

Since the level of scientific (or trans-scientific) uncertainty is so high, concepts like 'acceptable risk doses', 'virtual safety', and 'no observed effect level' (NOEL) —commonly used by risk regulators, especially with reference to potentially toxic substances—leave ample room for discretionary choices and rules of thumb. What a distinguished statistician wrote in the 1970s remains largely true today:

> All present safety evaluation procedures, whether involving the use of NOEL's, or of some favored non-threshold dose-response function with a 'virtually safe' level, must be regarded as mathematical formalisms whose correspondence with the realities of low-dose effect is, and may long remain, largely conjectural (Cornfield, 1977, p. 698).

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

The preoccupation with methods of analysis and evaluation that emphasize outcome rather than process, and the interest in what decisions are made, rather than in how they are made—are typical of situations where certainty is assumed. Indifference toward procedures and the formal layout of arguments is understandable if one assumes that there exists a one best decision in a given situation. If the correctness of the outcome can be determined unambiguously, the manner in which the decision is made is largely immaterial; only results count. This is the reason why the key concept in the theory of decision making under certainty, whether in economics or in management science, is *optimization*. But 'optimization' has no well defined meaning when the consequences of each feasible course of action are uncertain (one should not, for example, maximize the *expected* return without considering also its variance). Hence, the key concept in

the theory of decision making under uncertainty is not optimization but, as we shall see, *consistency*, a characteristically procedural notion. Indeed, when the factual or value premises of a decision are moot, when no generally accepted criterion for the correctness of a solution exists, then the process or procedure of decision making acquires special significance. This is the basic insight on which the classical theories of judicial and legislative procedures are based; the reason why procedures play such an important legitimating function in the decisions of courts and legislatures (Luhmann, 1975). In general terms, the more complex a system, the greater the reliance on procedural rationality, for, as Talcott Parsons writes: 'Only on the basis of procedural primacy can the system cope with a wide variety of changing circumstances and types of cases without prior commitment to specific solutions' (Parsons, 1966, p. 27). In the following pages, as well as in the next two chapters, I shall work out in some detail what procedural rationality means and what it entails in the case of risk regulation. I begin by considering the important topic of procedural harmonization.

2. Procedural Harmonization

The purpose of harmonization, as the term is used in the present context, is to make the regulatory requirements or public policies of different jurisdictions more similar, if not identical. Regulatory regimes, and the political and institutional systems in which they are embedded, can differ in numerous aspects. Hence, several broad types of harmonization may be usefully distinguished (Leebron, 1996). First, specific rules or standards that prescribe the desired characteristics of the outputs of production processes, institutions, or transactions could be harmonized. For example, emission limits for polluting factories located in different countries may be made more similar. We may call this 'output harmonization' since the goal is to reduce pre-existing differences in certain characteristics of the relevant outputs or outcomes. Second, international regulatory harmonization may relate to certain governmental policy objectives—for example, the central banks of the G-7 countries attempt to keep inflation within agreed limits—or to general policy principles such as the 'polluter pays' and the precautionary principles.

Finally, harmonization of institutional structures, procedures or methodologies is often sought. Thus, some of the provisions of the North American Free Trade Agreement (NAFTA; the reference here is to the NAFTA 'side agreement' on the environment) require that certain procedures for enforcement of domestic laws, including appellate review, be harmonized. Procedural harmonization usually serves to reinforce other types of harmonization. If the aim is to harmonize decisional outcomes, both substantive criteria and decisional processes are implicated. Rules, policies, and principles will generally not be truly harmonized unless the procedures and institutions for implementing them are made more

similarly effective, and doing so may mean making them more similar (Leebron, 1996, p. 46). This, incidentally, is the reason why EU-level harmonization, for example in the environmental field, fails to produce identical, or at least very similar, results across the Union. EU measures are typically implemented by national administrations, but the Community is not competent to harmonize national administrative procedures and processes. The problem has been recognized for some time, and certain directives attempt to harmonize not only national laws and policy objectives, but also the institutional design of the 'competent authorities' at national level (E.g. with respect to their independence in the case of telecommunications). The results so far have been rather disappointing (Majone, 2000).

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

An important example of purely procedural harmonization is provided by the WTO Agreement on Sanitary and Phytosanitary Measures (SPMs), to be further discussed in the next chapter in connection with a critical evaluation of the precautionary principle. Harmonization is discussed in Article 3, which states, in part, that: a) In order to harmonize SPMs on as wide a basis as possible, member states shall base their measures on international standards, guidelines or recommendations, where they exist; b) SPMs that conform to international standards shall be deemed to be necessary to protect human, animal or plant life or health; c) Member states may, however, introduce or maintain SPMs which result in a higher level of protection than would be achieved by measures based on the relevant international standards, provided there is 'scientific justification' for the stricter measures; d) Member states are required to 'play a full part, within the limits of their resources, in the relevant international organizations and their subsidiary bodies', such as the Codex Alimentarius Commission (see chapter 5).

This article is noteworthy in several respects. First, nothing substantive is said about the level of the international standards, not even of a qualitative nature. By way of comparison, the NAFTA Agreement on Environmental Cooperation stipulates that 'each Party shall ensure that its laws and regulations provide for high levels of environmental protection and shall strive to continue to improve those laws and regulations'. At the same time, the Agreement recognizes 'the right

of each Party to establish its own levels of domestic environmental protection'. Thus, at least according to a widely accepted interpretation, a member of NAFTA is permitted to set its own levels of protection, as long as those levels are 'high' by some more or less objective standard (cp. Also Article 95[3] TEC, according to which 'The Commission, in its proposals […] concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection…').

By contrast, the approach of the WTO SPS Agreement is purely procedural, as shown also by the requirement that the member states play an active role in the activities of the international standardization bodies. Also the requirement that a country provide 'scientific justification' if it wishes to adopt a higher level of protection than what is provided by international standards, goes in the same procedural direction: given the uncertainty surrounding the scientific basis of risk regulation, 'scientific justification' can only mean that the relevant arguments should satisfy generally accepted rules of scientific methodology. This interpretation seems to be supported by Article 5 (on *Assessment of Risk and Determination of the Appropriate Level of Sanitary and Phytosanitary Protection*), which imposes purely methodological constraints on the freedom of each member state to choose its own levels of safety: risk assessments based on the available scientific evidence and on relevant inspection, sampling, and testing methods; consideration of relevant economic factors and of the relative cost-effectiveness of alternative approaches to limiting risks; consistency in the application of the concept of the appropriate level of protection, and so on.

It seems clear that in an area as politically sensitive as the protection of health and life, and where at the same time regulators face great scientific uncertainty and trans-scientific problems, the only way to promote international regulatory cooperation is through the harmonization of procedures. This, at any rate, is how progress has been achieved in the international harmonization of testing procedures for new medical drugs: the so-called ICH process, in which the European Agency for the Evaluation of Medicinal Products (EMEA) has played a leading role (Majone, 2002). Precisely for this reason, as we argue in chapter 2, it is essential that the procedural requirements of the SPS Agreement, and all other requirements of the same nature, be respected and, if possible, improved, rather than weakened or circumvented, allegedly in the name of risk prevention but in fact, for short-term political or economic advantages.

3. Consistency in Decision-Making

It has already been suggested that our intuitive notions of means-end rationality and optimality must be revised when decisions are made under uncertainty (strictly speaking, all human decisions are uncertain in their outcomes, but here we consider situations where it is impossible to rely on some simple 'certainty equivalent' such

as an average value). Probabilistic thinking does not come naturally, even to scientists or to intellectually sophisticated persons, but it is essential to a logically defensible regulation of risk. It seems more natural to think of decisions and institutions in teleological terms. According to this conception, as formulated by John Rawls in his critique of utilitarianism, 'those institutions and actions are right which of the available alternatives produce the most good, or at least as much good as any of the other institutions and acts open as real possibilities'. Rawls adds:

> Teleological theories have a deep intuitive appeal since they seem to embody the idea of rationality. It is natural to think that rationality is maximizing something… Indeed, it is tempting to suppose that it is self-evident that things should be arranged as to lead to the most good (Rawls, 1973, p. 24-25).

Also modern decision theory prescribes to maximize something, namely, expected utility, but this decision rule has procedural, not substantive, significance: it 'only' guarantees consistent decision-making. Here I can do no more than sketch the argument, starting with the key assumption of the theory: that there is only one form of uncertainty and that all uncertainties can be compared. Thus decision theory does away with all old-fashioned and theoretically untenable distinctions such as that between statistical and non-statistical events, or Frank Knight's (1971) distinction between risk and uncertainty. By saying that there is only one kind of uncertainty, and that therefore all uncertainties can be compared, it is meant that if E and F are any two uncertain events then either E is more likely than F, F is more likely than E, or E and F are equally likely. Moreover, if G is a third uncertain event, and if E is more likely than F, and F is more likely than G, then E is more likely than G. The first requirement expresses the *comparability* of any two events; the second expresses a *consistency* in this comparison.

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

Let c_{ij} be the consequence if we choose alternative A_i and event E_j occurs, i = 1, 2, …, n; j = 1, 2, …, m. Note that the consequences may be qualitative as well as

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

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

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

The discussion so far may be summarized as follows. A decision problem can be expressed as a list of alternatives and a list of possible events. On the assumption of consistent comparison of events and of consequences, probabilities can be assigned to events, and utilities to consequences. Each alternative can also be assigned a utility, calculated as the expected value of the corresponding

consequences. The best alternative is the one with the highest utility. A few more comments on the general approach follow.

First, the consistency argument is essentially one that hinges on how separate assessments—probabilities of events, utilities of individual consequences and of alternatives—are going to fit together and make a consistent whole. Second, the rule of maximization of expected utility does not guarantee better actual results than other decision rules—including decisions made in purely intuitive fashion. It *does,* however, guarantee consistency in decision-making, and no other known decision rule can claim the same. Third, consistency is important not only logically but also practically: it facilitates communication among experts, between experts and policy makers, and with the general public; by showing how to break down the whole decision problem into separate but coherent components, it also facilitates accountability; moreover, as mentioned in the following section on learning, the method provides a way of consistently updating one's beliefs in light of new information. The type of decision analysis sketched here may even facilitate risk taking. Thus, if managers are evaluated exclusively on outcomes, they will naturally be reluctant to engage themselves in very risky undertakings. A more sophisticated method of evaluation, which in addition to results also includes the quality of the decision process, can reduce the cost of failure by distinguishing between foresight and outcomes due to chance.

One final point. Any decision under uncertainty, even one which does make explicit use of probabilities, in fact implies at least a partial probability assessment. There is nothing mysterious in this statement, which is only a straightforward application of a line of reasoning frequently used also in elementary game theory; see, for example, James D. Morrow's *Game Theory for Political Scientists* (1994, p. 170-180). Suppose a decision maker has to choose between two alternatives with the consequences indicated below:

	E_1	E_2
A_1	10	1
A_2	3	2

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

the unknown probability of E_1, hence 1-p the probability of E_2, the expected values of the two alternatives are:

$$M(A_1) = 10p + (1-p) = 9p + 1$$
$$M(A_2) = 3p + 2(1-p) = p + 2$$

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

4. Policy Learning

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

In the remainder of this section we are going to discuss policy learning, in the area of risk regulation, in a broader, but less rigorous, sense than that of decision theory and Bayesian statistics. However, in this and in the following chapters, we should always keep in mind the fundamental lesson of the preceding discussion, namely, that ideas should not be considered in isolation, but should be related to other relevant ideas to see how they fit together in a coherent manner. To a large extent, policy learning means learning this lesson, as we try to show by considering the slow but steady, improvement in the conceptual foundations of risk regulation in the United States. It is convenient to trace this development through a sequence of four regulatory principles: prohibitions; lowest feasible risk; elimination of significant risk; balancing the costs and benefits of risk reduction. While this is not

a linearly progressing, or monotone increasing, sequence—since different principles coexist even in the same area, such as food safety—we shall argue that a trend can be detected in the direction of a broader inclusion of relevant factors, and of greater consistency in putting together the various elements of the regulatory problem.

Prohibitions represent one of the earliest and least sophisticated approaches to risk regulation. To say this is not to deny that in some cases an outright ban may be the most appropriate regulatory response, but only to say that the appropriateness of such a radical measure has to be proved, rather than simply assumed. One of the best-known illustrations of the problems raised by an apparently clear-cut prohibition is provided by the so-called Delaney Clause in the Federal Food, Drug and Cosmetic Act. The Clause appears in the provision of the Act that empowers the Food and Drug Administration (FDA) to license food additives. The Food Additives Amendment was added to the law in 1958, and it directs the FDA to refuse approval of any food additive not shown to be safe. To this general instruction the Delaney Clause adds the proviso that:

> No additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animals.

According to FDA officials, this proviso authorizes the agency to exercise scientific judgment in determining whether a test is an appropriate one, and whether the results demonstrate induction of cancer. Once the agency has made its determinations concerning these two matters, however, no further inquiry is allowed. For example, the agency may not establish a maximum level of safe use, or authorize further use of an additive based on a judgment that the benefits of continued use outweigh the risks involved (Mashaw *et al.* 1999). For nearly twenty years the Delaney Clause had little influence on FDA's actions, since only very few additives had been shown to cause cancer in animal experiments. On March 9, 1977, however, the FDA announced its intention to ban the use of the artificial sweetener saccharin because of a recent Canadian study showing that saccharin (in doses equivalent to 800 cans of diet soft drinks a day!) induced cancer in test animals. At the time no other non-nutritive sweetener was approved for use in the United States. Hence the FDA announcement threatened the marketing of all artificially sweetened foods and beverages and, consequently, precipitated intensive public controversy. Representatives of health organizations testified at congressional hearings, that saccharin provides enormous health benefits to persons, such as diabetics, who must restrict the intake of sugar.

Responding to these concerns, Congress, through the Department of Health and Human Services, commissioned two studies by the National Academy of Sciences, one to assess the scientific evidence concerning saccharin's safety; the other to evaluate the law's current food safety standards and suggest alternative approaches. The Academy's assessment of the scientific evidence confirmed

that saccharin was a carcinogen in laboratory animals, although a weak one. It found no reliable evidence that saccharin caused cancer in humans, but it stressed that epidemiological methods were not capable of detecting increases in the incidence of bladder cancer of the magnitude the animal data suggested saccharin could cause.

The second Academy study found that the standards for regulating food additives were inadequate. One proposal was to amend the law to allow FDA to rank additives in three risk categories: those so serious as to merit prohibition; those so trivial as to warrant no regulatory action; and those whose acceptability should depend on an assessment of benefits and on the availability of alternatives. The proposals did not lead to any radical amendment of the legislation, but the FDA found other means to avoid a ban if a food additive presented only slight risks, or offered substantial benefits. Thus, the agency has sometimes concluded that a substance is not a 'food additive', and hence subject to the Delaney Clause, even though it occurs in food, arguably through human agency (Mashaw *et al.*, 1998, p. 129-134). For example, FDA has refused to regulate compounds such as PCBs and aflatoxin. Proceeding in this fashion, by the mid-1980s the agency had effectively narrowed the application of the Delaney Clause to direct food additives.

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

4.1 Least Feasible Risk

According to this principle, human exposure to health risks should be reduced to the lowest possible level. This is a sort of second-best rule. The first-best regulatory policy would be one that ensures a risk-free working and living environment, but because of technical and economic constraints a risk-free environment is unattainable; hence the need of a second-best rule. Thus, Section 6(b)(5) of the 1970 Occupational Safety and Health Act directs the Occupational Safety and Health Administration (OSHA), in regulating worker exposure to toxic substances, to set standards that:

> [M]ost adequately assure, *to the extent feasible*, […] that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard […] for the period of his working life (emphasis added).

Trade union representatives claimed that this instruction obliged OSHA to mandate the use of whatever available technology an industry could afford without bankrupting itself. Justice Brennan of the U.S. Supreme Court expressed a similar view: 'Congress itself defined the basic relationship between costs and benefits, by placing the "benefits" of worker health above all other considerations save those making attainment of the "benefit" unachievable' (cited in Graham *et al.*, 1988, p. 97). The meaning of 'feasibility' is crucial in the present context. A body of analysis and case law has thus emerged to clarify this term.

According to some court decisions, a standard may be considered technologically feasible even if no existing devices would allow industry to comply with the standard, as long as there is evidence that companies 'acting vigorously and in good faith', can develop the technology. This 'technology forcing' approach implies that regulatory agencies are not limited to set standards based on existing devices, but may require improvements in existing technology, or even the development of new technology. This may be quite expensive, so the issue of technical feasibility is inseparable from the issue of economic feasibility. It is clear that regulators estimate the costs of proposed standards, but it is less clear which criteria they use to judge whether a given standard is 'affordable'.

At least as far as the Occupational Safety and Health Act is concerned, American courts have ruled that an expensive standard is not necessarily economically infeasible. Although some firms may find safety standards particularly expensive or even financially prohibitive, courts have not excused individual firms from such standards. As one court put it in a 1978 case:

> It would appear to be consistent with the purposes of the [OSH] Act to envisage the economic demise of an employer who has lagged behind the industry in protecting the health and safety of employees and is consequentially financially unable to comply with new standards as quickly as other employers (cited in Graham *et al*., 1988, p. 99).

Thus, economic feasibility has been interpreted quite strictly: a standard is to be considered 'infeasible' only if it would cripple or bankrupt an entire industry, rather than some technologically backward firms.

It is clear that the least-feasible-risk approach is very far from any sort of balancing of marginal costs and benefits. In fact, marginal considerations are rejected on the ground that the two sides of the basic relationship are incommensurable. As the opinion of Justice Brennan, cited above, makes clear, health benefits have to be considered 'above all other considerations'. Even if one accepts this value judgment, however, serious conceptual problems remain. First, the approach fails to consider possible alternatives to standards, such as information disclosure or greater reliance on liability rules. It also omits any consideration of probabilities of possible events, so that standards are set without any knowledge of the expected number of deaths or accidents prevented.

Second, setting standards strictly is a significant cause of the slow pace of the standard-setting process. This means that relatively few standards can be set, so that many hazards remain unregulated; hence, over-regulation leads to under-regulation (Mendeloff, 1988). Third, the emphasis on industry viability means that very dangerous occupations in marginally profitable industries may be unregulated, while other jobs may be made so safe at such high cost that employment levels and wages shrink—another instance of over-regulation leading to under-regulation. Finally by ignoring one of the key lessons of economics and policy analysis—that decisions should be based on marginal costs and benefits—the approach wastes resources that could have been used to control more risks.

4.2 The Significant-Risk Doctrine

As was indicated above, federal courts generally upheld OSHA's standards. The striking exception was the benzene standard, which reduced the occupational exposure to this carcinogen from 10 parts per million (ppm) to 1 ppm. In the case *American Petroleum Institute v. OSHA* (1978), the Fifth Circuit Court of Appeals held the regulation invalid on the ground that the agency had not shown that the new exposure limit was 'reasonably necessary and appropriate to provide safe or healthful employment' as required by the statute. Specifically, the court argued that OSHA had failed to provide substantial evidence that the benefits to be achieved by the stricter standard bore a reasonable relationship to the costs it imposed. The court added:

> This does not mean that OSHA must wait until deaths occur as a result of exposure levels below 10 ppm before it may validly promulgate a standard reducing the permissible exposure limit. Nevertheless, OSHA must have some factual basis for an estimate of expected benefits before it can determine that a one-half billion dollar standard is reasonably necessary (cited in Mendeloff, 1988, p. 116-117).

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. Unlike other agencies such as the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA), OSHA had always maintained that quantitative risk analysis is meaningless. Thus, in the preamble to the benzene standard it stated that it was 'impossible to derive any conclusions regarding dose-response relationships'. As Mendeloff notes, OSHA's reluctance to follow the example of the EPA and the FDA reflected trade union pressures, combined with staff preferences for protection to override any interest in the use of more analytic approaches. It was feared that if the agency performed quantitative risk assessments (QRAs), these might be used as a weapon by those who opposed strict standards.

On the other hand, an agency like EPA with a much broader mandate, was aware that not every risk could be reduced to the lowest feasible level.

The Fifth Circuit Court's decision stunned OSHA's leaders, who viewed it as a total challenge to their regulatory philosophy and to their idea of the agency's mission (Mendeloff, 1988, p. 117). They decided to appeal the decision. In *Industrial Union Department (AFL-CIO) v. American Petroleum Institute* (1980), a badly split Supreme Court (the nine justices issued five separate opinions!) upheld the Fifth Circuit's decision, but not all parts of its argument; in particular, it expressed no opinion about the requirement of a cost-benefit assessment. Justice Powell, concurring in part and concurring in the judgment, did however note that

> A standard-setting process that ignored economic considerations would result in a serious misallocation of resources and a lower effective level of safety than could be achieved under standards set with reference to the comparative benefits available at a lower cost (cited in Mashaw *et al.*, 1998, p. 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 lowest-feasible-risk approach:

> We think it is clear that the statute was not designed to require employers to provide absolute risk-free workplaces whenever it is technologically feasible to do so, so long as the cost is not great enough to destroy an entire industry. Rather, both the language and structure of the Act, as well as its legislative history, indicate that it was intended to require the elimination, as far as feasible, of *significant* risks of harm (cited in Graham *et al.*, 1988, p. 100. emphasis added).

In other words, zero risk cannot be the goal of risk regulation. Justice Stevens insisted that 'safe' is not the same as risk-free, pointing to a variety of risks in daily life—ranging from driving a car to 'breathing city air'—that people find acceptable. Hence, before taking any decision, the risk from a toxic substance must be quantified sufficiently to enable the agency to characterize it as significant 'in an understandable way'. Conceding the difficulty of quantifying risks, the plurality opinion emphasized the scientific elements of the significant-risk determination. In fact, OSHA was not required to support its finding that a significant risk exists with anything approaching scientific certainty. So long as the determination is supported by a body of reputable scientific thought, the agency is free to use conservative assumptions in interpreting the data, risking error on the side of overprotection.

The problem with the proposed regulation was procedural rather than substantive: the question was not whether the standard of 1 ppm was 'correct', but whether sufficient justification for this determination had been provided. According to the plurality opinion, this had not been done, hence the standard-setting process was flawed. Thus, OSHA did not ask for comments as to whether or not benzene presented a significant health risk at exposures of 10 ppm or less. Rather, it asked

for comments as to whether 1 ppm was the minimum feasible exposure limit. Also the evidence of adverse health effects of benzene exposure at 10 ppm was sketchy at best. OSHA had not attempted to make any estimate, based on the available scientific studies, of how significant the risk would be at exposure of 10 ppm or less. Rather, it stated that because of a lack of data it was impossible to construct a dose-response curve at this time, even rejecting an industry witness' testimony that a dose-response curve could be constructed on the basis of the reported epidemiological studies. In short, the agency had simply concluded—from the government's generic carcinogen policy—that, in the absence of definitive proof of a safe level, it must be assumed that *any* level above zero presents *some* increased risk of cancer. But, as the justices pointed out:

> In view of the fact that there are literally thousands of substances used in the workplace that have been identified as carcinogens or suspect carcinogens, the Government's theory would give OSHA power to impose enormous costs that might produce little, if any, discernible benefit (cited in Mashaw *et al.*, 1998, p. 813).

Since the government's generic carcinogen policy provides no guidance as to which substances should be regulated first, an important merit of the significant-risk doctrine is to raise the crucial issue of regulatory priorities. Most risks are regulated in response to petitions or pressures from 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, perhaps more significant, risks. By requiring OSHA to show significant risk as a prelude to standard setting, the justices were insisting on some analysis in priority setting: regulatory priorities should be directed toward the most important risks—which are not necessarily those that are politically most salient.

In conclusion, the significant-risk doctrine places a higher analytical burden on regulators than the lowest-feasible-risk approach. Not all potential risks are treated equally; only those substances shown to pose a significant risk of cancer will be regulated, focusing limited agency resources on the most important health risks. In addition, the doctrine, without requiring a formal marginal 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 (Graham *et al.*, 1988, p. 103-105). *Industrial Union Department (AFL-CIO) v. American Petroleum Institute* is a landmark case also from the point of view of the methodology of risk analysis. The U.S. Supreme Court not only confirmed the legitimacy of quantitative risk assessment; it effectively made reliance on the methodology obligatory for all American agencies engaged in risk regulation. In most subsequent disputes over regulatory decisions to protect human health, the question has not been whether a

risk assessment was required but whether the assessment offered by the agency was plausible (Mashaw *et al.*, 1998, p. 823-825). This historical background may explain American 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 European Commission. As we shall see in the next chapter, risk assessment is the standard by which trade-restricting health regulations are evaluated as necessary and compatible with the rules of the World Trade Organization.

4.3 Balancing Costs and Benefits

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

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

severely criticized by students of the regulatory process. No judicial decision, however, could conceal the growing economic impact of risk regulation.

With the great expansion of environmental, health, and risk regulation in the 1970s, the need to calculate more precisely the costs of the proliferating regulations, as well as the corresponding benefits, became increasingly evident. According to many advocates of regulatory reform, only the executive could provide a continuous and systematic oversight of the regulatory process. Important steps to improve the quality of federal regulation were taken under President Carter, when the notion of a 'regulatory budget' was first introduced. The oversight mechanism was perfected in the late 1980s, during the second term of the Reagan administration. The Office of Management and Budget (OMB), in the president's executive office, was given responsibility for setting the budgets of all regulatory agencies, and for monitoring the rule-making process. Instead of simply imposing a cost-effectiveness requirement, as previous presidents had done, Reagan moved to a fully fledged cost-benefit test with his Executive Order No. 12291 of 1981: regulatory action was not to be undertaken unless the potential benefits to society outweigh the potential costs; among alternative approaches to any given regulatory objective, the alternative involving the least net costs to society has to be chosen; finally, agencies are required to set regulatory priorities with the aim of maximizing the aggregate net benefits, taking into account the condition of the particular industries affected by regulations, the condition of the national economy, and other regulatory measures contemplated for the future. If the cost-benefit test conflicts with the agency's legislative mandate—as it did at the time for most risk and environmental regulations—the test is not binding, in the sense that the standard need not be based on the result of the cost-benefit calculations; but a complete analysis must be submitted to the OMB nevertheless.

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

passed by new regulations. The key congressional concerns were that regulations be based on an accurate assessment of the risks involved, rather than on worst case scenarios, and that regulatory agencies proceed with regulations only if the benefits exceed the costs (Viscusi *et al.*, 1996, p. 27-28).

This brief survey of policy and institutional developments in the United States reveals a steady improvement in the understanding of the various dimensions of risk regulation — scientific, economic, legal, and political — and of the methodologies for fitting together these partial analyses in a coherent manner. The progress from the early reliance on outright bans or simple 'feasibility' tests to the applications of key principles of decision theory not only to agency rule-making but also to the enabling legislation, is an outstanding, and in many respects unique, example of policy learning. Compared to these developments, risk regulation in Europe, especially perhaps at Union level, is still at a rather primitive stage. Indeed, in comparative terms, some recent episodes—such as the strenuous advocacy of the precautionary principle, to be discussed next week—appear to be manifestations of an infantile disorder of risk regulation rather than progressive moves. As we have seen, policy learning in America has been made possible by the interaction among different, partly cooperating, partly competing institutions. A more detailed study would have revealed also the importance of a style of policy discourse that puts a high premium on reliable quantitative information and on analytic sophistication. While American institutions and political culture cannot be replicated on this side of the Atlantic, a discussion of the foundations of risk regulation would be seriously incomplete without at least mentioning some of the institutional issues still waiting a satisfactory solution at European level.

5. Institutional Reform

A serious problem of Community regulation in general, and of risk regulation in particular, is the mismatch between the growing complexity of the tasks and the inadequacy of the existing regulatory institutions. The root cause of this problem is to be found in the non-delegation doctrine promoted since the 1950s by the European Court of Justice, and enthusiastically supported by the European Commission Incidentally, it is interesting to note that in the United States a corresponding non-delegation doctrine—prohibiting the delegation of rule-making powers by Congress to regulatory agencies—has not been applied by the federal courts since the 1930s, despite the centrality of separation-of-powers in the federal constitution. The ECJ's 'Meroni doctrine', dating from 1958 (case 9/56, *Meroni v. High Authority*) and relating specifically to the European Coal and Steel Community Treaty, remains 'good law', and is supposed to apply to all European treaties. It still acts as a barrier to the delegation of tasks to institutions not mentioned as such within the European treaties—even when the scientific or technical complexity of the tasks exceed the expertise of a generalist administration

like the European Commission. In the Court's reasoning, the Commission could, in fact, delegate tasks to bodies not named in the treaty, but such delegation was subject to strict constraints:

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

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

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

This pragmatic solution can perhaps be defended as a reasonable compromise between the rigidity of the official non-delegation doctrine and the need of regulatory discretion in highly technical matters. However, such a compromise entails costs which a clearer delegation of authority would avoid. First, as the agency itself complains, the need to wait for the Commission's formal decision means that precious time is lost before a new, and possibly life-saving, product reaches the market. Moreover, the present situation blurs the line of accountability, and because of its ambiguity presents risks for the Commission, which some day

might be called upon to bear the responsibility of decisions in whose formation it did not play any substantive role.

In the case of the European Food Safety Authority, the tension between the desire to improve the credibility of EU regulation by appealing to independent scientific expertise, and the refusal to delegate regulatory powers to the agency, has been temporarily resolved by the doubtful expedient of separating institutionally risk assessment (the task assigned to the Authority) and risk management (which remains the responsibility of the Commission). Such institutional separation has been tried in several countries, usually with disappointing results. For example, the already mentioned U.S. Occupational Safety and Health Act of 1970 created the National Institute for Occupational Safety and Health (NIOSH), directing it to perform research and risk assessments for the newly established regulatory agency, the Occupational Safety and Health Administration (OSHA). While NIOSH is an independent agency within the Department of Health and Human Services, OSHA has been placed within the Department of Labor—an institutional design largely dictated by political reasons. This organisational separation, however, yielded functional separation to only a limited extent. On the one hand, NIOSH's 'criteria documents' not only provided risk assessments, but also recommended occupational standards. On the other, OSHA tended to take on more of the risk assessment function itself. NIOSH continued to assist OSHA in the preparation of risk assessments, but gradually OSHA asserted control over the entire standard-setting process. As the author of a detailed case study writes:

> Despite its separation from OSHA, or indeed perhaps because of it, NIOSH's criteria documents were often found to be deficient as bases for issuing standards. OSHA regulators found them to be little beyond compendium summaries of the literature, with little effort to evaluate the quality of relevant studies or to resolve scientific disputes. The lesson appears to be that such complete organisational separation of functions is counterproductive (Greenwood, 1984, p. 118).

The institutional separation of risk assessment and risk management is counterproductive because while the two functions are conceptually distinct, they are closely intertwined in practice. Thus, the setting of rational regulatory priorities entails scientific, economic, and political judgements that are not easily separable. Again, under conditions of scientific uncertainty the determinations of the risk analysts can effectively pre-empt the decisions of the risk managers. For example, it is often impossible to know whether a dose-response function follows a linear or a non-linear (threshold) model, yet the scientists' choice of one or the other model is crucially important for the determination of the acceptable level of safety. If risk assessment and risk management are not separable in practice, then it follows that accountability and efficiency are best achieved when an expert agency, rather than a collegial body of political executives like the Commission, is solely responsible for the entire regulatory process. As in the case of pharmaceuticals so in the case of

food safety, the refusal to delegate powers to independent bodies creates a serious accountability deficit, as well as a growing credibility problem.

The credibility of Community regulation suffers also from the growing politicisation of the Commission. The idea of reducing the democratic deficit of the EC policy-making process by assigning a larger role to the European Parliament, and in particular by involving the EP in the appointment of the Commission, is not new. However, the procedure introduced by Article 214 EC contains a number of radical changes with respect to previous practices, amounting to a deep transformation of the relationship between the EP and the Commission. In the future, the Commission will be fully responsible to the Parliament, whose influence will be felt in all its activities, whether legislative, administrative, or regulatory. Of course, an increasing level of politicisation of EC policy-making becomes unavoidable as more and more tasks involving the use of political discretion are shifted to the European level. At the same time, the progressive parliamentarisation of the Commission raises important questions about the coherence and credibility of EC regulation.

Both theory and experience suggest that regulatory powers should be delegated to independent European agencies. However, because of the above-mentioned Meroni doctrine, such a solution appears to be infeasible without changing the Treaty. In the opinion of many legal scholars, and even of some Commission officials, the required changes could be effected at the next IGC, by analogy with the inclusion in the Treaty of Nice (Article 229a) of a clause allowing the creation of judicial bodies in specialised areas. However, for the powerful anti-delegation faction within the Commission (led by the Legal Service) an *ad hoc* change of the Treaty would not be sufficient to overcome the doubts about the legality of delegating rule-making powers to independent agencies. An isolated modification of the Treaty in order to make possible the delegation of such powers to bodies other than the Council, the European Parliament, and the Commission, it is argued, would necessarily upset the institutional balance within the EC/EU. Moreover, the argument continues, even a partial limitation of the regulatory competencies of the Commission could compromise the technical capacities of its departments, thus affecting the exercise of other essential competencies, in particular the monopoly of legislative initiative. Such an amendment would undermine the very foundations of the Community method, and thus could not be contemplated without a prior constitutional debate on the future of the Community institutions.

The obvious counter-argument is that the balance of powers between the policymaking institutions has changed continuously since the creation of the European Communities; in fact, the rate of change has increased since the Maastricht Treaty introduced the pillar structure of the Union. In addition the delegation of rule-making powers to agencies could actually strengthen the Commission, by allowing it to concentrate its limited resources on policy initiation and on the other Treaty-based powers, as well as on the new managerial and

political tasks entailed by enlargement. The crucial point, however, is that the growing complexity of the Community policy-making system should be matched by greater functional differentiation, in particular, by the explicit assignment of an autonomous role to a 'European regulatory estate'—the extended network of national, sub-national, and supranational, organisations operating in the various areas of regulatory policy making The lack of a European administrative infrastructure means that between the supranational level of rule-making and the national, or sub-national, levels of enforcement there is an institutional vacuum which is supposed to be filled by the loyal cooperation of all the competent authorities. Unfortunately, in many cases such cooperation is not forthcoming, while significant differences in the resources, expertise, and political independence of the various regulators—differences which can only increase with the enlargement of the Union—impede a uniform application of the common rules. One important function of a European regulatory estate would be to fill this institutional vacuum by straddling the line that still separates the supranational from the national (or sub-national) levels of regulatory governance. This would send a clear signal to the various economic and social interests whose plans depend on a reasonably consistent enforcement of EC regulations, that henceforth they will be able to operate in a predictable environment.

In an globalizing world, managing international regulatory interdependence is almost as important as filling the institutional vacuum separating the European and the national levels of regulation. One of the negative consequences of the politicisation of the Commission is the risk of international isolation on regulatory issues. Thus, as we shall see in greater detail in the next chapter, the Commission, spurred on by the Council and the European Parliament, 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 challenged by the WTO, the United States, and by many other developed and developing countries. Thus, the proposals presented to the Codex Alimentarius Committee on General Principles in April 2000 were opposed by the U.S. and 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—which would seriously affect the agricultural exports of the poorest African countries for negligible health benefits to Europeans—and the beef hormones dispute which for years has opposed the EU to its major trading partners. In this dispute the Commission found itself in the position vis-à-vis the WTO bodies which various 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).

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

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Chapter 2

What Price Safety? The Precautionary Principle and its Policy Implications*

Giandomenico Majone

1. 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*).

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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 (*ibid.,* 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.

2. 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, p. 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.

3. 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.

4. 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, p. 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.

5. 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.

6. 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:

Table 1

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

Table 2

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

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 $E_1, \ldots, E_n$ 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.

7. 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, undiplomatic.

8. 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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Chapter 3

European Regulatory Agencies: The Dilemma of Delegation of Powers in the European Union

Giandomenico Majone

1. Introduction

The Commission's White Paper on *European Governance* contains a short section on 'Better application of EU rules through regulatory agencies'. The section lists the main conditions for the creation of such agencies at European level. These conditions are mostly negative in nature: agencies can be granted the power to take individual decisions in specific areas but cannot adopt general regulatory measures; they cannot be granted decision-making powers 'in areas in which they would have to arbitrate between conflicting public interests, exercise political discretion or carry out complex economic assessments'; they cannot be given responsibilities for which the Treaty has conferred a direct power of decision on the Commission (CEC, 2001, p. 43).

Now, there is nothing peculiar about the unwillingness of the Commission to give up its regulatory powers. In any political system the delegation of such powers always raises political as well as constitutional problems, but this has not prevented the recent proliferation of more or less independent regulatory bodies in developed and developing countries. Also in the United States, for example, the creation of a new agency 'is viewed always with regret and frequently with hostility. Efforts are constantly made to entrust the discharge of these new functions to the officials of an existing branch of government' (Landis, 1966 [1938], p. 25). This has not prevented Congress from establishing scores of independent regulatory

commissions, boards and agencies, and from delegating to them all the necessary powers of rule-making, adjudication and enforcement.

The delegation of regulatory powers to independent agencies raises normative as well as political problems. Both in Europe and in America the key normative problem is, in Richard Stewart's words, how 'to control and validate the exercise of essentially legislative powers by administrative agencies that do not enjoy the formal legitimation of one-person, one-vote election' (Stewart, 1975, p. 1688). The American polity has grappled with this issue for more than a century. The 'non-delegation doctrine' was the first attempt to resolve the normative problems raised by the emergence of a modern system of administrative regulation. For several decades the doctrine enjoyed such widespread acceptance that it came to be regarded as the traditional model of administrative law. The model conceives of the regulatory agency as a mere transmission belt for implementing legislative directives in particular cases. Vague, general, or ambiguous statutes create discretion and thus threaten the legitimacy of agency action. Hence, when passing laws Congress should decide all questions of policy, and frame its statutes in such specific terms that administrative regulation will not entail the exercise of broad discretion by the regulators (Stewart, 1975).

The non-delegation doctrine had already found widespread acceptance when the first institutionalisation of the American regulatory state, the Interstate Commerce Commission, was established by the Interstate Commerce Act of 1887. The Act, with its detailed grant of authority, seemed to exemplify the transmission-belt model of administrative regulation. However, the subsequent experience of railroad regulation revealed the difficulty of deriving operational guidelines from general standards. By the time the Federal Trade Commission was established in 1914, the agency received essentially a blank check authorising it to eliminate unfair competition. The New Deal agencies received even broader grants of power to regulate particular sectors of the economy 'in the public interest'. The last time the US Supreme Court used the non-delegation doctrine was in 1935, when in *Panama Refining Co. v. Ryan* (293 US 388) and in *Schecter Poultry Corp. v. United States* (295 US 495) it held the delegation in the National Industrial Recovery Act unconstitutional.

The doctrine against delegation unravelled because the practical case for allowing regulatory discretion is overwhelming. At the same time, however, the question of whether and under what conditions a legislature should be permitted to delegate rule-making powers to other institutions or branches of government is central to the theory and practice of a constitutional democracy based on the principle of separation of powers. The tension between efficiency in decision-making and constitutional principles creates the dilemma of delegation of regulatory powers. At any rate, the US Supreme Court's reiteration of the non-delegation principle, coupled with its very sparing use to strike down legislation, illustrates a continuing judicial effort to harmonise the modern regulatory state with

traditional notions of separation of powers, representative government, and the rule of law (Mashaw, Merrill and Shane, 1998).

In the EC/EU the adaptation of the institutional framework to the growing volume and complexity of regulatory tasks has proved much more difficult, and the dilemma of delegation is correspondingly more complex. It is the aim of this paper to explain the reasons of these peculiar difficulties. A first observation is that, while in the USA the non-delegation doctrine is based on the principle of separation of powers—Congress rather than administrators should make the law—in the EC/EU the corresponding doctrine is based on the very different principle of institutional balance. Hence, any attempt to explain the dilemma of delegation of power at the European level, must start from an explanation of the latter principle. The recent Commission's Communication on the role of European agencies in the Community system of governance (CEC, 2002) provides a convenient starting point for our analysis.

2. Taxonomic Problems

We start by examining some classificatory problems of the document, for such problems reveal underlying conceptual and political problems. The Commission's opposition to the creation of full fledged European regulatory agencies is well expressed by the restrictive conditions mentioned at the beginning of the preceding section. The White Book on governance did not spell out the reasons for this opposition, but it did anticipate a document defining in greater detail the criteria for the creation of new regulatory agencies, and the framework within which they should operate, as well as setting out the Community's supervisory responsibilities over such agencies. That document has now appeared: it is the Communication on *The Framework for European Regulatory Agencies* of 11 December 2002 (CEC, 2002). This document is useful, not only for understanding the current position of the Commission concerning this specific problem, but more generally, for assessing the capacity of the Community method to evolve and adapt to new tasks and new situations. I shall conclude that the reluctance to delegate regulatory powers is a revealing indication of the rigidity of the method—a rigidity which creates serious obstacles to policy and institutional innovation. The implications of this conclusion become clear when one realises that much of the work of the constitutional convention boils down to various attempts to answer the single question: what is the role of the Community method in the next stages of the integration process? Before tackling these more general issues, however, it may be instructive to examine the political roots of some of the terminological and conceptual ambiguities of the Communication.

The scope of this document at first sight appears to be rather limited. The proposed 'operating framework' only applies to a fairly small, if strategically important, subset of European agencies: those which come within the heading of

regulatory agencies (see below), and that have been set up within the institutional framework of the EC Treaty. At present there are 15 agencies created under the EC Treaty—ranging from the European Centre for the Development of Vocational Training, and the European Foundation for the Improvement of Living and Working Conditions, both established in 1975, to the three bodies established in 2002: the European Food Safety Authority (EFSA), the European Maritime Safety Agency, and the European Aviation Safety Agency. Currently pending is also a proposal for a Regulation establishing a European Railway Agency. One agency has been created under the Euratom Treaty (the Euratom Supply Agency, created in 1958), while four more bodies have been established under the second and the third pillar of the European Union: the European Police Office ('Europol', established by the Convention of 26.07.1995); the European Union Institute for Security Studies (Joint Action of 20.07.2001); the European Union Satellite Centre (Joint Action of 20.07.2001); and Eurojust (the prosecution agency established by Council Decision of 28.02.2002).

Of the 15 EC agencies, the Commission's Communication identifies the profiles of two main types: executive and regulatory. Executive agencies are 'responsible for purely managerial tasks, i.e. assisting the Commission in implementing the Community's financial support programmes and are subject to strict supervision by it' (CEC, 2002, p. 3). Note, however, that in other parts of the same document the term 'executive agency' is used in a somewhat different sense, to characterise a subset of *regulatory* agencies, namely 'those which have no independent power of decision vis-à-vis third parties but perform all other regulatory tasks […] in order to enable the Commission to discharge its duties' (CEC, 2002, p. 8). In this sense, both the European Agency for Reconstruction and the European Agency for the Evaluation of Medicinal Products (EMEA) are 'executive agencies'—a terminological confusion produced by a conceptual oxymoron: a regulatory agency without regulatory powers! The confusion is not dispelled by the formal definition: 'The concept of European Regulatory Agency designates agencies required to be actively involved in exercising the executive function by enacting instruments which contribute to regulating a specific sector' (*ibid.,* p. 4).

The Commission recognises that the executive/regulatory dichotomy does not cover some of the existing European agencies, but seems unwilling to acknowledge that its taxonomic difficulties are the consequence of deeper conceptual and political problems. In fact, also the proposed trichotomy of regulatory agencies is far from being exhaustive. The document identifies three groups of regulatory agencies: those, such as EMEA and EFSA, whose function is primarily to provide assistance in the form of opinions and recommendations, which form the technical and scientific basis for the Commission's decisions; those, like the European Maritime Safety Agency, providing assistance in the form of inspection reports, in order to enable the Commission to meet its responsibilities as guardian of EC law; finally, those empowered to adopt individual decisions which are legally

binding on third parties: the Office for Harmonisation in the Internal Market (Trademark Office), the Community Plant Variety Office, and the European Aviation Safety Agency.

It will be noted that the European Environment Agency (EEA) does not fit into any of these three groups, in fact it does not even qualify as a regulatory agency since it is not 'actively involved in exercising the executive function'. Yet, all member states, political parties, and European institutions voiced support for the proposal of an environmental agency at European level, made by Commission President Delors in January 1989. However this general agreement concealed deep divisions concerning specific institutional choices, especially those concerning the regulatory powers and effective independence of the new agency (Majone, 2002a, p. 308-9). The European Parliament, green parties, and some top Commission officials, like the then Environment Commissioner, Ripa di Meana, wanted a body with regulatory 'teeth'. In varying degrees all member states opposed the idea that the agency could monitor the implementation of EC environmental legislation, preferring to restrict its task to collection of environmental information. The idea that the EEA could become a sort of inspectorate of national environment inspectorates, along the lines of the existing Fisheries Inspectorate, had a number of influential supporters in the Commission. Being aware of the opposition of the member states, however, in the end the Commission did not propose any inspection tasks for the agency. At any rate, the majority of the college of Commissioners were reluctant to surrender any significant regulatory powers to an agency operating at arm's length.

Thus, the political struggle over institutional choice led to the establishment of an agency that does not fit into any of the categories now proposed by the Commission. The main task assigned to the EEA is to provide the Community and the member states with information on the state of the environment in Europe, and in particular 'to provide the Commission with the information that it needs to be able to carry out successfully its task of identifying, preparing, and evaluating measures and legislation in the field of the environment' (Article 2 of Regulation 210/90 of 07.05.1990). The wording is sufficiently vague, however, that it is not clear whether the agency would be allowed to influence directly policy formulation, for example by evaluating alternative proposals for environmental regulatory measures. In fact, until now the EEA has not been allowed to carry out research that is directly policy relevant. This example reveals with particular clarity the political roots of the taxonomic and conceptual difficulties which beset the Communication. Other examples could be cited. Thus, the reason that the European Maritime Safety Agency and the European Aviation Safety Agency have been given different tasks and hence assigned to different categories (see above), is very likely political: the member states prefer to have maritime safety regulated by an international organisation, the International Maritime Organisation, than by a Community body with the power to take legally binding decisions (I owe this

observation to Sara Poli). One is reminded of Terry Moe's observation concerning the politics of institutional choice:

> However grand and lofty the policies that emerge from the political process, it is virtually guaranteed that the bureaucratic arrangements that go with them are the product of compromise and, thus, in part, are designed by opponents to ensure that policies are not achieved (Moe, 1990, p. 27).

3. The Proposed Framework

Before discussing the extent to which the Commission is prepared to delegate powers to regulatory agencies, it is useful to examine the legal, organisational and financial arrangements proposed by the Communication. Concerning the creation of agencies, the document introduces some significant innovations with respect to the practice generally followed so far. Arguably, the most important innovation—or, rather, codification of the most recent practice—concerns the legal basis. In the past, agencies were created using Article 308 of the EC Treaty, according to which:

> If action by the Community should prove necessary to attain […] one of the objectives of the Community and this Treaty has not provided the necessary powers, the Council shall, acting unanimously on a proposal from the Commission and after consulting the European Parliament, take the appropriate measures.

Now it is proposed that the legal base for establishing an agency be the same as that which authorises the corresponding Community policy. The argument is simple and convincing: since the regulatory agency is an instrument of implementation of a specific policy, the legal act creating it should be based on the same provision of the treaty which constitutes the specific legal basis for that policy. This logic has already been followed in the creation of the Food Safety Authority and of the two agencies dealing with transport safety.

This innovation in no way affects the Commission's monopoly of policy initiation—so that it is always up to the Commission to decide whether an agency is needed in a given policy area—but it changes significantly the role of the European Parliament. Under Article 308 the EP had only to be consulted. Hence its capacity to affect the institutional design and the powers of the agency was minimal. But if the basis of the legal instrument creating the agency is the same provision of the EC Treaty which authorises the policy the agency is supposed to (help to) implement, then in all areas of co-decision (which is to say, in most internal market legislation) the EP should be able to influence the design of the agency, rather than seeing its proposals ignored by the other European institutions—as in the case of the European Environment Agency, see above and Majone (2002a, p. 308-10).

Another apparently quite sensible proposal concerns the location of the agencies. Disagreements among the member states over the siting of various European bodies and institutions have been a constant feature of institutional development in the EC/EU. The legislation creating most of the existing agencies did not specify the location of their headquarters. Hence, the siting decision was taken at the level of the European Council, applying by analogy Article 289 EC which says that the seat of the institutions of the EC is to be determined by common accord of the national governments But it often took years before such an agreement could be reached. Now the Commission proposes that the seat of each agency should be specified in the instrument of establishment. The proposal is sensible, in principle, but it may be politically infeasible because of the foreseeable opposition of the member states. Even if accepted, it could simply move the conflict over siting from the diplomatic to the legislative stage, further delaying approval of the Commission's proposal. Under the present system, as long as there is no agreement in the Council about siting, the agency can at least operate in provisional headquarters, in Brussels or elsewhere.

Concerning organisational arrangements, the Communication challenges the composition of the management boards of existing agencies. These management (or administrative) boards are the steering bodies of the agencies, having responsibility for defining their general operating guidelines and work programmes, approving their budgets, and appointing their executive directors. At present, the boards are composed of one or two representatives of each member state, a Commission representative; in some cases, they also include members appointed by the European Parliament or the social partners. The Commission argues that such arrangements are administratively too cumbersome, especially in view of the upcoming enlargement of the Union, and too dominated by the member states. Because of the numerical dominance of the national representatives, it is claimed, the boards fail to take sufficient account of the Community interest. The Communication argues in favour of smaller boards where national and supranational interests are more evenly represented. Concretely, it suggests a 15-member administrative board, including six representatives appointed by the Commission, six by the Council, and three, with no voting rights, representing the interested parties.

In an earlier proposal for the organisation of the Food Safety Authority, the Commission had suggested that the management board of that body should include four representative appointed by the Council, four appointed by the Commission, four appointed by the EP, and four representatives of consumers and industry, to be designated by the Commission. This proposal, and a similar arrangement for the Maritime Safety Agency, were rejected by the member states. In the case of the EFSA, however, the member states did draw some lessons from the BSE crisis. They recognised the need to give up, at least in part, the principle of national representation in the board of the authority in order to stress its independence and

the scientific quality of its advice on food safety. In the end, the member states accepted the idea of a rotation of the different countries of origin of the members of the management board 'without any post being reserved for nationals of any specific Member State' (Recital 41 of the Preamble of Regulation 178/2002 of the European Parliament and the Council, *OJ* 2002, L 031/1). As a result, the board of EFSA is composed of one Commission representative and 14 members appointed by the Council, in consultation with the EP, on the basis of a list drawn up by the Commission. Of these 14 members, four must have experience of working with consumer organisations and other relevant interest groups. To compensate for the partial loss of national representation, an Advisory Forum was established. It is composed of representatives of national regulatory bodies, one for each member state; its task is to advise the executive director of the agency on the EFSA's working programme and on other matters, such as the resolution of conflicts of scientific opinion. At any rate, the case of EFSA is exceptional. The principle of national representation was again adhered to in case of the maritime and aviation safety agencies.

Thus, it seems doubtful that the national governments will accept the Communication's proposal of smaller boards, with rotating national representatives and an equal number of Commission representatives. Another proposal may have better chances of being accepted. While in the past the Commission always pleaded in favour of including EP representatives in the boards, now the Communication argues that appointments by the EP are:

> Inappropriate in view of the regulatory agencies' work and the fact that the Parliament must be free to exercise external political supervision over their activities, without feeling tied by its membership of the administrative board (CEC, 2002, p. 9).

The point seems to be well taken, since most agencies depend at least for part of their revenue, on Community subsidies. As non-compulsory expenditures, these subsidies are ultimately determined by the EP. Discharge for the implementation of agency budgets being given by the Parliament (on the recommendation of the Council), the presence of MEPs in the agency boards could create situations of conflict of interest. In order to increase the financial control which EP and Commission can exert on the agencies, the Communication suggests that all European agencies should receive subsidies from the EC budget. At present, some of the key regulatory agencies charge service fees which cover in whole (the case of the Office for Harmonisation in the Internal Market) or in part (e.g., EMEA) their operating expenses.

Finally, the Communication proposes a procedure for the appointment or dismissal of agency directors that would greatly strengthen the influence of the Commission on the functioning of the agencies. At present, the director is appointed by the Commission only at the two 'first generation' agencies: the European Centre for the Development of Vocational Training and the European

Foundation for the Improvement of Living and Working Conditions. Both agencies were created in 1975, and cannot be considered as regulatory agencies in the sense defined in this document. In all other cases, the appointment of the director is one of the most important functions of the administrative boards which, as we saw, are largely dominated by the member states. The new proposal differentiates between decision-making agencies and those agencies which only assist the Commission in the implementation of regulatory policies. In the former case, appointment (and dismissal) should be by the Commission on the basis of a list of candidates put forward by the administrative board, while in the case of 'executive' agencies the procedure is reversed: appointment by the administrative board from a list of candidates put forward by the Commission. Making the Commission the appointing authority in the case of the decision-making agencies is necessary, it is argued, if this institution 'is to assume its responsibility for the executive function at European level effectively while respecting the autonomy of the decision-making agency'. The director must be able of gaining and maintaining the confidence of the administrative board and, 'especially, of the Commission as the authority ultimately in charge of implementation' (CEC, 2002, p. 10).

4. Delegation of Powers and Institutional Balance

As we saw, the Commission has changed its traditional position on a number of points concerning the organisation and the functioning of European regulatory agencies. On the central issue of the delegation of rule-making powers, on the other hand, its official position has hardly changed over the years: agencies may not be empowered to adopt legislative measures of general applicability. The only exception to a strict non-delegation doctrine is the admission that agencies may be allowed to adopt individual decisions in clearly specified areas of Community legislation, 'where a single public interest predominates and where they do not have to arbitrate on conflicting public interests, exercise powers of political judgement or make complex economic assessments' (CEC, 2002, p. 11). The Office of Harmonisation in the Internal Market, which deals with trademarks and industrial property, the Community Plant Variety Office, and the European Aviation Safety Agency, have been deemed to satisfy these conditions and hence have been allowed to adopt legally binding decisions in the adjudication of particular cases.

The Agency for the Evaluation of Medicinal Products and the Food Safety Authority seem to satisfy the same conditions: EMEA is exclusively concerned with the safety and efficacy of new medical drugs; EFSA, with the safety of the food we eat. Yet, these agencies have been denied any decision-making power: in both cases, the Commission makes, at least formally, the final determinations. Once more, the lack of logical consistency reveals the unwillingness to surrender politically and economically important powers. What interests us here are the

arguments used in order to justify this unwillingness in the debate now taking place not only in public, but also within the Commission itself. In fact, the official position expressed by the White Paper on European governance and by the Communication on the operating framework for the European regulatory agencies is not shared by everybody. A number of Commission officials now openly advocate the creation of European agencies with powers of rule-making as well as adjudication. This internal opposition is particularly vocal in the Commission services dealing with policy areas, such as transport, energy, telecommunications, and risk regulation, where the shortcomings of the traditional legal approach to market integration are most evident. The reformers are not yet strong enough to overcome the resistance of the traditionalists—in 2001 the Directorate General for Transport had to withdraw its original proposal of a fully fledged agency for aviation safety—but feel that time is working in their favour (Yataganas, 2001; Majone, 2002b).

A striking feature of the debate taking place within the Commission between opponents and advocates of independent European agencies, is the importance both groups attach to the principle of institutional balance. In a sense, this agreement is not surprising since the Court of Justice itself attaches constitutional value to the notion of institutional balance or, equivalently, 'balance of powers'. In *Meroni* (case 9/56 *Meroni v. High Authority* [1957-8], ECR 133) the Court justified the limitations on the lawful delegation of powers by referring to 'the balance of powers which is characteristic of the institutional structure of the Community', and which must be seen as 'a fundamental guarantee granted by the Treaty in particular to the undertakings [...] to which it applies'. The Court concluded that 'to delegate a discretionary power, by entrusting it to bodies other than those which the Treaty has established to effect and supervise the exercise of such power within the limits of its own authority, would render that guarantee ineffective'. Thus for the ECJ 'balance of powers' plays in the Community system a role analogous to that of 'separation of powers' in modern constitutional democracies.

Separation of powers is the centrepiece of modern constitutionalism. When countervailing branches of government are correctly arranged, then, in Montesquieu's words, 'power arrests power'. Elaborating on suggestive remarks by the French philosopher, James Madison clarified how separation of powers could be maintained by giving each branch of government a 'constitutional control' over the others. This control consisted in 'a partial agency in the acts of the others', for instance the presidential veto over measures passed by Congress, or the Senate's power of refusing consent to certain of the President's appointments (citation in Beer, 1993, p. 284). What separation of powers is to modern constitutionalism, institutional balance is to the much older type of polity known as 'mixed government'. As I have argued elsewhere (Majone, 2002b), the European Community is best understood, in constitutional terms, as a latter-day version of mixed government. Here it is sufficient to point out that both the theory of

separation of powers and the theory of mixed government share the idea of using different 'powers' (in the EC context, different institutions) to check and balance one another. But as Samuel Beer (1993, p. 285) has pointed out, the end served by these controls is quite differently conceived by the two models. While the modern theory refers to the separation of *branches of government*, in the model of mixed government, the division of power among 'estates', such as King, Lords, and Commons in England, was designed to balance *different social and political interests*. All the estates shared in the legislative power. 'Balance' resulted since the consent of each was necessary to the exercise of that power. Each, therefore, was a check on the others since it could withhold its consent. Unlike the control by partial agency of Madison's scheme, however, this check was not intended to confine each to a certain function but to prevent any of the social interests represented by the estates from becoming dominant.

It is hardly necessary to remind the reader that the constitutional architecture of the Community is not based on the principle of separation of powers. One of its characteristic features is the impossibility of mapping functions onto specific institutions. Thus the EC has no legislature but a legislative process in which the Council, the Parliament, and the Commission have different parts to play. Similarly, there is no identifiable executive since executive powers are exercised for some purposes by the Council acting on a Commission proposal, for other purposes by the Commission, and overwhelmingly by the Member States in implementing European policies on the ground (Dashwood, 1996).

Perhaps the most striking violation of separation-of-powers is the Commission's monopoly of legislative initiative: not a right—as in parliamentary systems where the executive has a right of legislative initiative—but an actual monopoly, so that the other institutions cannot legislate in the absence of a prior proposal by the Commission, while the Commission cannot be compelled to take a legislative initiative when it thinks that such initiative is not in the interest of the Community (Lenaerts, 1993). This extraordinary grant of monopoly power—which has been only slightly diminished by the right of the European Parliament to submit directly to the Council its amendments at second reading in the co-decision procedure—should be understood as a form of pre-commitment to the process of European integration by the framers of the Treaty. If the Council had a right of legislative initiative, it could undo previous pro-integration legislation any time this appeared to be politically advantageous. By the same logic, but also to preserve the balance between Community institutions, the right of legislative initiative is denied also to the popularly elected Parliament—one of several instances where the value of integration trumps democratic values.

The persuasiveness of the theory of the mixed polity depended on its ability to involve in the government all of the social orders of the body politic—to combine in the polity the 'powers of society', and not simply governmental functions. On the other hand, the constituent elements of the mixed polity were pre-eminently

interested in questions of privileges and rights ('liberties'): rights of the territorial ruler as against the estates, and vice-versa; or the respective rights of each estate vis-à-vis the others. Hence the prime theme of the internal political process was, as in today's EC, the tug-of-war among autonomous power centres over the extent and security of their respective jurisdictional prerogatives and immunities. However, the contest was tempered, again as in the EC, by a high degree of institutionalisation. In principle, law in the mixed polity could not be modified at the will of any one party, since it was not seen as the product of unilateral will in the first place (Poggi, 1978, p. 46-59).

It seems unlikely that the framers of the Treaties establishing the European Communities were directly inspired by ancient theories of government, but they did make a conscious choice between two distinct conceptions: that of separating the functional branches of government, and that of mixing the 'estates' of the polity in the legislature—where the three 'political' estates are not, of course, the Crown, Lords and Commons, as in the classical English model of mixed government, but the national governments, the supranational institutions, and the 'peoples of the States brought together in the Community' (Article 20 of the ECSC Treaty; Art. 107 of the EAEC Treaty; Art. 137 of the EEC Treaty), represented—at least virtually—first in the Common Assembly and then in the European Parliament.

Jean Paul Jacqué has emphasised the fact that the organising principle of the Community is not the separation of powers but the representation of interests. Each Community institution is the bearer of a particular interest which it strives to protect and promote. The nature of the prevailing interest determines the structure of decision-making. Thus, when the framers of the Treaty deemed that national interests should hold sway in a policy area of particular relevance to national sovereignty, such as fiscal harmonisation, they required a unanimous vote in the Council. On the other hand, where it appeared that national interests had to be reconciled with the common interest, it was decided that the Council should legislate by qualified majority, thus enhancing the significance of the Commission proposal. Again, where it was thought that the common, rather than the national, interest should prevail, the Commission was given an autonomous power of decision. In short, each subject matter has its own decision-making procedure according to the nature of the interest receiving special protection (Jacqué, 1991, p. 289-91).

In a mixed polity the balance between interests, and between the institutions that represent those interests, has constitutional value. The principle of institutional balance does not of course imply an equal allocation of power among the various institutions. Rather, it refers to the preservation of the relative position of each interest in the governance of the polity. In fact, the overall order of the mixed polity results from the harmonious *disparitas* among its constituent elements (Mannori and Sordi, 2001, p. 23). In the Community context it is the task of the Court of

Justice to ensure the respect of a balance of powers which reflects the basic agreements reached at the constitutional level.

The rule that 'each institution shall act within the limits of the powers conferred upon it by this Treaty' (Article 7 (1), ex Art. 4 (1), EC Treaty) must be read in the light of the principle of institutional balance. This means that each institution (1) has the necessary independence in exercising its powers; (2) must respect the powers of the other institutions; and (3) may not unconditionally assign its powers to other institutions or bodies (Lenaerts and Van Nuffel, 1999, p. 414). The centrality of the norm of institutional balance is what makes the delegation problem particularly troublesome in the EC.

5. The Community Method and Institutional Rigidity

The official non-delegation doctrine is only one manifestation of the institutional rigidity induced by the Community method. Let us briefly recall the essential elements of the method:

- The Commission *alone* makes legislative and policy proposals, and is independent of the other European institutions. Its independence is meant to strengthen its ability to execute policy, act as the guardian of the Treaty, and represent the Community in international negotiations.
- Legislative and budgetary acts are adopted by the Council of Ministers and the European Parliament, always on a proposal made by the Commission.
- The European Court of Justice guarantees the maintenance of the balance among European institutions, and respect for the rule of law.

Several idiosyncratic features of the Community method should be noted. First, the Commission and the ECJ are major players under the method, while they have no significant role in the second and in the non-communitarized parts of the third pillar. Second, these major players are non-elected bodies, operating within poorly defined accountability structures. For example, even though the Commission may be submitted to parliamentary censure, in practice censure is often a strategic instrument in the struggle between the EP and the Council, rather than an instrument of control of the Commission by the Parliament (Magnette, 2001). Relative to the political systems of the member states, non-majoritarian institutions thus play an exceptionally large role in Community governance, a fact which is at the root of the perception of a 'democratic deficit'. Again, one should note the Commission's aspiration—expressed in the concluding pages of the White Book on governance, but also pervading the Communication on the European regulatory

agencies—to add to its monopoly of legislative initiative also the role of sole executive power at European level.

The most striking feature of the Community method is its violation both of the basic principle of parliamentary democracy—the parliament as the source of legislation—and of the principle of separation of powers, as discussed above. The Commission's monopoly of legislative and policy initiative—its agenda-setting power—has no analogue in parliamentary democracies. For, if it is true that in such systems most bills are initiated by the executive, neither civil servants nor their political masters can preempt the right of initiative of parliamentary parties and individual members of parliament. Besides, national executives are the expression of the party or coalition which won the last election, and this is certainly not the case of the Commission.

It is important to appreciate what is implied by the Commission's monopoly of agenda setting. First, other European institutions cannot legislate in the absence of a prior proposal from the Commission. Second, the Commission can amend its proposal at any time while it is under discussion in Coreper or in the Council, while the Council can amend the proposal only by unanimity (except in the conciliation phase of the co-decision procedure, see below). Thus if the Council unanimously wishes to adopt a measure which differs from the Commission's proposal, the latter can deprive the main Community legislator of its power of decision by withdrawing its proposal. Finally, neither the Council nor the EP or a member state can compel the Commission to submit a proposal, except in those few cases where the Treaty imposes an obligation to legislate.

For these reasons, the Community method, which for several decades has been a powerful engine of market integration, is increasingly perceived as too rigid to accommodate the needs of an increasingly complex and diversified polity. As Jean Paul Jacqué argues, it is not possible for Community institutions to achieve more than incremental adjustments within the given framework, since the Court of Justice polices very carefully the principle of institutional balance:

> For a significant evolution to take place it would be necessary that an institution renounces to exercise its prerogatives to align its position on that of another institution. This is hardly conceivable since each institution is the representative of interests which it is its duty to protect (Jacqué, 1991, p. 252; my translation).

This rigidity of the traditional method is the reason why since the early 1990s most significant institutional innovations and new policy developments have been taking place outside the Community framework.

In the institutional architecture designed by the 1992 Treaty on European Union the Community method is confined to the first 'pillar'. The other two pillars (Common Foreign and Security Policy and Justice and Home Affairs) are only partly adjusted to the Community method. The European Council—the only

distinct organ of the EU—does not act subject exclusively to a proposal from Commission, and is not subject to any control by the EP, or to the scrutiny of the Court of Justice, except indirectly. The Commission is supposed to be 'fully associated' with the tasks in CFSP and JHA, but its power to monitor the fulfillment of treaty obligations by the member states has been explicitly omitted and its power of agenda setting, severely restricted. The EP is simply informed about decisions taken in CFSP and in JHA, and may express its opinion, while the jurisdiction of the ECJ is excluded not only in these areas, but also with regard to the 'Common Provisions' (Title 1, TEU). Even in the first pillar, the TEU defined new competencies in a way that limits the exercise of Community power, for example by excluding any harmonisation of national laws and regulation in the new policy areas.

6. Two Strategies of Regulatory Reform

Given the rigidity of the legal framework, how is reform of European regulatory policies and institutions possible? The Commission's Communication, in spite of its conceptual ambiguities, indicates rather clearly the limits of what can be achieved by the Community method, as defined and interpreted by the Commission and the ECJ. Under this method only the Commission can initiate policy, so that no significant reforms can be expected from this direction. But without such reforms the credibility crisis of European regulation (Majone, 2000) will persist and probably even deepen. I argue that this dilemma can be resolved only by going outside the Community framework. This could be done following two different strategies which, if properly implemented, could be mutually reinforcing rather than mutually exclusive.

The key idea of the first strategy is that the growing complexity of policy-making at European level should be matched by greater functional differentiation, in particular, by explicitly assigning an autonomous role to the 'regulatory estate'—the extended network of national, sub-national and European organisations operating in the various areas of regulatory policy-making. This autonomous role would be acknowledged in all the areas of regulation not assigned by the Treaty to the exclusive responsibility of the Commission. The model here is the European System of Central Banks (see below) but the notion of a regulatory estate—a term meant to recall the nature of the EC as a mixed polity—is analogous to the concept of the 'fourth branch of government' used by American scholars to denote the distinctiveness and underlying unity of the regulatory process, as well as its importance to modern governance. This process is not simply an extension of the executive process. Rather, to quote one of the most distinguished students and practitioners of regulation in America:

> In the grant (to the regulatory process) of that full ambit of authority necessary for it in order to plan, to promote, and to police, it presents an

> assemblage of rights normally exercisable by government as a whole. Moreover, its characteristic is the concept of governance, limited, of course, within those boundaries derived from its constituent statutory authority (Landis, 1966 [1938], p. 15).

At present, the lack of a European administrative infrastructure means that between the supranational level of rule-making and the national level of enforcement there is an institutional vacuum which is supposed to be filled by the loyal cooperation of the national authorities. Unfortunately, in many cases such cooperation is not forthcoming, while significant differences in the resources, expertise and political independence of national regulators—differences which can only increase with the enlargement of the Union—impede a uniform application of the common rules. One important function of the European regulatory estate would be to fill this institutional vacuum by straddling the line that still separates the supranational and national (or sub-national) levels of regulatory governance. This would send a clear message to the various economic and social interests whose plans depend on a reasonably consistent enforcement of European rules, that henceforth they will be able to operate in a predictable environment.

As suggested above, the European System of Central Banks (ESCB), composed of the European Central Bank and the national central banks, provides a heuristically useful model. As is well known, the ECB is completely independent from the European institutions (the Bank itself being not an institution within the meaning of Article 7 TEC, and thus able to escape the constraint of 'institutional balance') as well as from the national governments, while the national banks must be independent from their respective governments as a condition of membership in the monetary union. Although regulatory agencies cannot be expected to be as independent as central banks, the broad relevance of the ESCB model is increasingly recognised. For example, two well known financial experts, Jacques de Larosière and Daniel Lebégue, have suggested that the growing integration of markets in Europe 'could lead to the creation of a European system of national regulation in the same vein as the European Central Bank, with decisions taken centrally but applied nationally' (*Financial Times*, 14.9.2000, p. 17).

At this stage of the debate on regulatory reform, it is more important to stress the importance of a functional separation of the regulatory and executive powers at European level than to attempt to draw a specific blueprint of an autonomous regulatory estate and its relations to the European institutions. The design of a suitable system of accountability and control will be a particularly challenging task, but the inclusion in the treaty of Nice (Article 229a) of a clause allowing the creation of judicial bodies in specialised areas points the way towards a novel system of judicial review.

7. Back to Negative Integration?

The second strategy that can be followed in order to resolve the dilemma of delegation of powers in the EC, consists in rethinking the rationale for the assignment of regulatory powers to the European level. After more than forty years of market integration, approaches which appeared necessary in the early stages of the process, are seen now to be either unnecessary or, at any rate, infeasible. We have already referred to the progressive weakening of the harmonisation requirements. From the early 1960s to about 1973—the date of the first enlargement of the EC—the Commission's approach to harmonisation was characterised by a distinct preference for detailed measures designed to regulate exhaustively the problem in question to the exclusion of previously existing national laws and regulations—the approach known as total harmonisation. Under total harmonisation, once European rules have been put in place, a member state's capacity to apply stricter rules by appealing to the values protected by Article 30 TEC, in particular the protection of the health and life of humans, animals, and plants, is excluded. Also the ECJ supported total harmonisation as a foundation stone in the building of the common market.

By the mid-1970s, however, it had become clear that total harmonisation confers on the Community an exclusive competence which it is ill-equipped to discharge (Weatherill, 1995). This realisation, together with mounting opposition from the member states to what they considered excessive centralisation, convinced the Commission that this approach had to be used so as to interfere as little as possible with the regulatory autonomy of the national governments. The emphasis shifted from total to optional and minimum harmonisation. Optional harmonisation aims to guarantee the free movements of goods while permitting the member states to retain their traditional forms of regulation. Under minimum harmonisation, the national governments must secure the level of regulation set at European level but are permitted to set higher standards, provided the stricter national rules do not violate Community law. This is the approach currently followed in social regulation: environmental and consumer protection, occupational health and safety, food safety.

While total harmonisation was justified by the alleged need of a single set of rules in a single market, the justification usually given for minimum harmonisation is the desire to avoid a 'race to the bottom' in social regulation within the EC/EU: minimum standards, it is claimed, are needed because competition for industry would otherwise lead member states to enact sub-optimally lax social standards in an effort to attract more investments and to give existing firms a competitive advantage with respect to firms in countries with stricter standards. However, it has been shown that race-to-the bottom arguments are theoretically unsound, and lack empirical support (see, for example, chapters 10-12 in Bhagwati and Hudec, 1996, and literature cited therein). If countries have different preferences for

environmental protection or risk regulation, the standards that maximise social welfare will be different rather than harmonised.

Moreover, even if there was a race to bottom in, say, environmental quality, European regulation would not necessarily be an appropriate response. As Richard Revesz has noted, race-to-the-bottom arguments appear to assume that countries compete over only one variable. But if minimum harmonisation prevents such a race in environmental quality, countries, under our assumption, would try to compete along other regulatory dimensions. If other regulatory areas are harmonised, it would be possible to compete for industry by using fiscal incentives—or by lax implementation of European rules. Thus, the race-to-the-bottom rationale for (minimum) harmonisation seeks to solve a problem that can be addressed only by wholly eliminating the autonomy of the member states. What Revesz says with reference to American federalism, applies *a fortiori* to the EU:

> The prisoner's dilemma will not be solved through federal environmental regulation alone, as the race-to-the-bottom argument posits. States will simply respond by competing over another variable. Thus, the only logical answer is to eliminate the possibility of any competition altogether. In essence, then, the race-to-the-bottom argument is an argument against federalism (Revesz, 1992, p. 1247, footnotes omitted).

A return to negative integration means that positive integration (harmonisation) would take place at the European level only if it could be shown that the EU represents, relative to a given problem, the optimal regulatory area. In general, regulatory responsibilities would be left with the people most directly affected by the problem, with the European institutions monitoring closely the behaviour of lower jurisdictions to make sure that they do not abuse their autonomy for protectionist purposes. Both fiscal federalism and functional federalism offer a number of criteria for identifying optimal regulatory jurisdictions (for a useful survey see Holzinger, 2000). According to such criteria—homogeneous preferences, scope of negative externalities, similar costs in the provision of public goods, etc.—the EU would be the appropriate level of regulation in a fairly limited range of situations. On the other hand, fiscal and, especially, functional theories of federalism tend to produce a great variety of different but overlapping jurisdictions. The proliferation of *ad hoc* regions can be reduced if to the above mentioned economic and functional criteria we add the criterion of *political accountability* in case of regulatory failure. This means that an optimal regulatory area should also include well defined political and legal mechanisms which citizens can activate in case of regulatory failures. This additional criterion would again tend to exclude the EU as the appropriate level, but would favour a coincidence of functional jurisdictions with existing political (national and sub-national) units.

But what about the single European market? Is there a danger that the kind of regulatory decentralisation envisaged here may lead to its segmentation and,

ultimately, to a return to separate national economies? An adequate answer to such questions would require a separate treatment. Here I can only sketch the key points of my argument. First, to repeat a point already made, if preferences, levels of economic development, costs of provision of public goods, environmental conditions etc. vary across jurisdictions, then harmonised rules cannot be welfare enhancing. Thus, the demand for harmonisation must be driven by a different—a political—agenda. Political integration is a perfectly legitimate objective, but it should be pursued openly as such, rather than under the guise of market integration. Second, a growing body of theoretical and empirical literature proves that harmonisation, particularly of social standards, is not necessary for free trade to be 'fair' or undistorted. Thus, the Treaty of Rome never mandates that social policies be harmonised prior to or concurrently with trade liberalisation within the common market. The single exception to this stance concerns the condition of equal-pay for male and female workers. The founding fathers expected that a rapid amelioration of living standards throughout the Community would bring about an *ex post* harmonisation of social conditions.

In fact, and this is my third point, it has been recently proved formally (Casella, 1996), not only that an initial difference in standards need not distort trade, but that it is trade itself that leads to their (*ex post*) convergence. This is because standards concerning environmental quality, risk control or consumer protection are positively correlated with the standard of living. Thus, as wealth grows as a result of free trade, the endogenous demand for higher standards grows as well. It follows, paradoxically, that the *ex ante* harmonisation of standards as a precondition for free trade could be counterproductive, since it may prevent or limit free exchange, and the wealth effects it produces.

Finally, market integration is not an absolute value. At least since *Keck* the ECJ has recognised that the regulatory autonomy of the national governments is a value which deserves protection, so that the two values—market integration and national autonomy—may have to be traded off at the margin. In some policy areas, market integration has been sacrificed for political reasons. For example, laws on minimum wages, collective contracting, hiring and firing, duration of the working week, flexible labour contracts, qualifications, and a host of other factors continue to differ among the member states. In the words of Jacques Pelkmans: 'Member States, alone and together, will do everything to protect national labour market regulation, even at the cost of hardening the fragmentation of the EU's labour market' (Pelkmans, 1997, p. 137). Why do we not take the same relaxed attitude towards regulatory autonomy in the case of food safety, and other areas of risk regulation, where national preferences are known to differ widely?

8. Conclusions

In every political system the delegation of regulatory powers to more or less independent agencies raises normative and institutional problems, but these problems are nowhere as severe as in the EC/EU. One could think that resistance to delegation of rule-making functions to executive bodies would be strongest in a strict separation-of-powers system, such as the United States. In fact, a strict non-delegation doctrine was first formulated there. But as we saw, the doctrine eventually unravelled because the practical case for delegation is overwhelming. At the same time, the fact that American courts have never formally renounced the doctrine, while in practice applying it only rarely, indicates that doubts about the legitimacy of transferring essentially legislative functions to another branch of government, continue to persist. In order to minimise such doubts an impressive array of control and monitoring mechanisms have been developed. Congressional hearings, monitoring by specialised legislative committees, budgetary reviews, sanctions, procedural constraints—such as those imposed by the Administrative Procedure Act and the Freedom of Information Act—and judicial review, are some of the instruments used in an effort to limit regulatory discretion and ensure democratic accountability.

Also parliamentary systems—where the principle of ministerial accountability to the legislature represents the key legitimating mechanism for the activities of the executive—do not seem to provide a favourable environment for the delegation of discretion to regulators. Indeed, in most European countries, independent regulatory agencies are still regarded as constitutional anomalies, but this has not prevented their proliferation in recent years. Actually, in a country such as the United Kingdom, where regulatory institutions are both numerous and powerful, the fear now is that the regulators may have been given too much discretion, creating the possibility that UK regulation could evolve, in the words of Cento Veljanovski, into the rule of men (the regulators) rather than the rule of law. Weak accountability—the Parliament exercises little systematic supervision over the agencies—weak judicial review—British courts, unlike their American counterparts, generally do not interfere on the merits of agency decisions—and absence of procedural safeguards comparable to those developed in the United States, are perceived as serious problems, but these concerns have not prevented an extended delegation of regulatory powers to independent bodies.

Why, then, is the delegation problem so intractable in the EC/EU? The present paper has attempted to provide an answer. In a sense, the Commission is right when it argues that it is not sufficient to add an article to the Treaty in order to make delegation of rule-making power constitutionally possible at the European level. Such delegation would violate the principle of institutional balance, and thus undermine the very foundation of the Community method. It follows that no possibility of real institutional innovation can exist as long as the principle is

interpreted so rigidly, not only by the Commission, but also by the Court of Justice. The real dilemma the Community is facing today, therefore, is preserving the Community method, at the price of a mounting loss of efficiency and credibility of European regulations, or to limit the scope of the method, according to one or the other of the two strategies outlined above.

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Chapter 4

The Emerging EU Regulatory Framework on Genetically Modified Organisms: Dilemmas and Challenges*

Sara Poli

1. Introduction

In the last ten years, relations between the European Union and the US have grown increasingly tense in the field of food safety. Whereas the use of growth hormones in beef has been the object of a trade dispute, which was eventually adjudicated by the organisms of the WTO, the marketing of genetically modified organisms (hereafter 'GMOs') did not develop into a legal dispute but certainly generated tension between the two blocs.[1] At the origin of the dichotomy[2] on the use of

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1 On the possible reasons why the trade tension has not so far become a trade dispute, see Pollack M. A. and Shaffer G. C. (2000) 'Transatlantic conflict over genetically modified organisms: why the US is avoiding a trade war', in *The Washington Quarterly,* No. 23.

2 On the differences between the EU and the US regulatory approaches to GMOs, see Echols M. E. (1998) 'Food safety regulation in the European Union and United States: different cultures, different laws', *Columbia Journal of European Law*, No. 4, p. 525; Vogel D. (2001) *Ships passing in the night: the changing politics of risk regulation in Europe and in the US,*

GMOs was the decision, taken by the European Council in 1999, to suspend the authorisation procedure leading to the marketing of GMOs.[3] The decision was made as a result of the rising of a consensus amongst the Member States against the use of these organisms.[4] Since the US is the world's principle producer of GMOs, the EU stance on GMOs clearly affected American commercial interests. For the first time, the EU Member States showed their opposition to the use of GMOs for

(contd.)

EUI Working Papers, RSC No. 2001/16; Princen S. 'EU regulation and transatlantic trade', *Kluwer Law International*, p. 195-266. For a criticism of some aspects of the United States regulatory system see Bratspies R. (2002) 'The illusion of care regulation, uncertainty and genetically modified crops', in *New York University Environmental Law Journal*, Vol. 10, p. 297.

3 See the Environment Council of 25 June 1999. In the minutes of this meeting the Member States made two declarations. The Danish, Greek, French, Italian and Luxembourg delegations announced to suspend the release of new GMOs authorisations. The other delegations invited the Commission to make a proposal for the effective implementation of the provisions regarding labelling and traceability of GMOs through the Comitology procedures foreseen in Directive 90/220 (the framework Directive). These delegations also noted the possibility for Member States to introduce national measures in conformity with the relevant paragraphs of Art. 95.

4 The Member States' consensus against the marketing of GMOs was born during the authorisation procedure for the marketing of a certain variety of GM maize, under Directive 90/220. In the framework of the approval procedure, the Commission asked for the opinion of three advisory scientific committees on the safety of GM maize. These committees were consulted after the comitology committee, set up by Directive 90/220, had failed to deliver an opinion on the request of authorisation to market the variety of GM maize concerned. The three committees took the position that GM maize did not pose risks for health. Therefore the Commission authorised the marketing of the GM maize in December 1996. (Commission Decision 97/98, *OJ* [1998] L 31/69). Even though the Member States were bound to accept the Commission's decision, a majority of them opposed it. In March 1997 Austria, Italy and Luxembourg enacted bans of the GM maize, relying on the safeguard clause of Art. 16 of the 90/220 Directive. The other Member States supported this initiative. In this situation, the Commission consulted its advisory scientific committees in order to understand whether the bans enacted by the Member States were justified. These committees found that the article 16-ban was not justified since it was not based on new scientific information capable of affecting the original risk assessment provided by the notifier. (See the Opinion adopted by the Scientific Committed on Plants on the invocation by Austria of Art. 16 [30 November 2000], published on http://europa.eu.int/comm/food/fs/sc/scp/out85_gmo_en.html; see also the opinion of the same committee on the invocation by France of Art. 16 against GM oil seed rape available at the following address: http://europa.eu.int/comm/food/fs/sc/scp/out37_en.html.) In the light of these opinions, the Commission asked the concerned Member States to repeal the bans. However, they disregarded the Commission's request. There are currently nine on going article 16 cases involving Austria, Luxembourg, France, Germany United Kingdom. (See MEMO/02/160**,** Brussels, 15 October 2002, 'Questions and Answers on the Regulation of GMOs in the EU', of 15 October 2002, http://europa.eu.int/comm/food/fs/gmo/gmo_index_en.html.) In consideration of the wide consensus against the marketing of GMOs, the Commission has not taken legal action against the Member States, although they were not complying with the EC GMOs legislation.

commercial purposes during the approval procedure of a specific variety of genetically modified maize.[5] The European national governments decided to suspend the approval procedure for the marketing of GMOs pending the approval of new legislation giving adequate guarantees against the risks presented by GMOs. This European position was criticised by the US and other countries, which pointed out the potential conflict between the *moratorium* (suspension of the authorisation), essentially inhibiting trade in GMOs, and the WTO agreements.[6] In 1999, the Commission set out to tackle the crisis by undertaking a number of reforms, sketched out in the White Paper on Food Safety,[7] with the aim of re-defining and clarifying the European strategy in food safety matters. The overhaul of the food safety policy has been a challenging task for the Commission since, as one author points out:

> The EC procedures must deal with the paradox of the denationalisation of risk issues, set against the growing importance of national interests and national perceptions on risk, while at the same time having to take the decisions which are defensible in international *fora*, such as the WTO.[8]

The reform envisaged by the Commission, and as yet unfinished, is based on different pillars. Firstly, the Commission has defined some interpretative guidelines of the precautionary principle—which plays a fundamental role in the European decision-making dealing with health-related and environmental issues—in a 'soft law' act.[9] Secondly, a new horizontal framework Directive on GMOs[10] (which replaced the original framework Directive of 1990)[11] has been adopted; the institutional setting of bodies dealing with food safety has been radically changed through the setting up of a European Food Safety Authority (hereafter 'EFSA' or

5 See the GM maize crisis described above No. 4. For a full account of this crisis see, Hervey T.K. (2001) 'Regulation of Genetically Modified Products in a Multi-Level System of Governance: Science or Citizens?', in *Review of European Community and International Environmental Law*, 10 (3), p. 321.

6 For a detailed analysis of the conflict between the EU ban on GMOs and the SPS agreement see Charles W. Smitherman III (2002) 'World Trade Organization Adjudication of the European Union—United States Dispute Over the Moratorium on the Introduction of New Genetically Modified Foods to the European Common Market: A Hypothetical Opinion of the Dispute Panel', in *Georgia Journal of International & Comparative La*w, 30, p. 475, in particular p. 497.

7 COM (1999) 7S19 final.

8 Tromans S. (2001) 'Symposium: sustainable development, agriculture and the challenge of genetically modified organisms: promise, peril, precaution: the environmental Regulation of genetically modified organisms', in *Indiana Journal of Global Legal Studies*, 9. p. 202.

9 COM (2000) 1.

10 Directive 2001/18, *OJ* (2001) L 106/1.

11 Directive 90/220, repealed by Directive 2001/18.

'Food Authority').[12] Finally, the Commission has put forward a package of measures of sector-related legislation on GMOs designed to solve this *impasse*, which has blocked the approval procedure to trade genetically modified organisms. This paper focuses on this strand of the reform. More precisely, two Commission proposals for a Regulation, as amended by the Council and the Parliament in its first reading, will be the primary object of this paper. The first concerns GM food and feed[13] and the second on the traceability and labelling of GMOs and the traceability of food and feed products produced from GMOs.[14] These proposals, together with the new framework Directive, represent the most significant legislative changes to the EU regulatory framework on GMOs since the outbreak of the genetically modified maize crisis.[15] The text of the two proposals is far from final. Given the highly contentious nature of the subject matter, the Parliament might propose substantial amendments[16] to the proposals in its second reading. It is, however, already possible to identify the spirit, challenges and dilemmas of the emerging EC measures.

The analysis of the proposed legislation, of which only the most salient provisions will be presented, has three aims. Firstly, the paper will pinpoint the impact of the two proposals on the EU regulatory process leading to the marketing of GMOs by assessing whether the legislative changes proposed by the Commission are mere cosmetic makeup or whether they meaningfully strengthen the EU regulatory framework on GMOs. In order to assess how the new legislation will affect the old GMOs regime, a description of the proposed legislation will be provided. Special emphasis will be placed on the scope of the Member States' powers to adopt unilateral measures, suspending or limiting the circulation of a given genetically modified food/feed on the grounds of public health or environmental protection. In analysing this issue, I will also consider whether and how Art. 95 can be used by Member States to introduce or maintain national measures, derogating from a Community measure. Secondly, an evaluation will be made of the likelihood that the draft Regulations, which are felt to 'hold the key' to

12 See Regulation 178/2002, *OJ* (2002) L31/1.

13 See the Commission's proposal in COM (2001) 425. This paper will consider the latest version of the draft Regulation, that is to say, the common position achieved by the Council on the 17th March 2003. See Council document No. 5204/3/03.

14 See the Commission's proposal in COM (2001) 182, as modified by the political agreement reached at the Environment Council meeting of 9 December 2002. The document may be found at http://register.consilium.eu.int/pdf/en/02/st15/15460en2.pdf.

15 See above No. 4.

16 On the first reading, the European Parliament made 111 amendments to the Commission's proposal on GM food and feed. The Commission accepted only 16 amendments in their entirety and 38 in a part or in principle. See the Parliament's legislative observatory.

the lifting of the *moratorium*,[17] will secure Member States' consent to the marketing of GMOs in the Community market. This is the most important challenge of the emerging legislative framework. Should Member States decide to abandon the *moratorium*, the future commercial presence of GMOs in Europe would depend entirely on consumers, who might welcome these products or decide not to buy them. Possible problems, resulting from the shape that the EC institutions decide to give to the GMOs reform, will also be examined. In particular, since scholars have extensively commented on the (in)compatibility of the GMOs marketing regime of the 1990s and the WTO rules,[18] it will be explored whether the proposed measures potentially conflict with the trade rules of the Geneva organisation. Dilemmas which the WTO bodies might face in applying the WTO agreements to the proposed GMOs legislation will also be underscored.

2. The Scepticism of the Member States Towards the 1990s EU Legislation on GMOs

It was the crisis leading to the blocking of authorisation in the genetically modified maize saga[19] that first revealed the Member States' great fear that the use of GMOs, in food or for other purposes, could cause unforeseen health and/or environmental

17 Francescon S. (2001) 'The New Directive 2001/18/EC on the Deliberate Release of Genetically Modified Organisms into the Environment: Changes and Perspectives', in *Review of European Community and International and Environmental Law,* 10 (3), p. 320.

18 Bentley Q.C.P. (2000) 'The re-assessment of article XX, paragraphs (b) and (g) of GATT 1994 in the light of growing consumer and environmental concern about biotechnology', in *Fordham International Law Journal* Vol. 24, No. 1/2, 107*;* Buckingham D.E. (2001) 'Hot Potato, Hot Potato: Regulating Products of Biotechnology by the International Community', in *Journal of World Trade* Vol. 35, No. 1, p. 1; Fredland J.S. (2000) 'Unlabel their Frankenstein foods!: evaluating a U.S. challenge to the European Commission's labelling requirements for food products containing genetically-modified organisms', in *Vanderbilt Journal of Transnational Law* Vol. 33, No.1, 183; House R., Mavroidis P.C. (2000) 'Europe's evolving regulatory strategy for GMOs—the issue of consistency with WTO law: of kine and brine', in *Fordham International. Law Journal,* Vol. 24, No. 1/2, p. 317; Krenzler H.G., MacGregor A. (2000) 'GM food: the next major transatlantic trade war?', in *European Foreign Affairs Review* 5 297; MacMillan F., Blakeney M. (2000) 'Regulating GMOs: is the WTO agreement on sanitary and phytosanitary measures hormonally challenged? Part 1', in *Internal Trade Law Review*, p. 131; McMillan F., Blakeney M. (2000) 'Regulating GMOs: is the WTO agreement on sanitary and phytosanitary measures hormonally challenged? Part 2', in *Internal Trade Law Review*, p. 161; Pardo Quintillán S. (2000) 'Free trade, public health protection and consumer information in the European and WTO context: Hormone-treated beef and genetically modified organisms', in *World Trade Journal* Vol. 33, No. 6, p. 147; Perdikis N.O., William A. Kerr, Jill E. Hobbs (2001) 'Reforming the WTO to defuse potential trade conflicts in genetically modified goods', in *World Economy*, Vol. 24, No. 3, March, p. 378; Smithermann III C. W. above No. 6.

19 See above No. 4.

problems. This crisis also highlighted two more elements. The first was that Member States distrusted the opinion of the scientific advisory committees of the Commission.[20] It should be noted that these committees not only approved of the marketing of GM products that the Member States were not willing to accept,[21] but also found that the suspension of the authorisation for the marketing of GMOs was unjustified.[22] The second concerned the conditions under which the use of GMOs could be acceptable to national authorities. It was made clear that Member States would consent to GMOs only if there were adequate guarantees that these organisms did not pose substantial risks when placed in the environment or the food chain. More precisely, the EU legislative framework, which was enacted in the 1990s,[23] was considered insufficient to cope with the risks associated with GM material. No traceability rules were contemplated by horizontal or sector-related legislation. As for labelling, although under Regulation 258/97 (hereafter 'the Novel Food' Regulation),[24] it was stated that GM Novel Food should be labelled, in reality 'the Commission had not produced guidelines on detailed labelling rules to accompany the regulation.'[25] As a result, only two GM crops,[26] which were placed in the market before the adoption of the Novel Food Regulation, had to be labelled. In addition, GM feed was not subject to labelling requirements, although more than eighty percent[27] of genetically modified soya apparently went into animal feed. Finally, no labelling thresholds were established for the adventitious or technically unavoidable presence of GMOs.[28]

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20 The authority of the scientific committees has been contested since the BSE crisis. In the context of this crisis, 'The Inquiry Committee of the European Parliament found that the scientific committees had not been free from external, non-scientific influence.' See Vos E. (2001) 'Differentiation, harmonisation and governance', in (De Witte B., Hanf D., Vos E., eds.) *The Many Faces of Differentiation in EU Law*, p. 175.

21 See above No. 4.

22 See above No. 4.

23 Directive 90/220 and the Novel Food Regulation No. 258/97.

24 *OJ* (1997) L 43/1.

25 Franks J.R. (1999) 'The status and prospects for genetically modified crops in Europe', in *Food Policy*, 24, p. 573.

26 These were the Monsanto soya and the Novartis maize which were subject to labelling requirements under Regulation 1139/98.

27 This is a percentage which is reported in Francescon S. and Mackenzie R. (1999-2000) 'The regulation of genetically modified food in the European Union: an overview', in *New York University Environmental Law Journal*, 8, p. 553.

28 The only exception is Regulation 49/2000 which exempts from labelling requirements foodstuff from non-GM sources where material derived from GMOs is present in food ingredients, or in the food as a single ingredient, in a proportion which is no higher than 1% if the presence of the material is adventitious.

In order to reassure the Member States, the Commission filled these lacunas by enacting a new GMOs framework Directive, which introduced labelling[29] and traceability requirements[30] and a new authorisation procedure for the release of GMOs.[31] Moreover, some specific pieces of legislation on GMOs were enacted.[32] However, some Member States, supported by the European Parliament, took the position that they would not lift the ban on the authorisation of GMOs until a separate regime of environmental liability for GMOs was set up and more comprehensive rules on traceability of GMOs enacted.[33] While the proposed environmental liability Directive does not envisage (as it stands)[34] separate rules on damages resulting from genetically modified organisms, extensive rules on labelling and traceability were laid down in two proposals for a Regulation.[35] Furthermore, the authorisation procedure for the marketing of GM food and feed was revisited with respect to the Novel Food Regulation.

The reforms undertaken by the Commission to secure an improved legislative framework against the risks of GMOs encouraged this institution to restart the procedure for authorising genetically modified crops and foods.[36] In March 2003, the Commission informed the EU Environment Council that nineteen applications were in the pipeline, including ten for genetically modified crops. The news caused a divided reaction amongst the Member States.[37]

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29 Art. 21 and Annex IV.

30 Art. 4(6).

31 Directive 2001/18. On the deficiencies of Directive 90/220 and the news of the proposed framework Directive (as of 1999), see Douma W. and Matthee M. (1999) 'Towards new EC rules on the Release of Genetically Modified Organisms', in *Review of European Community and International and Environmental Law,* 8, p. 152. For a description of the content of the framework Directive see Lawrence D., Kennedy J., Hattan E. (2002) 'New controls on the deliberate release of GMOs', in *European Environmental Law Review*, p. 51.

32 See Regulation 50/2000 concerning labelling of foodstuffs and food ingredients containing additives and flavourings that have been genetically modified or have been produced from genetically modified organisms.

33 'Moratorium on New GMOs Set to Stay', in *ENDS* report February 2001, Issue No. 313.

34 The current text (as of June 2002) of the proposal on environmental liability with regard to the prevention and remedying of environmental damage covers, *inter alia*, environmental damages followed by the deliberate release of GMOs, including the placing on the market (see point 14 of annex I of the Council document 10458/02 of 28 June 2002).

35 See above No. 13 and 14. The two proposals are strongly intertwined. In fact, they will enter into force at the same time.

36 See 'EU Ministers divided over liability, cool on bathing water reforms', in *ENDS Report* No. 338 of March 2003.

37 The UK led a minority of Member States which was in favour of taking a decision on the pending applications. Germany and other Member States objected the initiative of the Commission. See *END report* No. 338 of March 2003.

3. Overview of the New Legislative Framework

In accordance with the strategy laid down by the White paper on food safety,[38] as from 2001, the Commission, proposed several pieces of sector-related legislation in the field of GMOs. Although the Commission was keen on re-starting the authorisation procedure for the marketing of GMOs, it certainly did not choose the shortest way. For example, greater use of comitology procedure could have been made instead of following the legislative procedure.[39] However, the Commission preferred the second approach, hoping that the enactment of the new legislative instruments would gain the Member States and the Parliament's support toward the envisaged reform more easily. The legislative changes that it proposed encompass three Regulations and three Council/Commission decisions.

The first Regulation concerns genetically modified food and feed; the second is related to the traceability and labelling of GMOs products and the traceability of GM food and feed. The Council has agreed on a common position on both proposals,[40] which will be sent to the EP for a second reading. Political agreement on the traceability Regulation was voted in December 2002, although the UK, the Netherlands, Luxembourg and Denmark voted against it.[41] The UK and Luxembourg also disagreed on the compromise reached at the Council meeting of 28 November 2002 on GM food and feed.[42] A third proposal for a Regulation, aimed at implementing the Cartagena Protocol within the EC Community framework,[43]

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38 See above No. 7.

39 In order to introduce traceability and labelling requirements on GMOs, the Commission evaluated the merits of three solutions: a) the adoption of technical measures, implementing Directive 90/220, through comitology procedures, b) the introduction of traceability and labelling requirements in the sector-related legislation; c) a new horizontal instrument on traceability and labelling. The Commission chose the latter legislative approach, thus discarding the first option which would have been the less time consuming. See the working document of the Commission on traceability and labelling of GMOs and products derived from GMOs, doc. ENV/620/2000, p. 8-13.

40 See above No. 13 and 14.

41 See Council document 15101/02, p. 8, published on: http://register.consilium.eu.int/pdf/en/02/st15/15101en2.pdf.

42 See http://www.foodstandards.gov.uk/science/sciencetopics/gmfoods/gmfoodfeedproposals/gm2811. Austria was the third Member State who voted against the political agreement on GM food and feed.

43 On February 2002, the Commission proposed to implement the Cartagena Protocol, concerning both the export and imports procedure of living genetically modified organisms. The draft Regulation is intended to set up a procedure to export GMOs. As far as imports of GMOs are concerned, the EU legislation will continue to operate. The implication is that the EC legislation on the imports of these organisms complies with the provisions of the Cartagena Protocol and, as such, no additional implementing measures are needed. See the proposal for a Regulation on the transboundary movement of genetically modified organisms in COM (2002) 85 final of 18 February 2002. The Commission proposal was amended by the

was put forward by the Commission. However, it will not be examined since it lies beyond the scope of this paper.[44]

In addition to this legislation, three decisions were issued, laying down detailed guidelines on some technical aspects of the approval procedure leading to the placing of GMOs on the market. These pieces of technical legislation, adopted through comitology procedures, complete the legislative framework established by Directive 2001/18.[45] The guidelines in these three instruments were needed to make the framework Directive fully operational.[46]

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Parliament in its first reading. For the proposed amendments see COM (2002) 578 of 16 October 2002. The Protocol was approved on 25 June 2002. See Council decision 2002/628, *OJ* (2002) L 201/48.

44 See COM (2002) 85, p. 21.

45 Above No. 10.

46 The first Decision lays down detailed guidelines on the objectives, elements, general principles and the methodology of the 'environmental risk assessment' (See Commission Decision of 24 July 2002 establishing guidance notes supplementing Annex II to Directive 2001/18/EC and repealing Council Directive 90/220/EEC, in *OJ* [2002] L 200/22). This notion is defined by Art. 2.8 of Directive 2001/18 as 'The evaluation of risks to human health and the environment, whether direct or indirect, immediate or delayed, which the deliberate release or the placing on the market of GMOs may pose.' A description of the way in which this assessment should be carried out is crucial for a correct and complete notification process and, eventually, for the positive outcome of the authorisation procedure.

The second Decision concerns detailed guidelines on how the notifiers should implement monitoring plans in order to trace and identify any direct or indirect, immediate, delayed or unforeseen effects on human health or the environment of GMOs as or in products after they have been placed on the market. (Council Decision of 3 October 2002 establishing guidance notes supplementing Annex VII to Directive 2001/18/EC and repealing Council Directive 90/220/EEC, in *OJ* [2002] L 280/27.) The 'surveillance mechanism', set up by this Decision, goes in the direction of preventing possible damages (to human health or to the environment). Therefore it should be seen as a means to strengthen the safety net surrounding the use of genetically modified products. This is all the more so if one considers that the 2002 guidelines on the monitoring plans are stricter for the notifier than those of the framework Directive. Indeed, with respect to the guidelines of the framework Directive (See Annex VII of Directive 2001/18) the 2002 guidelines expand on the objectives for monitoring, expand on the general principles for monitoring and provide an outline for a general framework for the development of appropriate post-market monitoring plans.

The third Decision is aimed at standardising the format of the summary notification that national authorities are bound to send to the Commission. (Council Decision of 3 October 2002 establishing, pursuant to Directive 2001/18/EC, the summary notification information format for notifications concerning the deliberate release into the environment of genetically modified organisms for purposes other than for placing on the market, in *OJ* [2002] L 280/62.) A comprehensive, unified and clear summary notification is particularly important since on the basis of this notification—which is first sent to the Commission and then forwarded to the other Member States—national competent authorities decide whether or not to raise objections against the marketing of the GMO. The fact that the summary notification is standardised in a detailed manner makes sure that the information related to the

3.1 The Proposed Genetically Modified Food and Feed Regulation

This Regulation lays down the specific pre-marketing approval and labelling requirements with which genetically modified food and feed will have to comply in order to be placed on the Community market.

The objectives of the draft Regulation are very broad, as is also shown by the triple legal basis (Arts. 37, 95 and 152[4]). The Regulation aims to achieve 'a high level of protection of human life and health, environment and consumer's interest in relation to genetically modified food and feed.'[47] It is noteworthy that the objectives of the Novel Food Regulation—which the proposed Regulation intends to revise—are focused on the protection of the common market[48] and of public health.[49] The latter is an ancillary objective with respect to the former, as it reveals the choice of Art. 95 (100.a) as the legal basis.

The proposed Regulation covers food which falls within one of these three categories:[50] a) genetically modified organisms for food use, (i.e. GM maize); (b) food containing or consisting of genetically modified organisms, (i.e. GM tomatoes); (c) food produced from or containing ingredients produced from genetically modified organisms (i.e. flour produced from genetically modified maize).[51] It may be noted that the scope of the proposed Regulation partially overlaps with that of the Novel Food Regulation and of the GMOs framework Directive. Indeed, category a) encompasses living GMOs which are also covered by Directive 2001/18, while categories b) and c) are included within the scope of the Novel Food Regulation.[52] After the entry into force of the proposed Regulation, the three groups of GM food will be authorised exclusively on the basis of the authorisation procedure established by the GM food and feed Regulation.[53] Thus, certain provisions of the Novel Food Regulation[54] and of the framework Directive[55]

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request for authorisation to market the GMO is as complete as possible. This will enable, in turn, the Member States to take a well informed decision on the basis of uniform data.

47 Art. 1.a.

48 The legal basis is Art. 100.a (Art. 95).

49 See recital No. 2 of the Novel Food Regulation.

50 Art. 3.

51 For the sake of convenience, food consisting of, or containing GMOs, and food produced from GMOs will be referred to as 'GM food.'

52 See Art. 1.2.a and b of the Novel Food Regulation.

53 Art. 4(2).

54 According to Art. 38, the following provisions of the Novel Food Regulation are repealed: Art. 1.2.a and b; Art. 3(2) second paragraph and (3); Art. 8(1) d; Art. 9. The GM food and feed also repeals Regulations 1039/97, 49/2000, 50/2000.

55 See Art. 5(5) b last indent and 17(5) b.

will be respectively repealed or considered inapplicable. However, Reg. 258/97 remains good law for non-GM Novel Food.[56]

One important feature of the proposed Regulation is that it covers GM feed, as it was not previously included within the scope of any piece of legislation. The new Regulation will apply to a) genetically modified organisms for feed use (for example, certain varieties of GM soya); b) feed containing or consisting of genetically modified organisms; c) feed produced from genetically modified organisms (feeding stuff produced from GM fodder beet).[57]

Another group of food which the Parliament wanted to regulate in the proposed Regulation was food produced with a GMO.[58] However, the Parliament did not win the Commission's support on this point. In practical terms, this means that food produced from an animal fed with genetically modified feed[59] and food which was produced with a GM enzyme, leaving no traces of genetically modified material in the final product, will not be subject to the restrictions of the Regulation. Should there be any doubts on whether a certain category of GM food/feed falls within the scope of the Regulation, the Commission is empowered, together with the comitology committee, to clarify this issue.[60] It is striking that the opinion of the EFSA is not required in a decision of this kind.

Let us now turn to the approval procedure to place GM food/feed on the market. First of all, an authorisation to this effect will be released only if the applicant gives 'adequate and sufficient evidence'[61] that the GM food and feed[62] meet the following conditions:[63]

- They do not present an unacceptable risk for human health and the environment;
- They do not mislead the consumer;[64]

56 Non-GM Novel Food is listed in Art. 1.2.c, d, e, f.

57 Art. 15.

58 See amendment 15 of recital 6, in the Parliament report of 7 June 2002 on the proposal for a Regulation on genetically modified food and feed (A5-0225/2002).

59 Likewise, food produced from animals, which are treated with genetically modified medicinal products falls outside the scope of the Regulation.

60 See. Art. 3(2) and 15(2). This flexibility was also provided by the Novel Food Regulation. See Art. 3(4), last indent.

61 Art. 4(3) and 16(3).

62 See Art. 16(1) d.

63 Art. 3(1) and Art. 16(1).

64 The proposed Regulation provides a slightly different wording of the second and third conditions that an application for genetically modified feed must satisfy. Art. 16(1) c provides that GM feed should not, *inter alia*, mislead the user and harm or mislead the consumer by impairing the distinctive features of the animal products; Art. 16(1) d states that GM feed

– They do not differ from the food which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer.

The wording of the proposed Regulation presents similarities with Art. 3.1 of the Novel Food Regulation,[65] except for the first indent. While the Novel Food Regulation states that genetically modified food can be authorised if 'it does not present a danger for the consumer', the threshold for releasing authorisation is lower in the proposed measure—GM food is authorised if it does not present an *unacceptable* risk for human health and the environment. This change is not merely editorial, since it affects the chosen level of protection. The implication is that EU institutions are ready to give the green light to a request of authorisation for the marketing of a certain GM food/feed, if the risk it creates is acceptable. The shift from 'no danger' to 'acceptable risk' should not be underestimated: the new emphasis on acceptable risk is capable of limiting resort to outright bans, since the Commission is bound to take measures which are proportional to the chosen level of protection.[66]

It is now appropriate to consider the requirements of the authorisation procedure[67] and how the final decision on the application is made. When submitting an application to national competent authorities, the operator (called the 'notifier' in the jargon of the GMOs legislation) is required to gather accompanying documents and information[68] so as to enable the EU authorities to evaluate whether the request complies with the requirements of the Regulation.[69] It is noteworthy that the number of documents and information that the applicant must present appears more comprehensive (or burdensome according to the point of view) than that of the Novel Food Regulation. For example, a source of information which the notifier should include in the application is a copy of the studies, including, where available, independent, peer-reviewed studies, which have been carried out and any

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should not differ from feed which it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for animals or humans.

65 This article states that: 'Foods and food ingredients falling within the scope of this Regulation must not: a) present a danger for the consumer; b) mislead the consumer; c) differ from foods or food ingredients which they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for the consumer.'

66 COM (2000) 1.

67 See Art. 7 and 17. The authorisation procedure contains time limits which are here omitted due to space constraints.

68 Art. 5(3) and 17(3).

69 The information requested from the notifier also serves the purpose of preparing the ground for the placing of the GM food/feed on the market. Amongst other, the notifier should specify labelling and handling conditions beyond, where required, post marketing monitoring for the use of GM food/feed. (Art. 5.3.h; k and Art. 17.h; k)

other material which is available to demonstrate that the food complies with the criteria laid down in article 3(1) and 16(1).[70] In addition, the operator should give information as to whether the food gives rise to ethical or religious[71] concerns.[72] Finally, it should be noted that further information is required for food/feed consisting of, or containing, GMOs.[73]

One of the factors which is assessed by the national competent authority during the authorisation procedure is whether the GM product, which is the object of the notification, is 'substantially equivalent' to its non-genetically modified counterpart.[74] It should be noted that the principle of 'substantial equivalence', which has operated since the Novel Food Regulation[75] and was maintained in the new piece of legislation,[76] applies differently in the GM food and feed Regulation with respect to the 1997 Regulation. In the latter, it applies to limited cases,[77]

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70 See Art. 5.3.e and 17.3.e.

71 The Novel Food Regulation only referred to ethical concerns, which had to be mentioned on the label of the GM product. See Art. 8.c.

72 Art. 13.2.b and 25.3.d. In case the GM food/feed gives rise to these concerns, this should be stated on the label.

73 The notifier must provide a risk assessment and a monitoring plan for the environmental effects. See Art. 6.5.a; b and Art. 17.5.a; b.

74 The criteria to define a GM food or food ingredient as 'substantially equivalent' to its conventional counterpart concern their composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein (Art. 3.4). The Commission has also adopted Recommendation No. 97/618 (*OJ* [1997] L 253/1) to illustrate scientific aspects of this concept. The latter has formed the object of detailed analysis in the opinion of the Advocate General Jacobs (of 13 March 2003) in the *Monsanto* case, C-236/91, pending. In this case Italy contested the 'substantial equivalence' of some GM products. See for more details on this case section No. 3.2. It should also be noted that the substantial equivalence principle of the Novel Food Regulation was seen with scepticism by other Member States. See Young A. R. 'Trading up or trading blows? Us politics and transatlantic trade in genetically modified organisms', RSC EUI working paper No. 2001/30, p. 13.

75 See Recital No. 2 and Art. 5.

76 It should be noted that in the GM food/feed Regulation reference is not explicitly made to the principle of substantial equivalence. However, this concept is incorporated in the draft Regulation. See the combination of Art. 19.3.h and 27.3.c in case of GM feed and the combination of Art. 6.3.h and 14.2.a in the case of GM food. The characteristics which are considered to make a GM product different from a non-GM counterpart are the following: composition, nutritional purposes, intended use, implications for human health or for the health of certain species or categories of animals.

77 Article 3(4) of the Novel Food Regulation establishes to which categories of Novel Food the principle of substantial equivalence applies. They are foods and food ingredients produced *from*, but not containing, genetically modified organisms (Art. 1.2.b); foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae (Art. 1.2.d); foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by usual propagating or breeding practices and having a history of safe food use (Art. 1.2.e).

whereas in the former, it does not apply only to products produced from GMOs but also to *all* GM food/feed and does not give rise to a different procedure.[78] Moreover, in the Novel Food Regulation, when a novel food was produced from GMOs and was substantially equivalent to its traditional counterpart, it was approved of according to a simplified procedure.[79] By contrast, in the new draft Regulation, a single authorisation procedure applies both to substantially equivalent and non-substantially equivalent products. The abolishment of the simplified procedure is a welcome step[80] since, as the Commission has always recognised, substantially equivalent GMOs products are not safe in themselves; what, therefore, is the point of submitting them to an approval procedure which is different from that of non-substantially equivalent GMOs food?

Let us now turn to the decision making, leading to the authorisation or rejection of the application, which involves the Member States, the Commission and a newly established actor: the EFSA. The main stages of the authorisation procedure are sketched below. The procedure is set in motion when the person, seeking the authorisation to market GMO food/feed, applies to the competent national authority, providing the information previously described. For the sake of procedural economy, where a product is likely to be used both as food and feed the operator will submit a single application and a single decision will be made by the relevant competent authorities.[81] The application and related information is sent to the EFSA,[82] which will make it public,[83] and will forward it, in turn, to the Commission and other Member States.[84] The final decision on the application is

78 The only difference in the treatment between substantially equivalent GM food/feed and GM food/feed which is different from the traditional counterpart consists in the labelling obligations, that is to say, a non-'substantially equivalent' GM food can be placed on the market only if the differences with respect to the conventional counterpart—and appropriate information about the nature and the character of the food concerned (Art. 13.3) are mentioned on the product's label. See Art. 13.2 a and 25.3.c. It should be noted that, in this respect, the GM food and feed regulation is no different from the Novel Food Regulation which required that non-substantially equivalent food was labelled (Art. 8.1.a).

79 See Recital 2 and the simplified procedure of Art. 5. It should be noted that this procedure allows operators to place on the market a certain GM food, after they have notified the Commission of the GM product that they intend to place on the market and have provided evidence of its substantial equivalence to conventional counterparts.

80 It appears that this procedure does not enjoy Member States' support. The opinion of the Advocate general in the *Monsanto* case reports that several Member States in the comitology committee which examined the Italian decision to suspend the marketing of the *Monsanto* maize asked for clarification on the use of this concept. See par. 30 of the opinion. For more details on the case see section No. 3.2.

81 Art. 27.

82 Art. 5.2.a.iii and Art. 17.2.a.iii.

83 A summary of the application will be made available to the public. See Art. 5.2.b.ii and 17.2.b.ii.

84 Art. 17.2.b.1 and ii and Art. 5.2.b.1 and ii.

made by the Commission and Member States, whereas the role of the EFSA is advisory.[85] The EFSA's most important task is thus the release of an opinion[86] on the request for authorisation by the notifier, which is then communicated to the Commission and the Member States. The EFSA's opinion may be favourable or unfavourable but, in any event, it must be appropriately justified. A positive opinion of the Food Authority has to contain certain bits of information,[87] including the restrictions or conditions to place the genetically modified food/feed concerned on the market.[88] This opinion will be made accessible to the public, which can send comments to the Commission.[89] An oddity in this respect can be observed: public reactions and comments will have to be addressed to the Commission and not to the EFSA itself.

Coming back to the authorisation procedure, the Commission will decide on the application for authorisation in co-operation with the Standing Committee on the Food Chain and Animal Health (a comitology committee). Factors which can be taken into account in the authorization process are the opinion of the EFSA, any relevant provisions of Community law, and other legitimate factors relevant to the matter under consideration.[90] It goes without saying that the opinion of the EFSA is not binding for the Commission; the latter has only a duty to explain why it took a different position from that recommended by the EFSA. It is interesting that the final decision on the authorization can be affected by 'other legitimate factors.' This is an expression which was used for the first time by the most important food standard setting organization, the *Codex Alimentarius Commission*, in 1995.[91] General Principles for Risk Analysis recognised at the international level, in the framework of the activity of the *Codex Alimentarius* Commission, 'allow[s] risk managers to take into account not only the results of a science-based risk

85 The Food Authority also have other minor duties. It replaces the Commission in performing certain tasks for which the Commission was responsible in the old GMOs regime. For example the EFSA receives and forward the notification to the Member States, it asks the applicant for additional information, it may ask the competent national authority to carry out safety assessment o environmental risk assessment. A further power consists in the possibility to propose, modify, suspend or revoke the authorisation. This power is shared with the Commission and the Member States. See Art. 10. The EFSA finally advises the Commission in laying down implementing rules for the renewal of the authorisation. See for example Art. 11.5.

86 Art. 6. The Authority has six months to release its opinion.

87 Art. 6(5) and 18(5).

88 For example, the EFSA may decide that post marketing monitoring requirements are needed. See Art. 6.5.e and Art. 18.5.e.

89 Art. 6.7 and 18.7.

90 Art. 7.1 and 19.1.

91 Juke D. (2000) 'The role of science in international food standards', in *Food Control*, 11, p. 181.

assessment but also other legitimate factors relevant for the matter under consideration.'[92] Thus, the phrase refers to the fact that science provides the key factor in establishing *Codex* standards but, that other legitimate factors (OLFs) can be used.[93] The following interests were discussed within the Codex—without consensus being reached—as possible 'other legitimate factors': consumer preferences, environmental concerns, animal welfare.[94]

Although it is legitimate to consider factors other than sound science in taking risk management decisions, these factors should be named and made clear in the definitions of the Regulation. This notion, if left unspecified, gives the impression of being a catch-all clause to justify political decisions rather than risk management measures.[95]

Before making a decision, the Commission may also consult the European Group on Ethics in Science and New Technologies, which delivers an opinion on ethical issues.[96] Eventually, the decision taken by the Commission will be published in the Official Journal. The approved GM food or feed will be entered in a register[97] which is accessible to the public. It is noteworthy that where an authorisation is given, this is time-limited: valid for ten years,[98] it is renewable according to special procedure.[99]

Products which fall within the scope of the GM food and feed Regulation and which have been lawfully placed on the market *before* the entry into force of the proposed Regulation can circulate in the market,[100] but they will be subject to a 'double check' procedure by the Community reference laboratory,[101] which will

92 McFarlane R. (2001) 'Integrating the consumer interest in food safety: the role science and other factors', in *Food Policy*, p. 11.

93 See Juke above No. 91, p. 186.

94 *Ibid.*, p. 190-191.

95 See section 5 for more comments on 'other legitimate factors.'

96 Art. 33.

97 Art. 28.

98 Art. 7(5) and 19(5).

99 Art. 11 and 23.

100 Art. 8 and 20.

101 Art. 32. The Commission has also launched a European Network of Genetically Modified Organisms Laboratories (ENGL). The network is composed of 45 national laboratories whose personnel is appointed by national authorities. The main duties of ENGL are to look at the different GMOs put on the market, and to ensure that the control laboratories can trace GMOs throughout the food chain. The ENGL will primarily have to develop and validate methods for detecting and quantifying GMOs in food and feed. Once a method has been optimised, ENGL will set up internal inter-laboratory tests to check if the methods are suitable for control purposes and if so, labs will use them in their control work. See for

test and validate the method of detection and validation proposed by the applicant. Should the operators responsible for the placing on the market of such products fail to give the necessary information to the Commission, or where this information is incorrect, they will be sanctioned with the withdrawal of the products from the market.[102]

The proposed Regulation also contains extensive labelling provisions, which are coordinated with those of the traceability and labelling Regulation. While the labelling provisions of the former apply to foods/feeds containing, consisting of, or produced from GMOs, the labelling provisions of the latter concern GMOs which are not used in food or feed. By prescribing the use of positive labels—i.e. 'this product may contain GMOs'—that is to say, labels that indicate the presence of genetically modified material, the EU ruled out two labelling options:[103] the use of voluntary and negative labels—i.e. 'this product is GM-free'.[104] It is not clear whether the latter kind of labels will be prohibited,[105] so as not to mislead the consumer.

Not all GM food/feed needs to be labelled. The proposed GM food and feed Regulation imposes detailed labelling requirements on those genetically modified foods and feeds which contain GMOs in a proportion higher than a certain threshold.[106] The introduction of minimum thresholds for labelling raised considerable controversy which was settled in 'last minute agreements'. On the basis of this compromise, if the level of minute traces of adventitious GM material[107]

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further information the Commission press release IP/02/1795 and MEMO/02/279 of 4 December 2002.

102 This decision will be made by the Commission in the framework of the comitology procedure. See Art. 8(6).

103 The Commission explains the reasons why it discarded those options in COM (2001) 182, p. 13-17.

104 In the preparatory work of the GM food and feed Regulation, the Commission considered whether it would have been preferable to adopt negative labels. However, that option was turned down as the Commission argued that consumers preferred to know what was in products, and that, in any case, GM-free products were already supplied by the organic production scheme.

105 By contrast, in the Novel Food Regulation, it was not clear whether a negative labelling was prohibited. Recital 10 seemed to leave that labelling option open. Recital 10 reads as follow: 'Whereas nothing shall prevent a supplier from informing the consumer on the labelling of a food or food ingredient that the product in question is not a Novel Food within the meaning of this Regulation or that the techniques used to obtain Novel Foods indicated in Article 1(2) were not used in the production of that food or food ingredient.'

106 Art. 12(2) and 24(2).

107 The operator wishing to market the GM food/feed will have to supply evidence that he had taken appropriate measures to avoid the presence of GMOs.

does not exceed 0,9%,[108] labelling is not applicable. Lower thresholds may be set through the comitology procedure, in particular with respect to foods containing or consisting of genetically modified organisms or 'in order to take account advances in science and technology.'[109]

Adventitious traces of GMOs are also tolerated in food/feed containing, consisting of, or produced from *unauthorised* GMOs, provided that they have (nevertheless) been assessed as being risk-free. For this category of GMOs, the threshold below which labelling is not required is 0.5%.[110]

A basic principle of the proposed Regulation is to give as wide as possible access to information. The public will be able to read the application for authorisation, supplementary information from applicants, opinions from the competent authorities designated in accordance with Article 4 of Directive 2001/18/EC, monitoring reports and information from the authorisation holder, excluding confidential information on the website of the EFSA.[111] The content of this information is identified by the notifier who cannot, however, avail himself of confidentiality as a justification to conceal information identifying the GM product or its effects.

3.2 The Scope of Member States' Powers to Introduce Emergency Measures

A particularly important aspect of the draft Regulation concerns the Member States' powers of enacting unilateral measures, suspending or limiting the circulation of a given genetically modified food/feed—which was lawfully placed into the Community market—on the grounds of public health or environmental protection.[112] This powers is regulated by the so-called 'safeguard clauses'. The scope of this power may be regarded as a decisive factor in convincing Member States to give up the *moratorium*.

Before looking at the provision of the draft Regulation dealing with this issue, three remarks need to be made. The first is that devising the possibility for Member States to act unilaterally to suspend the trade of genetically modified food/feed is a politically delicate task for Community institutions. Indeed, the marketing of genetically modified products is closely connected, on the one hand, to the

108 The text of the Commission proposal (2002)559 provides for a threshold of 1%. A political compromise was reached at the Council meeting of 28 November 2002 for a threshold of 0,9%.

109 Article 12(4) and 24(4).

110 See the minutes of the Environment Council meeting of 9 December 2002. See document 15101/02 published on http://ue.eu.int/pressData/en/envir/73567.pdf.

111 Art. 29(1).

112 See on this issue Scott J. (2003) 'European Regulation of GMOs and the WTO', in *Columbia Journal of European Law*, 9, p. 213.

functioning of the internal market, an exclusive competence of the EC, and, on the other, to the protection of public health, which falls within the realm of shared competences. Thus, Community institutions must ensure the functioning of the internal market, a task the Commission is entrusted with, and, at the same time, accommodate the right of the Member States to evaluate risks in a manner which is different from that of the Community institutions. A further noteworthy issue is that the Commission has a difficult task in assessing Member States' unilateral measures because of the high degree of scientific uncertainty that surrounds the use of GMOs. Indeed, it is tricky for the Commission to distinguish between scientifically sound national measures, restricting the marketing of GMOs—because of the serious risks that they pose to consumer's health—and measures which are instead founded on (political) grounds which have nothing to do with consumer welfare. The third point concerns the reason why Member States are keen on maintaining the power to enact unilateral measures. This is because this power allows them to opt for a different position from that achieved at Community level. Since there are remarkable differences in the attitudes of the Member States toward the use of GMOs, national competent authorities wish to maintain the possibility to opt out of a Community measure which may have been adopted against their will. To put it bluntly, safeguard measures are included in the GMOs legislation because a feeling of mutual distrust pervades the relationship amongst Member States. This statement is confirmed in a recent preliminary ruling currently before the ECJ (the *Monsanto* case)[113] in which the Italian Ministry of Health raised objections against the evaluation of the English Advisory Committee on Novel Foods and Processes that a certain type of GM maize[114] was substantially equivalent to its traditional counterpart. The risk assessment made by the English authority had important consequences; it legitimised recourse to a simplified procedure to market novel food in the EU. The use of this procedure is politically sensitive since it allows a novel food to be placed onto the market bypassing the control of fourteen national competent authorities. It is a significant fact that this procedure has never been used. The only time it was resorted to by a Member State (the UK), another Member State (Italy) invoked the safeguard clause of Art. 12 to object against the scientific opinion which activated the simplified procedure.

It is now appropriate to take a closer look at the safeguard clauses. These allow Member States to derogate from a Community measure, authorising the marketing of a given GMO, by enacting unilateral measures to limit the circulation of GMOs.

113 C-236/01, *Monsanto Agricoltura Italia SpA and Others c. Presidenza del Consiglio dei ministri and Others*, no year. See the opinion of the Advocate General Jacobs of 13 March 2003, no year.

114 This is genetically modified maize, Bt 11, MON 810 e MON 809.

They are included in all major pieces of GMOs legislation.[115] Safeguard clauses were used (and even abused) by the Member States on several occasions.[116] They are an important part of the GMOs legislation since they have been the triggering factor of the political[117] or legal disputes[118] which arose in connection to the trade of GMOs in the European Community.[119]

The 1997 Regulation contained a safeguard clause in Art. 12. The common position on genetically modified food and feed does not include a safeguard clause worded along the lines of Art. 12 of the Novel Food Regulation. Art. 53 of the draft Regulation on GM food/feed regulates the adoption of the so-called 'emergency measures', that is to say, measures which are to be enacted when a given genetically modified food or feed is likely to represent a serious risk to human health, animal health or the environment. Art. 35 reads as follows:

> Where it is evident that products authorised by or in accordance with this Regulation are likely to constitute a serious risk to human health, animal health or the environment, or where, in the light of an opinion of the Authority issued under Article 10 or Article 22, the need to suspend or modify urgently an authorisation arises, measures shall be taken under the procedures provided for in Articles 53 and 54 of Regulation (EC) No. 178/2002.

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115 Safeguard clauses are provided in the first (90/220), the second framework directives (2001/18) and in the Novel Food Regulation. Art. 12 of the latter states: '1. Where a Member State, as a result of new information or a reassessment of existing information, has detailed grounds for considering that the use of a food or a food ingredient complying with this Regulation endangers human health or the environment, that Member State may either temporarily restrict or suspend the trade in and use of the food or food ingredient in question in its territory. It shall immediately inform the other Member States and the Commission thereof, giving the grounds for its decision. 2. The Commission shall examine the grounds referred to in paragraph 1 as soon as possible within the Standing Committee for Foodstuffs; it shall take the appropriate measures in accordance with the procedure laid down in Article 13. The Member State which took the decision referred to in paragraph 1 may maintain it until the measures have entered into force.'

116 It may be recalled that the *moratorium* on the marketing of GMOs was legally possible because Directive 90/220 provided a safeguard clause, Art. 16, which enabled the Member States to temporarily prohibit the marketing of a certain type of genetically modified maize. Some Member States abused of these clauses, since they did not use them as a basis for temporary measures, but as a tool to maintain a five year-moratorium. It should also be noted that Art. 12 of the Novel Food Regulation is the legal basis which founded the Italian decision to restrict the circulation of a certain type of genetically modified maize and which has formed the object of the above-mentioned *Monsanto* case, see above No. 113.

117 See for example the invoking of Art. 16 of Directive 90/220 in the Ciba-Geigy request of authorisation to market a certain kind of genetically modified maize.

118 See for example the Italian recourse to Art. 12 of the Novel Food Regulation in the *Monsanto* case, see above No. 113.

119 The only exception is the *Greenpeace* case, Case C-6/99 *Greenpeace France and others* ECR (2000), p. I-1651.

In order to know how emergency measures may be enacted, it is necessary to read first Art. 53 and then 54 of the EFSA Regulation. Art. 53 regulated the situation in which an emergency breaks out in a Member State. In these circumstances, the Commission, in co-operation with a Comitology committee,[120] is empowered to approve of protective measures with respect both to food/feed imported from third countries and food/feed of Community origin. These measures may be enacted by the Commission on its own initiative or at the request of the Member State affected by the emergency. In both cases, the Commission follows the Comitology procedure. It must be added that possible protective measures which were adopted by the Member State concerned *before* informing the Commission of the emergency taking place within its territory, can be maintained until Community measures have been adopted. This means that should the Commission formally decide that the national protective measures are no longer necessary, the Member State concerned by the emergency is required to withdraw them.

Art. 54 rules on 'other protective measures'. The first paragraph of Art. 54 states: 'Where a Member State officially informs the Commission of the need to take emergency measures, and where the Commission has not acted in accordance with Article 53, Member States may adopt interim protective measures.' Art. 54.3 states that these measures will be confirmed, amended or abolished by the Commission in the framework of a Comitology procedure.

Art. 54 is akin to the safeguard clause established by Art. 12 of the Novel Food Regulation and by the text of other pieces of GMOs legislation. Indeed, under Art. 54, the initiative to take protective measures is in the hands of the Member State and not of the Commission (as established by Art. 53). However, Art. 54 differs from the safeguard clause (in Art. 12) of the Novel Food Regulation since the latter allowed Member States *of their motion* to either temporarily restrict or suspend the trade in and use of a given GMOs or genetically modified food on their territories. The Commission (in the framework of the Comitology procedure) intervened to review these national measures only after the Member State in question had enacted them. By contrast, in my opinion the main feature of Art. 54 is that Member States' unilateral action is possible only *after* the Commission's failure[121] to take protective measures, under Art. 53. It is not clear what happens in

120 This is a regulatory committee: the food chain and animal health EFSA standing committee. See Art. 58.1 of Regulation 178/2002.

121 Joanne Scott rightly argues that it is ambiguous what is the triggering factor allowing Member States to act under Art. 54. It could be the Commission's failure to take measures under Art. 53 or the Commission's refusal to authorise protective measures. She concludes that it is more appropriate 'for Member States to be able to introduce interim unilateral emergency measures merely when the Commission has not acted, subject to the substantive and procedural requirements laid down.' See Scott J., above No. 112, p. 16, ft. 39. A

case that the Commission explicitly refuses[122] to take protective measures. This is not clarified by the text of the Regulation.

The procedure of Art. 53 and 54 deserves a few comments. Firstly, the relationship between the protective measures of Art. 53 and the 'other protective measures' of Art. 54 is quite ambiguous. In what way do these measures differ? It may be thought that whereas Art. 53 gives the Commission the possibility to take emergency measures, Art. 54 grants Member States the power to adopt independent measures to overcome the lack of action by the Commission. This reading is supported by the fact that the triggering factor for the Member States' unilateral measures is the Commission's failure to adopt protective measures under Art. 53.[123] However, unilateral measures adopted under Art. 54 are not lawful in themselves; in order for the Member State to lawfully maintain these measures, it is necessary to submit them to the scrutiny of the Commission and the Comitology committee, set up by the EFSA Regulation. This procedural requirement makes them identical to measures under Art. 53, which are enacted by the Commission with the involvement of a Comitology committee (Art. 53.1). Therefore, it looks as if Art. 53 and 54 provided for largely overlapping measures from the procedural point of view; indeed, in both cases the enactment of protective measures require the support of the Commission—in co-operation with the Comitology committee—and of the Member State (where the emergency took place).[124]

(contd.)

comparison between the English and the French/Italian/Spanish version of Art. 54 also strengthens this interpretation.

122 A possible scenario in which the Commission refuses to adopt protective measure is when a Member State requests the Commission to take protective measures under Art. 53. The Commission submits a request for the adoption of these measures to the comitology committee, set up by Art. 58.2 of the EFSA Regulation, but neither the Comitology committee nor the Council of the European Union—which may be involved in the decision making process, according the regulatory committee procedure—do not achieve the necessary quorum to approve of protective measures. In these circumstances, the final decision is left to the Commission which may decide against the adoption of protective measures.

123 A possible scenario in which the Commission fails to adopt protective measure is when a Member State requests the Commission to take protective measures under Art. 53, but this institution denies the authorisation since the Comitology committee (and eventually the Council of the European Union) do not achieve the necessary quorum to approve of protective measures.

124 In the first case, measures are enacted by the Commission (and a Comitology committee), even if Member States may request the Commission to do so; in the second case measures are enacted by the Member States, should the Commission decide that there is no need for protective measures. In this second case, Member States' measures will be scrutinised by the Commission and a Comitology committee with the view of confirming/amending or abolishing them.

What are the effects of the emergency measures on the substance, that is to say, on Member States' powers to derogate from Community decisions, authorising the marketing of genetically modified products? Are these powers enhanced or diminished with respect to the previous novel food regime? It should be noted that, similarly to Art. 54, the safeguard clause of Art. 12 entrusted the Commission, within the Comitology procedure, with the power to scrutinise unilateral measures. Therefore, it may be concluded that, despite minor procedural differences, the emergency measures of the draft Regulation and the safeguard clauses of Art. 12 are similar in terms of Member States' power to introduce unilateral measures. More precisely, the old safeguard clause and the new emergency measures clause set up the same type of Community control procedure over national unilateral measures. This implies that the draft Regulation leaves Member States the same degree of autonomy offered by the Novel Food Regulation.

A further issue concerns how Member States will use the power to enact emergency measures. Any statement on this issue rests on shaky grounds, since it is always difficult to make predictions. However, it is always possible to speculate. In my opinion, Art. 54 will be used by Member States not only when the Commission fails to take protective measures, but also to enact *and maintain* measures suspending the marketing of genetically modified food/feed, should they not like a decision taken at Community level refusing to adopt protective measures. In theory, the Commission can always review the national unilateral measures of Art. 54 and, where necessary, oblige Member States to abolish them. However, it is uncertain whether the Commission would take this step, especially if there is a serious disagreement between the Member State (where the emergency took place) and the Community institutions over the risk posed by a given genetically modified food/feed. After all, a conflictual relationship between the Commission and several Member States was at the origin of the moratorium! In view of this precedent, it would not be politically wise for the Commission to 'forcefully' deny protective measures when Member States want to enact them. A similar decision touches upon the sphere of public health, an area in which Member States are very jealous of their powers. It is likely that the Commission, reminiscent of all troubles it had with the Ciba-Geigy application in 1996—this application led to the enactment of the *moratorium*—would attempt to avoid a direct clash with Member States in this area of regulation. The danger (or the benefit?) created by this situation is that the Commission may end up being constrained by the level of risk to human health that Member States deem acceptable for their citizens. This last remark leads me to a very final conclusion on this issue: Art. 35 of the draft Regulation lends itself to the same abusive use of the emergency measures which was made of the safeguard clauses in the framework of Directive 90/220.

It should not be forgotten that the precautionary principle, by which the Commission is bound, can be invoked by Member States to defend their right to differentiate their risk evaluations from that made at Community level. Although

the ECJ has recently warned against a purely hypothetical approach to risks in the *Alpharma* case[125] (par. 156), it has also legitimised competent public authorities to take preventive measures 'when such measures appear essential given the level of risk to human health which the authority has deemed unacceptable for society' (par. 173).

Having said this, it should not be forgotten that Art. 95 offers a second legal instrument to Member States to depart from the draft Regulation,[126] which is aimed, *amongst others*, as the legal basis tells us, at ensuring the functioning of the internal market.

The significance of this article to justify national measures aimed at ensuring a higher level of protection of public health than that afforded by a Community harmonising measure is illustrated by a recent case: C-3/00 *Denmark v. Commission.*[127] However, Art. 95 may raise false hopes for Member States. Paragraphs 4 and 5 of Art. 95 allow Member States to respectively maintain and introduce national measures after the adoption of a harmonising measure. Maintaining national measures is easier than introducing new derogating measures since the grounds and conditions for introducing new national measures are respectively more limited (only for environmental reasons; public health is excluded) and more stringent (scientific evidence need be given). Furthermore, national derogating measures should comply with the proportionality principle. These limits should be taken carefully into consideration by Member States in applying for a derogation from a Community measure authorising the marketing of a certain genetically modified food/feed. The Commission has been quite strict in

125 T-70/99 *Alpharma v. Council,* no year.

126 On the possibility for the Member States to resort to Art. 95 of the EC Treaty or to the safeguard clause to derogate from Directive 2001/18, see Dabrowska P. (2002) 'The division of powers between the EU and the Member States with regard to deliberate release of GMOs (the new Directive 2001/18)', in *German Law Journal,* Vol. 3, No. 5, 1 May.

127 Reference to this case is crucial for Member States wishing to *maintain* national measures on grounds of public health. The important paragraphs of this ruling are No. 63 and 64. The ECJ affirms that a Member State may justify maintaining derogating national provisions, invoking the argument that 'its assessment of the risk to public health is different from that made by the Community legislature in the harmonisation measure.' Furthermore, the Court makes clear that: 'In the light of the uncertainty inherent in assessing the public health risks posed by, amongst others, the use of food additives, divergent assessments of those risks can legitimately be made, without necessarily being based on new or different scientific evidence' (par. 63).

The ECJ also emphasises the conditions to trigger Art. 95.4. In par. 64, it is stated that Member States need to prove that the national derogating provisions ensure a level of health protection which is higher than the Community harmonisation measure and that they do not go beyond what is necessary to attain that objective.

admitting national derogating measures and the ECJ has in most cases[128] upheld the Commission's refusal to authorise the Member States' application for derogation.

Even more fundamentally, it should be borne in mind that Member States are precluded from using Art. 95 where the draft Regulation fully harmonises the marketing of genetically modified food/feed. Reliance on Art. 95 is only possible should the draft Regulation in question partially harmonise this area of regulation. It is therefore necessary to carry out a preliminary analysis on the nature of the draft Regulation.

Can the draft Regulation be considered an example of total or *minimum* harmonisation?[129] The answer is not straightforward and a full examination of this point is not possible due to space constraints. However, in my opinion, there is more evidence in favour of total harmonisation. First of all, the act in question is a Regulation designed to leave Member States as a narrow as possible a margin of manoeuvre both in the achievement of the aims of the act in question and in the instruments needed to attain this goal. Secondly, the draft Regulation is set out so as to reduce the opportunity for the Member States to deviate from the Community legislation insofar as Art. 4.5 states that: 'An authorisation [to market genetically modified food] […] shall not be granted, refused, renewed, modified, suspended or revoked except on the grounds and under the procedures set out in this Regulation.' This provision, which was not included in the Novel Food Regulation, is set out to accentuate the centralised character[130] of the procedures involving the trade of genetically modified food and feed. Thirdly, contrary to the 1997 Regulation, which rested upon Art. 100.a (Art. 95), the draft Regulation is based on Art. 95, Art. 152.4.b) (public health) and Art. 37 (agriculture). The Commission, whose interest was to centralise the authorisation procedure to place genetically modified food/feed into the Community market as much as possible, was the first to propose that draft Regulation be based on all three legal bases. The fact that Art. 152.4.b and 37 were used together with Art. 95 as the legal basis for the draft Regulation is one of the factors indicating that the draft Regulation harmonises the marketing of genetically modified food/feed exhaustively. It may be strange to argue in favour of total harmonisation when one of the legal bases concerned relates to public health.

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128 See for exceptions the mentioned case C-3/00 *Denmark v. Commission* of 20 March 2003, no year and C–473/98, *Kemikalieinspektionen v. Toolex Alpha AB (*2000) ECR I–5681.

129 On the meaning and occurrence of minimum harmonisation within the Community legal order, see the insightful analysis of Dougan M. (2000) 'Minimum harmonisation and the internal market', in *Common Market Law Review,* 37*,* p. 853.

130 It should be noted that Member States have not so far contested the accentuated centralisation of the procedure, during the discussion leading to the drafting of the Council's position on the two proposed Regulations. The Parliament highlights that 'a large majority of delegations expressed their wish to keep a centralised [authorisation] procedure as proposed by the Commission.' See the Parliament's legislative observatory.

However, had the Treaty authors wanted Art. 152.4.b) to allow for the adoption of more stringent protective measures, they would have explicitly provided for it, as is the case for Art. 152.4.a) or as is laid down by other Treaty provisions concerning the environmental[131] and consumer protection.[132] However, this is not a compelling argument. Should the ECJ be asked in the framework of a preliminary ruling whether the draft Regulation pre-empts Member States' independent action, the answer may be difficult to predict. Certainly the Court would not consider the lack of an explicit *minimum* harmonisation clause in Art. 152.4.b) sufficient to prove total harmonisation. Indeed, as Dougan points out, '*minimum* harmonisation need not be provided for explicitly. The Court of Justice has on several occasions held Community measures to constitute non-exhaustive standards by process of implication.'[133] Therefore, even if Art. 152.4.b) does not contain a 'minimum harmonisation' proviso such as that of Art. 152.4.a), this does not mean that it should be regarded as a provision founding a 'total harmonisation' measure. However, another piece of the puzzle of the ECJ caselaw on minimum harmonisation should be added to the picture. This is the *Compassion World Farming* ruling in which the Court maintained that a minimum harmonisation clause of a Directive (Art. 11.2 of Directive 91/629) did not preclude the Directive from exhaustively harmonising the powers of the Member States in the area of regulation (the protection of calves) concerned.[134]

It may be concluded that the ECJ caselaw is unsettled on minimum harmonisation. In this confused state of affairs, perhaps a further point may be raised to tilt the balance in favour of total harmonisation. Comparing the legal basis of the Novel Food Regulation and the new draft Regulation, one can argue that the Commission based the draft Regulation on a greater number of legal bases than the original Novel Food Regulation to remove any lingering doubts over the degree of harmonisation pursued by the new genetically modified food/feed Regulation, a degree of harmonisation which could have been considered '*minimum*' when the Novel Food Regulation had a single legal basis (Art. 100.a),[135] but which was intended to be 'exhaustive' if the legal basis were extended to three.

The last point, concluding my speculations on the legal basis of the draft Regulation, is the following. It is odd that the draft Regulation is founded on

131 See Art. 176 of the EC Treaty.

132 See Art. 153.5 of the EC Treaty.

133 See Dougan M. above No. 129, p. 856.

134 See the case *Compassion in World Farming*, C-1/96 (1998) ECR-I-1251.

135 As it was emphasised in ft No. 3, during the Environment Council meeting of June 1999 some Member States alluded to the possibility of invoking Art. 95 to adopt national unilateral measures derogating from the framework Directive. Maybe the Commission decided to expand the legal basis the of the draft Regulation so as to avoid the danger that Member States appealed to Art. 95 to derogate from the Novel Food Regulation.

Art. 152.4.b) *and* Art. 37 since it appears from the letter of Art. 152.4.b) that when measures in the veterinary and phytosanitary fields have as their direct objective the protection of public health they are based upon 152.4.b). This makes Art. 37 redundant. Therefore, the Regulation concerned should have been based only upon Art. 95 and 152.4.b). The possibility of a legal action introduced by a Member State against the future Regulation for inappropriateness of its legal basis should not be excluded, since annulment actions of this kind are quite often used by Member States to invalidate a Community measure that they do not like.

3.3 The Traceability and Labelling of GMOs and the Traceability of Food and Feed Produced from GMOs

The objective of the draft Regulation is to facilitate 'accurate labelling, monitoring of the effects on the environment and, where appropriate, on health, and the implementation of the appropriate risk management measures including, if necessary, withdrawal of products.'[136]

As the title implies, this measure[137] rules on two aspects: 1) how to identify traces of GMOs (traceability)[138] in genetically modified food/feed[139] or products containing them,[140] and 2) when and how products containing or consisting of GMOs (i.e GM cotton) should be labelled (labelling).[141] Neither traceability nor labelling are related to the safety of GMOs, which is an issue considered by the framework Directive and by the GM proposed food and feed Regulation. According to the Commission, this is the reason why no mention is made of the precautionary principle[142] which concerns the safety assessments of GMOs. The traceability and labelling Regulation may be defined as a 'flank measure' with respect to the two above-mentioned acts since it eases the implementation of risk management measures.

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136 Art. 1.

137 COM (2001) 182 as modified by the political agreement reached on the 9 December 2002. See document above No. 14.

138 The proposed rules supplement the traceability provisions of existing legislation (Art. 4(6) of Directive 2001/18, which already contained traceability rules for GMOs) and lay down new obligations for food/feed containing or consisting of GMOs and for products produced from GMOs.

139 Art. 5.

140 Art. 4(1).

141 Art. 4(6). Labelling provisions of food/feed containing or consisting of GMOs are provided in the GM food and feed Regulation.

142 It is noticeable that the Commission rejected the Parliament's suggestion to make explicit reference to the precautionary principle in the draft Regulation. See point 3.3. of the amended proposal for Regulation concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, in COM (2002) 559, of 23 September 2002.

Let us now look at the content of the proposed Regulation. The traceability provisions address problems which may arise *after* the placing on the market of products containing or consisting of GMOs and food/feed produced from GMOs. Indeed, it might happen that authorised GMOs turn out to have adverse effects on human health, animal health or the environment, as was shown by the problems of the StarLink in the US.[143] Hence, they need to be withdrawn from the market. Another possibility is that operators label authorised GMOs incorrectly, thus misleading users on the actual content of the labelled product. In order to facilitate the implementation of controls on the labels and withdrawal of products, where this is necessary, GMOs need to be identifiable. The proposed Regulation makes GMOs traceable in products by obliging the latter to be assigned a code (called 'unique identifier').[144] Operators are required to inform the person who receives the product containing GMOs of what its unique identifier is. This information should also be passed on in writing to other operators involved in the subsequent stages of its placing on the market.[145] Special and more burdensome traceability provisions are also laid down for food and feed produced from GMOs, although the UK opposed their inclusion within the scope of the proposed Regulation.[146]

The second element of the proposed measure is labelling. Products consisting of, or containing, GMOs should be labelled as indicated by the Regulation.[147] An exception applies if traces of GMOs in products used as GM food or feed do not exceed a proportion of 0.9%, provided that the presence is adventitious or technically unavoidable.[148] Different labelling thresholds apply to products consisting of, or containing GMOs which are not intended for food use.[149]

Inspections and control measures on the implementation of the Regulation are delegated to Member States. The latter must test products using the harmonised and

143 On the problems of the Starlink, see Nelson A.P. (2002) 'Starlink see Legal Liability in the Wake of Starlink TM: Who Pays in the End?', in *Drake Journal of Agricltural Law* 7, p. 241.

144 A system of unique identifer will be defined by the Commission in the framework of Comitology procedure. Development in international *fora* will be taken into account in defining the identifiers. See Art. 8.

145 Operators will have to keep track of the information concerning the transaction (the operator from which the GMOs material was received, data related to the GMO material and the addressee of the transaction) for a period of five years.

146 The UK was the only Member State to support the exclusion of food and feed produced from GMOs. See Council document 14076/02, p. 2.

147 Art. 4(6).

148 Art. 4(7).

149 These products are labelled according to Art. 21(2) and 21(3) of Dir. 2001/18, as modified by Art. 7 of the proposed Regulation on traceability and labelling. See Art. 4(8).

validated methods decided at Community level by the Commission and comitology committees and by the Community Reference Laboratory.[150]

A final issue which deserves attention is the financial impact of this Regulation on economic operators. The Commission admits that it is difficult to estimate the costs of introducing traceability specifically for GMOs and products produced from GMOs.[151] However, it draws the conclusion that since the transmission and retention of information can be largely incorporated into existing (documentary) systems of transaction, they should not imply significant extra costs for operators and consumers.[152] As we will see in section 7, however, the financial implications of the proposal are a matter of controversy.

4. Beyond the Technicalities of the Proposed Legislation: Elements of Reassurance for the Member States

It is now useful to give an evaluation of the proposed regime of authorisation, labelling and traceability of GM food and feed.

It may be said that the draft of the GM food and feed Regulation softens some of the excessively strict aspects of the old GM food regime which made it unworkable.[153] For example, although the GM food/feed Regulation is inspired by the precautionary principle,[154] there has been a shift in the level of protection chosen against the risks of GM food and feed. As mentioned earlier, in the Novel Food Regulation it is stated that the GM food must not present a danger […]. This threshold evinces 'a zero risk' approach[155] in the use of GMOs which cannot be

150 Art. 9(2).

151 COM (2001) 182, p. 8.

152 COM (2001) 182, p. 9.

153 It must be pointed out that no food or food ingredient was authorised under the standard authorisation procedure of the Novel Food Regulation. For eleven kinds of GM food the authorisation procedure is pending. Several products produced from GMOs were notified to the Commission under the simplified procedure. See the Commission press release, 'Questions and answers on the Regulation of GMOs in the EU', above No. 4.

154 The European Parliament suggested to include reference to this principle both to make clear that the Regulation was drafted in the light of the precautionary principle and to require that this principle is taken into account when implementing the Regulation. Reference to the precautionary principle is incorporated in the draft Regulation of COM (2002) 559 which includes the amendments of the Parliament which were accepted by the Commission.

155 United States and Canada criticised the draft Regulation on GM food and feed for its initial emphasis on standards of zero risk approach. The text of the proposed Regulation was changed taking into account the comments of the transatlantic States. See the document G/SPS/GEN/337 and G/TBT/W/179 of 26 July 2002 entitled 'Responses from the European Commission to comments submitted by WTO members under either or both G/TBT/N/EEC/6

achieved. Under the new Regulation, GM food and feed can be authorised if they do not present an *unacceptable* risk for human health, animal health and the environment. Secondly, the principle of 'substantial equivalence' is applicable not only to food produced from GMOs but to all GM food/feed. Moreover, where GM food/feed is not 'substantially equivalent' to its conventional counterpart, it can still be traded provided that it is appropriately labelled to inform consumers. Thirdly, traces of *unauthorised* GMOs are acceptable if certain conditions are met, whereas in the Novel Food Regulation they were not allowed to circulate in the market under any condition.

While it is true that the draft Regulation relaxes, in certain limited respects, the previous regime, the impression should not be given that the new legislation will open the European borders to transatlantic GM food and feed—this is only made possible, but it is far from simple. The prevailing feeling amongst the European institutions[156] towards GMOs is still that of scepticism, although not intolerance. Therefore those Member States which were particularly concerned about the effects of the principle 'one key-one door'[157] for the purposes of marketing GMOs should not be alarmed. The complex and sophisticated reform, carried out by the Commission through the proposals for Regulations examined above, seem in fact to strengthen the regulatory framework provided for by the 1990's GMOs regime, from both a procedural and substantive point of view. The labelling and traceability obligations for food/feed and products produced from GMOs actually ensure that Member States are now well equipped to authorise, in collaboration with the Commission, the safe use of GMOs in food/feed and products. Although other third countries regulated the use of GMOs,[158] the EU Regulation is probably the tightest of all possible regimes,[159] leaving aside an outright ban on the use of GMOs. As a result, Member States should feel encouraged to unblock the authorisation of GMOs or food/feed products containing them or produced from GM material. A

(contd.)

AND G/SPS/N/EEC/149'. This document is published on http://europa.eu.int/comm/food/fs/gmo/gmo_ongoinit_en.html.

156 The Commission is in favour of resuming the authorisation procedure of GMOs whereas the Parliament and the Council seem convinced that applications of biotechnology, although offering potential opportunities, should be treated 'with caution.'

157 This principle allows a GMOs (or its derivatives) to circulate in the territory of all Member States if the commercial release of this GMOs has been authorised by a national competent authority and neither the Commission, nor the other Member State have raised objections against the placing of the GMO concerned on the market.

158 For example Switzerland, Australia, New Zealand, Japan laid down mandatory labelling requirements.

159 For an overview of GMOs legislation in third countries see Zarrilli S. '*International trade in genetically modified organisms and multilateral negotiations—a new dilemma for developing countries*', United Nation Conference on trade and development, 5 July 2000, published on http://www.unctad.org/en/docs/poditctncdd1.en.pdf.

further postponement of the lift on the *moratorium* would not be justifiable by arguing that the legislative framework does not offer adequate guarantees to protect human/consumer health and/or the environment. Therefore, once the current proposed rules become final, it will be legally difficult to keep the *moratorium*. From a political point of view, however, the situation may be different. Member States have no interest in opening their markets to food to which their consumers are hostile. Therefore, it is not clear whether the internal pressure of the Commission, which sees biotechnology as an opportunity which Member States hesitate to seize,[160] and the external pressure of transatlantic trade partners will be enough to persuade Member States to resume the GMOs authorisation procedure.

However, it should be reiterated that Member States' concerns are no longer justified in the light of the GMOs reform. Evidence that the GMOs regulatory framework was re-invigorated by the proposed Regulations is provided by the following elements. The scope of the GM food/feed Regulation is more extended than that of the Novel Food Regulation. Even if such scope is not as comprehensive as the Parliament would have liked,[161] this does not raise any worries since food produced with a GMOs does not contain any genetically modified material. Moreover, it should be noted that further sector-related legislation,[162] expanding the scope of the EC legislation is in the pipeline.

It is noteworthy that GM food/feed is subject to a single authorisation procedure. The simplified notification procedure, set out by the Novel Food Regulation for 'substantially equivalent' food produced from GMOs has been abandoned. This secures gains in terms of procedural economy.[163] Certainly, this procedure had the advantage of warranting speediness in the approval of substantially equivalent genetically modified novel food. However, Member States, rightly or wrongly, have hardly used it; the only occasion on which one Member State, the UK, made recourse to it, another Member State, Italy, claimed that it should not have been used.[164] Therefore, the dumping of this procedure presents the further benefit of accruing Member States' support for the food and feed draft Regulation.

A further substantive element which should contribute towards reassuring Member States is the mandatory labelling of safe GMOs and derivatives. In the

160 See COM (2002) 27 'Life sciences and biotechnology—a strategy for Europe', p. 8-9.

161 The Parliament supported the view that the Regulation should extend to food and feed produced with GMOs.

162 The Commission has announced the Parliament that it will put forward new legislation on GM enzymes.

163 Two different authorisation procedures are replaced by one.

164 See the *Monsanto* case see above No. 113.

Novel Food Regulation, labelling requirements were more limited[165] and no labelling threshold was provided for adventitious or a technically unavoidable presence of GMOs. With the new Regulation, the clear identification of GMOs in products or GM food and feed will enhance the consumer's freedom to decide which products to buy. In addition, although minimum traces of adventitious or technically unavoidable GMOs are tolerated, the thresholds below which they will not be labelled is very low. In all likelihood, the EU is the area with the lowest tolerated presence of GMOs.[166] Hopefully, it will be possible to enforce these labelling provisions.

Finally, the importance of the inclusion of traceability obligations for operators dealing with GM food/feed and products at all stages of the marketing chain should not be underestimated. These measures will enable the Member States to take *ex-post* marketing action, in the case of any unforeseen adverse effects of GMOs on public health and/or the environment.

The new proposed rules have also made the regulatory framework on GMOs *procedurally* tighter. For example, the applicant is asked to supply a number of documents and information supporting his applications (in particular, the lodging of reference material and methods for detection and identification). This ensures that the final decision on the dossier is made on the basis of comprehensive information. More importantly, the procedure to carry out the scientific risk assessment on GM food/feed is more streamlined,[167] reliable and transparent with respect to the previous regime. The procedure is also rationalised from an institutional point of view, since the EFSA will replace a *panoplia* of committees,[168] which were previously involved in the approval procedure. Moreover, the involvement of the EFSA in the authorisation procedure makes it more trustworthy, since the Food Authority guarantees independent scientific expertise.[169] This is particularly important for the Member States, given that the lack of trust in the evaluation of the Commission's advisory scientific committees was one of the reasons underlying the Member State's scepticism towards the Community authorisation procedure.[170] The new procedure also gains in

165 Labelling requirements did not extend to feed containing, consisting of, GMOs, or produced from GMOs.

166 For example Australia, Japan, New Zealand have higher thresholds.

167 Beyond the Comitology committees, several scientific committees were involved: the Scientific Committee on plants, the Scientific Steering committee and the Scientific Committee of food. See http://europa.eu.int/comm/food/fs/gmo/gmo_scientadvice_en.html.

168 Above No. 167.

169 See Art. 37 of Regulation 178/2002.

170 During the crisis which was triggered by the request of authorisation for the marketing of GM maize, the Commission advisory committees took the position that the GM maize did not pose risks for human health. However, the Member States decided to halt the authorisation

transparency, since the Authority will have to make several documents—including the opinion of the EFSA on the authorisation of a certain GM food/feed—accessible to the public.

Amongst the most qualifying points of the proposed Regulations is one which is particularly important for the Member States: the role of national authorities in the release, suspension and withdrawal of the authorisation to market GM food/feed. It may be noted that the competent national authorities have kept the power to block the authorisation procedure.[171] However, the exercise of this power is subject to the constraints of Art. 4.5.[172] Member States also maintain the power to adopt unilateral measures on the grounds of public health or environmental protection and having the effect of halting the trade of an authorised genetically modified food/feed, in the case of an emergency within their territory. This power is regulated according to the same 'check and balances' of the Novel Food Regulation. Member States cannot, legally speaking, maintain unilateral measures unless they are backed by the Commission and the Comitology committee set up by the EFSA Regulation. However, it was also argued that Member States are likely, politically speaking, to take independent action, even if the Commission and the Comitology committee do not approve of this.

5. The Proposed Regulations: Criticism and Ambiguities

If, on the one hand, the draft Regulations are praiseworthy since they address a number of Member States' concerns, on the other, they also contain certain shortcomings and ambiguities.

The first critical remark that can be made concerns the legislative style. The proposed Regulations turn the legislation on GM food and feed into a fragmented patchwork which is not easy to read. For example, the GM food and feed Regulation does not replace the Novel Food Regulation as a whole. Therefore, rules on GM food may be found in two different legal instruments. Furthermore, the Commission chose to adopt a horizontal instrument on treaceability and labelling instead of inserting traceability and labelling provisions into the sector-related legislation (such as in the GM food and feed Regulation). In sum, it is

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procedure. See above No. 4. It should be noted that the EFSA will rely on the activity of some scientific committees which will in part be composed of the same persons who sat in the former advisory committees of the Commission.

171 Indeed, they may object the marketing of GM food/feed, after EFSA has released an opinion on the application. In such a circumstance, the Commission will take the ultimate decision on the application, in cooperation with the Comitology committee. See Art. 8(1) a.

172 'An authorisation (to market genetically modified food) […] shall not be granted, refused, renewed, modified, suspended or revoked except on the grounds and under the procedures set out in this Regulation.'

regrettable that rules applicable to a single type of GM material (be it a living genetically modified organism, or food/feed containing or consisting of GMOs, or products containing or consisting of GMOs) are not contained in a single legal instrument.

Turning to the substance, the Regulation can also be criticised for its 'vulnerability to fraud and the wider question of enforcement'[173] as far as the labelling requirements are concerned. The Commission seems to underestimate these problems.

A further shortcoming of the proposed Regulation is the limited role that it reserves to the EFSA. The institutional architecture of risk decision-making is based, on the one hand, on the Food Authority, which will be responsible for risk assessments and, on the other, on the Commission and the Member States, which take risk management decisions. It is felt that this institutional distinction, which is criticised by some authors,[174] is a legitimate choice, since 'judging what is an acceptable level of risk for society is an eminent political responsibility.'[175] However, this does not mean that the involvement of the EFSA in the authorisation procedure on GM food/feed should be kept at a minimum. Indeed, the setting up of the European Food Safety Authority is a good occasion to boost the credibility of the European food safety policy, which, in the opinion of the US, 'is hostage to political concerns with complete disregard for science and sound regulatory decision-making.'[176] It is regrettable that the Authority is not consulted systematically on all issues pertaining to the safety of GM food/feed and products.[177] In some cases, decisions are taken by the Commission, in the framework of the comitology committees, without consulting it at all.[178] Furthermore, it is regrettable that the Member States and the Commission can decide on an application to market GM food and feed, and take into account only the EFSA opinion. This means that it is possible for the Member States and the Commission to disregard a positive (scientific) opinion given by the EFSA—provided that they state the reasons for

173 See the opinion of the Economic and Social Committee on genetically modified food and feed, CES 694/2002, of 30 May 2002, p. 7.

174 Majone G. 'Foundations of Risk Regulation: Science, Decision-Making, Policy Learning and Institutional Reform', chapter 1 in this volume.

175 COM (2000)1.

176 See G/SPS/GEN/337 and G/TBT/W/179 of 26 July 2002, above No. 155.

177 For example the opinion of the EFSA is not required for the adoption of emergency measures or for the enlargement of the scope of the GM food and feed Regulation.

178 Comitology committees decide in case one or more national authorities object the granting of authorisation, or on the withdrawal from the market of the GM food/feed, or on the opportunity to introduce labelling thresholds which are lower than the existing ones.

departing from the latter.[179] There should, however, be a heavier burden on these in order for them to reject the Authority's opinion. Otherwise, suspicions could arise that the Commission and the Member States can simply ignore EFSA opinion, even in the absence of valid reasons.

The broad discretion of the EC institutions in taking risk management measures[180] seems to distinguish the European approach to food safety from the American one. However, it is important that this discretion be exercised with scientific evidence in mind. This does not, for instance, mean that 'other legitimate concerns', such as consumer resistance to GMOs, should not come into play. 'If the decisions are to have any legitimacy among the public […] there is a need for the risk assessment process to incorporate them as equal partners.'[181] However, there should be a way to define, as well as to gauge, these legitimate concerns. If this is not done, it becomes difficult to reject the US's allegation that the ambiguity of this notion can be used by the EC to 'arbitrarily delay or block (GMOs) approvals.'[182] It should be noted that the European Community has requested a discussion of the definition of 'other legitimate concerns' at the Codex Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology, set up in 1999. However, the US has been reluctant to define standards on this aspect. In order to gauge public opinion, the Commission seems to rely on Eurobarometer surveys,[183] which are the only available means to sound this out.

In the draft Regulation on GM food and feed, two ambiguities should also be signalled. The first concerns the administrative review of the EFSA's action.[184] Private parties can submit a complaint[185] to the Commission against an EFSA

179 It must be specified that the duty to state reasons for departing from the EFSA's opinion also applies in the event the Member States or the Commission are favourable to grant authorisation whereas the EFSA opposes it.

180 Recently, the wide scope of the EC institution's discretion was confirmed by the CFI in the *Alpharma-Pfizer* rulings (see T-70/99 *Alpharma v. Council* delivered on the 11 September 2002 and T-13/99 *Pfizer v Council* delivered on the 11 September 2002, not yet reported.). In these cases, the ECJ recognised that in risk management decisions, the Commission may reach different conclusions than those of the scientific committees, provided that, the scientific material the EC institutions rely on, is founded on the principle of excellence, independence and transparency. See for a comment Segnana O. (2002) 'Case note on Alpharma-Pfizer', in *German Law Journal*.

181 See McFarlane R. above No. 92, p. 11.

182 See G/SPS/GEN/337 and G/TBT/W/179 of 26 July 2002, above No. 155.

183 See for example Eurobarometer 55.2 'Europeans, Science and Technology', December 2001, European Commission, DG Research, which also contains some data on GMOs. The results of the survey are published on: http://europa.eu.int/comm/research/press/2001/pr0612en.html.

184 Art. 36.

185 It should be noted that Member States and the Commission of its own motion can also submit a complaint against an action or failure to act of the Authority.

decision or a failure to act, if they are directly and individually concerned by such a decision or failure. The Commission will decide on the matter within two months, requiring the EFSA, if appropriate, to withdraw its decision or to remedy its failure. It is clear that the Commission will have to make clear a number of details of this provision.[186] For the moment, suffice it to attract attention to one of the most important issues: it is unclear which private parties will be able to rely on this provision. Possible interested parties in reviewing the EFSA's action are those applicants whose request for authorisation has not passed the screening process of the Food Authority, as well as competitors of the applicant. Public interest groups also have an interest in submitting complaints, although it seems that, from the letter of Art. 36.a, referring to 'private parties', they will be excluded. Moreover, it is unclear whether they would pass the 'individual and direct concern' test.[187] It would be desirable if the Commission interpreted this provision in the direction of accepting the complaints of public interest groups, since this would increase the legitimacy of the EFSA's decisions.

The second ambiguity touches upon an issue which is connected to the problem of the legitimacy identified above, that is to say, it concerns the accountability of the EFSA's action and, in reality, is not specifically related to the draft Regulations but pertains to the overall institutional structure of the European food safety policy. The problem is that it is unclear which body is politically accountable to the public for decisions concerning the realm of food safety. Should there be a food scandal involving the use of GMOs, who will be held responsible? Will it be the Executive Director of the EFSA? Or the SANCO Commissioner or the *collège* of Commissioners? It is regrettable that this is not mentioned in the draft Regulations or elsewhere. In principle, since it is the Commission that takes risk management decisions, the political responsibility should lie with it. At all events, clarifications on accountability are important to make the GMOs' new regime and any other decision on food safety fully acceptable to the public. It is crucial that the Commission take up this issue.

6. The Potential Application of the WTO Law to Measures Restricting the Use/Marketing of GMOs: An Overview of the Legal Problems

When the Member States halted the authorisation procedure for the marketing of GMOs, many authors speculated on the legality of such decision in WTO terms

186 For example, the Commission should lay down the procedural requirements of its power of administrative review and the grounds of review.

187 According to well established case-law, the interpretation of 'direct and individual' concern of the ECJ, under Art. 230 of the EC Treaty, is very narrow and tend to exclude public interest groups.

and, more generally, on the compatibility between the restrictive EU legislation on genetically modified organisms and the WTO obligations. The most important legal issues raised by commentators are summarised below.

It was argued that an EU measure treating *all* GMOs (regardless of their national origin) differently from 'like products' (i.e. conventional products) could breach Article XI of the GATT and/or the non-discrimination principle of Article III of the GATT.[188] The assumption was that products containing, consisting of, or produced from GMOs were 'like products' with respect to products which were manufactured without the use of biotechnology. However, this was far from clear. There were two legal dilemmas surrounding the violation of these WTO articles:

- Are GMOs products 'like' conventional products?
- Can consumers' preferences be taken into consideration when carrying out the test of likeness?
- Moreover, should GMOs be considered as 'like products' with respect to traditional products, could the EU justify its restrictive use of GMOs as a necessary measure under Art. XX b), protecting, amongst other things, human health?

The second WTO agreement, which was considered important for establishing the legality of a GMOs measure, was the SPS agreement.[189] The latter places a strong emphasis on the fact that measures which are designed to protect human, animal or plant life or health from food-borne risks or protecting plants from pests and diseases' should be based on sound science.[190] In particular, measures which aim at a level of sanitary or phytosanitary protection which is higher than that achieved by measures based on international standards may be adopted[191] but must comply with strict requirements.[192] It was found that where the EC rejected an application to market GMOs submitted by an American firm, the US could claim that the scientific factors used by the EC in making this decision were inaccurate.[193] The SPS agreement would therefore be invoked. It is felt that trade restrictive measures on GMOs to protect human or animal life may fall 'within the spirit, if not the letter, of the SPS Agreement. There is, however, no consensus on this

188 Howse R. and Mavrodis P. above No. 18.

189 Howse R. and Mavrodis P. above No. 18.

190 See Art. 2.2 SPS.

191 Art. 3.3 SPS.

192 See Art. 5 paragraph 1 to 8 of SPS.

193 See Krenzler above No. 18, p. 310.

assumption.'[194] Should the European Community wish to maintain these kinds of measures in relation to GMOs, the following related questions would arise:

- Can the EC take restrictive measures with respect to the marketing of GMOs on the basis that they endanger human health even if a risk assessment evinced no such threat? To what extent can the precautionary principle justify these measures?[195]
- Are these measures justifiable on the basis of the consumer's preferences (i.e. the European consumer's reluctance to buy GMOs products?)
- In any event, is article XXb) and g) applicable to measures which violate the SPS agreement?[196] If so, what interest, amongst those mentioned by Art. XX b and g, does a trade restrictive measure of GMOs seek to protect?

The possibility of introducing mandatory labelling schemes raised the following doubts: do they fall within the SPS or the TBT agreement?[197] Is compulsory labelling the least trade restrictive measure? These questions have been left unanswered so far since to date no WTO members have triggered the WTO dispute settlement procedure.[198] However, the EU GMOs legislation, in particular the draft Regulations analysed in this paper, have been the object of a number of critical comments by several WTO members.[199]

194 Zarrilli S. above No. 159, p. 24.

195 See on this issue MacMillan F., Blakeney M. (second part of the article) above No. 18, p. 161-164.

196 For a positive answer, see Bentley above 18.

197 See MacMillan F., Blakeney M. (first part of the article) above No. 18, p. 133-134. Zedalis considers that labelling practises on GMOs could also be reached by Art. IX GATT. See Zedalis Rex J. 'Labeling of genetically modifed food—the limits of GATT rules', p. 308.

198 It should be noted that the EU regulatory framework on GMOs has been repeatedly the subject of controversy in the TBT committee. See Howse R. and Tuerk E. (2001) 'The WTO impact on internal regulations-a case study of the Canada. EC asbestos dispute', p. 284 in De Búrca G. and Scott J. (ed.) *The EU and the WTO Legal and Constitutional Issues* Hart publishing.

199 Australia, Argentina, Brazil and the US also made comments on Regulation 1139/98. See G/TBT/W/184, 4 October 2002.

7. The Comments of Third Countries with Commercial Interests in GMOs to the Proposals on GM Food/Feed and Labelling/Traceability of GM Products

The Commission notified the proposal for a Regulation on GM food and feed[200] under both the SPS and the TBT agreement in consideration of the fact that the provisions contained therein were capable of falling within the scope of both agreements. The same was done for the proposal on traceability and labelling.[201]

A number of issues were raised by some third countries, Australia, Canada, US, Brazil, Argentina and Switzerland[202] many of which have important interests in marketing agricultural biotech products.[203] This group of States made comments on virtually every single provision of the proposed Regulation on GM food and feed, requesting clarifications both on the meaning of the terminology[204] used in the proposal and on procedural and institutional aspects of the GMOs regime.[205] The

200 The Commission notified the proposal as set out in COM (2001) 425. Therefore the comments that were made by WTO members do not take into account the political compromise reached in November 2002 by the Council. See 'Responses from the European Commission to comments submitted by WTO members under either or both G/TBT/N/EEC/6 AND G/SPS/N/EEC/149', above No. 155.

201 The Commission notified the proposal as set out in COM (2001) 182. See the notification G/TBT/N/EEC/7 and G/SPS//N/EEC/150. See also 'Responses from the European Commission to comments submitted by WTO members on the proposal for a Regulation of the European Parliament and of the Council on traceability and labelling of genetically modified organisms and traceability of genetically modified food and feed—COM (2001) 182 final' published on http://europa.eu.int/comm/food/fs/gmo/gmo_ongoinit_en.html. The comments that were made by WTO members do not take into account the political compromise reached in December 2002 by the Council.

202 It was not the first time that EU GMOs legislation attracted the criticism of third countries. See G/TBT/W/184, of 4 October 2002 in which Argentina, Brazil, Canada, New Zealand and United States criticised Regulation 1139/98 on the foods and food ingredients produced from genetically modified soya and genetically modified maize.

203 It must be emphasised that the position of Switzerland differ from that of the other countries since this country does not have a prominent interest in GMOs.

204 Clarifications were requested in relation to items which were included and excluded in and from the scope of the Regulation. Queries were made on the application of the 'substantial equivalence' principle in the new rules, and on the meaning of 'other legitimate factors' and of 'public'. The labelling statements 'misleading the consumer,' and 'it gives rise to religious concern' also raised doubts. Explanations were asked on the threshold applicable to unauthorised GM material.

205 Elucidation was asked for on the involvement of the European Group on Ethics in Science and New Technologies in the authorisation procedure and on the role of competent national authorities and of the Community reference laboratory. Further raised issues were the degree of autonomy of the Member States to take decisions related to authorisation to market GM food and the time frame of the Commission for the release of an authorisation. Critical remarks were also made on the operation of the register of authorised GM food.

idea which is canvassed in the criticism of both the first and the second EU proposal is that the EU regulators treat GMOs as inherently unsafe products, while there is no scientific evidence that this is the case. According to the countries mentioned above, in particular for Canada and the US, the EU food and feed regime is unworkable[206] and unenforceable,[207] the role of the EFSA is limited,[208] it contains many ambiguities[209] and, chiefly, the prominence of non-scientific factors in the authorisation procedure is still significant.[210] Similar critical remarks were reserved to the traceability and labelling draft Regulation: the rationale for this measure has been contested;[211] the regime set out by the Regulation is discriminatory[212] and also too costly to implement;[213] in addition, the result of its application would be the erosion of consumer confidence. A common remark, made in relation to both proposals, was that they are characterised by a lack of sufficient detail or additional guidance on technical aspects of the proposed Regulations.

It should be noted that the UK, which voted against the political compromise reached within the Council on the two draft Regulations,[214] expressed (in part) concerns along the same line. The UK emphasised the need for 'a policy based on sound science and which was practicable and enforceable. The compromise text failed to meet these objectives.'[215]

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206 One of the reasons which make the labelling system unworkable is that the labelling threshold of 1% is too low. The detection method for a very low presence of GMOs may not be technically available. This can also pave the way to fraud.

207 For example the US is concerned that Member States will not be able to enforce the legislation in the absence of a standardised testing methodology.

208 EFTA is not included in decision-making leading to the adoption of emergency measures; moreover, its opinion in the authorisation is not binding either for the Commission or the Member States.

209 It is unclear what are the criteria, which will guide the Commission in imposing post market monitoring plans upon applicants.

210 Beyond the fact that the role of the EFSA is too limited in the authorisation procedure, it is emphasised that the importance of 'other legitimate concerns' in the risk management decision is unclear.

211 The need for rules on traceability and labelling is doubted given that GM products/food and feed have already undergone a risk assessment and have been approved. It is argued that this measure is unnecessary.

212 This is due to the fact that conventional products are not subject to the same traceability and labelling requirements.

213 According to Canada, comprehensive traceability would have enormous costs. Switzerland and the US respectively suggest that the proposal would be burdensome for the administration and for operators. Finally, in case of non-compliance, the exposure of operators to liability costs would increase.

214 See above No. 13 and 14.

215 Two further reasons which induced the UK to vote against the political compromise were that it could not support threshold values less than 1% nor the revised authorisation procedure

A second set of comments submitted by the WTO members focused on the compliance of the new authorisation, labelling and traceability rules with WTO law. It was emphasised that GM food and feed products and their non-GM counterparts are 'like products' for the purpose of the WTO Agreements. The EU proposed legislation should thus treat them in the same way. Instead, the EU draft measures infringe the WTO obligation not to discriminate by distinguishing products in relation to 'production methods'—the use of biotechnology—rather than 'product characteristics'—the presence/absence of genetically modified material. Canada added that 'even within this processed based system, the EC appears to be inconsistent in its application, i.e. by including foods produced "from GMOs" while excluding foods produced "with GMOs"' A further criticism, which is related to the previous one, concerns the labelling regime. The EC's choice to label, *inter alia*, food/feed produced from a GMOs but which contains no traces of GM DNA and/or protein in the final product is questioned. How can the EC argue that this material is 'unlike' a conventional product? Finally, it is argued that the proposed labelling scheme would not be the less trade restrictive option.[216] More precisely, the proposals would be more trade-constraining than is necessary to fulfil a legitimate objective of the TBT agreement.[217]

8. The EC Clarifications and the Problematic Compatibility Between the New Rules on GM Food and Feed and the WTO Principles

The Commission offered clarification on several points raised by the commenting countries, making extensive reference to the activity of the *Codexalimentarius commission.*[218] In most cases, it defended its proposed measures, while accepting

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without the Article 308 as a legal base. See for this information the website of the English food safety authority.

216 A voluntary labelling scheme was less trade restrictive than the proposed one.

217 This is a comment made by Australia.

218 The Commission draws the attention on some agreed principles of the Codex Alimentarius Commission, in particular the Statements of Principle Relating to the Role of Food Safety Risk Assessment, to justify the functional separation of risk assessment and risk management activities. The Commission relies on the Codex standard for food labelling to emphasise that traceability is a recognised process in adopted Codex texts and to rebut the Canadian argument that traceability obligations are unworkable and too costly. The Commission stresses the importance of the Codex's activity in sampling and detection methods of genetic modifications in food. It emphasises that the EC's choice to subject food produced from GMOs is consistent with the work in progress of the Codex Alimentarius Task Force on food derived from Biotechnology. The Commission quotes the proposed draft principles for the risk analysis of food derived from Modern Biotechnology to justify post-marketing monitoring requirements for the use of GM food. The Commission refers to general principles for risks analysis to prove that reliance on factors different from science in risk management decisions is legitimate.

the criticism of its trading partners on one issue.[219] The most interesting part of the Commission's answers lies in the Commission's rebut of the alleged non-compliance of the EU draft legislation with WTO obligations.

The EC challenged the statement that GM food and feed products are 'like' their non-GM counterpart. Firstly, the examination of 'likeness' of products should be made on a case-by-case basis; secondly, a wide range of factors should be considered when carrying out this assessment. Beyond physical characteristics and other features which are likely to influence the competitive relationship in the market place, the Commission mentions consumers' preferences, tastes and habits, provided that they are proved by empirical evidence. In Europe, Eurobarometers surveys show that consumers do not consider GM products as substitutes of conventional products. Consumers' preferences are also invoked by the Commission to justify the labelling obligations for food/feed which was produced from GMOs but which does not have any traces of GM material. The Commission claims that even if this kind of food/feed does not contain GM material, 'there is solid evidence'[220] that European consumers do not perceive it as its traditional counterpart.

It appears that the Commission's defence is centred around the need to meet consumer preferences. It should be noted that this defence creates two difficulties, regardless of the applicable WTO agreements.[221] The first is that it is not clear

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219 Article 4.1 of the GM food and feed proposed Regulation required all biotech food not to present 'a risk for human health or the environment.' The comment was made that this provision imposed a 'no risk standard', which is scientifically impossible to achieve. The Commission accepted to bring the issue to the attention of the Parliament and the Council, which agreed to change the words of the provision in question. Indeed, as noted elsewhere in this paper, Art. 4.1 now reads biotech food 'must not present an unacceptable risk.'

220 'Responses from the European Commission to comments submitted by WTO members under either or both G/TBT/N/EEC/6 AND G/SPS/N/EEC/149,' above No. 155.

221 As the Commission acknowledged, both the SPS and the TBT agreements are capable of reaching the EC draft Regulations. As for GATT, it is submitted that because of the broad definition of 'technical regulation' in the TBT, most claims on non commercial purposes will not be decided under Art. III GATT.

It should be decided on a case-by-case basis which of the two agreements is applicable. The position of the Commission on this matter is thoroughly justified. Given the heterogeneous nature of the interests protected by the draft measures (human life, environment, consumer's interest), these measures could fall within the scope of both WTO agreements. For instance the traceabilty provisions of the traceability and labelling Regulation are likely to fall within the TBT since those provisions are aimed, *inter alia*, to prevent deceptive practises. At the same time, the labelling provisions prescribed by the draft Regulation concerns consumer's health and as such they could also fall within the SPS agreement. Let us take the GM food and feed Regulation. A refusal to authorise the marketing of GM food on the ground that it might be dangerous for human health would concern the SPS agreement. Viceversa, the imposition of certain labelling requirements on a notifer from a third country could be challenged under the TBT agreement.

whether consumer preferences would be accepted as one of the factors which make two products 'unlike'. Secondly, it is unclear whether the proposal on GM food and feed is dictated by the need to protect consumer preferences or consumer health. The difference is important for WTO purposes. Whereas consumer health could be considered a legitimate objective[222] under the TBT to justify a discriminatory labelling scheme (assuming that the labelling scheme is a technical measure),[223] consumer preferences[224] may not. The EC could argue that the GM food and feed Regulation intends to protect consumer health as it can be deduced from the legal basis. In this case, the EU labelling scheme could be justified under the TBT agreement, provided that it is shown that it is the less trade restrictive measure. However, two weaknesses can be found even in this argument. First of all, it is contentious that the EU labelling scheme is the least trade restrictive measure.[225] Secondly, it remains difficult for the EU to justify, in the name of consumer protection, the labelling obligations for GM food and feed which does not contain GM material. Indeed, production processes may be important to show that two products are unlike, but only subject to the condition that such production processes are detectable in the final product. This is not the case for food/feed produced from GMOs. Reliance on consumer preferences to justify this aspect of the Regulation is not possible since we have seen that it is not contemplated by the TBT. A way out for the EC could be the adoption of an international labelling standard by the *Codex Alimentarius Commission,* allowing the inclusion of 'other legitimate factors'[226]—i.e. consumers' preferences—amongst the reasons justifying the introduction of a trade

222 Under Art. 2.2, one of the legitimate objectives for a TBT measure is the protection of human health of which the protection of consumer's health could be considered an aspect.

223 See on this issue the opinion of Pardo Quintilian who argues that a labelling requirement intended to inform consumers and not directly related to food safety would fall under the scope of the TBT. See above No. 18, p. 190.

224 Some authors argue that consumer's concerns should be explicitly recognised as a legitimate reason for countries to apply trade measures. See Perdikis N.O., William A. Kerr, Jill E. Hobbs (2001) 'Reforming the WTO to defuse potential trade conflicts in genetically modified goods', in *World Economy*, Vol. 24, No. 3, March, p. 397.

225 This is an argument which was raised by several third countries. The Commission justified the labelling option it chose on the basis of the following points: a) voluntary 'GMO-free' schemes are beset by a number of technical, commercial and other difficulties; b) Consumers clearly prefer to be informed of what is in products and not of what is not in products. c) 'GMO-free' products are already supplied by the Organic Production scheme, which excludes the use of GMOs in the whole production chain on a very strict basis. A second 'GMO-free' production scheme is therefore also considered to be confusing for consumers and potentially misleading. See above No. 155.

226 This issue is under exam at the Codex Committee on General Principles (CCGP). The issue was also discussed by the Task force on Biotechnology. See the Report of the first session of the codex ad hoc intergovernmental task force on foods derived from biotechnology, Chiba, Japan 14-17 March 2000.

restrictive measure. Thus, the EC could rely on this standard to enact a labelling scheme which meets consumer preferences, without incurring the violation of the TBT. However, in the light of recent discussion in the codex committees, it seems unlikely that some countries, such as the US, New Zealand and Canada would legitimise reliance on factors other than science.[227]

It should also be borne in mind that the SPS agreement could be invoked against the GM food and feed authorisation procedure and against the labelling scheme provided herewith. However, the possibility of the EC justifying, under the SPS agreement, the refusal to authorise the marketing of a certain GM food/feed is even more limited than in the case of the TBT agreement. Indeed, the SPS provisions place much greater emphasis than the TBT on the 'scientific basis' of SPS measures. It is therefore difficult to accommodate consumer concerns within the SPS agreement. It follows that it would be unlikely for the above-mentioned SPS measure to pass the screening of the WTO bodies in the event that such a measure was based on factors other than science, i.e consumer preferences.

In the previous sections, potential clashes were identified between the proposed EC legislation and the spirit of the SPS and TBT agreement. There are reasons to doubt that the new rules on GM food/feed are compatible with the letter of the WTO law. However, it is noteworthy that a strictly trade-oriented interpretation of these agreements undermines one of the fundamental principles of WTO law: each Member State can choose the level of protection that it deems appropriate to protect human, animal or plant life or health (and environment in the case of TBT) within its territory, provided that its policy is not arbitrary and does not verge toward disguised protectionism.

Should WTO bodies be asked to adjudicate on a conflict between i.e. the US and the European Community, they would feel unease about dealing with issues such as what the risks acceptable for a given society are. Nor would it be legitimate for them to interfere with choices belonging to regulators.

9. Conclusions

The GM food and feed draft Regulation and the traceability and labelling draft Regulation are two complex measures which strengthens the GMOs regulatory framework enacted by the European institutions in the 1990s. Therefore, Member States, which made the lift of the *moratorium* conditional upon the undertaking of major reforms in the field of food safety, have no legal reasons to keep the ban. Amongst the strengths of the draft Regulation, there is a more streamlined and

227 See on this issue the works of the Codex Committee on general Principles. See also the Report of the first session of the codex ad hoc intergovernmental task force on foods derived from biotechnology, Chiba, Japan 14-17 March 2000.

centralised authorisation procedure, enhanced transparency, and extensive labelling provisions. Furthermore, although the draft Regulation on genetically modified food and feed is likely to exhaustively harmonise the marketing of these GM products, Member States maintain the power to introduce unilateral emergency measures. Yet again, it is clear that the EU legislative framework incorporates the risk approach whereby it is better to err on the side of caution, although it is more realistic than the first generation of GMOs legislation in pursuing targets of consumer/environmental protection.

The second part of the paper focused on the shortcomings and ambiguities of the two draft Regulations. It was found that they are difficult to read, assign little influence to the EFSA, and do not clarify which body is held accountable for food safety decisions. Moreover, a further point which is not clear is whether public interest groups would be able to review the EFSA's action. Hopefully, the Commission will cast some light on these issues in the near future. As to the draft Regulation on the traceability of GM products, it was noted that the Commission might have underestimated problems of enforceability of the draft Regulation.

Critical remarks on the two proposals were also made by some WTO members which found that the authorisation procedure privileges political factors to the detriment of scientific evaluations. It was also noted that the traceability and labelling rules are disproportionate to the risks posed by GMOs, being both costly and unenforceable. The new EU measures were, finally, accused of clashing with some principles of WTO law. The most important alleged breach is the violation of the non-discrimination principle between GM products and their 'like' traditional counterpart products. The Commission's defence is centred around the need to take consumer preferences into consideration; however, this defence would probably not be accepted in a possible legal dispute before the WTO. This is regrettable in the light of another principle of the WTO, on the basis of which each country should be able to choose the level of protection which it deems appropriate.

The final conclusion of this paper is that it is in the best interest of countries wishing to export GMOs to Europe not to challenge the new GMOs rules before the WTO. This is because, although they are complex, burdensome and difficult to implement, they may be the only rules which the Member States are willing to accept. It should be remembered that the Commission made substantial efforts to review the legislative framework so as to convince the Member States to resume the GMOs authorisation procedure. It would be a 'trade success' if the Member States accepted the invitation of the Commission to allow the authorisation of the GM food/feed under the new rules. Should the new regime be challenged before the WTO bodies, the marketing of GM food/feed in Europe will probably be further delayed. Therefore, a trade war on GMOs would be politically opportune for those countries which are major exporters of GMOs. Recent events show that the latter have opted for a different strategy. In May 2003 the United States, Canada, Argentina requested consultation with the European Community, pursuant

to Art. 4.4 of the DSU, against the *moratorium* on the approval of biotech products.[228] We shall see if this move will help the parties of the dispute to reach a compromise or whether it will reinforce their positions as happened with the hormone-in-beef controversy.

228 See WT/DS291/1 of 20 May 2003, WT/DS/203/1 of 21 May 2003, WT/DS292/1 of 20 May 2003.

Chapter 5

Setting Out International Food Standards: Euro-American Conflicts within the Codex Alimentarius Commission

Sara Poli

1. Purpose of this Chapter

The Joint FAO/WHO Codex Alimentarius Commission (hereafter the 'Codex Commission' or 'CAC') is an inter-governmental body set up in 1962, whose role is to promote international trade in food through the adoption of standards, aimed at ensuring fair trade practises and the protection of consumer's health.

The Codex Commission has played an increasingly important role[1] in international food trade since 1995, the year in which the World Trade Organization (WTO) was founded. Indeed, under the WTO agreements, national measures which are based upon food standards, adopted by this organisation (amongst others), are presumed to comply with WTO principles.[2]

1 See generally on the Codex Alimentarius Commission, Boutrif E. (2003) 'The new role of Codex Alimentarius in the context of WTO/SPS agreement', in *Food Control,* 14, p. 81-88.

2 Art. 3.2 of the SPS agreement states that: 'Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations (of the Codex Alimentarius Commission, amongst others) shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994.' Art. 2.4 of the TBT agreement affirms: 'Where technical regulations are required and relevant international standards (adopted by the Codex Alimentarius Commission, amongst others) exist or their completion is imminent, Members shall use them, or the relevant parts of them, as a basis for their technical regulations except

It is the primary purpose of this paper to assess whether the Codex Commission has the 'structural capability'[3] to fulfil its new role.[4] In order to do so, we will look at whether and how the main areas or issues of conflict between the members of the European Community and the US were settled within this organisation.

Firstly, this chapter will highlight the importance of Codex standards within the WTO legal system. Special emphasis will be placed on the WTO 'sardine case'. Then, the role of Codex standards in European Community law will be briefly considered. Reference will also be made to the European Commission's efforts to change the Codex Commission's internal rules so as to allow the full membership of Regional Economic Integration Organisations, such as the European Community. Secondly, consideration will be given to Euro-American conflicts on the general principles underlying Codex decision-making, these being at the heart of more specific instances of conflict. Thirdly, the most recent example of Euro-American conflict will be illustrated: this is the adoption of standards related to food derived from biotechnology. The description of these conflicts within the Codex Commission, will be followed by conclusive remarks highlighting the 'lessons to learn' from these conflicts and the usefulness of holding a discussion, in an attempt to solve these conflicts, within the Codex Commission.

2. The Sardine Case: An Illustration of the New Role of the Codex Alimentarius Commission as a Benchmark for Food Standards in the WTO Legal Order

The new role of the Codex Commission, as a satellite organisation of the WTO legal system, has two consequences. Firstly, it has become increasingly difficult to agree on the content of food standards.[5] Secondly, Codex standards were invoked by WTO members in disputes before the Dispute Settlement Body (DSB) to prove that certain SPS or TBT measures, not complying with Codex standards, also conflicted with the TBT and the SPS agreements. For example, Codex standards

(*contd.*)

when such international standards or relevant parts would be an ineffective or inappropriate means for the fulfilment of the legitimate objectives pursued, for instance because of fundamental climatic or geographical factors or fundamental technological problems.'

3 Terence P. Stewart and David S. Johanson (1998) 'The SPS Agreement of the World Trade Organisation and International Organisations: the roles of the codex alimentarius Commission, the international plant protection convention, and the international office of epizootics', in *Syracuse Journal of International Law & Comparative,* Vol. 26, 27, 29.

4 On this issue, see R. Romi (2001) 'Codex Alimentarius: de l'ambivalence à l'ambiguité', in *Revue juridique de l'environnement* 1. See also OECD (2000) *Food Safety and Quality: trade considerations.*

5 David G. Victor (2000) 'The sanitary and phytosanitary of the World Trade Organisation: an assessment after five years', in *New York University Journal of International Law & Policy*, 32, 865.

were crucial in the 'hormones in beef' case, which concerned an SPS measure—a Regulation of the European Community banning the use of hormones—which was 'not based' on the maximum level of residues of hormone in meat, established by a Codex standard of 1995. More recently, compliance with Codex standards turned out to be important in the context of the TBT agreement. The compatibility of a TBT measure, (i.e. a European Regulation) with WTO principles was evaluated taking as reference a Codex standard of 1978. The dispute, generally referred to as the *Sardine* case, revolved around an EC Regulation, reserving the name 'sardine' to certain fish species (sardine pilchardus, amongst others, available in the Mediterranean sea) to the exclusion of others (the Peruvian Sardinops sagax), thus precluding Peru to market its sardine species under the name of sardines within the territory of the EC. The Panel's finding that the EC legislation breaches Art. 2.4 of the TBT agreement is interesting because in assessing whether the concerned measure is compatible with Art. 2.4 of the TBT, the Panel considers a Codex standard on sardines, adopted in 1978, as a 'relevant international standard'. This standard laid down common marketing standards for preserved sardines and covered twenty sardine species, including the species of pilchardus and Sardinops sagax. The most interesting part of the standard was that it allowed the name 'sardine' to be used not only for the Pilchardus species but also for other sardine-type species, thus making possible for the Peruvian sardines to be placed on the EC market with the name of 'sardines'. The Panel who adjudicated the dispute, found that the EC had not used the Codex standard 'as a basis' for the EC Regulation on sardine,[6] since the EC had not considered the standard concerned as 'the principal constituent or the fundamental principle'[7] of the technical regulation. The EC appealed, amongst others, against this point of law. It argued that 'using a standard as a basis for a technical regulation' means that a technical regulation is informed in its overall scope by the international standard. In other words, the EC argued that there must be a 'rational relationship' between the technical legislation and the standard on the substantive aspects of the standard.[8] This was the case for the EC regulation since it used part of the standard as a basis for the Regulation. The Appellate body did not accept the EC's argument; stating that 'something cannot be considered a "basis" for something else if the two are contradictory.'[9] The technical regulation under consideration contradicted the Codex standards concerned, because it prohibited to use the label 'sardine' for fish species other than Sardina pilchardus. By contrast, the Codex Standard allowed Sardinops sagax to be marketed under the appellation 'sardines'. Thus, it could not be maintained that the European Regulation took Codex standards as a basis.

6 WT/DS231/R of 29 May 2002.

7 This is definition of 'conform to international standard' given in the hormone case.

8 Report of the Appellate Body, WT/DS231/AB/R, of 26 September 2002, par. 241.

9 Par. 248.

The sardine case provides an example of how important the definition of the content of food standards within the Codex Commission is; it also helps understanding why the adoption of food standards within this organisation can be controversial and give rise to conflicts amongst delegations which last for many years.

3. The Role of Codex Standards Within the European Community Legal System

Although Codex standards are voluntary, they were taken into account in the adoption of the European foodstuff legislation. There are many instances of EC legislation which are based on Codex standards or incorporate its guidelines.[10]

The standards of the CAC were even invoked in cases before the European Court of Justice. For example, the Court has used the provisional works of the Codex Commission to clarify the meaning of the words 'hazard' and 'scientific risk assessment'.[11] In another case, the Court referred to Codex standards to determine the characteristic features of yoghurt in a case on the labelling of foodstuffs[12] and in deciding whether a food additive presented a risk to public health or met a real need, especially a technological one.[13] In a third case,[14] Advocate General Leger referred to Codex standards on the limits for lead and cadmium in certain foodstuffs.

Probably the most interesting reference to Codex standards is that of Advocate General Fennelly, who ventured to consider Codex standards as a source of information (for the Community judicature) as far as the 'objective characteristics and properties'[15] of foodstuff or the maximum tolerated presence of undesirable substances in food are concerned.

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10 Reference will be made only to some recent examples: Regulation 1181/2003 *OJ* (2003) L165/17 laying down common marketing standards for preserved sardines. This Regulation amends the EC legislation taking into account the outcome of the WTO sardine dispute. See also Commission Directive 2002/82 laying down specific purity criteria on food additives other than colours and sweeteners *OJ* (2002) L292/1; Commission Directive 2002/63 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin *OJ* (2002) L187/43*;* Commission Directive 2001/50/EC laying down specific purity criteria concerning colours for use in foodstuffs *OJ* (2001) L190/14.

11 See T-13/99 *Pfizer Animal Health SA v. Council of the European Union*, (2002) ECR II-3305, par. 147 and 156.

12 Case C-298/87 *Smanor* (1988) ECR 4489, par. 22.

13 Joined Cases C-13/91 and C-113/91 *Debus (*1992) ECR I-3617, par. 16 and 17.

14 See the opinion of Advocate General Leger of 20 January 2000, in case C-465/98 *Unwesen in Handel und Gewerbe KölneV v. Adolf Darbo AG.*

15 See the opinion of Advocate General Fennelly of 8 June 2000 in Case C-42/99 *Fábrica de Queijo ERU Portuguesa Ld v. Tribunal Técnico Aduaneiro de Segunda Instância*, par. 33.

The most recent reference to a Codex Commission-related activity may be found in the opinion of Advocate General Alber in the *Monsanto* case.[16] Mr. Alber considered the conclusions of the Joint FAO/WHO Expert Consultation on Biotechnology and Food Safety as a relevant source to give interpretative guidelines on the meaning of the principle of 'substantial equivalence'[17] between genetically modified products and non-GM products, a principle which was incorporated in the European legislation on GMOs.

4. Towards the Accession of the European Community to the Codex Alimentarius Commission

Whereas single European countries are full Codex members,[18] the European Community, being a Regional Economic Integration Organisation, has observer status[19] within the CAC. However, Art. II of the Codex Commission's rules of procedure allows members of FAO to become Codex members. Since the European Community acceded to FAO in 1991, it would be legally possible for the European Community to become a member of CAC, subject to an amendment of the Codex rules of procedure, explicitly allowing the membership of Regional Economic Integration Organisations.

At the time of the EC accession to FAO, an explicit reference was made to the possibility of the European Community becoming member of the Codex Commission.[20] The Council had authorised the Commission to negotiate the conditions and the modalities of such accession in 1993.[21] However, the European Commission has not taken action for many years. In 2001, the European Commission sought full membership of the European Community to the Codex Commission and put forward a proposal to this effect.[22] The European executive justified the EC's full membership in the following way:

> Accession of the European Community as a full member of the Codex […] Commission, alongside its Member States, is essential in order to ensure that the primary health and other interests of the European Community and its Member States are taken into consideration during

16 Case C-236/01, *Monsanto Agricoltura Italia SpA e a. v. Presidenza del Consiglio dei Ministri*.

17 Conclusions of Advocate General Alber of 13 March 2003.

18 Rule VII of the Procedural Manual.

19 Art. 3 of the Procedural Manual.

20 Report of the 16th meeting of the CCGP, 2001, par. 134.

21 See proposal Council decision on the accession of the European Community to the Codex Alimentarius Commission, COM (2001) 287.

22 See proposal Council decision on the accession of the European Community to the Codex Alimentarius Commission, COM (2001) 287.

> the preparation, negotiation and adoption of such standards, guidelines or recommendations and other provisions by this organisation.[23]

Moreover:

> The accession of the European Community as a full member to the Codex Commission should help reinforce coherence between the standards, guidelines or recommendations and other provisions adopted by the Codex Commission and other relevant international obligations of the European Community.[24]

It is clear that the EC's accession to the Codex Commission was made necessary by the acquired importance of Codex's role in the WTO system.[25] Codex standards had been crucial in the two disputes in which the EC had lost: the hormone-in-beef and sardine cases. Maybe the standards at stake in these cases could have a different content, had the European members of Codex spoken with a single voice.

In 2001, with these considerations in mind, the observer of the European Community asked 'to establish clear Rules of Procedure for the membership of regional economic integration organizations in the work of Codex, including the membership of the European Community.'[26]

The European Commission pushed hard within the Codex Committee of General Principles[27] (hereafter the 'CCGP') to have the issue of membership for Regional Economic Integration Organisations settled as soon as possible. In the meeting of the CCGP of 2003, the observer of the European Community urged Codex members to deal with the EC accession, stating that: 'New legislation had entered into force in the European Union that required the European Community to take into account the international food standards of Codex when introducing new or harmonizing existing food legislation.'[28] Moreover, the WTO, of which the EC is a member, encouraged the participation of Members of the WTO in the international standards-setting bodies.

The idea of having members of the European Community speaking with one single voice did not raise the enthusiasm of any Codex delegation. The strongest views against the idea were those of the delegation of the United States. They

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23 Recital 3 of COM (2001) 287.

24 Recital 4 of COM (2001) 287.

25 See TBT and SPS agreement.

26 Report of the 16th meeting of the CCGP, 2001, par. 127.

27 This is a subsidiary body of the Codex Commission which deals with 'procedural and general matters referred to it by the Codex Alimentarius Commission. These include the establishment of the General Principles that define the purpose and scope of the Codex Alimentarius, the nature of Codex standards and guidelines for Codex Committees.' See *BRIDGES,* Vol. 3, No. 7, 17 April 2003, available online.

28 Report of the 18th meeting of the CCGP, 2003, par. 75.

emphasised that the membership of regional economic integration organizations in any United Nations body should not infringe the principle of 'one nation, one vote,' and that the admission of regional economic integration organizations into FAO should not be seen as a precedent for other UN bodies. They noted that full Codex membership for the European Community would allow this organisation to enjoy privileges not available to other Members and it would eliminate a strength of Codex decision-making: the possibility of all Member countries to express diversity of views.[29] Other delegations, such as Canada, Australia, Malaysia and Singapore, supported the American position.

At the current stage of the negotiation within the CCGP, it seems that the EC will succeed in changing the rules of procedure and acceding to the Codex Commission. However, clarifications are needed on some technical issues. The first is how the vote will be organised, within the Codex Commission, in case of mixed competence between the regional economic integration organization and its Member States.[30] The US delegation has made the point that it would be burdensome for the Chairpersons of Codex meetings to assess the consensus where the adoption of a Codex standard concerned matters which fall within the mixed competence of the EC and Member States.[31]

The second controversial point is whether the Regional Economic Integration Organization can exercise the voting right of a Member, that may have submitted credentials or have registered as a participant, but that was not present at the time of the vote.[32] Some delegations expressed the opinion that 'if the voting right of a registered, but absent, participant could be exercised this practice would dilute the rights of other Members, especially those smaller countries with single person delegations.' [33]

In the last meeting of the CCGP (2003), the provisional conditions governing the accession of Regional Economic Integration Organisations were clarified:[34] no additional rights or privileges would accrue to members of Regional Economic Integration Organizations as a result of the changes to the rules of procedure; voting rights of Regional Economic Integration Organisation are limited to the

29 Report of the 16th meeting of the CCGP, 2001, par. 129.

30 Report of the 18th meeting of the CCGP, 2003, par. 80.

31 Report of the 18th meeting of the CCGP, 2003, par. 81. The American delegation also put forward a proposal of amendment to the rules of procedure dealing with the issue of mixed competence, which has not been accepted by the EC since it does not ease the task of the chairperson and 'it would limit the debate and the diversity of opinion necessary to reach a consensus.' See ALINORM 03/26/ 5: add.1 in the Report of the 26th meeting of the CAC, 30 June-7 July 2003.

32 Report of the 17th meeting of CCGP, 2002, par. 108.

33 Report of the 17th meeting of CCGP, 2002, par. 108.

34 See Report of the 18th meeting of CCGP, 2003, par. 78.

number of members of these organisations present at the time a vote was taken. A solution in case of mixed competence has not yet been achieved.

The efforts made by the European Commission to convince Codex members to allow the accession of the European Community imply that the European institutions attach great importance to the Codex Commission. Which advantages would accrue to the European Community in case this organisation became member of the Codex Commission? The benefit of being a full Codex member would not come from having a greater number of votes, since the principle 'one State-one vote' would remain. However, the EC would gain strength in negotiating Codex standards; the opposition of the EC to the adoption of a standard would prevent consensus from being reached and, conversely, draft standards supported by the EC would stand greater chances of adoption. So far the negotiating positions of European delegations were very similar but it was quite difficult for these States to impede the adoption of standards unless they were supported by other delegations. In sum, the bargaining power of the 'European block,' comprising 15 members (and in the near future, even more than 15) would be perceived as stronger than that of the sum of its 15 single members.[35]

5. Areas of Conflict Between the European Community and Transatlantic Partners

There have been at least three cases[36] in which the adoption of specific standards proved to be problematic due to conflicting views of the members of the European Community on the one hand, and the US on the other. In all these cases consensus could not be achieved, and eventually the corresponding standards were adopted by majority vote, a procedure which is rarely used within Codex.[37] One of these conflicts, concerning the MLRs ('Maximum Levels of Residues') of hormones in beef, did not remain confined in the CAC;[38] in 1998 it became a trade dispute

35 Consumer International pointed out to a disadvantage linked to the accession of the European Community to the Codex Commission. It would be difficult for civil society (i.e NGOs protecting consumer interests) to channel their concerns or interests to Brussels; the accession would result in the diminished ability of consumers' organizations to interact with these organisations. Single national delegations are certainly more accessible for NGOs with short of economic resources. See Report of the 16th meeting of the CCGP, April 2001, par. 132.

36 These cases concerned the adoption of MLRs for growth promoting hormones for beef cattle, the bovine somatotropin (BST) and natural mineral waters. For a brief description of the three controversial Codex decisions, see Terence P. Stewart and David S. Johanson, above No. 3, p. 41-45.

37 Terence P. Steward and David S. Johanson (2003) 'A Nexus of Trade and the Environment: The Relationship Between the Cartagena Protocol on Biosafety and the SPS Agreement of the World Trade Organization', in *Colorado Journal of International Environmental Law & Policy*, 14, 48.

38 The laying down of the MLRs of BST has not been settled, yet.

which was adjudicated by the Dispute settlement body of the WTO. We can say that this trade dispute was anticipated by the heated discussion which has being held within various Codex Committees since 1988.

The US and the Codex members, belonging to the European Community, have fundamentally different views on the Codex Commission's areas of competence and the principles underlying its decision-making. In the next sections, these fundamental differences will be highlighted in relation to two issues: the place of the precautionary principle within the Codex system and the role of factors other than science in the approval of Codex food standards.[39]

Subsequently, an account will be given of the most recent case of Euro-American conflict: the adoption of Codex standards/guidelines on labelling and traceability of food derived from biotechnology. This is another area, in which the Euro-American divergence of views became clear at the level of the Codex Commission, but they are not likely to be reconciled in the Codex framework,[40] as it happened in the hormone case.

5.1 Contrasting Views on the Role of Precautionary Principle Within the Codex Commission

Given the attention that has been paid to the precautionary principle in the last decade (see chapter 2), it is not surprising that Codex committees had an intense discussion on this topic before including a very loose version of the principle in the Codex Procedural Manual.[41]

The opportunity for a debate on the precautionary principle was offered by the adoption of Codex working principles for risk analysis, which were to be addressed to Codex Committees and Member Governments. The CCGP was charged with the development of these principles by the Codex Commission in 1997[42] and in 2003 the Committee completed its works.[43]

The discussion on the definition of principles for risk management led inevitably to consider the issue of how to address uncertainty in scientific evaluations.[44] Thus,

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39 The activity of the CCGP will be the privileged, though not exclusive, source to develop this part of the article.

40 In May 2003, the US and other delegations asked the DSB to have consultations with the European Community on the subject of the European moratorium of the marketing of GMOs.

41 Report of the 26th session of the Codex Commission of 30 June-7 July 2003.

42 The guidelines had to be ready by 2003.

43 The CCGP asked the CAC to adopt the Draft Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius at Step 8 of the Codex Procedure, for inclusion in the Procedural Manual. See ALINORM 03/26/06 in the Report of the 26th CAC meeting of 2003.

44 Report of the 14th meeting of the CCGP, 1999, par. 27.

the precautionary principle was immediately called into play. The main problematic issues were the following: should Codex lay down guidelines on this principle or should it leave this task to national authorities? A further related question was: how to respond to potential consumers' health situations where complete scientific data were not available? In other words: what kind of action should the CAC take when scientific data are insufficient? Should it adopt standards or should it refrain from doing so until it has sufficient scientific information? Consensus on the solutions to these questions proved to be very difficult.

The US and the EC had (and still have) diverging views on all issues highlighted above. This was evident since the first meeting of the CCGP in which the debate started (1999).

The European countries advocated the inclusion of the precautionary principles within the principles underlying risk management and supported the elaboration of guidelines on the use of the principle[45] since 'this was also essential to build the confidence of consumers in the risk analysis process and reflect that the protection of public health was the primary objective of Codex.'[46] The representative of the EC and other Codex members considered that uncertainty should not prevent necessary measures to protect public health. Sweden proposed the following draft principle clarifying the role of the precautionary principle within Codex:

> Lack of full scientific certainty shall not be used as a reason to delay measures intended to prevent adverse effects on human health from hazards present in food. When a preliminary risk assessment indicates a threat of adverse effects on human health from a hazard present in food, it is justifiable to take measures to prevent such effects without awaiting additional scientific data and a full risk assessment. Such measures should be proportionate to the potential health risk and should be kept under review.[47]

The delegation of the United States opposed the inclusion of the precautionary principle within the Codex working principles for two reasons: no internationally recognised definition was available and secondly 'a precautionary approach was already built in risk assessment; this concept should not be used by risk managers to overrule risk assessment.'[48] The American delegation recalled that Article 5.7 of the SPS Agreement already addressed the issue of insufficient scientific evidence.

At the 2000 meeting of the CCGP, held in Paris, the French representative, opening the meeting, emphasised that the precautionary principle should be regarded as an appropriate tool of risk management, provided that it was not used

45 Report of the 14th meeting of the CCGP, 1999, par. 29.

46 *Ibid*. See also Report of the 16th meeting of CCGP, 2001, par. 66.

47 Report of the 14th meeting of the CCGP, 1999, par. 28.

48 Report of the 14th meeting of the CCGP, 1999, par. 30.

as an excuse to establish unwarranted and arbitrary trade barriers.[49] The basis of the discussion was not the Swedish proposal but a text prepared by the delegation of the United States, the member countries of the European Community and several other delegations. The text described the use of precaution in taking risk management measures;[50] moreover, a footnote in the text indicated that this was referred to as the 'Precautionary Principle' in certain member countries.

Notwithstanding the extensive discussion[51] on the new draft, consensus was not achieved. Additional work was required on the text. A working group was convened on purpose.[52]

During the CCGP meeting of 2001 many delegations (Argentina, Bolivia, Paraguay and Uruguay) supported the deletion of any reference to the precautionary principle in the risk management principles claiming that it was not a principle of international law[53] and should not be mentioned as such in the framework of Codex; other delegations were against the precautionary principle because 'all necessary measures to protect consumers' health when scientific evidence was insufficient were covered by the SPS Agreement and that any additional reference could foster the use of precaution for the purpose of trade protection.'[54] Yet, detractors of the precautionary principle were counterbalanced by its traditional supporters. Meanwhile different proposals concerning precaution in risk analysis were put forward.[55]

Given the highly contentious nature of the debate, the Codex Commission was invited by the CCGP to clarify certain aspects of its mandate. Was it appropriate for the Codex to elaborate standards when scientific evidence was not sufficient? The Codex emphasised that 'precaution was and should remain an essential element of risk analysis in the formulation of national and international standards.'[56] It was felt

49 Report of the 15th meeting of the CCGP, 2000, par. 3.

50 The text was drafted as follows: When relevant scientific evidence is insufficient to objectively and fully assess risk from a hazard in food, and where there is reasonable evidence to suggest that adverse effects on human health may occur, but it is difficult to evaluate their nature and extent, it may be appropriate for risk managers to apply precaution through interim measures to protect the health of consumers without awaiting additional scientific data and a full risk assessment. However, additional information for a more objective risk assessment should be sought and the measures taken reviewed accordingly (within a reasonable time frame/until a more complete risk assessment is performed).

51 See par. 43-61.

52 Report of the 16th meeting of the CCGP, 2001, par. 52.

53 These were Argentina, Bolivia, Paraguay and Uruguay. See 16th CCGP meeting, par. 58.

54 Report of the 16th meeting of CCGP, 2001, par. 61.

55 See ALINORM 01/33A, Appendix IV of the report of the 16th meeting of the CCGP.

56 Report of the 24th meeting of the CAC, 2001, par. 77.

that the 'Codex Alimentarius Commission was the most appropriate forum to discuss this issue.'[57]

However, the views on the precautionary principle remained sharply divided during the 2001 CAC meeting. On the one hand, it was felt that the Commission should not elaborate 'standards and related texts' when data were insufficient, as Codex recommendations represented a reference at the international level and should be based on adequate scientific evidence. The situation was different at the national level, as governments had the possibility to take provisional measures to protect their population, as recognized under the SPS Agreement.[58] On the other hand, it was claimed that precaution had already been applied in Codex work, and that the Commission had adopted codes of practice and other recommendations when scientific data did not allow the establishment of a standard. Thus, Codex was required to make every effort to develop recommendations to protect consumers' health even when scientific evidence was insufficient.[59]

At the end of the 2001 meeting, the following compromise text was adopted, although consensus on it was dubious:

> When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as a code of practice, provided that such a text would be supported by the available scientific evidence.[60]

In the 2002 meeting of the CCGP, attempts were made to open the discussion on the agreed compromise.[61] Noting however that considerable effort had been made in achieving a consensus on this issue, the Committee agreed to retain the text as drafted.[62]

Finally in 2003, the CCGP submitted the Draft Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius to the Codex Commission, which endorsed them in July 2003. For our purposes, attention is demanded by paragraphs 10 and 11 of the section on 'risk analysis-general aspect:'[63]

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57 *Ibid.*

58 Report of the 24th meeting of the CAC, 2001, par. 80.

59 Report of the 24th meeting of the CAC, 2001, par. 81.

60 Many delegations supported this text as a compromise reflecting the need for a scientific basis while allowing for flexibility in the elaboration of 'related texts'. (Par. 82.) However, most of the members of the EC expressed reservations and the UK complained about the way in which the decision was made.

61 It was suggested to amend the paragraph dealing with precaution, in particular to delete the introductory sentence (Argentina) and to provide more detailed clarification on the nature of the risk and its potential public health consequences (USA). See report of the 17th meeting of 2002, par. 28.

62 Report of the 17th meeting of CCGP, 2002, par. 28.

63 See appendix I, ALINORM 26/06/ adopted at the 26th session of the CAC.

> 10. When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Codex Alimentarius Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as a code of practice, provided that such a text would be supported by the available scientific evidence.
>
> 11. Precaution is an inherent element of risk analysis. Many sources of uncertainty exist in the process of risk assessment and risk management of food related hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis. Where there is sufficient scientific evidence to allow Codex to proceed to elaborate a standard or related text, the assumptions used for the risk assessment and the risk management options selected should reflect the degree of uncertainty and the characteristics of the hazard.

What are the implications of these paragraphs for the Codex Commission's activity? Paragraph 10 serves to discourage the Codex Commission from adopting standards in situations of scientific uncertainty. At most, a code of practise may be adopted in these circumstances. This drafting reflects the view of the US and those other countries which are favourable to stick to the scientific evidence in taking risk management decisions.

Paragraph 11, first paragraph states the obvious: precaution is important in risk analysis. The second paragraph is convoluted and it has hardly any meaning; in any case, it does not offer valuable guidelines in situations of scientific uncertainty since it envisages a situation in which sufficient scientific evidence is available. This second paragraph appears to stress the need to reflect the degree of uncertainty in taking risk management options even when sufficient scientific evidence is available. Thus, it seems that the precautionary principle is here evoked with the same meaning as the proportionality principle. The precautionary principle, in the sense given to it by the members of the European Community, was lost somewhere, amongst the different texts which circulated within Codex Committees.

5.2 The Role of Factors Other than Science in Codex Decision-Making: Hidden Protectionism or Legitimate Concerns?

The Codex Commission is bound to adopt food standards on the basis of 'the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information.'[64] Sound scientific analysis is the tenet of Codex decision-making. However, the Codex Procedural Manual also provides that:

> When elaborating and deciding upon food standards, the Codex *Alimentarius* will have regard, where appropriate, to *other legitimate*

64 See the first statement of principles inspiring Codex decision making, were adopted by the Commission in 1995 (21st meeting of the Commission) and were included in the Appendix of the Manual of Procedure.

> *factors* (emphasis added) relevant for the health protection of consumers and for the promotion of fair practices in food trade.[65]

This statement is quite ambiguous since it is unclear what are 'the other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade.' The definition of these factors is important because they are capable of affecting the content of a standard—or even potentially impeding its adoption. Therefore, guidance was needed for the identification, management, application and interpretation of these factors.

In 1998 the CCGP started to discuss about the definition of these factors,[66] following the decision of the CAC to suspend 'consideration of the adoption of the MRLs for Bovine Somatotropin pending […] examination of the application of "other legitimate factors" in relation with BST by the CCGP.'[67] The BST is an hormone, increasing milk production, whose maximum level tolerable in milk was at the centre of discussions within the Codex Committee for the Residues of Veterinary Drugs in food. During this discussion, the need to consider other legitimate factors than science was invoked for the first time by the Codex members of the European Community.

A paper of the Secretariat[68] revealed that broad categories of 'other legitimate concerns' were potentially considered eligible to be considered in setting food standards. These were: economic sustainability, the lack of appropriate methods of analysis, technological need, technical feasibility, safety factors. Other specific factors, i.e. environmental risks, consumer concerns,[69] animal health and welfare, ethical/religious/ cultural factors[70] were mentioned by delegations on other occasions.

These factors were seen by certain delegations, in particular, those of the members of the European Community, as being essential in ensuring a wide acceptance of Codex standards. Other Codex members, in particular the US delegation, took the position that 'giving consideration to […] these factors could open a Pandora's box.'[71] Thus, the delegation of the United States, supported by

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65 Second statement of principles included in Appendix of the Manual of Procedure, see footnote 64.

66 Report of the 13th meeting of the CCGP, 1998, par. 59-70.

67 See the 22nd Report of the CAC, 1997, par. 67-68.

68 This is CX/GP/99/9. Reference to this paper is reported in D. Juke (2000) 'The Role of Science in International Food Standards', in *Food Control*, 11, 189.

69 See for example the opening of the 15th meeting of CCGP of 2000 in which the French representative emphasized that legitimate factors other than strictly scientific data could not be ignored by governments and that the development of world trade could not take place without having regard to the legitimate rights of consumers.

70 This category of OLFs was considered relevant by some delegations in adopting standards on food derived from biotechnology. See report of the first meeting of the *ad hoc* IGTF on food derived from biotechnology, of 14-17 March 2000, par. 15.

71 OECD (2000) *Food Safety and Quality: Trade Considerations*, p. 34.

other delegations, took a very restrictive view of these factors. The protection of interests which were not relevant to the protection of consumers' health and the promotion of fair practices in food trade was not within the mandate of Codex[72] and were likely to create barriers to trade.

As previously mentioned, the discussion on OLF started in the framework of the BST case. The US was in favour of adopting the MLRs of the BST whereas members of the European Community opposed it. The position of the EC was that consideration of other legitimate factors, such as the technological justification of using the hormone concerned, animal welfare[73] and consumer concerns[74] had to be considered when adopting the BST standard. Other delegations stressed that science-based risk assessment should be the determining factor when addressing a food safety issue such as the setting of MRLs for veterinary drugs.

No consensus on the application of OLFs in the case of BST was achieved. However, the EC asked and obtained[75] to suspend consideration of the adoption of the MRLs for Bovine Somatotropin pending re-evaluation of scientific data by JECFA[76] and the CCRVDF[77] and examination of the application of 'other legitimate factors'.[78]

In 1999, a general discussion on the role of OLFs in Codex decision-making was held at the 14th meeting of the CCGP with the view of setting out interpretative criteria of the Statements of Principle on the Role of Science and the Extent to which Other Factors are Taken into Account.

In this meeting, the conflict between the European countries and the delegation of the United States became apparent. The US expressed the view that the scientific basis of risk assessment was essential in the decision process and that the introduction of 'other factors' that are more appropriately considered at the national level was, by contrast, not appropriate within Codex. According to this delegation, environmental aspects did not fall within the Codex mandate. The delegation also pointed out that the precautionary principle should not be considered as one of these factors as it related to uncertainty, which was already addressed in the

72 Report of the 15th meeting of CCGP, 2000.

73 Reference was made to a potential reduction of animal immune defences and the risk of increased antibiotics use as a consequence. See 13th session ALINORM 99/33, September 1998.

74 Some consumers opposed the use of BST.

75 13th session ALINORM 99/33, September 1998.

76 Expert Committee on food additives and contaminants.

77 Codex Committee for the Residues of Veterinary Drug in Food.

78 The EC had enacted a moratorium on the use of BST in the European Union until the end of 1999.

framework of risk assessment. This position was supported by several countries and by the Observers.[79]

Amendments to the Manual of Procedure, laying down the conditions under which OLFs may be invoked, were discussed in 2000, during the 15th meeting of the CCGP and endorsed during the 16th session of 2001. Finally, the Codex Commission adopted the amendments at its 24th session. They were included in an appendix to the Procedural Manual entitled 'General Decisions of the Commission'[80] and listed as follows:

> a) When health and safety matters are concerned, the Statements of Principle Concerning the Role of Science and the Statements of Principle Relating to the Role of Food Safety Risk Assessment should be followed;
>
> b) Other legitimate factors relevant for health protection and fair trade practices may be identified in the risk management process, and risk managers should indicate how these factors affect the selection of risk management options and the development of standards, guidelines and related texts;
>
> c) Consideration of other factors should not affect the scientific basis of risk analysis; in this process, the separation between risk assessment and risk management should be respected, in order to ensure the scientific integrity of the risk assessment;
>
> d) It should be recognized that some legitimate concerns of governments when establishing their national legislation are not generally applicable or relevant world-wide;
>
> e) only those other factors which can be accepted on a world-wide basis, or on a regional basis in the case of regional standards and related texts, should be taken into account in the framework of Codex;
>
> f) The consideration of specific other factors in the development of risk management recommendations of the Codex Alimentarius Commission and its subsidiary bodies should be clearly documented, including the rationale for their integration, on a case-by-case basis;
>
> g) The feasibility of risk management options due to the nature and particular constraints of the production or processing methods, transport and storage, especially in developing countries, may be considered; concerns related to economic interests and trade issues in general should be substantiated by quantifiable data;
>
> h) The integration of other legitimate factors in risk management should not create unjustified barriers to trade; particular attention should be given to the impact on developing countries of the inclusion of such other factors.

79 Report of the 14th session of CCGP, 1999, ALINORM 99/33A.

80 Report of the 12th meeting of CCGP, November 1996.

The 2001 amendments to the Manual of Procedure make possible to invoke on a case-by case basis OLFs than science in risk management decisions. The very same fact that OLF than science can be invoked in risk management processes is a victory for the supporters of these factors and a loss for the US, which had unsuccessfully proposed that risk management was 'grounded on science-based risk assessment'.[81] Certainly, the use of OLFs in Codex decision-making is constrained in many respects. Firstly, 'Consideration of other factors should not affect the scientific basis of risk analysis.' This means that in case the inclusion of OLFs conflicts with scientific evidence, they are not to be taken into consideration in Codex standards. Otherwise, these factors could be used for protectionist purposes. Secondly, these factors should not excessively restrict trade and should be accepted on a world-wide basis. Thirdly, factors which are only recognised at national level cannot be invoked in the adoption of Codex standards. Finally, reliance on OLFs should not have an impact on developing countries.

It is quite disappointing that no consensus was reached on the exemplification of factors (relevant for health protection and fair trade practices). The CCGP proposed to include certain factors if they were included in recommendations of relevant multilateral intergovernmental organizations.[82] Along this line, Sweden suggested that 'concerns relating to the environment, animal and plant health and animal welfare' were taken into account 'if international requirements or recommendations of the competent international fora' existed.[83] However, this proposal was rejected.

So far, these OLFs have never been taken into consideration explicitly in the adoption of a Codex standard. However, the acknowledgement that OLFs can be invoked when adopting food standards has now encouraged some Codex Members to ask that these factors be taken into consideration in specific cases. For example, the need to identify OLFs related to modern biotechnology was identified at the end of the work of the *ad hoc* Task Force on food derived from biotechnology.[84] This means that the debate on this notion is not ended and delegations will come back on its meaning in the future.

5.3 Recent Conflicting Views on Food Derived from Biotechnology

Divergent views on the conditions allowing the marketing of food derived from biotechnology surfaced in various Codex committees (CCFICS, CCFL) and within an Inter-governmental *ad hoc* Task Force on food derived from biotechnology

81 *Ibid* par. 33.

82 Report of the 16th meeting of CCGP, 2001, par. 95.

83 Report of the 16th meeting of CCGP, 2001.

84 Fourth report of the *ad hoc* Task Force on food derived from biotechnology, 2003, par. 82.

(hereafter 'Task Force' or 'IGTF'), set up by the CAC in 1999 to discuss about food standards in this sector.

a) Labelling Food Derived from Biotechnology: A Trade Barrier or a Means to Inform Consumers?

In 1991 the CAC agreed that work on the safety, labelling and nutrition aspects of biotechnology, being undertaken by relevant Committees.[85] The CCFL was entrusted with the task of developing the labelling aspects of biotechnology. This Committee has discussed about the definition of key-terms (i.e. what are food or food ingredients obtained through certain techniques of genetic modifications/genetic engineering), the objective and the scope of labelling requirements of food derived from biotechnology since 1996. Attention is drawn here on the debate considering the need to label biotech products.

It is still early to evaluate the choices made by the CCFL on labelling since, this committee has only agreed 'draft guidelines for the labelling of food and food ingredients obtained through certain techniques of genetic modifications/genetic engineering' in the last meeting of 2002.[86] However, it is certainly possible to emphasise the most important points in the debate.

So far no consensus on labelling options has been reached because the US delegation and European Codex members have different positions. The former considers that the Codex Commission should limit itself to lay down voluntary labelling indications, embracing food derived from biotechnology to the extent that it 'differs substantially' from conventional food. Food derived from biotechnology which is not substantially different from its conventional counterpart should not be labelled.[87] The US did not want to consent to labelling based on the method of production.[88]

By contrast, the latter prefer comprehensive labelling obligations, which apply systematically to all categories of food derived from biotechnology,[89] including food produced from GMOs when it is not 'substantially equivalent' to conventional food. It should be noted that the EC internal legislation goes further than the position taken by the Codex members of the European Community within the relevant Codex Committees. The Council has recently approved a piece of

85 Report of the 25th meeting of the CCFL, APPENDIX VI - Proposed Draft Recommendations for the Labelling of Food Obtained through Biotechnology, par. 1.

86 ALINORM 03/22, Appendix IV, Report of the 30th meeting of the CCFL, 2002. During the last meeting of the CCFL in 2003, this committee agreed to postpone the discussion on this point to the next session of the committee. See point 74 of Report of the 31st meeting of the CCFL, 2003.

87 Report of the 27th meeting of CCFL, 1999, par. 41.

88 Report of 30th meeting of the CCFL, 2002, par. 52.

89 Report of the 27th meeting of CCFL, 1999, par. 43.

legislation[90] which extends labelling to all food containing or consisting of GMOs and produced from GMOs, irrespective of the equivalence or differences of this GM food with respect to existing ones.

The European Codex members argue that the objective of labelling food obtained through techniques of genetic modification is to inform consumers of the origin and nature of the foods which they purchase. Indeed, adequate labelling is crucial to gain consumer's confidence.[91] In particular, European consumers want to know whether the food that they buy derives from GMO or not; thus, labelling need to be as much comprehensive as possible. According to the US delegation, it is not necessary to inform consumers when food derived from biotechnology is equivalent to existing food, otherwise the impression can be given that the products concerned are unsafe and ultimately consumers are misled. This debate clearly echoes the discussion on the role of OLFs, ie consumer preferences, in the adoption of Codex standards.

b) Product Tracing of Food Derived from Biotechnology: An Unnecessary and Costly Burden or an Essential Risk Management Tool to Gain Consumer's Confidence?

The most recent bone of contention between the US and EC is the definition of traceability, which has been discussed within the Task Force since its first meeting in 2000.[92] The concept of traceability was known to the Codex Commission,[93] although 'it had not been treated in a systematic manner.'[94] However, the Codex Commission had never embarked on a discussion on this issue in the context of foods derived from biotechnology. Thus, the development of guidelines on the monitoring and traceability of food derived from biotechnology became a priority in the works of the Task Force.[95]

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90 This is the Regulation on genetically modified food and feed, which was finalised end of July 2003.

91 Report of the 30th meeting of CCFL, 2002, par. 42.

92 Initially, the Task Force agreed to have a better understanding of the meaning and implications of this concept, which was considered as a horizontal issue potentially interesting all Codex activities, by involving in the discussion other Committees. These are the CCGP, CCFL and CCFICS. The US wanted traceability to be considered within CCFICS, whereas the Codex members of the European Community favoured consideration of this matter within the CCGP.

93 France reports in its paper on traceability that an ISO standard defined traceability as 'the ability for the retrieval of the history and use or location of an article or an activity through a registered identification'. See point 8 of the discussion paper, in CX/FBT 01/6, Report of the 2nd meeting of the *ad hoc* Task Force on food derived from biotecnhlogy.

94 Report of the 49th meeting of the executive committee, 2001, par. 29.

95 Report of the first meeting of the *ad hoc* Task Force on foods derived from biotechnology, Chiba, 2000, par. 18.

The Codex Members of the European Community exercised pressure to introduce this concept within the principles on risk analysis of foods derived from biotechnology and eventually they obtained a partial success, as we will see *infra*.[96]

What is a traceability system? It is a 'mechanism providing a continuous flow of information, allowing the retrieval of the history and of the origin of a product at any point in the food chain;'[97] it consists in placing unique identifiers on products and in setting up a system of registration of products.

In its broadest definition, traceability is a risk management tool, serving two purposes. The first is to make easy the recall of products from the market, in case they are found to be hazardous for human health, following their placing on the market. Using WTO jargon, a measure imposing traceability requirements, for the purpose described above, is an SPS measure because it has a food safety objective. The second function of a traceability system is related to consumer information; indeed, by making products identifiable, a traceability system allows to verify the authenticity of labelling claims, thus guaranteeing consumers that the information stated on the label is correct.[98] A measure promoting this second objective of a traceability system, i.e. consumers information, would be considered a TBT measure, fulfilling a legitimate objective.

The definition of traceability just described reflects the European position, which was illustrated in a circular letter presented by France to the Task force in 2002.[99] This position is consistent with recent initiatives of reform of the European GM food legislation, which placed great emphasis on the functioning of a traceability system.[100]

The US and other delegations strenuously opposed the European approach to traceability. The US claimed that the issue of traceability was not unique to foods derived from biotechnology.[101] Hence, there was no need to include this concept within the principles of risk analysis of foods derived from biotechnology. However, when they realised that there was consensus[102] on the inclusion of

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96 Report of the 26th meeting of the Codex Alimentarius Commission, 30 June-7 July 2003, forthcoming.

97 Report of the second meeting of the intergovernmental *ad hoc* Task Force on food derived from biotechnology, 2001, par. 34.

98 This is why traceability was also discussed within the CCFL. See for example report of the 25th meeting of the CCFL of 2002, par. 4-9.

99 See CX/FBT 01/6 Discussion Paper on Traceability above No. 93.

100 In 2001, the Commission put forward a proposal centred on the treaceability of GMOs. See COM (2001) 182.

101 Report of the third meeting of the Task Force on biotechnology-derived foods, March 2002, par. 24.

102 In addition, the Executive Committee, which was asked guidelines on the scope of traceability, agreed to retain both aspects of traceability, even if first consideration had to be

traceability within these principles, they attempted to circumscribe the scope of this notion as much as possible. While supporting the use of 'product tracing'[103] for the purpose of public health, the US did not agree on the application of this concept to the labelling of food derived from biotechnology.[104]

The tracing of products was included as a possible risk management option during the second meeting of the Task Force (2001).[105] The scope of traceability was finally settled through a 'Solomon-like solution,' achieved at the third meeting of the Task Force (2002). It was agreed to include tracing of products amongst the 'tools facilitating the implementation and enforcement of risk management measures, without prejudice to its use for other purposes (that is to say to for labelling purposes).'[106] This was a partial success for the European Codex delegations.

The most thorny issue remained the provision of a definition of traceability/ product tracing which was acceptable to all Codex members. An open discussion on traceability was required for this purpose and it was held during the fourth meeting of the Task Force (2003).

In the course of the debate the US fully displayed arguments against traceability requirements for foods derived from biotechnology, as proposed by France in 2002.[107] The US objected to the definition of traceability provided by France. Mandatory product tracing requirements are necessary when public health is at risk. 'The need for traceback for other than public reasons should be driven by market forces.'[108] The US support the use of product tracing to the extent that this implies tracing products 'one step back and one step forward'[109] in the food chain—as opposed to ensure product tracing at all stages of the food chain—in compliance

(*contd.*)

given to traceability as a risk management option in the working principles for risk analysis. See Report of the 49th meeting of the executive committee, September 2001, par. 31. See also Report of the 50th meeting of the executive committee, 2002, par. 48.

103 The US considered the meaning of 'product tracing' more restricted than that of traceability and in the discussion preferred to use the former term. However, the terms were used interchangeably since 2001.

104 Report of the 4th meeting of the IGTF, 2003, par. 68.

105 See par. 21 in Appendix II, Report of the second meeting of the Task Force in 2001. Paragraph 21 (retained in the final version of the principles) states: 'Specific tools may be needed to facilitate the implementation and enforcement of risk management measures. These may include appropriate analytical methods; reference materials; and, the tracing of products for the purpose of facilitating withdrawal from the market when a risk to human health has been identified or to support post-market monitoring in circumstances as indicated in paragraph 20.'

106 See Report of the 3rd meeting of the IGTF, 2002, par. 27. Tracing of products is mentioned in paragraph 21 of the principles of risk analysis of foods derived from biotechnology.

107 See the comprehensive paper presented by the US, CX/FBT, CRD 9.

108 See the document CX/FBT, CRB 9, p. 6, presented at the 4th meeting of the IGTF, 2003.

109 This means to allow the identification of the immediate previous sources and the immediate subsequent recipients of food. See the document CX/FBT, CRB 9, p. 2.

with the choice made by the Food and Drug Administration for the proposed domestic legislation on food.[110]

The US put forward several reasons against the inclusion of traceabilty within the principles inspiring foods derived from biotechnology. 'Safe bio-engineered food'[111] is not inherently unsafe since it has been reviewed for safety before marketing; thus the use of traceability to inform consumers is a costly requirement, which is not justified unless there is a clear public health justification. Moreover, traceability requirements are certainly very burdensome for developing countries.[112] The US disagreed with the European position that the cost implications of product tracing were not significant.[113] The use of product tracing as an instrument to monitor the unintended effects of foods derived from biotechnology should be determined on a case by case basis and employed in exceptional cases related to human health concerns;[114] as to the use of traceability to preserve the identity of products, the US argued that this issue concerns private commercial relationships rather than the Codex.[115]

It should be noted that it has hitherto been impossible to agree on a Codex definition of traceability. However, a consensus was reached as to the need of developing such a definition.[116] This is left to future work of the CCGP.

6. Possible Conclusions

What lessons may be drawn from the conflicts between the US and the Codex members of the European Community? Is there an added value in discussing and attempting to settle these conflicts within the Codex Alimentarius Commission? Three points may be noted:

- After lengthy discussions, these conflicts led to poor compromises, which do not have practical impact on the activity of the Codex Commission. This is the case of the conflict on the precautionary principle.
- Discussion of controversial issues within the CAC does not seem to have any positive effect in preventing WTO litigation. The setting out of MLRs of hormones in beef was debated for many

110 Report of the 4th meeting of the IGTF, 2003, par. 68.

111 See the document CX/FBT, CRB 9, p. 5.

112 See the document CX/FBT, CRB 9, p. 5. Developing countries indeed oppose the use of traceability.

113 See the document CX/FBT, CRB 9, p. 8.

114 See the document CX/FBT, CRB 9, p. 6.

115 See the document CX/FBT, CRB 9, p. 6.

116 Report of the 18th meeting of the CCGP, April 2003, par. 97.

years within several Codex Committees but eventually the impossibility to reconcile the positions of the European Community and the US led the latter to trigger the DSB procedure. Very recently, the US has asked for consultations with the European Community in order to unblock the authorisation process for the marketing of GMOs. Therefore, notwithstanding the attempts to harmonise Euro-American positions on labelling and traceability of foods derived from biotechnology, the US will challenge the European GMOs legislation before the DSB.

– Sometimes the Euro-American conflicts brought about clarifications, as it happened when the conditions, upon which OLFs may be invoked in the adoption of standards, were endorsed. However, so far these clarifications were not relied upon in any specific case.

Two alternative conclusions may be drawn from the Euro-American conflicts described in previous sections. The first is that the Codex Commission is not a suitable arena to settle politically sensitive issues or find compromises on them. Discussing about these issues within Codex is just a vain attempt to 'reconcile the irreconcilable' and sooner or later the intervention of a judicial body will become necessary. The hormone-in-beef case and the likely WTO dispute on the European moratorium on GMOs support this conclusion. The Codex's poor capacity to settle very controversial issues questions the very need of having a Codex Alimentarius Commission.

The second and opposite conclusion does not place emphasis on the Codex Commission's (in)ability to solve politically sensitive issues—this is not the Codex Commission's role—but rather on the fact that the Codex Commission provides a useful and world-wide forum to debate about issues upon which the positions of delegations are very far apart. This opportunity is highly appreciated by Codex members, as is shown by the interest manifested by the European Commission in acceding to the CAC.

Chapter 6

Enlarging the EU Food Safety Regime: Selected Problems in Adjusting the Polish Food Safety Regime to EU Food Safety Requirements

Aleksander Surdej

What they are short of is imagination
Officialdom can never cope
with something really catastrophic.
(Albert Camus, *The Plague*)

1. Introduction: The Growing Internationalization of Food Safety Regulations

Public regulations regarding the production, transportation and sale of food are by no means an invention of contemporary governments receptive to the pressure of wealthy citizens susceptible to food scares. Rather, they go at least as far back as to ancient Athens, where beer and wines were inspected for purity and soundness, while the Romans had a well-organized state food control system to protect consumers from fraud or bad produce. In medieval Europe individual countries passed laws concerning the quality and safety of eggs, sausages, cheese, beer, wine and bread. Some of these ancient statutes still exist today.[1]

1 This paragraph has been drawn from the information contained in the text 'Origins of the Codex Alimentarius' from http://www.fao.org/docrep/W9114E/W91114e03.htm.

Initially food quality and safety legislations were a purely local matter. By the late nineteenth century, however, leading countries had adopted general food laws and established law enforcement inspections; food safety regulations had thus become national in scope. The multi-ethnic (if not multi-national) nature of some of the large imperial states made them precursors of modern attempts at internationalization of food safety regulations as their food safety legislation had to take into consideration different production techniques and different consumer tastes. Thus, for instance, between 1897 and 1911 the Austro-Hungarian Empire developed a series of standards and product descriptions for a wide variety of foods, known as the *Codex Alimentarius Austriacus*, which, although lacking legal force, was used as a reference by the Empire's courts to determine standards of identity for specific foods. The present day FAO/WHO *Codex Alimentarius* draws its name from this Austro-Hungarian code.

For a long time food safety regulations seemed to be first and foremost a policy response to domestic public health problems, but with the intensification of international trade in foods the threats to public health also increased. International trade in foods predates modern times, but until the end of 1800s such trade was limited in quantity and variety. Large-scale imports of products from exotic countries started in the mid-1800s when bananas were first shipped to Europe from the tropics. In the late 1800s long-distance food transportation started with the first shipments of frozen meat from Australia and New Zealand to the United Kingdom.

Today international trade in foods amounts to 10 percent of the world food production. In 2000 in the group of most developed countries (the OECD area) import penetration of food reached 20 percent showing a steep rise from 7 percent in 1992. The 1990s was a period of rapid growth of international trade in food, but it was, to a large extent, an increase of food trade within the OECD area. In the future, however, a fast growth of share of less developed countries in the international food trade is forecast as the index of their food auto-sufficiency decreased from 97 percent in the 1960s, to 91 percent in the late 1990s and is expected to fall further to approximately 89 percent by 2010. International food trade is likely to grow since there will be an increasing mismatch between areas of food abundance and areas of food shortages.[2]

Food safety regulations are really risk regulations in that they are rules issued by the public authority to reduce the threat to people's health stemming from consumption or from contact with contaminated foods. Unlike selected environmental regulations which can produce international negative externalities, domestic food regulations cannot directly affect other countries unless food is internationally traded and physically transported. It might seem thus that food safety is a domain of easy international regulatory co-operation, in which food

2 International trade in food grows also in response to the need for food variety.

safety standards are mutually recognized, found equivalent in outcomes or even internationally harmonized.

Protecting one's own citizens against risks stemming from the consumption of imported unsafe food is possible unilaterally, but at high costs of intensive border controls and possibly diminished food variety. A better solution would be to create bilateral or multilateral arrangements assuring a minimal level of convergence in food safety regulations and their implementation within a food trading area.

The latter would reduce international trade conflicts when spontaneously (in response to emergency situations) or strategically (that is out of intent to exploit regulations to gain advantage over other countries) countries create domestic regulations which can be considered as technical barriers (invisible tariffs)[3] to trade in foods.

Even if universalism of science seems to guarantee the common definition of health threats stemming from food consumption, an international regulatory harmony in the domain of food safety is undermined by three main factors: the intrinsic uncertainty of scientific knowledge about the long term-effects of the consumption of certain foods; public perception of existing threats; and the costs of effectively protecting citizens against food safety risks.

The international dimension of food safety was recognized a long time ago. The first international regulatory initiatives in the area started at the beginning of the twentieth century. Today international sanitary and phytosanitary standards are being developed by three international organizations: *the Codex Alimentarius Commission*; the International Office of Epizootics; and the International Plant Protection Convention. The conformity of national standards with the standards set by these organizations protects from legal challenges under the World Trade Organization (WTO) rules, making it beneficial for countries to maintain these standards, unless they consider them too low or want to use food safety regulations for strategic trade purposes even at the cost of being challenged in the WTO.

International regulatory bodies take the lead in elaborating basic (minimum) food safety standards. Other, be they regional or national, standards can exceed these standards only if a country or a regional grouping can show scientific evidence in support of such stricter rules. But even if food safety rules are widely accepted as appropriate, they might not be evenly applied, thus creating a food safety risk. It seems that as an open challenge to international food safety standards is becoming increasingly difficult, international disputes over food safety risks are tending to move to the area of the proper implementation of international standards.[4]

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3 The term invisible tariffs was first used by Percy Bidwell (1939) *The Invisible Tariff,* New York: Council of Foreign Relations.

4 This line of argument has been tried by the EU in the WTO case regarding beef hormones, where the EU pointed to the danger of hormone abuse by cattle ranchers, even if the Codex

The issue of properly enforcing the implementation of regulatory rules becomes crucial both in the construction of the European Union food safety regime and in evaluating the impact of the ongoing enlargement on the EU food safety regime.

2. Food Safety Regulations: Problems and Methods

It is a widely shared opinion that regulating food out of concern for health and environment is a difficult task due to the interplay of scientific uncertainties and risky human comportment.[5] In what follows no attempt is made to give a comprehensive picture of these difficulties: issues have been chosen because of their relevance to the discussion of the impact of the ongoing enlargement on the EU food safety regime.

2.1 Basic Concepts Related to Food Safety

What is a safe food? An answer to this seemingly easy question can be stated only in general terms such as 'a safe food is one that does not cause harm to the consumer when it is prepared and/or eaten according to its intended use'[6]. The safety of food is thus not an intrinsic feature of food, but a product of food's characteristics and the ways food is handled.

At the very general level food-related health problems can be divided into those resulting from microbiological and chemical hazards.[7]

At the origin of health problems resulting from microbiological hazards there is a propagation in food of micro-organisms like *Salmonella spp., Campylobacter jejuni, Listeria monocytogenes or E. coli 0157.*[8] Sound comparative international

(*contd.)*

Alimentarius studies are right that hormones are 'safe' when used in accordance with good veterinary practices (See Alan O. Sykes [2002] 'Exploring the Need for International Harmonization: domestic regulation, sovereignty, and scientific evidence requirements: a pessimistic view', in *Chicago Journal of International Law*, Fall.).

5 See, for instance, section 1 of the book edited by Julian Morris and Roger Bate (1999) *Fearing Food: Risk, Health and Environment,* Butterworth Heineman.

6 R. B. Tompkin (2001) 'Interactions between government and industry food safety activities', in *Food Control*, No. 2.

7 The major breakthrough in ensuring food safety arrived with the birth of modern chemistry in the nineteenth century. Its development created a scientific base for modern food safety controls, as it allowed the understanding of the chemical parameters of food composition. Science began to provide tools with which it was possible to disclose dishonest practices in the sale of food and to distinguish between safe and unsafe edible products.

8 *Salmonella* is a rod-shaped, motile bacterium—nonmotile exceptions *S. gallinarum* and *S. pullorum*—, nonsporeforming and Gram-negative. There is a widespread occurrence in animals, especially in poultry and swine. Environmental sources of the organism include water, soil, insects, factory surfaces, kitchen surfaces, animal faeces, raw meats, raw poultry, and raw seafoods, to name only a few. *Campylobacter jejuni* is a Gram-negative slender, curved, and motile rod. It is a microaerophilic organism, which means it has a requirement

statistics of the scale of microbiological hazards does not exist as incidence rates of microbiologically caused foodborne diseases (MCFD) are reported according to different national definitions and diagnostic systems.[9] Despite popular beliefs that microbiological hazards haunt only civilizationally backward societies, MCFD never fully disappear in any society and once control measures and public awareness to the risk are weakened, they can reemerge as local or regional epidemics, as happened in Latvia and Lithuania between 1985 and 1992 and in the Czech Republic or Hungary between 1995-97.[10]

Although it is impossible to achieve zero risk, controlling practices aimed at the identification and elimination of MCFD should target as closely as possible the state of no('zero')-microbiological contamination, as in favorable conditions micro-organisms rapidly multiply and might threaten human health. MCFD regulations are thus an example of situations in which regulation attempts to eradicate the threat.[11]

Health problems can also be due to chemical contaminants in foods. Chemical contaminants in foods include natural toxicants such as mycotoxins, environmental contaminants such as dioxins, mercury, lead or food additives, pesticide and veterinary drugs.

The contamination of food by chemical hazards is a major public health concern in Europe. The use of various chemicals (like food additives, pesticides, veterinary drugs and other agrochemical substances) is comprehensively regulated and controlled by state inspections.

(*contd.)*

for reduced levels of oxygen. It is relatively fragile, and sensitive to environmental stresses (e.g., 21 percent oxygen, drying, heating, disinfectants, acidic conditions). *Listeria monocytogenes* is a motile by means of flagella. Some studies suggest that 1-10 percent of humans may be intestinal carriers of *L. monocytogenes*. It has been found in at least 37 mammalian species, both domestic and feral, as well as at least 17 species of birds and possibly some species of fish and shellfish. *E. coli* is a normal inhabitant of the intestines of all animals, including humans. When aerobic culture methods are used, *E. coli* is the dominant species found in faeces. Normally *E. coli* serves a useful function in the body by suppressing the growth of harmful bacterial species and by synthesizing appreciable amounts of vitamins. A minority of *E. coli* strains are capable of causing human illness (Source: US FDA).

9 One could thus postulate the harmonization of the format in which the data about foodborne diseases are collected and reported.

10 Cristina Tirado, WHO (2002) *Statistical Information on Food-Borne Disease in Europe: Microbiological and Chemical Hazards*, a paper to the FAO/WHO Pan-European Conference on Food Safety and Quality, Budapest, February.

11 But, for instance, USDA applies 'zero-tolerance' policy to the detection of *L. monocytogenes* in ready-to-eat products, whereas countries such as Canada and Denmark have a 'non-zero tolerance' for *L. monocytogenes* for some classes of foods. (See the website of 'Health Canada' http://www.hc-sc.gc.ca/english/index.html.)

Chemical hazards to food might result as, for instance, in Western Europe from the 'industrialization' of agriculture production, but they might also results as, for instance in Central and Eastern Europe, mostly from industrial contamination of air, soil and water.[12]

Scientific analytical methods can usually establish the thresholds of non-harming doses of agrochemicals in food. But despite the existence of comprehensive regulations and precise standards, it is not possible to exclude the re-appearance of cases like that in Spain when in 1981-1982 rape seed oil denatured with aniline killed more than 1,000 people and disabled another 25,000.[13] In the Spanish case, the agent responsible was never identified despite intensive investigations.[14]

2.2 The Role of Scientific Evidence in Making Food Safety Regulations

The safety effects of food hazards need to be cautiously and credibly assessed. This depends first and foremost on scientific and technological progress, but also on procedural and institutional factors. The accent on scientific evidence results from the search for objective, scientific truth (science is expected to establish certain knowledge whether and how a given microorganism can harm health) and from an attempt to discipline regulatory rulemaking by demanding scientific justification for any regulatory decision.

Scientific proof is supplied by mainstream science based on reasoning from the experimental evidence.[15] The minority scientific views do, of course, matter, but only when they bring with them convincing evidence. And if they are convincing, in a normal scientific development, they are expected to become a part of new mainstream views.[16]

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12 The use of fertilizers and pesticides is several times lower in Poland than in the EU countries. See *Rolnictwo i gospodarka zywnosciowa w Polsce w aspekcie integracji z Unia Europejska,* Report of the Polish Ministry of Agriculture, Warsaw, 2002, p. 13.

13 See The Guardian Weekend, 25 August 2001, http://education.guardian.co.uk/higher/research/story/0,9865,542111,00.html.

14 According to the data from the US Centers for Disease Control and Prevention estimate 76 million gastrointestinal illnesses, 325,000 serious illnesses and 5,000 deaths each year from foodborne illness in the United States. The economic impact resulting from medical costs and productivity losses for diseases caused by five key foodborne bacterial pathogens totals $8.3 billion annually—see Thomas J. Billy (2002) 'HACCP—a work in progress', in *Food Control*, 13, p. 359-362.

15 No serious scientist would subscribe to the radically sociological view on science expressed, for instance, by Bruno Latour, who, according to Sokal and Bricmont (Alan Sokal, Jean Bricmont [1998] *Fashionable Nonsense: Postmodern Intellectuals' Abuse of Science* Piccador), challenged as anachronistic the report of French scientists who examined the mummy of Ramses II and declared that the pharaoh had died of tuberculosis, because the tuberculosis bacillus came into existence only when Robert Koch discovered it in 1882.

16 'An interpretation that accepts the minority opinions of consultants as "risk assessment" effectively converts scientific evidence requirements into minimal procedural hurdles that can

The requirement to present scientific proofs for food safety regulations serves, as was, for instance, expressed in the WTO SPS (Phytosanitary Protocol), to limit, if not to exclude, the instances of the arbitrary use of food safety regulations to protect domestic producers from foreign competition. Food safety regulations should not become technical barriers to trade, nor be a part of the strategic use of regulations.[17]

Strictly speaking food safety regulations, if applied equally to domestic and foreign producers, are not *a discriminatory measure*, but can still be called *protectionist measures* since they might increase rivals' costs as domestic producers are usually better suited to meet them.[18]

Uncertainty intrinsic to many scientific results should not serve as an easy justification for the introduction of tighter food safety regulations. Science-based regulatory making is contested not because of the knowledge of scientific disputes, but because the refutation to accept scientific arguments often serves to exploit ignorance, misunderstandings, people's desire to return to nature and irrational fears so common in contemporary societies which want to enjoy the benefits of technological progress without incurring its risks.

2.3 The Public Quest for Safety: Public Expectations and Regulatory Feasibility

No scientific evidence matters if citizens are frightened enough by influential books, other publications or the media.[19] This case is best illustrated by a ban on the pesticide DDT introduced in the US in 1972 in the wake of a book by an influential American media person, Rachel Carson, entitled 'Silent Spring'. The ban was introduced despite numerous scientific testimonies which concluded that:

> DDT is not a carcinogenic hazard to man... DDT is not a mutagenic or teratogenic hazard to man… The use of DDT under the regulations involved here does not have a deleterious effect on freshwater fish, estuarine organisms, wild birds or other wildlife.[20]

Governments want to reassure their citizens about food safety risks. But they face difficulties in conveying the simple message that food safety is always a matter

(*contd.*)

be met easily by any determined regulators, high-minded and protectionists alike' introducing into an international trade system the element of American tort system with its high litigiosity (Alan O. Sykes [2002] 'Exploring the Need for International Harmonization: Domestics Regulation, Sovereignty and Scientific Evidence Requirements: A Pessimistic View', in *Chicago Journal of International Law*, Fall).

17 See David Orden and Donna Roberts (eds.) (1997) *Understanding Technical Barriers to Agriculture Trade* The International Agricultural Trade Research Consortium.

18 They can, for instance, not apply hormone treatment of animals and the ban on it does not affect them.

19 See Joanne Cantor (2002) 'Fright Reactions to Mass Media', in Jennings Bryant, Dolf Zillmann (2002) *Media Effects: Advances in Theory and Research,* LEA Publishers: London.

20 See *The DDT Ban* By Steven Milloy, Copyright 2000 Junkscience.com, January 1, 2000, http://www.junkscience.com/jan00/century.htm

of degree, that risks are lower or higher, but there is no world of zero risk. For this reason even 'The FDA does not state that American food is so safe that only 1 in 10 million Americans will be killed by bacteria contamination, but rather it declares that food is safe and makes unqualified commitments to maintaining this safety'.[21]

People do react to what might be called an emotive side of food safety issues, and this reaction is strengthened by the fact that health is central to other personal values, that the majority of risks to health cannot be organoleptically identified, and that the causes of these risks are difficult to understand for a layman. What seems to matter for people's attitudes to food-related health risk is not so much the nature of risk as the dimensions that characterize the risks.[22]

The outcomes of psychological research indicate that attitudes towards risk (these attitudes can be placed on the axis from risk-proness to risk-averseness) depend on the following risk descriptors:

- Whether risk is taken voluntarily or involuntarily;
- Whether the effects of exposure to risk are felt immediately or with a delay (this delay can sometimes be an intergenerational one);[23]
- Whether the risk is concentrated in space or diffused;
- Whether the risk is catastrophic or it is a recurrent risk;[24]
- Whether the risk is one of mortality or one of illness (morbidity).[25]

The high scare factor of foodborne risks makes food safety regulations dependent on today's public opinion pressures, which might make them ill-targeted and thus ineffective and inefficient. 'Smart risk regulation' cannot be passed or implemented in the havoc of media-induced food panic. Risk regulation should be based, as is argued by Cass R. Sunstein, on science and procedures requiring a comprehensive analysis of its costs and benefits.[26]

2.4 Approaches to Risk Regulation

Approaches to risk regulation can crudely be divided into a technological and economic approach. In principle the two could go together, but there is often a strong tension between them.

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21 Richard J. Zeckhauser, W. Kip Viscusi (1996) 'The Risk Management Dilemma', in *The Annals of the American Academy of Political and Social Sciences*, May.

22 That it might derive from the consumption of food.

23 As J.M. Keynes used to say 'Long run is a misleading guide to current affairs. In the long run we are all dead', in 'A Tract on Monetary Reform', chapter 3, London 1924.

24 That is, it happens once.

25 Adapted from Paul Slovic (2000) *The Perception of Risk,* Earthscan, p. 173.

26 Cass R. Sunstein (2002) *Risk and reason: safety, law and the environment,* New York, NY: Cambridge University Press.

The technological approach to risk regulation seeks, as its name suggests, to find a technical solution to all health and safety risks. It applies technical devices to risk-bearing equipment and technical controls to risk situations. This approach usually does not take into account either the changes in the behavior of individual risk-takers, or the cost tradeoffs. It tends to be preferred by governments of rich and risk-averse societies.

The economic approach to risk regulation starts from an assumption that the proper role of the government is not to eliminate the risk, but to attenuate market failures which cause an inefficient balance between risk reduction and its costs. When drafting a regulation, public authorities should identify cases in which regulation can generate more benefits to society than the costs incurred due to the regulatory intervention and to regulate only when a draft regulation passes this test.

The technological approach to risk regulation favors specification standards, which specify the technology that a firm must use, whereas the economic approach tends to favor performance standards which impose the requirements that a firm must achieve a specified level of product quality (safety) without specifying the technology that must be used to achieve the standard.[27] Generally, policy analysts argue that, whenever possible, it is better to rely on performance standards than on specification standards as the former give firms a chance to find the most efficient way to conform to the standard.[28]

2.5 Regulatory Trade-Offs: Safety Effects of Regulation Induced Wealth Changes

Regulations impose costs on food producers and distributors. These costs are called *compliance costs* and they are measured as the change (an increase) in the costs of production induced by compliance with the performance (or specification) standard imposed by the regulator.[29]

Usually regulatory costs are justified by a reference to expected benefits from regulation in the form of a decreased rate of mortality or a decreased rate of morbidity. But, as Joseph M. Antle noted, the balancing of regulatory costs and

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27 The typology of standards has been developed by Anthony Ogus in his (1994) *Regulation: legal form and economic theory,* Oxford: Oxford University Press.

28 See the discussion in: Paulette L. Stenzel (2000) 'Can the ISO 14000 Series Environmental Management Standards Provide a Viable Alternative to Government Regulation?', in *American Business Law Journal*, Winter.

29 Other costs resulting from food safety regulations include: court imposed fines; the cost of civil damages awarded to downstream users, including final consumers; reduced revenues due to the loss of reputation and 'goodwill' arising from adverse publicity; the costs of product recalls; the costs of investigating possible negligence by a supplier and the costs of legal services (legal fees).

benefits is not an easy task, as the calculation of benefits is based on several uncertain assumptions:

> The goal of statutory food safety regulation is to mandate that firms produce higher quality, i.e. safer, products for consumers. The key reason why it is difficult to design regulations to do this, and why it is difficult to measure the benefits and costs of these regulations, is that food safety itself is difficult to measure. Information about the various quality attributes of food products is imperfect for consumers, producers, government regulators, and researchers, and this is particularly true when microbial pathogens are involved. These pathogens cannot be readily observed or tested in the production process, and their health effects are often difficult for consumers to identify after a food product is consumed. Thus, a key challenge in modeling and measuring the benefits and costs of food safety regulation is to devise methods that can make the best use of the limited and imperfect data that are available. As recent experience in the United States with regulatory impact assessment shows, the data that are currently available provide, at best, highly uncertain estimates of benefits and costs of new regulations.[30]

Measuring the benefits of health safety regulations is not a simple task and it becomes even more difficult when we allow for the indirect health effects of regulation-induced changes (reductions) in consumers' income. This problem can be explicated in the following way: food safety regulations impose costs which are expressed as compliance costs, and which lead to price increases. This increase in turn reduces people's disposable incomes with adverse consequences for their consumption choices. A given regulation may thus lead to a reduction of death (or morbidity) by a given percentage, but if its implementation costs (joint compliance and opportunity costs) are too high, the end result might be an offsetting (or even greater) human loss due to increased death and morbidity resulting from the fall in GDP and personal incomes.[31] The comprehensive analysis of costs and benefits requires that the scope of analysis be broadened from the effects of a regulation on the likelihood of one hazard, to the analysis of its impact on other hazards and eventually to the analysis of its impact on the society's overall welfare.

2.6 Alternatives to Statutory Regulation

Statutory food safety regulations are not always the best (that is the most effective and efficient) means of enhancing food safety. It is worth remembering that there are alternatives to publicly mandated rules, and as a rule of thumb, before embarking on the path of statutory food regulations one should analyze its least restrictive alternatives whose comparative advantages should be assessed in the

30 John M. Antle (1999) 'Benefits and costs of food safety regulation', in *Food Policy*, 24, p. 605-623.

31 An accessible presentation of this argument can be found in W. Kip Viscusi (1998) *Rational Risk Policy,* Clarendon Press.

specific socio-institutional context. The list of the most important alternatives to statutory regulations includes:

- *Education and information.* Consumers themselves may influence the probability of contracting foodborne diseases by properly handling food products. Foods should be properly chilled and kept cold during processing, distribution, sale and storage. Meat and poultry products should be kept refrigerated until just prior to cooking.[32] Informing the public about the composition, proper ways of food handling and probable health effects may be a voluntary action by food producers or distributors or may be an obligation stemming from public regulations.[33]
- *Technology changes.* New options for controlling pathogens in food might come with the creation of new methods of food treatment. One such method, which has been approved by the American food safety agency but is still strongly contested by consumer movements in the US and elsewhere, is irradiation.[34]
- *Stimulating market responses to food safety problems.* Some food safety problems flow from the lack of consumer information and from weak market incentives to provide this information. A preliminary question before embarking on government regulations is whether these market failures cannot be diminished by altering the structure of the incentives that market players face. The latter can be done by, for instance, making changes in the liability law.[35]

Regulating food safety, it has to be repeated, is a complex issue, but public authorities have various policy instruments, which they have to use to optimize the combined outcomes of their interventions. The choice of proper ways to regulate

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32 A research by Neis and van Laanen (Nies, J. I. And P.G. van Laanen [1995] 'Effect of Safe Handling Programming on Participants' Food Handling Behaviors', in *Family and Consumer Science Research Journal*, Vol. 24, No. 2, Dec., p. 161-179) showed that when consumers were educated about food safety principles, the number of people consuming rare or pink hamburgers (that is undercooked) fell by 73 percent and other unsafe behaviors decreased.

33 See the discussion about the food labelling of food produced with addition of transgenetic components in the EU (http://europa.eu.int/comm/food/fs/fl/fl_index_en.html).

34 Irradiation is a ionizing radiation composed of short wavelengths capable of damaging microorganisms such as those that contaminate food or cause food spoilage and deterioration. For the discussion of consumers resistance to irradiated food see: Nayga, R. M. (2003) 'Will consumers accept irradiated food products?', in *International Journal of Consumer Studies*, July, Vol. 27, No. 3, p. 220-220 (1).

35 Firms' increased attention to food safety may also result their care for good reputation.

food safety should be made according to scientific analysis done by a community of professional regulatory policies analysts and not because of short-term political convenience or irrational public scares.[36]

In the perspective of this paper it is worth stressing that contemporary food safety regulations increasingly rely on mixed solutions, the overall evaluation of which requires an attention to institutional details and in particular to the difficulties in implementing these regulations and limiting their plausible unintended effects.

3. The EU and Food Safety: Between Reliance on Scientific Evidence and Responsiveness to Public Fears

3.1 EU Food Safety Regulations in the Pre-BSE Era

It can hardly be said that EU food safety regulations have been shaped exclusively by scientific evidence and careful policy analysis. Rather new European initiatives in the area of food safety have been driven by food scares and especially BSE crises.[37]

The question addressed below is how these recent developments in EU food safety policies might have affected the capacity of the EU to effectively influence the changes in food safety systems in candidate countries in the pre-accession period.

Ellen Vos[38] describes a pre-BSE crisis EU food safety regime as developed ad hoc and predominantly under the influence of the jurisprudence of the European Court of Justice. She points out that with regard to food safety assessment the Community used to resort to committees and especially to the Scientific Committee on Foodstuffs (SCF) composed of independent scientists; the Standing Committee on Foodstuffs (StCF) consisting of national representatives; and the Advisory Committee on Foodstuffs (ACF) composed of representatives of various interest groups. The SCF supplied scientific evidence, the ACF supplied opinions of interests involved, and the StCF ensured the political approval of the Member States at the risk management stage.

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36 This observation seems obvious, but it should be repeated when one observes a disparity in the expenditures on policy analysis between the US and Europe (see A. Martino [1996] *Aiutare lo Stato a Pensare,* FGA Torino).

37 See Ellen Vos (2000) 'EU Food Safety Regulation in the aftermath of the BSE crisis', in *Journal of Consumer Policy*, Vol. 23, p. 227-255; Sebastian Krapohl (2003) 'Risk Regulation in the EU between Interests and Expertise: the Case of BSE', in *Journal of European Public Policy*, April, p. 189-207, Skogstad Grace (2001) 'The WTO and Food Safety Regulatory Policy Innovation in the European Union', in *Journal of Common Market Studies*, September, Vol. 39, No. 3, p. 485-505 (21).

38 *Op. cit.* p. 229-240.

Until the mid-1990s this pragmatic way of dealing with food safety issues seemed to function relatively well, but the BSE crisis shattered the positive image of the Commission's regulatory actions. The report of the EP Temporary Committee of Inquiry into BSE in February 1997, revealed the shortcomings of 'the committee model', highlighting the political pressure exercised on formally independent members of the SCF, the scarce coordination and cooperation between the various DGs of the Commission active in the field of food safety, and most seriously, a true policy of disinformation on the part of the Commission.

3.2 The Commission's New Approach to Food Safety

In response to the perception of crisis in the EU food safety regime, the European Commission has laid down a conceptual and institutional basis for a new approach to food safety issues.

The first change introduced might be called *an institutional streamlining*. This consisted in bringing together all responsibilities for feed and food safety issues within the Directorate General for Health and Consumer Protection called, for the sake of simplicity, the DG Sanco.

Next, in a communication on 'Consumer Health and Food Safety', the Commission formulated the three basic principles of its new approach—namely, the separation of the responsibility for scientific advice from the responsibility for legislation and for implementation control from information and communication policies.[39] This change might be called *the separation of food safety policies into risk assessment, risk management and risk communication*.

In the following 'Green Paper on the General Principles of Food Law in the EU',[40] the Commission announced that it would like to ensure free movement of foods within the internal market, science based risk assessment and greater competitiveness of European food exports by placing greater responsibility for food safety on the food processing industry and increasing the effectiveness of official food control and enforcement. This line of changes is further developed in the Commission's 'Proposal for a Regulation of the European Parliament and of the Council on official feed and food controls', which stresses the need to develop a comprehensive audit system.[41]

Finally, in a White Paper on Food Safety published in January 2000[42] the Commission announced that it would like to base its food safety policy on a 'comprehensive and integrated approach' which covers the whole food chain 'from farm to table'. It proclaimed that risk analysis will be the basis of its food safety

39 'Consumer Health and Food Safety', in *Communication* (1997) 183 Final. of 30 April 1997.

40 The General Principles of Food Law in the European Union COM (97) 176 30 April 1997.

41 COM/2003/0052 final–COD 2003/0030.

42 The White Paper on Food Safety of January 12, 2000 (COM [1999]) 719 final.

regulatory policies, that risk analysis will be based on the best scientific advice thanks to another institutional innovation—the establishment of the European Food Safety Authority with the task of providing independent scientific advice on food safety issues, collect and analyze data related to food safety issues, identify and warn about emerging risks, support the Commission in the case of crisis and communicate to the general public on food safety related issues.[43]

The direction of changes in the EU food safety regime is summarized in the table below.

Table 1

Evolution of EU Food Safety Control: From Controlling to Auditing

Control approach	Audit approach (EU legal base Council Directive 93/43/EEC of 14 June 1993), COM (2000) 438(03) and Proposal for a Regulation of the European Parliament and of the Council on official feed and food controls /* COM/2003/0052 final – COD 2003/0030 */
Reactivity: controls mostly when food has entered the market.	*Precaution:* controlling producers food operators practices
Virtual comprehensiveness: commitment to control all threats to food safety	*Selectivity:* intervening in critical points
Sectoriality: controls of different risks are handled differently	*Completeness:* Controls lacunas and overlapping get canceled
Community financing: Costs of running control system fall mostly on the EU budget	*Dispersed financing:* Costs of running control systems fall mostly on food businesses

43 The Regulation of the Council of Ministers from 28th January, 2002, Regulation EC (178/2002).

3.3 Dilemmas of the EU Food Safety Regime

In spite of continuing reforms the present European food safety regime is not free from conceptual and institutional ambiguities: it stresses the importance of science in risk analysis, but at the same time, via a certain interpretation of the precautionary principle,[44] remains open to the influence of extra-scientific considerations, the administration of food safety regulation is not free from political interference, thus undermining the credibility of European food safety regulations,[45] it intends to rely more on food industry self-regulation and companies' social responsibility but it also tries to enhance the controlling power of public inspectors and enforcement services and it struggles to reduce 'the implementation gap' stemming from the fact that regulations are made internationally, but executed nationally. The European Commission, in its development of European food safety policy, is struggling to balance three goals: to minimize the threat to public safety, to reduce regulatory tensions among the EU member states and to minimize possible conflicts with the rest of the world over food safety issues.

The creation of the European Food Safety Authority (EFSA) could have been instrumental to balancing these goals as an independent regulator is better suited to assure scientific excellence, to be impartial with regard to national interests and less susceptible to the accusations of using regulations as a protectionist device. However, the EU has not exploited the opportunity to create an independent European food safety regulatory authority and has limited the tasks of the EFSA chiefly to risk assessment.[46]

The conceptual and institutional drawbacks indicated above reduce the capacity of the European Commission to act credibly and effectively vis-à-vis member states and third countries. Nevertheless the European Commission possesses powerful policy safety instruments which can be used to improve food safety risks to European consumers. However, for reasons of space, only two of the numerous policy instruments in the hand of the European Commission will be discussed here.

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44 Giandomenico Majone (2002) 'The Precautionary Principle and its Policy Implications', in *Journal of Common Market Studies*, March, Vol. 40, No. 1, p. 89-109 (21), reprinted as chapter 2 in this volume.

45 Giandomenico Majone (2000) 'The Credibility Crisis of Community Regulation', in *Journal of Common Market Studies*, June, Vol. 38, No. 2, p. 273-302 (30).

46 The EFSA could test among others the idea of regulatory network as many member states have recently created national food safety agencies and have entrusted them the task of regulating food safety. National food safety agencies were created in: Great Britain (May 1997–the Food Standards Agency); in France (April 1999–the Agence française de la sécurité sanitaire des aliments), in Finland (the National Food Agency), in Ireland (1998–the Food Safety Authority of Ireland) and in Sweden (the Swedish National Food Administration (NFA), in Belgium (February 2000–the Belgian Federal Agency for the Safety of the Food Chain).

The two which seem most symptomatic of the ongoing changes in the EU food safety regime. The first instrument is applied to external trade partners (called 'third parties'), the second is developed with view to being applied to internal agro-alimentary businesses. The former instrument is referred to here as *market access requirements*, the latter as *an audit technique*.

3.4 Market Access as a Food Safety Instrument

The core of this instrument consists of rules that are applied to the importation of live animals and animal products from third countries.[47] The rules impose safety and supervisory standards which are equal or at least equivalent to the rules applied in the trade among EU member countries. Before getting an approval for exports to the EU countries a third country is inspected by the Food and Veterinary Office (FVO), which checks whether the EU veterinary requirements are met. This policy instrument was applied to EU candidate countries even before they applied for the EU membership. The Food and Veterinary Office (FVO) has carried out several inspections in candidate countries since the late 1990s.[48] Their purpose is to certificate food producers in order to give them 'market access' to the EU.[49] Besides 'ordinary missions', the FVO has conducted several special assessment missions to the applicant countries with a view to assessing their food safety system.

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47 The list of veterinary rules applied in such cases has been recently updated and published in the Food and Veterinary Office document entitled: 'General Guidance to Third Country National Authorities on the Rules to Be Followed For the Import of Live Animals and Animal Products into EU from Third Countries' 23 January 2003.

48 The missions are carried under the provision of the following Community legal acts: Commission Decision 86/474/EEC of 11 September 1986; Commission Decision 98/140/EC of 4 February 1998 and Council Decision 95/408/EC of June 1995.

49 The permission for imports of food (meat in particular) are issued based on the following EU regulations:

Council Directive 72/462/EEC on health and veterinary inspection problems upon importation of bovine, ovine and caprine animals and swine, fresh meat or meat products from third countries (as last amended) – *OJ* No. L302, 31/12/1972, p. 28.

Council Directive 92/118/EEC laying down animal health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A(I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC – *OJ* No. L62, 17/12/1992, p. 19.

Council Directive 94/65/EC laying down the requirements for the production and placing on the market of minced meat and meat preparations – *OJ* No. L368, 31/12/1994, p. 10.

Council Directive 96/93/EC on the certification of animals and animal products – *OJ* No. 13, 16/01/1997, p. 97.

Table 2

List of special veterinary missions to assess the conditions of food production in Poland

03/04-07/04/2000 - Special mission to assess the conditions for production of fresh meat, meat preparations and meat products
31/01-04/02/2000 - Special mission to assess the level of residues in live animals & animal products
31/01-04/02/2000 - Special mission to assess the conditions for production of game and rabbit meat
27/09-01/10/1999 - Special mission to assess the quality of fishery products
03/05-07/05/1999 - Special mission to analyze public health issues
23-25-26/03/1999 - Special mission to assess animal welfare during transport
08/06-13/06/98 - Special mission to assess the conditions for production of dairy products

Source: FVO http://europa.eu.int/comm/food/fs/inspections/index_en.html.

The task of ordinary missions is *to assess the state of individual food processing plants* in order to issue them an export licence, whereas special missions serve to assess a general state of food safety in a given industry in order *to approve the readiness of a country to join the single market*. The former is a judgment about an individual case; the latter is to a large extent a judgment about the shape of a food safety regime.

EU veterinary missions are unlikely to have been misled by the host country's decisions where they should go, what they should see and whom they should meet, since the programme of each mission is set by mutual agreement and mission officers could change the programme at will.[50] So meeting the requests of FVO inspections is a test for loyal cooperation in assuring food safety.

In the particular case of candidate countries the outcomes of special missions were of special importance as they were used to assess the progress of candidate countries towards the fulfillment of membership conditions.[51]

50 Accepting the wish of mission's inspector to alter the route is in itself an act of signaling good will and hence a credibility enhancing device. Just think: if the wish of inspectors is not met, they would register this fact in the final report and suspicion will arise that some irregularities are being hidden.

51 This falls under Heather Grabbe's category of 'gate-keeping mechanism', in which the outcomes of such controls are used to let candidate countries pass to further stages in the accession process. See 'Europeanization Goes East: Power and Uncertainty in the EU

3.5 The Emergence of Regulatory Auditing

The second policy instrument which is increasingly applied in the interest of food safety consists of *the move from direct food controls to regulatory auditing*. This move has been facilitated by the propagation of HACCP (Hazard Analysis and Critical Control Points) as a method of producer's controlling themselves. HACCP was originally developed by food businesses. Following the developments in US food safety regulations, the EC has tried to promote indirect methods, including HACCP, for the control of food safety. It does so by requiring all food processing plants to implement HACCP as their own inspection system.[52] The HACCP system strives to reduce human exposure to foodborne pathogens by requiring processing plants to scrutinize the critical control points in the production process—points where food safety hazards can be prevented, reduced to an acceptable level or eliminated.[53]

Placing HACCP at the core of food safety regulatory developments leads to two major changes in food safety policies: firstly, food safety inspections can move from *direct food safety controls to regulatory audits*; secondly, the costs of food safety controls are shifted from the budget of the government to the food processor.

The implementation of HACCP requires that the results of the company's internal controls be registered at critical points. Inspectors of food safety agency can then examine these records virtually 'in real time', as these reports can be transferred via internet to the central files of the food safety agency. The auditing is enhanced by a parallel, albeit rare sampling of the processed food for laboratory examinations, but the proportions shift: food testing becomes above all own responsibility of food processors. Furthermore, such a change alters the distribution of costs stemming from food safety controls. The public food safety agency initially invests in educating the industry in the HACCP method and then starts controlling HACCP implementation plans and monitoring the way companies run their own HACCP system. External controls are supposed first to certify the HACCP and next to control the way it is run. This change of method trusts producers, lowers the cost of controls, and allows a better targeting of the use of control resources.[54]

(*contd.)*

Accession Process', in K. Featherstone, C. Radaelli (eds.) (2003) *The Politics of Europeanization,* Oxford: Oxford University Press.

52 EU Council Directive 92/46/EEC.

53 A single and authoritative food safety agency would not only assume full responsibility for risk assessment and risk management, but it would help to streamline the implementation of industry process standards since 'Inconsistent HACCP implementation is just one of numerous problems that arise from having several agencies with separate responsibilities for food safety regulation', Caroline Smith DeWaal (2003) 'Safe food from a consumer perspective', in *Food Control*, Vol. 14.

54 Estimated benefits from the introduction of HACCP in the US vary very widely. Thus for instance Stephen R. Crutchield *et al.* (S. R. Crutchfield, Jean C. Buzby, Tanya Roberts,

It seems justified to say that the European food safety regime shows characteristics of both an enforcement and a management regime[55], since, as in a typical enforcement regime, the European Commission can monitor and sanction for misbehavior, and similarly to other international management regimes, the EC can help member countries to enhance the technical and institutional capacities to meet their commitments.

4. The Polish Food Safety Regime: Factors Influencing the Pace of its Changes in Response to the EU Regulatory Requirements

Food safety regulations are a crucial element of Poland's system for protecting public health. As in all modern food safety regimes the basic responsibility rests with producers, while the state (via its specialized services) issues general rules of conduct and controls their implementation.

The accession to the EU has been influencing the developments in the Polish food safety regime since the EU food safety regime is a 'deep international policy regime'[56] and adjustments required from an accession country are deemed by local food safety experts as significant.[57]

It is likely that changes in food safety regulations will affect developments in the whole Polish agro-alimentary sector in the long run, but it seems also true that the functioning of the food safety regime will be, at least in the short run, influenced by peculiar features of the Polish agriculture and food industry.

It is thus important to sketch out the most important features of the Polish agriculture and food industry (AFI) as the readiness to adjust the food safety regime and the capacity to meet the requirements depend to a large extent on the structural features of the Polish AFI.

(*contd.*)

Michael Ollinger and C-T. Jordan Lin [1997] 'An Economic Assessment of Food Safety Regulations', in USDA, Agriculture Economic Report No. 755) estimate that economic benefits from the introduction of HACCP controls may stay within the range of $1.9 billion to $171.8 billion depending on the effectiveness of HACCP implementation.

55 After Jonas Tallberg, see: Jonas Tallberg (2002) 'Path to Compliance: Enforcement, Management, and the European Union', in *International Organization*, Summer, p. 609-643.

56 The term 'deep regime' has been introduced by George W. Downs, David M. Rocke and Peter N. Barsoom 'Is the Good News about Compliance, Good News about Cooperation?', in *International Organization*, No. 3/1996, p. 379-406.

57 See D. Banati (2003) 'The EU and Candidate Countries: How to Cope with Food Safety Policies?' in *Food Control*, No. 2, March, p. 89-93.

Table 3

Size distribution of farms in Poland (as of 1996)

Size group (ha)	Number	Land area (ha)	Average size (ha)
1-2	462,206	650,634	1.41
2-5	667,588	2,199,048	3.29
5-7	260,713	1,541,820	5.91
7-10	260,103	2,171,527	8.35
10-15	217,202	2,631,547	12.12
>15	173,568	5,064,957	29.18
Total	2,041,380	14,259,525	6.99

Source: Siemienski (1999) 'The Change of property and area structure of Agriculture in Poland and Wielkopolska Region between 1988 and 1996', in S. Paszkowski (ed.) *Determinanty transformacji struktury agrarnej w rolnictwie polskim* czesc I, Poznan, p. 327-338.

Table 4

Agro-alimentary products in Polish foreign trade according to destination (in m USD)

	Exports			Imports			Trade balance		
	1999	2000	2001	1999	2000	2001	1999	2000	2001
EU	1,277	1,287	1,456	1,615	1,622	1,790	-338	-335	-334
Former SU	662	602	608	74	106	113	588	496	495
CEFTA	283	316	353	289	352	325	-6	-37	28
EFTA	29	30	40	150	140	174	-121	-110	-134
USA	100	107	116	108	74	81	-8	34	35
Others	317	308	457	1,139	888	923	-822	-581	-466
Total	2,668	2,650	3,030	3,374	3,183	3,406	-707	-533	-376

Source: GUS (Main Statistical Office)

4.1 Structural Conditions: The Weight of Agriculture and Food Industry in the Polish Economy

Agriculture accounts for 3.3 percent of the Polish GDP (as compared with 2 percent in the EU), but employs 18.8 percent of all working people (as compared to 4.4 percent in the EU).[58] Agriculture productivity in Poland is much lower than in the EU, but it has been steadily rising since the mid-1990s. In 1999 the Polish food-processing industry employed 480,000 employees and the value of processed food production amounted to 12 bl USD. By the late 1990s the productivity of the Polish food industry was rising yearly by more than 10 percent.[59]

Polish agriculture is composed of 1.88 m individual farms of an average size equal to 9.5 ha (as against an average size of farm equal to 18.4 ha in the EU). About half of all Polish farms do not produce for the market but only for themselves. Furthermore, it is estimated that agriculture activities of these farms are value subtracting, that is, their owners subsidize agriculture production from incomes derived from other sources.[60] Only farms larger than 10 ha generate at least part of their income from agricultural production.

Food expenditures account for 30-35 percent of family budgets (as compared with an average 17-18 percent in the EU countries). Possible food price increases due to changes in food safety regulation will thus be strongly felt by Polish consumers.[61]

Equally high market fragmentation characterizes the Polish food industry. Post-communist economic transformations resulted in a myriad of small enterprises in the food-processing industry. Out of more than 30,000 enterprises active in the food industry, only 1523 (as of 2001) employ more than 50 persons. The process of the concentration of food-processing industry in Poland is slow, apart from the brewing industry, the production of vegetal oils and the production of feed for animals, and small- and medium-size enterprises dominate all branches of the food industry. Food processing is not very profitable and almost 1/3 of functioning enterprises show financial losses.[62] This makes these enterprises unwilling and

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58 The data come from Susan Senior Nello (2002) *Food and Agriculture in an Enlarged EU,* EUI Working Papers, RSC No. 2002/58, p. 3.

59 These data come from the Polish diplomatic sources: http://www.poland.org.au/trade/pdf/food.pdf.

60 UKIE (2003) *The Balance of Costs and Benefits of Poland's Accession the EU (Bilans korzysci i kosztow przystapienia Polski do UE)*, April, p. 111.

61 According to the estimations done by the Office of the Committee for European Integration (UKIE) the application of food safety regulations might result in the increase of food prices by 4-5% and this mainly due to the forced change in the components used for food production see: Costs of production might rise, in *Rzeczpospolita*, from 14 February 2003.

62 The data in this section come from the Report '*Rolnictwo i gospodarka zywnosciowa w Polsce w aspekcie integracji z Unia Europejska*', Warszawa, 2002, different pages.

unable to invest much in the modernization of their production processes and in the compliance costs of meeting food safety regulations.

Poland and other candidate countries do not play any important role in the EU food imports. But the EU countries account for 43 percent of Polish agriculture exports and 48 percent of agriculture imports. The main item in Poland's imports from the EU countries is animal feeds and in the country's exports live animals and meat.

Difficulties in meeting EU quality standards and low experience in international marketing seem to be the main reasons for a poor performance of Poland's exports to the EU countries.

It is expected that the rise of productivity will lead to accelerated concentration in farming and also in food production, causing problems with the dislocation of the workforce, but at the same time facilitating the control of food safety.

4.2 Domestic Determinants of Food Safety Policy

4.2.1 Public Awareness of Food Risks

The European public has been always concerned about food safety, but especially so since the outbreak of the BSE crisis.[63] It is not surprising that the EC and national politicians try to ensure the public that the current enlargement will not compromise food safety purposes.[64]

The EC has a variety of instruments to reduce threats to food safety coming from the current enlargement. But their task would be made easier if, among other things, the food safety preferences of consumers in the present member states were the same as those in the candidate countries. Here I look at the preferences of Polish consumers.

These data seem to show that Polish society has a different perception of food threats, with less fear of BSE and other (like swine fever and dioxin) food scares so diffused in Western Europe. Responding to a survey made in December 2000, that is, after scientists had established a high probability of a link between BSE and a new variant of Creutzfeld-Jakob disease in humans, 58 percent Polish respondents

63 It seems, moreover, that Europeans place their trust with regard to food safety in the hands of public authorities. Thus, for instance, a *Eurobarometer* Survey from September 1998 reports that foodstuffs inspire more confidence in consumers when they have undergone national (66%) or European (43%) controls, as opposed to controls carried out by distributors.

64 Thus for instance, Laurens J. Brinkhorst, Dutch Minister of Agriculture, Nature Management and Fisheries speaking on 21 March 2002 emphasised 'Much more attention in the accession process should be paid to food safety. Without safe food no market performance, without market performance no (real) integration' (http://www.minlnv.nl/actueel/speech/2002/speech015.html).

said that they did not feel threatened by BSE as they believed that Polish cattle had not been affected by the disease. In June 2002, after the press reports that in May 2002 the first case of BSE had been identified 34% of respondents still said they did not believe in the existence of BSE in Poland.

Table 5

Beliefs in the safety of domestic cattle

In some countries of the EU cases of BSE have been registered. Do you believe that Polish cattle are affected by this disease?		
Date of the survey	December 2000	June 2002
Yes	19%	51%
No	58%	34%
Difficult to say	22%	15%

CBOS: December 2000 and June 2002, (CBOS–Centrum Badania Opinii Spolecznej).

In the case of Poland the perception of the BSE risk should be related to the perception of domestic food safety practices, as imports of meat to Poland are low and in the case of bovine insignificant (see the table below).

Table 6

Imports of meat to Poland (data for 1Q 2002)

Type of meat	Imports in tons
Pork	1262
Beef	3
Sheep meet	146
Poultry	6298

Source: Glowny Lekarz Weterynarii (http://www.wetgiw.gov.pl/).

The information about BSE has not in fact provoked major changes in the dietary habits of Poles. In December 2000 some 61 percent of respondents declared that they had not ceased eating bovine, and in June 2002 (that is after the identification of the first BSE case in Poland) this number had fallen only slightly to 54 percent.

Table 7

Modification of diet under the impact of BSE (in percentage)

Have you, in response to the information about BSE, limited or stopped the consumption of bovine?	The date of survey		
	January 1998	December 2000	June 2002
Yes, I have entirely stopped eating bovine	6	15	10
I have limited my consumption of bovine	16	24	17
I do not eat bovine for other reasons like taste	16	21	17
I have not ceased nor limited the amount of bovine	61	37	54

Source: CBOS, December 2000 and June 2002.

The statistical analysis shows a high correlation between beliefs in the existence of cattle affected by BSE and the decision to stop eating beef. Furthermore, as a rule, a higher sensitivity to the threat of BSE has been registered among the younger and better educated parts of the Polish population.

In a different survey people were asked whether they expect that accession to the European Union will improve or deteriorate food safety.

Table 8

Expectations as to the changes in food safety after accession to the EU (in percentage)

Will food in your country after the accession to the EU become?	Safer	Nothing will change	Less safe	Difficult to say
Poles	29	29	27	15
Hungarians	41	41	9	9
Czechs	23	50	11	16
Lithuanians	37	31	14	18
Rumanians	45	26	17	12

Source: CBOS, Survey November 2001.

The outcomes of this international survey suggest that Poles have ambiguous expectations related to the changes in the level of food safety after accession to the EU. A possible reason for this is that, feeling safe already, they pay little attention to the problem of food safety.

This hypothesis needs further investigation but there are indications which seem to confirm it. Firstly, (see Table 9) Poles consider food produced from domestic components as safer than food composed of mixed components or food imported from the EU countries.

Table 9

Perception of food safety according to its origin (in percentage)

Is food composed of:	Safe	Risky	Difficult to say
Poles			
Exclusively domestic components	86	11	3
Containing imported components	57	35	8
Imported from the EU countries	44	46	10
Imported from the US	40	46	14
Imported from other countries	33	52	15
Hungarians			
Exclusively domestic components	70	27	3
Containing imported components	55	40	5
Imported from the EU countries	58	35	7
Imported from the US	49	40	11
Imported from other countries	32	58	10

Source: CBOS, November 2001.

The choice of food by Polish consumers is guided by beliefs that domestic agriculture, which does not widely use the methods for the intensification of food production, offers safer food. This might be true if we consider chemical pollutants of foods due to the use of fertilizers, but it might not be true if we consider microbiological pollutants which tend to spread when not enough attention is paid to the hygiene of the production, transformation and distribution of food products.

Other data suggest that Poles do not seem to be cautious food consumers, as only 31 percent of consumers say that they always check the date of product

validity, only 7 percent check the composition of food products bought, and 7 percent buy products paying attention to its health claims.[65]

In general it seems justified to say that public opinion does not exert major pressure for changes in the Polish food safety regulations. This weak public attention to the issue might lead the government to place it low on the agenda of domestic policy actions. The agenda of policy changes resulting from accession negotiations does not coincide with the agenda of domestic policy actions. In such a situation one can expect that a candidate country might incur significant delay in implementing food safety measures.

4.2.2 Foreign Direct Investments as a Vehicle for Internationalization of Food Safety Practices

Classical works on regulations point to multinational corporations and FDIs as an important source of demand for the international harmonization of regulation.[66] Thus, one would expect it to embrace EU food safety regulations more readily, if a country's agro-alimentary sector is significantly internationalized.[67]

In this regard we can ask what is the weight of FDIs in agriculture and food processing in Poland, and could FDIs be of some importance for the decision of how rapidly to introduce adjustments to the EU food safety rules?

Aggregate data show that as of mid-2002, FDIs in Polish agriculture reached approximately 45 m USD, which is an almost negligible amount. On the other hand in food processing FDIs amounted to almost 6 bl USD, and accounted for 21 percent of all FDIs in manufacturing.[68] More than 60 percent of FDIs in manufacturing come from the EU countries—a circumstance facilitating the approval of EU food safety rules.

Furthermore, FDIs have often been linked with the privatization of the food processing sector in Poland, which has led to the dominance of foreign (mostly EU) food manufactures in the group of large food producers. If, as is assumed, large multinational companies tend to apply uniform production standards across countries in which their plants are located, a large presence of FDIs in the Polish agro-alimentary industry facilitates the reception of EU food safety regulations.[69]

The outcomes of several field researches seem to confirm that FDIs in the food sector help processing firms to upgrade their agri-food products to

65 See: Komunikaty z badan, CBOS, October 2001.

66 See Giandomenico Majone (ed.) (1996) *Regulating Europe,* Routledge.

67 Internationalization is measured not only by the role of FDIs, but also as a share of exports in an industry's output.

68 Data from the Polish Agency of Foreign Investments (PAIZ - http://www.paiz.gov.pl/facts2_4.html).

69 Harmonized regulations help smoothing intra-company trade.

international standards.[70] EU food safety regulations might have come to the Polish food processing sector with EU investors, in anticipation of Poland's membership in the EU.

4.3 Polish Food Safety Law and Other Food Safety Requirements

Polish food safety regulations date back to the interwar period (the first comprehensive food safety law was passed in 1929). The next major revision of legislation on food safety, health and nutrition was passed in Poland in November 1970.

Poland has been a member of the *Codex Alimentarius Commission* since its beginning, and the Polish Agricultural and Food Quality Inspection (earlier the Central Inspectorate of Standardization—CIS) has been participating in the work of other international safety standard setting bodies. Basic food regulations as written in the law under the communist regime did not deviate at all from international standards. What was different, however, was how the food safety law was implemented, and especially the communist state's heavy reliance on administrative and penal sanctions.

Economic transformations under way since the late 1980s have called for changes in food regulations mostly because of the changed socio-economic context in which they have been applied. Nevertheless it was not until the late-1990s, with the beginning of the negotiations for accession to the EU, that these changes began to take place.

The essence of these changes was the adjustment of the Polish food safety regime to the EU food safety regulations as the EU opening negotiation position was clear: 'the adoption of the *acquis communautaire* is the precondition for Poland's accession to the EU.'[71]

This negotiating position was accepted by candidate countries with no objection and no candidate country asked for transition periods in the transposition of EU food safety law.

The changes to food laws to meet EU requirements, were accepted and introduced by all candidate countries. Accordingly, on 11 May 2001 Poland brought the food legislation in line with the EU acquis by passing the Law on

70 See for instance J.F.M. Swinnen (2002) 'Transition and Integration in Europe: Implications for Agricultural and Food Markets', Policy and Trade Agreements', in *The World Economy*, p. 481-501.

71 A comprehensive survey of legal issues related to the adoption of the acquis communautaire can be found in A. Ott and Kirstyn Inglis (ed.) (2002) *Handbook on European Enlargement,* The T-M-C-Asser Press: The Hague.

Health Conditions of Food and Nutrition (Dz. U. No. 63, item 643, as amended), hereinafter referred to as 'the Food Law'.[72]

The 'Food Law' has modernized the system of food safety regulations in Poland.[73] Below I review its main provisions.

The Polish food law starts by defining food safety (Art. 3, p. 15) as 'a set of complex conditions, which must be met and activities which must be undertaken on all stages of food production and food distribution in order to ensure safety for people's health and life'. These conditions and activities are translated into product and process standards. Specific product and process standards are not part of this basic law: their formulation has been delegated to the Ministry of Health. The Ministry of Health also supervises the work of the General Sanitary Inspection which carries out field controls with regard to all foods except food of animal origin, the control of which is left to the State Veterinary Inspection under the supervision of the Ministry of Agriculture.

The law recommends that the maximum allowed levels of food contamination be based on 'the outcomes of scientific research and in order to protect human health and life' (Art. 7, point 2). This statement can be read as positing the essential role of scientific expertise in setting standards, but the law (Art. 45, point 2) relaxes this condition by stating that 'official inspection authorities can undertake anticipatory and proportional to the threat preventive actions in order to protect human life and health (*the precautionary principle*)' in case 'there are no scientific proofs confirming non-harming characteristics of food items' (Art. 45, point 2).

When searching for scientific expertise referenced laboratories should (Art. 44 point 2.7) transfer to state inspection authorities 'information about research methods applied in referenced laboratories in the countries – members of the EU'. National standard setters should thus draw on the best knowledge and experiences of EU referenced laboratories.

The law gives a definition of 'new food' (Art.3, point 26) as 'substances or their mixtures, which earlier have not been applied to feed people'. Genetically modified

72 Earlier the Law of 24 April 1997 on control of infectious diseases of animals, examinations of slaughter animals and meat, and on the Veterinary Inspection, (Dz. U. from the year 1999, No. 66, item 752, as amended) was passed which contains provisions concerning food of animal origin. And with regard to non-health related food quality, the most important is the Law of 21 December 2000 on Commercial Quality of Agricultural and Food Products, which replaces two former statutes and enters into force on 1 January 2003 r. (Dz. U. form the year 2001, No. 5, item 44, as amended). Latest modification of the Polish Food Law comes from 14 February 2003.

73 This law transposes more than 80 EU Directives. In general the EU food safety standards were more stringent than Polish ones, but in some cases like a smaller number of additives and preservatives and their lower permitted level of concentration, Polish food safety requirements were more restrictive than UE standards. (See 'Links to the West', in *Warsaw Business Journal*, 23 January 2003.)

food is considered a subcategory of new food and neither its production nor sale in Poland if 1) it is properly labeled (Art. 11, point 3 says that food product should be marked with information, 'product genetically modified', and 2) it has gone through a testing procedure with the General Sanitary Inspector, who, after reviewing the opinion of experts and scientific centers (Art. 11, point 5), issues a decision allowing or forbidding its production or sale. The firm wishing to produce or to sell genetically modified food must cover the costs of testing and obtaining an opinion from referenced experts and laboratories (Art. 11, point 6). This provision can be read as being in opposition to the EU ban on the market approval of GM foods But the lack of a precise threshold for the allowed content of GMOs and the approval rights placed in the hands of the General Sanitary Inspector make the introduction of genetically modified food to Poland time-consuming, costly and hence difficult.

Art. 6 of the law forbids the production of food from animals treated with hormones, or substances acting tyreostatically or beta-agonistically.

Art. 8 approves the production or sale of irradiated food, if 'it does not pose a threat to human health or life and if it is technologically justified'. The law adds that irradiation should not substitute normal hygiene practices or be applied to food which contains chemical substances serving to conserve or stabilize food (Art. 8, point 2). Specific rules regarding irradiation are fixed by the Ministry of Health in special rulings.

The General Sanitary Inspector should make publicly available the register of taken decisions (Art. 14, point 13) with all the documentation of the admissibility procedure, thus allowing for public control of the impartiality of decisions taken. There is, however, no appealing mechanism which would create an opportunity to contest its decision.

The power of the General Sanitary Inspector is enhanced by the fact that he can (Art. 17, point 3) issue a decision waiving the requirement to go through the whole testing procedure required for 'new food'.

Art. 24 of the law requires that the packing of all food and nutritional products should contain the information essential for the protection of human health and life and in particular: the composition of food products, the nutritional value of food products, the presence of permitted additional substances or food additives; the expiry date of food's nutritional usefulness; the instruction of use; the data which identify the producer or the company which introduces the product to the domestic market.

Furthermore, the information on the food 'should not mislead a consumer with texts or graphic signs' or 'should not attribute to the product nutritional values which it does not possess' (Art. 24, point 2). More specific rules for the labeling of a product are established by the ruling of the Ministry of Agriculture prepared in co-operation with the Ministry of Health.

Art. 28 of the law imposes on companies producing and selling food the obligation to meet food safety standards first and foremost by carrying out internal inspections. The same article makes HACCP a basis for the internal inspection system, and, states that all large companies should implement and document the proper working of HACCP control system as of 1 January 2004 (small- and medium-sized companies are not covered by this requirement). Art. 32 gives to the Minister of Health (acting jointly with the Minister of Agriculture) the delegation to define more precise rules for the working of HACCP and all internal inspections in general. These precise rules should take into account the food safety requirements of the European Union.

The application of HACCP is backed by a general rule (Art. 23) stating that technological processes and methods of processing applied in the production and distribution of foodstuffs should not cause the emergence of substances harmful for human health and safety.

A food company must spontaneously withdraw foodstuff (Art. 31) if it identifies food safety problems. The state of food produced or treated in a given company can, however, be verified ex post since all food companies are required to store samples of food products for certain period of time and allow food inspections to examine them on request.

The law (Art. 35) stipulates requirements regarding the state of the health of the employees of food safety companies. First of all, they must have a medical certificate confirming the fact that they are not affected by infectious diseases. They must also undergo training in food hygiene requirements in special courses, the contents of which is specified by the ruling of the Ministry of Health.

Operators who produce foodstuffs or sell them in violation of food safety rules are threatened with financial penalties or imprisonment up to two years (Art. 49).

In sum it might be argued that the Polish food law has been promptly modified to include EU food safety requirements and that it contains provisions on all important contemporary food safety issues. What may be called *the nominal harmonization of the Polish food law to EU standards* has been largely achieved.

However, the EU requires from candidate countries not only nominal regulatory harmonization, but also a faithful implementation of such regulations as a rule since the first day of membership. But is nominal harmonization a sufficient criterion to state that enlargement-related challenges to food safety in the EU have been positively solved? This question brings us to the issue of controlling the implementation of food safety standards since, as becomes more and more evident, the same regulatory standards may produce different safety outcomes depending on the way they are implemented and controlled.

Recently the EU has been paying more and more attention to the problem of effective implementation of EU legislation.[74] As mentioned above, to enhance implementation the EC applies both enforcement and management mechanisms, but in the particular case of food safety in candidate countries the EC seems to rely more on management instruments.[75]

Management instruments serve to strengthen the problem-solving capacity of the countries which participate in an international policy regime. Two in particular seem to be especially important in the context of the current EU enlargement: the interpretation (mostly clarification) of rules and procedures, and capacity building (creating institutions and assuring adequate resources for their functioning).

Before identifying the ways in which the EC can increase the likelihood that food safety regulations will be properly implemented, it is necessary to look at a particular political mechanism which weakens the link between the readiness of a given government to transpose European regulations into national laws and its willingness to implement them faithfully. This mechanism stems from the *pro tempore* character of democratic governments, which may create a cleavage between a government which signs to the agreement and a government which is called to deliver upon the agreement. Democratic alternation might create disturbances in the implementation of regulations. This mechanism seems to be of special importance in candidate countries, which is why the EC pays special importance to the continuity of policy commitment despite government changes.

4.4 Problems with Implementation of Food Safety Regulations

4.4.1 Institutional Setup and Procedural Rules of Food Safety Inspections

Transposition of law and nominal regulatory harmonization is not enough to ensure meeting regulatory goals.[76] These goals are pursued by the national food safety administration and supported by the government. Contemporary research on specialized public administration, as one of the main conditions for its effective and efficient functioning, posits its insulation from political (elected) bodies by statutory guarantees and procedural rules such as the technique of managers'

74 Controls fall within the wider guardianship role of the Commission to ensure that Community legislation is effectively applied and enforced within the Community as laid down in Article 211 of the EC Treaty.

75 The punishment of misbehaviour would consist in delaying accession and as such is deemed to severe to be credible.

76 The full implementation of European regulations should encompass four consecutive stages: Formal transposition; Practical application; Enforcement/control and outcomes/results. See Stava, P. (1993) 'Implementation of Community Law: Stronghold of National Control?', in Andersen, S.S. & Elinssen, K.A. (eds.) *Making Policy in Europe: The Europeanization of National Policy-making,* London: Sage p. 60.

appointment and the length of their tenure.[77] Without meeting these criteria it is unlikely that specialized public administration can take full advantage of its expert knowledge and be able to act in the public interest.

What are the statutory and procedural arrangements that guarantee the capacity for an independent regulatory action in the case of the Polish food safety inspection system? Let us take as an example the veterinary inspection. The law of 24 April 1997 on Veterinary Inspection[78] stipulates that the Chief Veterinary Inspector, called the Chief Veterinary Doctor (CVD), is nominated (Art. 34) by the Prime Minister and can be recalled by him at the proposal of the Minister of Agriculture. In principle the CVD can be dismissed any time as his post is not protected by the guarantees of minimum tenure, and he/she is therefore unlikely to keep his position when there is a change of government. In fact, all government changes in Poland (1993, 1997 and 2001) have resulted in the change of the person running the Chief Veterinary Inspectorate.

Down the inspection ladder the Regional Veterinary Inspector is nominated by the Governor of the Region (Art. 37), who in turn is appointed by the government in agreement with the Chief Veterinary Inspector. But again the period of his tenure is not specified and his position is weak, although in this case the nominating organ (that is, the Governor of the Region) is a part of the structure of the central government.

In Poland routine inspections of abattoir and food factories are conducted by the Veterinary Inspector of Province (VIP) (powiat), who until March 2003 was nominated by the President of the Province on the motion of the Regional Veterinary Inspector. Again this position was not protected by formal provisions guaranteeing the stability of the tenure, but, making it even weaker was its subordination to the President of Province—the person elected by provincial counselors. The data show that strongly represented on provincial councils are business people often owning or running food enterprises and in principle able to exert pressure on the decisions of the VIP. The drawback of this institutional design was that instead of being autonomous with regard to local business interests, the VIP was exposed to business pressure. Cases were in fact reported in the press of the VIP succumbing to such pressure and the press reported the cases in which succumbing to such pressure, especially, apparently, out of the desire, to preserve jobs in a given locality.[79] This situation was, however, changed by the amendment of the Polish Food Law of 14 February 2003, which referred to the way the Veterinary Inspector of Province is nominated. The VIP is now nominated by the

77 See Murray Horn (1995) *The Political Economy of public administration: institutional choice in the public sector,* Cambridge: Cambridge University Press.

78 Its full name is 'The Law about the fight against infectious animal diseases, examination of animals and meat and Veterinary Inspection'.

79 Solska Joanna (2002) 'Strach przed miesem (Fearing Meat)', in *Polityka*, 19.

Governor of the Region on the motion of the Regional Veterinary Inspector, thus vertically reintegrating veterinary inspection in Poland.

Veterinary (or sanitary) inspectors might decide that foodstuffs must be withdrawn from the market, food production suspended or even a plant closed—in sum, decisions, which might ruin an enterprise. They must thus be taken with caution, but once taken they have to be backed by the government. Such backing is a core factor for the credibility of food safety policies.

The sanctions for the violations of food safety rules have to be effectively implemented since the first day of their obligations since all new regulations are pre-announced and made valid with a delay which can be measured in months or even years. Firms thus have the time for making necessary investments, implementing them and learning new safety procedures. Furthermore, governments also subsidize and educate firms to enhance their capacity to smoothly apply regulatory requirements.[80] However, once the deadline arrives all regulatory requirements should be implemented. The credibility of food safety policies is important since without it firms and farmers will implement food safety rules less faithfully. The criterion of credibility was not, however, met by the Polish government, which were used to changing the deadline to introduce certain provisions of food safety regulations under the pressure of industries or even large enterprises.

The efficacy of food inspections is crucial both for preventing the outbreak of foodborne diseases and for the external credibility of domestic food safety policies. The latter become more and more important in the light of the food policy proposals contained in a recent 'Proposal for a Regulation of the European Parliament and of the Council on official feed and food controls'.[81] The main thrust of the proposal is a shift from direct controls to auditing via the control of the way the national control system operates. It is also increasingly important that national control systems operate according to precise plans, that the outcomes of inspections are properly documented and shown at the request of foreign partners. If the control documentation does not raise doubts about its effectiveness the country sends credible signals to its partners and strengthens international confidence in its domestic policies.

An early example of such 'control of control' can be found in the assessment of the Geographical BSE-risk of Poland done by the Scientific Steering Committee (SSC) and published in March 2001 which highlighted several drawbacks in the

80 Such a support is offered to Polish farmers within an accession package signed in Copenhagen on 13 December 2003. According to the agreement in the years 2004-2006 Polish farmers can get repaid for the costs of adjustments introduced in order to meet EU food safety standards up to 200 Euro per one hectar (Informacja na temat wyników zako_czonych negocjacji akcesyjnych z UE w obszarze 'Rolnictwo' 6 January 2003' http://www.minrol.gov.pl/Publikacje/negocjacje_rolnictwo.html).

81 COM/2003/0052 final – COD 2003/0030.

working of veterinary inspections in Poland.[82] The SSC identifies the following deficiencies of the BSE inspection system in Poland:

- No documentation of control of slaughter and movement of imported cattle (p. 3);
- No evidence that the Veterinary Inspectorate had excluded the possibility that meat-and-bone meal (MBM) was fed to cattle and not only pigs, poultry, fish and pets (p. 5);
- Late implementation of a ban for feeding MBM ruminants (the feed ban has existed since March 1997, but the legal basis for official controls of proper implementation of the MBM ban was adopted only in March 1999 [p. 7]);
- No possibility to assess the efficiency of the procedure for notification of BSE (compulsory since April 1997) (p. 10).

In addition, the SSC assessment warns about the possibility of cross-contamination in the process of rendering the carcasses of fallen stock, as Polish feed-mills prepare feeding stuffs for all animal species using the same production lines with only separation in time of the production process.[83]

The SSC points also out to the intrinsic difficulties in inspecting 6 million cattle dispersed over 2 million multi-species farms, each usually with only one cow, one or some pigs and a few poultry.[84]

The lack of procedural safeguards for independent actions by food administration and the deficiency of the food controlling system exemplified by negligence in properly documenting inspection rules and activities can undermine the credibility of the implementation of food safety rules in Poland.

There is, moreover, the barrier of limited resources which can be devoted to food controls in Poland and in other candidate countries. Contemporary food inspection is technologically intensive: 'scratch and sniff' examination of meat is not effective. Often, only a full laboratory analysis can detect a dangerous pathogen. Thus, for instance, the costs of cattle examination in the pre-BSE era in Poland were minimal amounting to 2 Euros per cow. Now the examination of all cattle older than 30 months is much more costly as the transportation of the

82 Remember: the assessment is based on the data voluntarily supplied by the country's authorities. The document's name is: *Report on the Assessment of the Geographical BSE-Risk (GBR) of Poland*, March 2001, http://europa.eu.int/comm/food/fs/sc/ssc/.

83 Basic regulation dates from 13 July 1939 with modifications from 24 April 1997.

84 The impact of farm structure on the implementation of food safety rules is discussed in the section on safety regulations for milk production.

material and examination in referenced laboratories costs as much as 40 Euros per cow. Poland needs to test some 0.5 million cattle yearly for BSE, which would cost some 20 million Euro.[85]

A country can improve the credibility of its commitment to the control of food safety if it shows that it devotes enough resources to inspection services.[86]

4.4.2 The Size Distribution Effect: Phasing in UE Milk Safety Rules

The ability to meet safety requirements depends on the size distribution of firms operating in a given industry since as a rule the relative costs of regulatory compliance decrease with the increase of a firm's size. The domination of small food producers seems to diminish the likelihood of meeting food safety requirements, since a) it increases the direct costs of inspections, and b) most small food farm producers are unable to cover the costs of compliance with all food safety regulations. Thus, it happens in various areas of social regulation that a regulatory authority excludes small farms (or small producers) from such obligations.[87] Food safety regulations, and especially regulations aiming to reduce microbiological risks, are, however, special as foodborne disease might spread from even a small production site. Hence, in principle, food safety regulations should be implemented uniformly with regard to the size distribution of firms.

But can food safety rules be applied uniformly if the industry is dominated by small and very small producers? A possible answer can be found in the example of milk production in Poland.

The quality of farm milk is influenced by a number of factors associated with the technology of farm production.[88]

The microbiological contamination of raw milk during the production on the farm may result in the presence of a variety of microorganisms, some of them pathogenic. To limit the incidence of safety failure, minimum standards and surveillance procedures are laid down in legislation. The table below presents milk safety norms in Poland and in the EU.

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85 Andrzej Komorowski, Jacek Zak, *Problemy bezpieczenstwa zywnosci w konteksie zdrowia publicznego* (Problems of food safety in the context of public health), mimeo, 2002.

86 Poland employs 13,500 persons in the institutions performing food controls. It is comparatively less than an EU average. It is not enough to examine all cattle slaughtered as, according to press report, some 5,5 million animals are slaughtered without being ante-mortem examined by veterinary inspectors (see: Joanna Solska (2000) 'Pasztet z miesem', in *Polityka*, 19).

87 Such 'waivers' are given most frequently in the area of environmental regulations and occupational health and safety regulations.

88 In the paragraph I draw on the PhD dissertation by Waldemar Guba (2000) *Competitiveness of Polish Milk Processing Industry during the Integration to the European Union – Analysis of Dynamic Competitive Advantages,* University of Gottingen.

Table 10

Milk safety standards in Poland and the EU (as of 1998)

Quality criteria	Units	EU quality categories (EU Directive 92/46/EEC)			
		Acceptable		Unacceptable	
Limits for the bacteria number	1 000 per ccm	<=100			
Limits for the somatic cells	1 000 per ccm	<400			
Freezing point	C	<=-0.515			
Density	g/ccm	1.028			
Quality criteria	Units	Poland (Polish norm PN-A-86002:1995)			
		Class Extra	Class I	Class II	Class III
Limits for the bacteria number	1 000 per ccm	<100	100-400	400-1000	>1000
Limits for the somatic cells	1 000 per ccm	<400	400-500	500-1000	>1000
Freezing point	C	<=-0.515			
Density	g/ccm	1.028			

Source: adapted from Waldemar Guba (2000) Competitiveness of Polish Milk Processing Industry during the Integration to the European Union – Analysis of Dynamic Competitive Advantages, University of Gottingen, p. 20.

As can be noticed, the strictest standards with regard to milk safety in Poland are the same as those of the EU because the former have been modeled on the latter. What differs, however, is the technique of diluting the rigor of these standards by introducing subcategories for milk safety, which allows Polish farmers to slow down (if not bypass) the adjustments needed to meet these standards.

The Polish milk safety and quality regulations distinguished four classes of milk according to its safety/quality parameters, but only Class Extra has corresponded to the quality standard acceptable in the EU.

In 1999 Poland eliminated Class III, but still in mid-2000 of the 450,000 farms which were supplying milk to milk factories, only 160,000 were producing exclusively milk of Class Extra Quality. Adjustment had, however, taken place

quickly as in 1999 there had only been 90,000 milk suppliers who produced exclusively milk of Class Extra quality.[89]

The average size of farms in Poland, however, limits further progress in this regard as the analysis of the IERiGZ (1999) shows that investments in milk safety are economically justified only in farms with at least five to six cows, but such farms account only for 30-35 percent of farms functioning in Poland. [90]

A similar situation can be observed one step up in the milk processing chain. In Fall 2002 only 9 percent of milk processing plants (dairies) met EU milk quality requirements, but a further 40 percent of them have declared to be ready for the moment of accession. Poland has received a three year transition period for the next 28 percent of milk factories, but, according to all estimates, 23 percent of all milk factories have to be closed.

In the accession period, Polish milk factories have been treated according to the rule of market access; that is, the EC was worried about food safety standards only in plants exporting to the EU, but once Poland becomes a member of the EU, the EC wants to see EU food safety rules uniformly. However, in tune with 'the management approach' to the international agreements, the EC do not impose rules, controls and punish, but try to help to build domestic capacities to meet food safety requirements. In the case of the Polish milk sector this is done in two ways: firstly, by giving more time for adjustments by accepting 'transition periods', and, secondly, by subsidizing the costs of regulatory compliance with EU funds.

Table 11

Transition periods for the Polish diaries agreed in the Treaty of Accession

Diaries, which:	Number	Share of the total
Already meet EU food safety requirements	38	9.3%
Are expected to meet EU food safety requirements by 1 May 2004	178	43.5%
Are expected to meet EU food safety requirements by 31 December 2006	113	27.6%
Are unlikely to met EU ford safety requirements by 31 December 2006	80	19.6%
Total	409	100

Source: Mleczarnie i rzeznie zagrozone, *Rzeczpospolita*, 9 May 2003.

89 FAPA (2000) *Stereotypy w UE dotyczace polskiego sektora rolno-spozywczego,* Warszawa, p. 15.

90 IERiGZ (1999) *Rynek mleka: stan i perspektywy*, Warszawa.

Table 11 shows that almost 28 percent of Polish dairies need a transitional period, during which they will be treated as producing exclusively for local (subnational) markets, and almost 20 percent are facing closure.

The situation in other accession countries (see table 12), with the exception of Latvia, is somewhat better, but in the future the EC can be tested in its determinacy to enforce its requirements, if transitional periods would expire without promised changes.

Table 12

Transitional periods for food processing establishments

Country	Poland	Czech Republic	Hungary	Latvia	Lithuania	Slovakia
Meat plants	332 till XII 2007	44 till XII 2006	44 till XII 2006	77 till I 2006	14 till I 2007	1 till XII 2006
Milk plants	113 till XII 2006	-	-	11 till I 2005	1 till I 2007	-
Fish plants	40 till V 2007	7 till XII 2006	-	29 till I 2005	5 till I 2007	1 till XII 2006
Egg establishment	- -	1 till XII 2006	-	-	-	-

Source: The Treaty of Accession.

If the deadline is not met the EC can invoke the safeguard clauses of articles 53 and 54 of Regulation 178/2002 on the General Food Law[91] (and Art. 38 of the Accession Treaty) whose main sanction is the suspension of the placing on the market or the ban on the consumption of the food in question.

The EC has eased its food safety requirements by granting transitional periods. It is an important policy implementation instrument as it helps to smooth out over time the distribution of adjustment costs.

4.5 HACCP and Regulatory Auditing in Poland

As has been stressed, the EC is building its new food safety controlling strategy by relying on firms' own control systems and their controlling the national control systems. This strategy emphasizes safety and quality management techniques such

91 Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, *OJ* L 031, 01/02/2002, p. 0001–0024.

as those certified by Good Manufacturing Practice (GMP), Good Hygiene Practice (GHP) or HACCP.

Accordingly HACCP is to become an important part of a new food safety regime in Poland. By law all Polish food producers have to have implemented a HACCP system no later than 1 January 2004. This obligation does not, however, apply to small and medium sized enterprises, that is, enterprises employing less than 50 people.[92] The size distribution of food processing enterprises in Poland creates a great problem for the implementation of HACCP control system, as, for instance, of 4139 meat-processing firms functioning in Poland in 2000, only 350 employed more than 50 persons, 520 employed between 6 and 49 persons and the remaining 3269 (that is 79 percent) employed lower than 5 persons. Of course, larger companies process the bulk of meat sold on the Polish market, but because the HACCP controlling will cover only 21 percent of all active companies, the Polish regulatory system cannot rely on indirect controls via the mechanism of regulatory auditing, but have to depend on the effectiveness of old style veterinary inspections.[93]

The diffusion of HACCP is part of a broader change in the strategy of food safety controls. This change consists in a greater reliance on companies' food quality and safety discipline[94] and a greater use of courts in search of better consumer protection,[95] but this change can be successful only if firms and the food industry structure change to meet new responsibilities.

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92 Still small food companies can apply HACCP on a non-binding basis and, if they do so, they can count on the subsidies from the EU funds going up to 60 percent of incurred costs, but no more that 25,000 Zloty per firm (HACCP–Safe Food, in *Warsaw Business Journal*, 29 November 2002).

93 According to the estimations done on the basis of firms survey the costs of implementing HACCP in the meat processing industry amount to Zl 1.2m per enterprise. For small and medium sized meat processing companies they seem to be prohibitively high. The same research estimates that other costs of adjustments to EU regulatory standards amount to Zl 4m per one enterprise, see IKCHZ (2002) *Udzial polski w jednolitym rynku–koszty I korzysci dla poszczegolnych grup I wybranych produktow*, December 2002.

94 Especially so since under the pressure of the European Commission candidate countries, including Poland, have to limit the scope of formal approval of food before placing it on the market (see for instance the speech by David Byrne, European Commissioner for Health and Consumer Protection to European Business Summit on 6 June 2003 [Speech/02/260]).

95 Drawbacks in the Polish system of legal consumer protection has been evidenced by M. Sengayen (2002) 'Consumer Sales Law in Poland: Changing the Law, Changing Attitudes', in *Journal of Consumer Policy*, Vol. 25, p. 403-437.

5. Conclusions: Enhancing Domestic Implementation of International Regulations

This paper has analyzed the problems of adjusting the food safety regime of a candidate country such as Poland to the EU food safety requirements, by, firstly, discussing the problems intrinsic to food safety regulations and to the choice of regulatory instruments in general, next, by sketching the main tendencies of the development of EU food safety regime and, then, by discussing the factors which have influenced the transposition of EU food safety regulation into domestic laws and regulations and which might influence the implementation of such regulations in the near future.

Without repeating the complex analysis which has led to such conclusions I would like to restate its main thesis: the lack of disputes over the transposition of EU food safety regulations seems to be a result of the low salience of food safety issues in the perception of Polish consumers (they tend to believe that domestic food is safe or even safer than imported food stuffs), and of the fact that democratic alternation of governments de-links the act of committing a country to international agreements from the responsibility for implementing the rules and delivering expected regulatory outcomes. Furthermore, if one considers the enlargement process as a kind of asymmetric bargaining between the EC and candidate countries, it becomes immediately obvious that candidate countries had to accept the requirement to transpose all *acquis communautaire*, if they were to be admitted to the EU.

However, nominal regulatory harmonization is not enough; future member states are also obliged to faithfully implement food safety regulations. It has been stressed that the EC is changing its strategy to assure a reasonable food safety level across member states by putting an increasingly stronger emphasis on the control of the national control systems as well as the company control systems. This change, although in tune with theoretical developments in the area of risk regulation, seems to create special difficulties in a candidate country such as Poland whose agri-alimentary sector is highly fragmented and whose institutional setup for food safety control is still evolving. My analysis predicts problems with implementing food safety rules in candidate countries, but the negative externalities of possible violations of the EU food safety rules are attenuated by the fact that food trade between Poland and the EU countries is at a relatively low level (especially trade in food of animal origins). Recognizing the fact that any drawbacks in the Polish food safety system are unlikely to spill over to other countries the EC has granted transitional periods for the adjustment of food establishments. Furthermore, it is expected that Poland will use a significant part of EU funds to upgrade its agri-alimentary sector and its capacity to meet food safety regulations.

Besides developing a new framework for the control of national food safety systems, the EC has introduced, in the Treaty of Accession, several safeguards

which allow it to restrict food trade in the case of the inappropriate implementation of food safety rules or in the case of outbreaks of foodborne diseases.

Furthermore, the actual membership of the EU is likely to change the relative bargaining power of the EC and new member states. The EC will face the same difficulties in controlling the implementation in new member states as it faces now in 'old' member states.

The growing stress on the control of the implementation of international agreements poses an enormous challenge to policy oriented research as theorizing policy implementation and drawing policy lessons is an almost impossible challenge due to the complexities of policy issues and several conceptual problems.[96] The continuation of research on the implementation of food safety regulations in candidate countries is an important task not only as a support of the task of creating a European framework to assure food safety, but also in the light of possible contribution to a better understanding of conditions for successful policy implementation.

Last but not least, it should be remembered that food safety is not only an internal issue of the EU, but a broader problem in efforts to create such conditions for international trade in foodstuffs, which would respect the rules of free trade, while paying attention to the concerns for food safety. The increase of internationalization will probably continue.[97]

96 For a recent survey of policy implementation theories see: Peter deLeon and Linda deLeon (2002) 'What Ever Happened to Policy Implementation', in *Journal of Public Administration Research and Theory*, No. 4, p. 467-492.

97 According to Silverman, 'food regulation in the last half of the twentieth century has been characterized in part by an accelerating shift from local regulation to a system of national standards or national "uniformity"'. We see this trend take place during the next fifty years, with national agencies giving up authority to international standard setting and scientific organizations. 'Emerging' or third world war nations appear to expect this to happen. While they do not seem to be creating their own independent scientific/regulatory infrastructure, they seem to rely on Codex and organizations such as the Joint Expert Committee on Food Additives to serve this function, Richard S. Silverman (2000) 'Report on the Future of Food Regulation', in *Food and Drug Law Journal*, No. 11.

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