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Gregory C. Shaffer
Mark A. Pollack

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Agricultural Biotechnology in the EU

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New York University School of Law
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Regulating Between National Fears and Global Disciplines: Agricultural Biotechnology in the EU[1]

Gregory C. Shaffer
University of Wisconsin Law School
Law Building
975 Bascom Mall, Room 8104
Madison, WI 53706
E-mail: gshaffer@wisc.edu

Mark A. Pollack
Temple University
Department of Political Science
461 Gladfelter Hall
Philadelphia, PA 19122
E-mail: mark.pollack@temple.edu

1. Introduction: Biotechnology, GMOs, and Risk Regulation

Few issues of European law and policy excite as much attention and concern as the creation and marketing of genetically modified organisms (GMOs). Lauded by many scientists, policy elites, and members of the biotechnology industry as a step forward in scientific and economic terms, genetically modified (GM) foods and crops have also been rejected as unsafe or undesirable by many environmentalists and consumer advocates, and by a majority of the

[1] A shorter, edited version of this paper will appear in Helen Wallace, William Wallace, and Mark A. Pollack, eds., *Policy-Making in the European Union* (New York: Oxford University Press, 2005). The authors would like to thank Timo Weishaupt for invaluable research assistance, and the Center for World Affairs and the Global Economy at the University of Wisconsin-Madison for financial support. Earlier versions of this paper were presented at the 2004 Conference on Europeanists, March 11-13, Chicago, IL, and at the 2004 annual meeting of the Law and Society Association, May 27-30, Chicago, IL. We thank the conference participants for their comments and suggestions. As in our previous joint work, we, a lawyer and a political scientist, have worked equally on this hybrid text, which (at least for us) has spawned a better result.

European public as recorded in successive polls over the past decade. Into this controversy have stepped the institutions of the European Union, which increasingly play the leading role in establishing the regulatory framework for the growing and marketing of GM foods and crops in the Union's 25 member states.

In this paper, we examine EU policy and policy-making in the area of biotechnology, with a specific focus on agricultural biotechnology – namely, the development and marketing of GM crops and foods. More specifically, the paper aims to summarize both the content of the EU's rapidly evolving regulations, and the process whereby these regulations have been promulgated, implemented, and comprehensively reformed in the space of just over a decade. As we shall see, EU policy in this area is predominantly regulatory in character, setting the increasingly detailed regulatory framework within which genetically modified foods and crops may be developed, introduced into the environment, and work their way into the food supply.

Throughout the paper, we develop three interrelated arguments about the nature of GMO regulation and the challenges it poses to the European Union. First, we highlight the inherently multi-sectoral nature of GMO regulation, which links together the internal market with industrial policy, research and technological development, environmental policy, food safety, agriculture, and international trade. As a multi-sectoral issue, the regulation of GMOs raises the challenge of coordinating policymaking horizontally among a large number of public and private actors with diverse perspectives about the aims and the content of EU regulation.

Second, we emphasize the multi-level nature of the process, which involves overlapping and sometimes conflicting regulations promulgated at the national, supranational/EU, and international levels. EU policy-makers, therefore, face not only the challenge of horizontal coordination across issue-areas, but also the vertical coordination of EU policies with a diverse and politically sensitive set of national policies, as well as with a growing body of international trade and environmental law governing the release and marketing of GMOs. As we shall see, EU policy has faced sharp political and legal challenges both from below (in the form of national revolts against the licensing of individual GM foods and crops) and from above (in the form of challenges from other countries within the World Trade Organization, or WTO).

Third, the regulation of GM foods and crops is an instance of a broader category of "risk regulation," in which government actors are called upon to adopt regulations about the acceptable degree of risk posed to society by products or industrial processes. Such decisions about risk

regulation raise questions about the degree of risk judged to be acceptable to society, as well as about how to regulate specific products or processes in the face of continuing uncertainty about the risks they may pose to human health and the environment. As we shall see, risk regulation – including the regulation of GMOs – not only mobilizes diverse interest groups, but also raises fundamental normative questions about the roles of science and politics in the management of risk, and hence about the *legitimacy* of EU decision-making – especially at the supranational level of EU institutions where direct democratic control is widely considered to be inadequate.[2]

The paper is organized in seven parts. Following this introduction, part 2 examines in greater detail the challenges of biotechnology as a case of risk regulation and as a multi-sectoral and multi-level policy, requiring horizontal coordination across issue-areas and vertical coordination among the national, EU, and international arenas. In part 3, we examine the adoption of the EU's first binding regulations regarding the release and marketing of GM foods and crops, examining the interactions of EU institutions, member states, and private actors, and laying out the provisions of the EU's landmark 1990 Directives on the deliberate release of genetically modified foods and crops into the environment. Next, in part 4, we examine the substantial challenges of implementing the Union's early regulations, including a revolt among member governments that invoked safeguard clauses against GM foods that had been licensed at the Union level, and that later imposed a de facto moratorium on the approval of new GM varieties. Faced with widespread governmental and public calls for a stricter and more comprehensive approach, the Union then engaged in a root-and-branch reform of EU policies. Examined in part 5 of the paper, this reform included the substantial revision of the 1990 Directive as well as new regulations establishing a European Food Safety Authority and setting out detailed rules regarding the labeling of GM foods and the traceability of GM crops "from farm to fork." In part 6, we examine the relationship between domestic EU regulations and international trade and environmental rules. As we shall see, the rules and jurisprudence of international institutions such as the WTO have shaped EU regulations, focusing these on the use of individualized scientific risk assessment as the basis for biotechnology regulation, while the EU has simultaneously sought to export its domestic regulatory principles, including its version of the "precautionary principle," to the international arena. The final section concludes with a

[2] The literature on the EU's "democratic deficit" has mushroomed in recent years. For a range of views, see Scharpf 1999, Greven 2000, Siedentop 2000, and Moravcsik 2002.

brief assessment of the Union's biotechnology policy in relation to Helen Wallace's typologies of modes of governance, and in particular the "regulatory mode." The EU governance of biotechnology policy is shaped by sustained, simultaneous, and countervailing challenges to the legitimacy of EU decision-making in this domain from above (the WTO) and from below (the member states and their constituents).

2. Regulating GMOs: Three Challenges

Before moving on to survey the history and the substantive aspects of EU biotechnology regulation, it is important to discuss the three fundamental challenges posed by GMOs to the Union's regulatory capacity. Specifically, we focus here on biotechnology as an issue that is inherently *multi-sectoral*, requiring horizontal coordination across a range of issue-areas; inherently *multi-level*, requiring vertical coordination across the national, supranational, and international arenas; and inherently concerned with *risk regulation*, requiring difficult, highly contested decisions about the role of science and politics in the assessment and management of risk to modern European societies. Let us consider each in turn.

2.1. GMOs as a Multi-Sectoral Challenge

The regulation of biotechnology, and even the narrower question of the regulation and marketing of genetically modified foods and crops, is an inherently complex and multi-sectoral policy, involving actors and perspectives from many distinct issue-areas. For example, within the Commission – which has played a leading role in both formulating and implementing EU policies – biotechnology policy raises important questions for the Directorates-General with responsibility for the internal market, industrial policy, research and technological development, environmental protection, food safety and consumer protection, agriculture, and international trade. Each of these issue-areas, moreover, raises distinct issues regarding the regulation of GMOs:

1. With regard to the *internal market*, the primary concern is the free movement of goods, services, labor and capital, and hence more specifically the free movement of genetically modified seeds, crops, and food within the Union. Indeed, as we shall see, the need to complete the internal market was claimed by the Commission as the primary legal basis of much EU legislation in this area.

2. In addition to the internal market, however, the question of biotechnology has consistently been an important question for the Union's *industrial policy*, as the Commission and others have sought to secure a regulatory environment conducive to the development of a European biotechnology industry capable of competing with that of the United States.

3. Related to this last point, biotechnology appeared at an early stage on the agenda of the Union's *research and technological development policy*, as an area in which the Union seeks to sponsor collaborative cross-national scientific research.

4. Any such promotion of biotechnology, however, must contend with the potential *environmental* effects of its use, particularly with regard to the release of living genetically modified organisms (i.e. seeds and crops) into the environment. Largely for this reason, the Commission's Directorate-General for the Environment has played a leading role in the formulation of EU biotechnology policy, which has been negotiated and adopted predominantly by the Council of Environment Ministers, with the European Parliament playing an ever-increasing, and now equal, legislative role.

5. In addition to such environmental concerns, the marketing of genetically modified foods raises questions of *food safety and consumer protection*, insofar as EU consumers worry about the safety of GM foods or simply insist on the right to know whether the foods they buy are genetically modified or contain a genetically modified ingredient. Indeed, as we shall see, consumer concerns about food safety have played a key role in the various controversies regarding the regulation and marketing of GM foods. By the same token, EU regulations on traceability and labeling of GM animal feed, food, and crops have significant implications for the Union's *Common Agricultural Policy*.

6. The EU's regulation of genetically modified foods does not take place in a vacuum, finally, but has repercussions for the Union's *international trade* relations. Even when adopted for entirely domestic reasons, the EU's regulation of genetically modified foods and crops can have an impact on the flow of genetically modified foods and crops from

third countries such as the United States (which we shall see has a very different and more permissive regulatory framework for GMOs), and hence falls under the jurisdiction of the WTO. Indeed, the need to justify EU policies within the legal framework of the WTO has led to substantial reforms of EU biotech policy over the past decade, although as we shall see, it is controversial whether these changes constitute a "watering down" or a "trading up" of EU regulations (Young 2003).

Not surprisingly, it has proven difficult for the European Commission and the other institutions of the Union to coordinate policy-making across so many issue-areas. Within the Commission, the regulation of biotechnology has prompted the establishment and repeated reform of various multi-sectoral working groups aimed at coordinating Commission policy across the numerous Directorates-General with an interest in the issue. The multi-sectoral nature of GMOs has also rallied diverse individuals and interest groups to organize opposition to GMOs from a variety of perspectives, including in relation to environmental risks, consumer fears raised by food safety failures, the ethical challenges of gene research, unease about corporate control of intellectual property rights in seed varieties and thus over agriculture, and misgivings over the impact of international trade rules and globalization pressures on EU regulatory decision-making. From this hybrid mix of politics, GMO policymaking has emerged as a volatile issue.

2.2. GMO Regulation as a Multi-Level Process: The National, Supranational, and International Arenas

In addition to this vertical division among various issue-areas, the regulation of biotechnology has been marked by a horizontal separation among three distinct regulatory arenas – the national, supranational/EU, and international – and by continuous tension among all three levels.

Prior to the adoption of the first EU regulations in 1990, biotechnology research and development in Europe was regulated entirely at the national level. These national regulations, moreover, demonstrated a wide range of variation, with countries such as Denmark and Germany imposing tight restrictions on genetic engineering research, while others such as the United Kingdom and France provided more permissive regulatory environments marked by self-

regulation; a large third group of member states had not yet adopted any regulations on GM foods and crops (Cantley 1995).

In this context, the European Commission came forward during the latter half of the 1980s with its first proposals for the regulation of GMOs at the EU level. Such European regulations, it argued, would serve the multiple purposes of securing a unified internal market in genetically modified foods and crops and encouraging the development of a competitive biotechnology industry in Europe, while at the same time providing uniform regulatory standards with regard to worker health and safety, environmental protection, and food safety. On the basis of these proposals, the Council of Ministers adopted the first binding EU directives on the contained use and deliberate release of genetically modified organisms in 1990. As we shall see below, however, those directives featured substantial roles for the EU's member governments, which would play an important part in the initial approval of new genetically modified foods and crops, and retain the ability to impose national-level safeguards against GMOs authorized at the EU level.

In addition to the national and EU arenas, finally, biotechnology regulation has featured with increasing importance on the agenda of the global trade, environment and food safety regimes. As we shall see, national and EU regulation of biotechnology, while aiming primarily at environmental protection, consumer protection, or food safety, also has important implications for international trade, insofar as those regulations can serve as non-tariff barriers impeding the free movement of GM foods and crops across national borders. The question of biotechnology regulations as non-tariff barriers became an important political and legal issue from the mid-1990s, as US farmers rapidly adopted GM foods and crops only to find themselves unable to export these crops to the European Union, where new varieties were slow to meet with regulatory approval and where even approved varieties encountered national barriers and strict EU labeling requirements. To many in the United States, the EU's stringent regulations, and the de facto moratorium on new approvals after 1998, smacked of protectionism and irrationality, and the US placed increasing pressure on the EU Commission to end the moratorium and resume approval of new GM varieties, culminating in the filing of a WTO legal dispute by the US against the European Union in May 2003. Within Europe, however, US pressure to accept GM foods and crops prompted a backlash from agricultural and environmental groups, and from some member governments, further politicizing an already sensitive issue. In between these conflicting national

and international pressures sat the European Commission, which has sought, with limited success, to reconcile the political demands of European citizens and national governments, on the one hand, with the legal obligations and political pressures from the international arena, on the other.

2.3 Risk Regulation and the Legitimacy of EU Governance

Finally, the regulation of biotechnology also intersects two broader, vitally important, and interrelated questions for the Union, namely the regulation of risk and the legitimacy of EU governance. In modern societies, governmental actors are frequently called upon to regulate the risks posed by various products or by industrial processes.[3] Risk, in this context, refers to "the combination of the likelihood (*probability*) and the harm (*adverse outcome*, e.g. mortality, morbidity, ecological damage, or impaired quality of life) resulting from exposure to an activity (*hazard*)" (Wiener and Rogers 2002: 320, emphasis in original). In principle, therefore, regulators faced with a novel product or process – such as the genetic modification of foods and crops – need to ascertain the potential harm caused by such activities, as well as the probability of such harm, in order to take a decision on the legality or illegality of that product or process.

In practice, however, risk regulation frequently requires regulators to act in the face of *uncertainty* regarding the nature and extent of the risks posed by new products and processes, raising the fundamental political question of how governments should regulate risk in the face of such uncertainty. Frequently, regulators take *precautionary* measures, regulating or even banning certain products or activities including in the absence of complete information about the risks posed by them. More specifically, Giandomenico Majone (2003: 18-26) argues, government regulators in the United States and other jurisdictions have responded in four distinct ways – prohibitions, least feasible risk, elimination of significant risk, and cost-benefit analysis – with a general trend over time from the first and least sophisticated to the fourth and most sophisticated approach. In the first of these approaches, regulators exercise a high degree of precaution by simply banning any product (e.g. food additives) that can be shown to pose some level of risk to human health (e.g. carcinogens). While clearly motivated by a concern for human

[3] Beck and Giddens have theorized "modernity" in terms of the emergence of a "risk society" in which risks increasingly are "manufactured," as opposed to being "natural" or "external" to human activity, and in which the management of risks becomes a defining element of societal conflict and social understanding. See Beck 1992 and Giddens 1991.

health, such outright bans ignore the potential societal benefits of the banned products, as well as the probability of risk posed by a given product, which in the case of carcinogens can run the gamut from significant to minor. For this reason, regulators in the United States and elsewhere have moved over time towards other, less blunt approaches toward the regulation of risk.

According to Majone's second principle of "least feasible risk," for example, regulators are required to set standards that minimize risk "to the extent feasible." This is a more discriminating standard than outright prohibition, but it begs the question of technological or economic feasibility, and once again makes no distinction between significant and minor risks. For this reason, Majone contends, US lawmakers, regulators and courts moved during the 1970s and 1980s toward a third approach, in which the goal of regulators was not to eliminate *all* risk but rather *significant* risks, which in turn would require regulatory agencies to engage in scientific (and typically quantitative) risk assessments as the basis for new risk regulations. Fourth and finally, Majone argues, this gradual process of policy learning culminated in the use of cost-benefit analysis as the basis for all risk regulation. Such an approach involved not only the use of scientific risk assessments as the basis for assessing the risk of a new product or process, but also the economic calculation of the potential costs and benefits of proposed regulations, which would be adopted only if the net benefits to society from those regulations exceeded their costs. In the space of some three decades, Majone concludes, American policymakers, regulators and courts progressed to a sophisticated approach to risk regulation, relying on scientific assessments of risk as well as economic assessments of costs and benefits – "an outstanding, and in many respects unique, case of policy learning" (Majone 2003: 26).

While a useful heuristic device to understand the range of possible approaches to regulating risk under uncertainty, Majone's classification scheme simplifies a complex US response to risk, which even today combines elements of all four approaches under different laws and in different issue-areas. Even more importantly for our purposes, Majone's ideal-typical progression fails to capture parallel developments in Europe, where risk regulation took place largely within national contexts until the 1980s, when EU institutions began to play an increasing role in harmonizing risk regulation across the EU's various member states. In the EU context, David Vogel (2001) and others have argued, Europe's approach to risk regulation has evolved quite differently than in the United States. Whereas the former began with highly precautionary legislation in areas like the environment, consumer protection, and worker health and safety, only

to adopt scientific risk assessment and cost-benefit analysis more recently, regulators in Europe have arguably become more precautionary and more risk-averse over time.[4] In effect, Vogel writes, US and EU risk regulation resemble "ships passing in the night," with the EU becoming more precautionary and the US less precautionary over time. A central cause of this increasingly precautionary approach, Vogel and others argue, has been the long series of European regulatory failures and crisis over the past several decades, including most notably the BSE or "mad cow" crisis discussed below. As we shall see, these crises have weakened public trust in EU regulators and scientific risk assessments, increased support for highly precautionary regulations, and called into question the *legitimacy* of EU regulations and EU institutions in European public opinion. Responding to this crisis of legitimacy, EU institutions have moved aggressively to overhaul EU risk regulation across a range of areas, adopting strict new regulations for products and processes like genetically modified foods and crops and elevating the "precautionary principle" to the status of doctrine in EU regulation.[5]

Other scholars dispute Vogel's "ships passing in the night" characterization of US and EU risk regulation, noting that the purported "flip-flop" in US and EU approaches to risk regulation draws disproportionately from a few controversial issue-areas such as the use of growth hormones in beef cattle and the regulation of GMOs. In a wide-ranging survey of US and European risk regulation, Wiener and Rogers (2002) find a more complex set of outcomes, in which the US is more precautionary in some areas (e.g. nuclear energy, particulate air pollution) while the EU demonstrates greater precaution in others (GMOs, hormone-treated beef). "This broader analysis indicates that neither the US nor the EU is a more precautionary actor across the board, today or in the past. Relative precaution appears to depend more on the particular risk than on the country or the era" (Wiener and Rogers 2002: 322-23).

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[4] "Between the 1960s and the 1990s," Vogel writes, "a number of US regulations were more stringent, innovating and comprehensive than those adopted by European countries and the EC/EU. However, since the mid 1980s, this pattern has changed. Now in a number of significant areas of regulatory policy, EU regulations are more stringent, innovative, and comprehensive than those adopted by the US. Prior to the mid 1980s, US policy-makers identified more products and processes as posing unacceptable risks to public health or the environment than did regulatory authorities in Europe. Now the latter regard a number of products and processes as posing unacceptable risks to consumers and the environment that US policy-makers do not. Since the mid 1980s, the political influence of constituencies favoring more risk averse regulatory policies have strengthened in Europe while since the early 1990s it has declined in the US. Likewise, since the mid 1980s regulatory politics and issues have become more politically salient in Europe, while since the early 1990s, they have declined in the US" (Vogel 2001: 2-3).

[5] The literature on the precautionary principle in risk regulation has mushroomed in recent years: for a range of supportive and critical views, see e.g. Bodansky 1991; Cameron and Abouchar 1991; European Commission 2000; Wiener and Rogers 2002; and Majone 2002.

For this reason, we resist extrapolating from our study of GMO regulation to the question of comparative precaution more generally. We note that, in comparison to the United States, Europe has historically adopted a contrasting approach to issues of food safety regulation in particular, summarized by Marsha Echols under the rubric "different cultures, different laws" (Echols 1998, 525-31). European governments and their consumers have been willing to accept the safety of traditional foods, such as raw milk cheeses and cured meats, while challenging the adoption of new technologies for food production and preservation such as irradiation and genetic modification. Americans, in contrast, have generally been skeptical of traditional European methods, while remaining more open to the use of new technologies in food production and preservation. Nevertheless, we do emphasize that the question of risk regulation under uncertainty presents challenges to the EU's regulatory capacity and legitimacy that have shaped policy processes and outcomes in this issue-area, and that have only recently been confronted by students of EU policymaking.[6] Moreover, the EU's high-profile disputes with the US over the regulation of GMOs has provided an important context and constraint for EU regulatory efforts over the past decade.

3. Historical Origins of EU Biotech Policy

The 1957 Treaty of Rome Establishing the European Community made no explicit mention of an EU policy for biotechnology, or even for the closely related areas of environmental protection and food safety, which remained primarily a national responsibility within each of the Community's member states. Nevertheless, just as the federal government in the United States used its interstate commerce authority to regulate food safety in the early 20th century, so the Union has developed a *de facto* policy on biotechnology over the past three decades, as the EU's policies on research and development, agriculture, food safety, and the internal market have all "spilled over" into the regulation of the content and labeling of GM foods and crops.

Genetic engineering is a technology used to isolate genes from one organism, manipulate them in the laboratory, and inject them into another organism. This technology, also known as recombinant DNA (rDNA) research, first emerged as a concern for national and international regulators in the 1970s, as biological scientists began making fundamental advances in rDNA

[6] On risk regulation and EU governance, see e.g. Neyer 2000; Vos 2000; Joerges 2001; Abels 2002; Chalmers 2003; Majone 2003; and Vogel 2003.

research.[7] The debate over the regulation of such research is often dated to the international meeting of scientists at Asilomar, California, in 1975, which pointed to the promise of biotechnology but also called on the scientific community to exercise caution and restraint in the creation of genetically engineered organisms that might prove hazardous. During this early period, from the 1970s through the mid-1980s, the development and marketing of GM foods and crops lay in the distant future, and regulators in Europe and elsewhere therefore focused primarily on issues relating to laboratory research and to the development of a competitive biotechnology industry. In 1978, the Commission Directorate-General for Science, Research and Development (then DG XII) proposed a Community R&D programme in molecular biology, together with a draft Directive requiring notification and prior authorization by national authorities for all biotechnology research. This latter proposal was withdrawn by the Commission in 1980, in favor of a non-binding 1982 Council resolution calling for notification of rDNA research to national authorities. Commission concerns about the competitiveness of the EU's biotechnology industry remained, however, and in 1983 the Commission incorporated biotechnology into its multi-annual Framework Programme for research and technological development.

By the mid-1980s, with the rapid development of genetic engineering and the early efforts to regulate biotechnology among the member governments, the Commission began more actively to explore the development of a Community framework for biotechnology regulation. Such proposals, Patterson (2000: 324-32) notes, created major challenges for the Commission, which responded by creating several inter-departmental coordinating bodies, most notably the Biotechnology Steering Committee (1984) and the Biotechnology Regulation Inter-service Committee (1985). Within these groupings, moreover, the center of gravity shifted gradually away from the DG XII, which had taken the leading role during the early years,[8] and increasingly towards other DGs and in particularly Environment (DG XI), which became involved during the late 1980s as biotechnology moved increasingly out of the laboratory and toward deliberate releases into the environment and eventually marketing of GM foods and crops. With DG Environment taking the lead, in 1986, the Commission released another Communication, "A

[7] This section draws liberally from Lee Ann Patterson's (2000: 319-32) analysis of the early history of EU biotech regulation, as well as from Cantley's (1995) detailed study.

[8] Prior to 1983, Cantley (1995: 535) notes, "the other DGs… saw the mysteries of biotechnology as still playthings of DG XII and the scientific community…" Hence, "[t]he Commission communications on biotechnology, although presenting a strategic approach, were in practice largely drafted by the research service, DG XII, with marginal additions by the other services" (Cantley 1995: 543).

Community Framework for the Regulation of Biotechnology," which laid out the Commission's rationale for a European regulatory regime and its plans for specific EC regulations (see chronology of key events in Box 1). The Commission noted that the European Parliament had already called (in 1987) for Community-level regulation, and that a number of member states had already moved to adopt a range of national measures, threatening to disrupt the EC's single market. "The internal market arguments for Community-wide regulation of biotechnology are clear," it argued. "Microorganisms are no respecters of national frontiers, and nothing short of Community-wide regulation can offer the necessary consumer and environmental protection."[9] The Commission therefore indicated its intention to come forward with concrete regulatory proposals covering both laboratory use and deliberate release into the environment of genetically modified organisms.

[9] Commission of the European Communities, "A Community Framework for the Regulation of Biotechnology: Communication from the Commission to the Council," COM(86)573 final of 4 November 1986, quoted in Cantley 1995: 553.

Box 1: Key Events in EU Biotechnology Regulation

1975	Asilomar conference on biohazards posed by GMOs
1978	Commission proposes Directive requiring prior notification and authorization of GM research (withdrawn 1980)
1983	Biotechnology included in EU Framework R&D Program
1984	Commission forms Biotech Steering Committee
Nov 1986	Commission report, "A Community Framework for the Regulation of Biotechnology"
1988	Commission proposes twin Directives on contained use and deliberate release of GMOs
1990	Council adopts Directives 90/219 and 90/220
1996 (March)	Start of BSE Crisis, questioning of EU food safety regulation
1997 (Jan)	Council adopts Novel Foods Regulation
1997 (Jan)	Commission approves sale of GM maize; three member states invoke safeguard clause
1998 (Oct)	Start of de-facto moratorium on approval of new GM varieties
1999 (June)	Declaration of moratorium on GM approvals by five member states
2000 (Jan)	White Paper on Food Safety
2000 (Jan)	White Paper on the Precautionary Principle
2000 (Jan)	Cartagena Protocol on Biosafety Adopted
2001 (March)	Council and EP adopt Directive 2001/18, replacing 90/220, on deliberate release of GMOs
2002 (Jan)	Establishment of European Food Safety Authority
2003 (May)	US launches WTO complaint over EU regulation of GMOs
2003 (Sept)	Council and EP adopt Regulation 1830/2003 on Traceability and Labelling of GMOs
2003 (Sept)	Council and EP adopt Regulation 1829/2003 on Genetically Modified Food and Feed
2004 (Apr)	Entry into force of Regulations 1829/2003 and 1830/2003
2004 (May)	Commission ends moratorium with approval of Bt-11 sweet maize

3.1. Directive 90/220 on the Deliberate Release of GMOs into the Environment

The Commission came forward in May of 1988 with its proposal for two new Directives, which ultimately became Directive 90/219 on the Contained Use of Genetically Modified Microorganisms and Directive 90/220 on the Deliberate Release into the Environment of Genetically Modified Organisms. The first of these Directives relates primarily to the safety procedures established for laboratory research into genetic modification, whereas the second concerned the release of GMOs from the laboratory to the environment as well as marketing of genetically modified foods and crops. For this reason, we concentrate here on Directive 90/220,

which would emerge during the 1990s as the primary, and controversial, EU regulation governing the approval and marketing of GM foods and crops.[10]

The Commission's (1988) proposal for a "Deliberate Release Directive" began by noting the extraordinary diversity of existing national regulations across the various member states, including: (a) a ban on deliberate release (subject to exceptions) in Denmark and Germany; (b) a case-by-case approach to the release of individual GMOs in a number of member states (UK, France, Belgium, Netherlands, and Luxembourg); and (c) an absence of legislation in other member states (Ireland, Greece, Italy, Spain, and Portugal).[11] These differences, the Commission argued, could in practice distort competition among member states in the biotech sector, as well as serve as an impediment to the development of a competitive European biotechnology industry. Accordingly, the Commission proposed a draft directive to be adopted under Article 100a (now Article 95) EC, and hence using the cooperation procedure established in the 1987 Single European Act.[12] Moreover, by contrast with the regulatory approach of the United States, which regulated GMOs according to the characteristics of the final *product* rather than genetic modification as a *process*, the Commission's proposal followed the approaches of countries such as Germany and Denmark in adopting a process-based approach, creating special and distinct regulations for the approval and marketing of GMOs.

The Commission's proposal emphasized the scientific uncertainty associated with genetic engineering, and therefore proposed an EU regulatory scheme that would provide for case-by-case assessment and authorization of the release of new GM varieties into the environment. Significantly, the Commission proposed a regulatory procedure that, at least in the first instance, involved regulatory assessment and approval by national regulatory authorities, followed by the sharing of information among the various member states, with EU institutions intervening to regulate directly only if member governments disagreed on the safety of a given GM variety.

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[10] For an excellent analysis of Directive 90/219, see Hunter 1999: 197-206.

[11] See also European Parliament 1989, Cantley 1995, and Patterson 2000 for good discussions of existing national regulations.

[12] Article 100a had the additional advantage of requiring only a qualified majority in the Council of Ministers, in cooperation with the European Parliament. More specifically, the Commission proposal would hence be considered first by the European Parliament, which could propose amendments that could be adopted or rejected by the Commission and by the Council in its common position. Following this common position, the Parliament would undertake a second reading, where it would have the opportunity to reassert its proposed changes, but the final decision would be taken by the Council of Ministers voting by qualified majority. By contrast, Directive 90/219, the "Contained Use Directive," was adopted under Article 130s on environmental regulation, requiring unanimous agreement within the Council.

More specifically, the Commission's proposal would require any individual wishing to release GMOs into the environment (e.g. for farming or marketing) to notify and provide a detailed risk assessment to the competent regulatory authority of the EU member state in which the release was proposed. That member state would then be charged with evaluating the application in line with the criteria laid down in the directive. If the member state rejected the proposal, the procedure would end, but if the member state accepted the proposal, the dossier would then be forwarded to the Commission and to the other member governments, which would have a limited period to object to the authorization. If no objections were put forward, the product would be authorized for release and/or placement on the market throughout the EU. By contrast, if one or more member governments or the Commission objected, the Commission would then undertake its own assessment and formulate a Decision to approve or deny the application. The Commission's draft Decision would be circulated to an advisory committee of member-state representatives, of whose opinion the Commission would have to take "utmost account"; the final decision, however, would remain with the Commission. In a final acknowledgement of member-state prerogatives, however, the Commission proposed a "safeguard procedure" whereby a member state could, if it had evidence of a serious risk to people or the environment from a previously approved GMO, "provisionally restrict or prohibit the use or sale of that product on its territory." Once again, however, the member state in question would have to inform the Commission of its actions and give reasons for its decision, and the Commission would retain the power to approve or reject the measures in question.

The European Parliament, in its first (1989) and later its second (1990) readings, criticized the Commission proposal as being too lax on a number of points, and proposed a number of amendments that would have substantially tightened regulatory restrictions on the approval of new GMOs. For example, the Parliament would have required applicants to demonstrate the "justification of the social desirability of the objective of the proposed deliberate release and assessment of possible alternatives to attain the same objectives" – a much higher and arguably more politicized standard than the scientific risk assessment called for in the Commission draft (EP 1989, Amendment No. 28). National authorities, similarly, would be required to base their decision in part on the same criterion of "social desirability" (Amendment 31). Elsewhere, the Parliament called for the insertion of new provisions including the establishment of absolute-liability arrangements (Amendment 21) and "effective penalties for infringements" (Amendment

22) as well the mandatory notification of the public located in the areas affected by the release of GMOs (Amendment 23). Furthermore, the Parliament proposed deleting the provision allowing the Commission to take a decision on the release and marketing of a product in the absence of agreement among the member governments. The United States government, by contrast, criticized both the Commission proposal and the Parliament's proposed amendments as unnecessarily strict and as arbitrary, particularly insofar as they proposed to regulate all GMOs regardless of the characteristics of the products to which they gave rise.[13]

The Council followed the broad lines of the original Commission proposal, thus rebuffing the core US objections, while at the same time rejecting the Parliament's most far-reaching amendments. The Council's final text of Directive 90/220 therefore laid out a complicated, multi-level approval process for the release and marketing of GM foods and crops.[14] Under the Directive, as under the original Commission proposal, a manufacturer or importer seeking to market a GMO or release it into the environment had to first submit an application to the national competent authority of an EU member state, including an extensive scientific risk assessment for the GMO in question. The member state to which the application was submitted then examined the dossier, and either rejected the application or accepted it. In the case of a favorable opinion, the dossier was then to be forward to the European Commission and to the other member governments, each of which had a right to raise objections. If no objections were raised, then the member state carrying out the original evaluation formally approved the product, which could be marketed throughout the European Union.

If one or more member states raised an objection, however, a decision had to be taken at the EU level. The Commission, acting on the basis of an opinion from its scientific committees, adopted a draft decision, as in the original Commission proposal. However, whereas the original Commission text provided for the Commission to be aided only by an advisory committee of member-state representatives, the final text featured a more constraining "regulatory committee."

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[13] "By basing the Directive on the technique by which the organism is modified, the EC is regulating organisms produced by a given process. This is not a functional category directly related with the characteristics of the organism. As expressed in the US coordinated framework for the regulation of biotechnology, the US generally regulates products rather than the process by which they are obtained. We are concerned whether differences in approaches and their implementation may lead to difficulties in our attempts to achieve international harmonization. It is important to understand that whether an organism is 'unmodified' or 'genetically modified' is, in itself, not a useful determinant of safety or risk." US Government, "International Harmonization in the Biotechnology Field," 7 July 1989, quoted in Cantley 1995: 559.

[14] Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms, *Official Journal of the European Communities* L117 of 08/05/1990, pp. 15-27.

Under the regulatory committee procedure, the Commission's draft decision was forwarded to a committee of member-state representatives, who could approve the decision by a qualified majority vote. If the regulatory committee did not approve the decision, however, it was to be sent to the Council of Ministers, which could approve the Commission decision by qualified majority or reject it by a unanimous vote. If the Council failed to act within three months, the directive provided that "the proposed measures shall be adopted by the Commission" (Article 21). Finally – and significantly, in light of later developments – the Council retained a slightly modified version of the Commission's safeguard clause, whereby a member state could, on the basis of new evidence about risks to human health or the environment, "provisionally restrict or prohibit the use and/or sale of that product on its territory." The member state in question would be required to inform the Commission, which would approve or reject the measures in cooperation with the regulatory committee mentioned above.

3.2 The Novel Foods Regulation

In 1997, the regulatory structure of Directive 90/220 was supplemented by Regulation 258/97, or the so-called Novel Foods Regulation.[15] According to the terms of the regulation, "novel foods" were defined as all foods and food ingredients that had "not hitherto been used for human consumption to a significant degree within the Community" and included both foods that had been genetically modified as well as foods produced from, but not containing GMOs (for example, oils processed from genetically modified crops but no longer containing any traces of GM material).[16]

The regulation went on to impose an authorization procedure for such novel foods, similar to the authorization procedure of Directive 90/220. As in the earlier directive, any individual seeking to market such novel foods would be required to submit an application in the member state in which it would first be placed on the market. That state would conduct a thorough assessment and take a decision, which once again could be contested by any member state, triggering the centralized EU regulatory procedure in which the Commission would again take

[15] Regulation (EC) No. 258/97 of the European and of the Council of 27 January 1997 Concerning Novel Foods and Novel Food Ingredients, *Official Journal* L 043, 14/02/1997, pp. 1-6. For excellent analyses of the regulation, see also Hunter (1999: 217-225) and Commission of the European Communities, "Novel Foods and Novel Food Ingredients," http://europa/eu.int/scadplus/leg/en/lvb/I21119.htm, accessed on 11 April 2004.

[16] The regulation would not apply to food additives, flavorings, or extraction solvents, governed by other EU legislation (Article 2).

the leading role, supervised by the Standing Committee on Foodstuffs consisting of member state representatives. Assuming that a given novel food was authorized for marketing, moreover, the Novel Foods Regulation also imposed additional requirements, including the labeling of foods containing GMOs or derived from GMOs (provided that the latter were "no longer equivalent" to their conventional counterparts).

Significantly, however, the regulation also went on to provide a simplified regulatory procedure for foods derived from, but no longer containing, GMOs, provided that those foods remained "substantially equivalent" to existing foods in terms of "their composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein" (Article 3). Such a determination would be made by the competent authority in the member state receiving the application, and would be notified to the Commission, which would in turn notify the other member states. In practice, this provision would prove to be significant in the coming years, as member states would approve a number of products as being "substantially equivalent" to their conventional counterparts.[17]

Finally, and again significantly in terms of later developments, the regulation (like the earlier Directive 90/220) contained a safeguard clause allowing member states, "as a result of new information or a reassessment of existing information" to "temporarily restrict or suspend the trade in and use of the food or food ingredient in question in its territory" (Article 12). As we shall see, this safeguard clause would later be invoked (by Italy) to contest the "substantial equivalence" of approved products, raising questions about the adequacy of the existing regulatory structure.

4. The Problems of Implementing EU Policy: Member-State Revolt and International Reaction

To understand successive attempts to regulate agricultural biotechnology in the EU, and the subsequent difficulties of implementing these regulations, we need to place EU agricultural biotech regulation in the context of a series of developments in the mid-1990s and, in particular, the BSE food-safety scandal that struck in 1996. In March 1996, the British government of Prime Minister John Major revealed a possible connection between Creutzfeldt-Jacob disease, a

[17] By contrast, no products consisting of or containing live GMOs have been authorized under the terms of the Novel Foods Regulation at this writing. See Commission of the European Communities, "Question and Answers on the Regulation of GMOs in the EU," MEMO/02/160-REV of 4 March 2003.

fatal disease for humans, and bovine spongiform encephalopathy (BSE), a disease spread among cattle through their consumption of contaminated feed, popularly known as "mad cow disease." The BSE disease infected some 150,000 cattle in the UK, triggering a wide-scale slaughter of cattle, a Community ban on the export of British beef, a plummet in beef sales throughout Europe, and a loss of consumer confidence in regulatory officials. The crisis did not abate quickly, moreover, with France and Germany reporting new outbreaks of the disease in 2000 and 2001. Perhaps most importantly for our purposes, the BSE scandal raised the question of risk regulation "to the level of high politics, and indeed of constitutional significance" (Chalmers 2003: 534-538), generating extraordinary public awareness of food safety issues and widespread public distrust of regulators and scientific assessments.[18]

It was in this political context that genetically modified crops were first commercially introduced in the United States and Europe. In April 1996, within a month of the ban on British beef, the Commission approved the sale of genetically modified soy products over member state objections.[19] In November 1996, GM soy was imported from the United States to the EU, spurring widespread protest by Greenpeace and other groups. Soybeans are ingredients in more than half of processed foods, and the US shipped between 25 and 40% of its soybeans to the EU (Vogel 2001: 10). Soy is also used in animal feed, stoking activist groups' concerns that GM soy would replace feed that had been banned in response to the BSE crisis. In short, widespread media coverage and public debate about GM foods began just as the BSE food crisis struck. News reports about genetic modification often mentioned the BSE crisis, helping link the two issues before the European public (Ansell et al).[20]

Two other events occurred in late 1996 that add important context to the contestation that was to engulf EU decision-making over GMOs. In December 1996, a Scottish scientist

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[18] A study showed that around 90% of US citizens believed the US Department of Agriculture's statements on biotechnology, whereas 12% of Europeans stated that they trusted national regulators. See Vogel 2003, citing J. Enriquez and R.A. Goldberg, "Transforming Life, Transforming Business: The Life Science Revolution, Harvard Business Review, Mar.-Apr. 2000, published at http://www.hbsp.harvard.edu/products/hbr/marapr00/R00203.html. Vogel notes that, in the BSE scandal, "the European Commission had relied on the advice of the Scientific Veterinary Committee, which was chaired by a British scientist and primarily reflected the thinking of the British Ministry of Agriculture, Fisheries and Food—advice which subsequently proved flawed." Id. at 27.

[19] See Commission Decision 96/281/EC of 3 April 1996 concerning the placing on the market of genetically modified soya beans (The decision states, "The competent authorities of other member states have raised objections to the said dossier" which the United Kingdom had forwarded with a favorable opinion).

[20] To give just one example of this pattern, the *European Voice* published two half-page articles under the topic "Survey: Consumer Protection" in its weekly edition of April 13, 2000. The article on the top half of the page is entitled "Spate of health scares pushes food safety to top of the EU agenda," while that on the bottom half is entitled "Union faces dilemmas as it debates new GMO rules." *See European Voice*, 13-19 April 2000, at 15.

announced to the world the first successful reproduction of a cloned mammal, a sheep named "Dolly," suggesting that the cloning of humans could follow shortly. The announcement spurred ethical challenges to biotechnological research. Also in December, the United States and Canada lodged complaints before the World Trade Organization challenging the EU's ban on hormone-treated beef on the grounds that the EU ban constituted a disguised barrier to trade and was not justified on the basis of a scientific risk assessment. The WTO judicial bodies subsequently held against the EU, and, when the EU failed to comply with the ruling, authorized the United States and Canada to retaliate by withdrawing trade concessions in an amount equivalent to their trading losses. Both countries did so, imposing trade sanctions worth US$116.8 million and CND$1.3 million per year. Targeted products included traditional French foods such as foie gras, Roquefort cheese, and Dijon mustard. The WTO case further rallied a federation of smaller French farm producers which was a fervent opponent of GMOs, the *Confédération Paysanne*, led by Jose Bové.[21] Bové quickly became a symbol for anti-globalization and anti-WTO movements worldwide, and a French national hero, at one time embraced by the leaders of each major French political party.[22]

The close succession of these events illustrates how the popular understanding of GM products in Europe became associated with consumer anxieties related to food safety crises,[23] distrust of regulators and scientific assessments, disquiet over corporate control of agricultural production,[24] ethical unease over genetic modification techniques, environmental concerns, and anger over the use by the United States of international trade rules to attempt to force "unnatural" foods on Europeans. A widespread cross-sectoral movement organized to oppose GMOs in Europe, bringing together environmentalists, consumers, and small farmers. The movement

[21] "The CP is a farmer's union styled as an alternative to the large mainstream union…. [It] expands agriculture into a social issue, directly opposing the industrial farming supported by FNSEA and advocating sustainable farming practices and various other social causes." Ansell, Maxwell and Sicurelli 2003.

[22] See Henley, Jon, 1999. "McDonald's Campaign Spawns French Hero: Political Activist Turned French Peasant Has Fast Food on the Run," *The Guardian*, 11 September, p. 14.) ("He [Mr. Bové] has had expressions of sympathy from all sides of the political spectrum, from the Greens to the far-right National Front, the Socialists to the Gaullists.")

[23] A second major food scandal broke when the public discovered that Belgian farm animals had been fed dioxin-contaminated feed, resulting in the removal of Belgian chicken, eggs, pork and beef from the entire EU market, and leading to the fall of the Christian Democratic government of Jean-Luc Dehaene. Later, there was a scare regarding possible contamination of Coca-Cola products in northern Europe and a French admission that sewage sludge containing human and animal wastes was found in feed destined for pigs and chickens. Barlow 1999.

[24] Indicative of Europe's greater reticence toward promoting biotechnology, the European Parliament first exercised its veto power over proposed EU legislation when it rejected the EU's biotech directive. The directive was finally passed in 1998, but only a few member states had implemented it when required in July 2000 (Gold & Gallochat 2001).

operated at multiple levels, working the media and local and national political processes, coordinating transnationally, and lobbying the Commission and EP (Ansell et al 2003). The British media dubbed GM products "Frankenstein" foods, playing off fears that scientists and public agencies could not control the release of GM products. Negative European attitudes toward GM crops and foods rose rapidly. In early 1996, 46% of the French were against GMOs, a figure that rose to 65% in 1999, and 75% in 2002.[25] Similarly, over 80% of Germans expressed negative opinions about GMOs by late 1998 (Gaskell, Allum, and Stares 2003).

In the midst of the fray, the Commission approved the sale of another GM food crop (Bt-maize) in January 1997, over the objection or abstention of all but one of the fifteen member states.[26] The Commission was able to do so because of the approval procedure set forth in Directive 90/220. As we saw, a member state (in this case France) could approve a GM variety and forward its decision to the Commission and the other member states so that the variety could be marketed throughout the EU. Since some member states objected to this approval, the Commission reviewed the dossier, which it did favorably. The Commission then submitted a draft authorization to the regulatory committee consisting of representatives from each of the member states. Eight member-state representatives on the committee abstained or voted against the approval, so that the Commission forwarded its proposal to the Council (operating as the Environment Council). However, the Council could only amend the Commission's proposal by a unanimous vote, and France announced that it supported the Commission's authorization (Bradley 1998, 212). As a result, even though fourteen member states refused to support the Commission, the approval went forward.[27]

The member states did not simply accept the Commission's decision. They undermined its implementation, invoking the safeguard clause of Directive 90/220 which permitted a member state to prohibit an approved GM variety in its territory if it had "justifiable reasons to consider that [the] product… constitutes a risk to human health or the environment." Austria was the first

[25] Compare, for example, Eurobarometer on Biotechnology, 1997, based on Oct.-Nov. 1996 data, indicating that those optimistic about genetic engineered outweighed pessimists by 43% to 22%.

[26] See Commission Decision 97/98/EC of 23 January 1997 (concerning the placing on the market of genetically modified maize). The vote in the regulatory committee in April 1996 showed four member states opposed and four abstaining. See Bradley 1998 for an excellent review of this case.

[27] At the time, the EU lacked any labeling requirement for the genetically modified soy. When the Novel Foods Regulation subsequently came into effect in May 1997, it did not require labeling where a variety was deemed "equivalent" to a traditional food in terms of quality (article 8). This approach to labeling was in conformity with existing OECD guidelines, and was preferred by U.S. authorities and the biotech industry, but it spurred heated opposition from anti-GMO activists, who sought mandatory labeling of all GM foods.

to act, promptly prohibiting the cultivation and marketing of the GM maize variety on February 14, 1997. Luxembourg followed suit on March 17. On April 8, the European Parliament, which held no power to block the approvals, nonetheless passed a resolution condemning the "lack of responsibility of the Commission in unilaterally taking decisions… in spite of the negative positions of most member states and the European Parliament."[28]

Member-state deployment of safeguard bans grew, undermining the central purpose of Directive 90/220 to create a single market for GM crops under a harmonized regulatory system. By January 2004, nine member-state safeguards, applied by Austria, France, Greece, Germany, Luxembourg, and the United Kingdom, were in effect (European Commission 2004b). Italy also invoked an analogous safeguard procedure under Article 12 of the Novel Foods Regulation to ban the sale of food products containing ingredients from four varieties of GM maize. The Commission forwarded to the regulatory committee a proposal to initiate a legal challenge against these member state bans, but proceeded no further when the committee refused to support it. The Commission decided to bide its time while it proposed new legislation governing GM crops and foods.

Opponents of GMOs worked not only the political process, they took their battle to the marketplace as well. Under pressure from potential consumer boycotts of their foods, many large European retailers refused to buy or sell GM foods. The EU trade association EuroCommerce demanded that U.S. producers and distributors segregate and label GM soybeans. Major purchasers of soybean imports into the EU, such as Unilever, simply refused to buy U.S. soybeans (Vogel 2001: 10). Large UK supermarket chains, such as Sainsbury, and food processors, such as Haldane Foods, pledged that their company-labeled foods would be GM-free. Monsanto organized a media campaign to raise support for GM products, but the campaign backfired, having served primarily to increase public awareness that GM food products had arrived or were on their way. Surveys in the UK and France indicated that negative perceptions of GMOs rose following the Monsanto advertising campaign (Vogel 2001: 12). Thus, although GM soy and maize varieties had been legally authorized for marketing throughout the EU and validated by risk assessments conducted by EU scientific committees,[29] they were subject to member state bans and were barely commercialized at all (Vogel 2001: 11).

[28] European Parliament, Resolution on genetically modified maize, final edition 08/04/1997.
[29] The Scientific Committee on Plants issued 16 favorable opinions on applications for placing GM plant varieties on the market under Directive 90/220/EEC, and only one unfavorable opinion "due to an insufficient risk assessment,"

Responding to the popular backlash against GMOs, a group of member states pronounced in June 1999 the need to impose a moratorium on approvals of GM products.[30] Since the earlier date of October 1998 (when two GM varieties of carnations were approved), no GM varieties had been authorized for sale in the EU market, the only exception being for foods derived from GM varieties deemed "equivalent" to traditional foods under the Novel Foods Regulation.[31] For all these reasons, any account of EU policymaking in the sphere of biotechnology must address not only the *legislative* politics of adopting EU Regulations and Directives, but also the subsequent and equally acrimonious politics of *implementation*.

The Commission was in a particularly delicate situation at the time. In February 1997, the European Parliament adopted the Medina report that criticized the Commission for its handling of the BSE issue and threatened censure.[32] Parliament's concern over the Commission's handling of EU finances eventually led to a highly critical report from five independent experts in January 1999 that triggered the resignation of the Santer Commission. Under the circumstances, the Commission did not wish to further provoke the member states and Parliament by using its powers under existing regulatory procedures to approve GM crops over their objections.

The Commission, nonetheless, was caught in a vise, as it faced determined opposition to the moratorium from the United States. U.S. regulatory policy tends to treat GM crops and foods as "substantially equivalent" to non-GM varieties, and, in consequence, relies largely on industry self-regulation (Pollack and Shaffer 2001; Shaffer and Pollack 2004). Unlike Europeans' reactions to GM products, the vast majority of U.S. consumers have not contested the marketing of GM foods. As a result, the vast majority of GM research, development, and production occur

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resulting in the withdrawal of the application. See Commission memo/02/160, Oct. 15, 2002 (questions and answers on the regulation of GMOs in the EU).

[30] In an annex to the press release of the Environment Council meeting in Luxembourg on June 24/25 1999, the Danish, French, Greek, Italian and Luxembourg delegations declared: "The Governments of the following Member States (Denmark, Greece, France, Italy and Luxembourg), in exercising the powers vested in them regarding the growing and placing on the market of genetically modified organisms (GMOs), [...] point to the importance of the Commission submitting without delay full draft rules ensuring labeling and traceability of GMOs and GMO-derived products and state that, pending the adoption of such rules, in accordance with preventive and precautionary principles, they will take steps to have any new authorisations for growing and placing on the market suspended." Council of Ministers, 2194 the Council Meeting—Environment—Luxembourg, June 24-25, 1999, Press 203—Nr 9406/99.

[31] This exception, however, was closed under new directives adopted in 2003, as discussed below.

[32] European Parliament (1997). Report on alleged contraventions or maladministration in the implementation of Community law in relation to BSE, without prejudice to the jurisdiction of the Community and national courts. Rapporteur, Manuel Medina Ortega. http://www.europarl.eu.int/conferences/bse/a4002097_en.htm

in the United States, where around two-thirds of all GM crops are grown.[33] By the end of 2003, around 81% of soybeans, 73% of cotton, and 40% of corn grown in the United States were genetically modified varieties, and these figures were rising annually.[34] U.S. exports of soy to the EU were valued at $1.5 billion in 1998, about thirteen times the value of lost beef sales to the EU in the earlier WTO dispute, but these sales have since plummeted.[35] Moreover, the use of GM varieties developed and patented in the United States was spreading to other countries, including such leading agricultural producers as Argentina, Australia, Brazil, and China, increasing the profit potential for U.S. biotech firms. In light of the growth and prospects of agricultural biotechnology for U.S. farmers and industry, their trade associations pressured U.S. authorities to challenge European trade restrictions bilaterally and under WTO rules. GMO regulation in the Union faced not only the challenge of multi-sectoral coordination, but also a multi-level one.

5. The Reform of EU Policy Since January 2000

Facing pressure on multiple fronts, the Commission looked for a way to resume approvals of genetically modified varieties, free up commerce in the internal market, assuage member states and their constituents that adequate controls were in place, implement an EU-wide labeling regime, and restrict member state opt-out rights under "safeguard" provisions. In particular, the Commission hoped that the problem of the moratorium on GM approvals could be addressed through new legislation that would replace or complement Directive 90/220 and the Novel Foods Regulation. As a stop-gap, the Commission adopted, on its own initiative, Commission Directive 97/35 on June 18, 1997, which essentially overturned the Novel Foods Regulation's rules on GM labeling.[36] The Commission directive required the labeling of GM foods through an indication that they "may contain" GMOs, even though the foods would have been deemed "equivalent" to

[33] See "Genetically Modified Crops in the United States," Pew Initiative on Food and Biotechnology Fact Sheet (2003); and "Genetically Engineered Crops Up 15 Percent; China, South Africa Report Biggest Increases," 21:4 International Trade Reporter (BNA) 124 (Jan. 22, 2004).
[34] Pew Initiative, supra note…, at 3 (citing figures for 2001-2003).
[35] See United States Department of Agriculture, Foreign Agricultural Service, Bico Commodity Aggregations, March 20, 2004 (noting decline of US soy imports into the EU from US$1.534 billion to US$1.113 billion, comparing 1998. Available at http://www.fas.usda.gov/ustrdscripts/USReport.exe (visited March 20, 2004). The US National Corn Growers Association estimates that US corn growers lose $300 million a year in lost sales on account of the moratorium. NCGA 2003.
[36] See Commission Directive 97/35/EC of 18 June 1997 adapting to technical progress for the second time Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms. See also Commission Regulation (EC) 1813/97 of 19 September 1997, which specifically required labeling of foods produced from the approved GM soy and maize varieties, even though they were approved prior to the Novel Foods Regulation having taken effect.

traditional foods under the Novel Foods Regulation. In May 1998, the Council passed Regulation 1139/98 requiring labeling of GM soy and maize varieties as "produced from genetically modified" organisms, in contrast to the Commission's more flexible ("may contain") requirement. In January 2000, the Commission amended this regulation, pursuant to the regulatory committee process,[37] to create a threshold pursuant to which labeling would not be required where the GM maize or soy was "present in a single ingredient in a proportion no higher than 1% of the food ingredients individually considered…, provided this presence is adventitious."[38] U.S. farmers and grain traders claimed that this threshold was much too low, and could only be met, if at all, at an expense vastly disproportionate to any perceived consumer benefit. Nevertheless, the internal pressure on the Commission to propose more stringent regulations continued.[39]

In January 2000 the Commission issued a White Paper, a form of general policy initiative, in which it proposed that the EU overhaul its food safety system and establish a new centralized EU agency, which was eventually named the European Food Safety Authority (EFSA), to assist with risk regulation.[40] The White Paper set forth the EU's general approach to risk regulation in the food sector, dividing "risk assessment" from "risk management." Specialized scientific committees within the new food authority would conduct risk assessments, and the new authority would provide food safety information to consumers and operate a rapid alert system in conjunction with member state authorities to respond to food safety emergencies. Risk *management*, in contrast, would remain under the control of the EU's political bodies. In an annexed "action plan," the Commission set forth over eighty new food safety-related measures to adopt, including amendments to Directive 90/220 and the Novel Foods Regulation.

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[37] Where the regulatory committee simply approved the Commission's proposal, the legislation is called a "Commission" directive or regulation. Where the regulatory committee referred the Commission's proposal to the Council and the Council adopted an amended version, the resulting legislation is called a "Council" regulation or directive.

[38] See Commission Regulation (EC) No 49/2000 of 10 Jan. 2000 amending Council Regulation (EC) No 1139/98 concerning the compulsory indication on the labeling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC.

[39] The stop-gap measures were eventually replaced by Regulation 1829/2003, discussed below.

[40] In 2002, the Council and European Parliament adopted EC Regulation 178/2002 pursuant to which the new agency, named the European Food Safety Authority, was created. While member states debated and lobbied over its ultimate location, the EFSA was temporarily housed in Brussels. The European Council finally determined in December 2003 that its headquarters would be established in Parma, Italy. See EFSA press release at http://www.efsa.eu.int/press_room/press_release/34_en.html. When fully operational, EFSA is expected to employ 250 people with a budget of 40 million euros, a tiny agency compared to the US Food and Drug Administration that employs over 9,000 people and has 2,100 scientists working for it (Buonanno 2003).

In February 2000, the Commission issued a Communication on the precautionary principle, indicative of EU authorities' more risk-averse approach in an increasingly politicized domain that was raising challenges to the legitimacy of EU law. The Commission declared that the "precautionary principle" would be applied whenever decision-makers identify "potentially negative effects resulting from a phenomenon, product or process" and "a scientific evaluation of the risk… makes it impossible to determine with sufficient certainty the risk in question [on account] of the insufficiency of the data, their inconclusiveness or imprecise nature." It stressed that "judging what is an 'acceptable' level of risk for society is an eminently *political* responsibility" (Commission's emphasis). The Commission nonetheless maintained that it hoped to provide some guidance regarding the application of the principle, which it acknowledged, was "giving rise to much debate and to mixed and sometimes contradictory views."[41] The Commission stated that where regulatory decisions are adopted in accordance with the principle, the resulting measures should meet a series of criteria, and, in particular, they should be proportionate, non-discriminatory, consistent, based on cost-benefit analyses where feasible, and subject to review and ongoing risk assessment. When the Council adopted a resolution on the precautionary principle at the Nice European Council in December 2000, its evocation granted policymakers further flexibility. The resolution maintained that risk assessments may not always be possible on account of insufficient data, and that cost-benefit analyses should consider the "public acceptability" of risk management decisions.[42] The EU's evocation of the precautionary principle, already too permissive in the views of US policymakers, had just become more so.

In response to challenges to the legitimacy of European GMO regulations from above and below, the Commission in 1998 proposed a new directive to govern the deliberate release of GMOs into the environment and the placing of GM food products on the market, replacing Directive 90/220. In the wake of the BSE crisis, the Commission had already reorganized its internal handling of food safety matters by centralizing them within a recast (and renamed) Directorate-General for Health and Consumer Protection (or, under the French acronym,

[41] Commission (2000) at 15. The Commission observed that, although the precautionary principle is not defined in the EC Treaty (which only prescribes its use to protect the environment in article 174 of the Treaty), the European Court of Justice's case law had recognized the principle's application in other domains (Scott 2003, 228).
[42] See Council Resolution on the Precautionary Principle, Annex III to the Presidency Conclusions, Nice European Council Meeting, 7-9 December 2000. See also Vogel 2001, 28-29.

SANCO) in 1997 (Skogstad 2003, 6).[43] Once more, the Commission was divided between those who desired less-restrictive authorization and labeling requirements (namely DG Industry, DG Research, and DG Trade), and those who sought stricter controls (such as DG Environment and DG SANCO) (Stewart & Johanson 1999, 273). By contrast to the early 1980s, however, the leading players in this later round of regulation were DG Environment and DG SANCO, both of which favored a precautionary approach to risk regulation. Overall, the Commission was eager to put in place some sort of system that would meet member-state demands on environmental and consumer protection, and in so doing bring an end to the de facto moratorium and fend off a potential US legal challenge.

Both the European Parliament and Council pressed the Commission for further regulatory controls. The majority of the European Parliament insisted on tighter restrictions regarding labeling requirements and thresholds pursuant to which products could contain traces of GMOs and still be sold in the EU.[44] The member states were mixed in their views, with some appearing to do everything possible to ensure that no GM crops would be grown in their territories (such as Austria and Luxembourg), and others being torn between the demands of GM opponents and those of the biotech sector (such as Germany and the United Kingdom). A "conciliation committee," consisting of the members of the Council and fifteen representatives of the European Parliament, drafted the final text.[45]

The resulting legislation, Directive 2001/18, was finally adopted in March 2001 by co-decision between the Council and European Parliament. The directive's twin objectives were to protect the environment and human health when GMOs are released into the environment and placed on the market "as or in products," in both cases to be applied "[i]n accordance with the precautionary principle."[46] The legal basis for the directive, once more, was Article 95 governing the functioning of the internal market. Once more, the need to assuage those member states that desired stringent regulation of GMOs had led to a ratcheting up of EU regulatory requirements for GMOs so as to facilitate the free circulation of agricultural and food products in a single EU

[43] This reorganization represented the Commission's move "away from an approach emphasizing food security…and towards an approach emphasizing food safety, linked to the protection of consumers" (Vos 2000).
[44] "Genetic Engineering: European Parliament's Vote on GMOs Described as a Step Backwards," *European Report,* 15 April 2000.
[45] For good accounts of the conciliation process, and the key issues separating the EP and Council delegations, see "Genetic Engineering: Key Issues in GMO Conciliation Become Clearer," *European Report*, 1 November 2000; and "Biotechnology: Conciliation Talks Move Towards Agreement on GMOs," *European Report*, 13 December 2000.
[46] The precautionary principle is noted in articles 1 and 4 and paragraph 8 of the preamble.

market (Young 2003). More specifically, under the directive's environmental release requirements, member state and applicant obligations had been enhanced to include a more extensive environmental risk assessment, further information concerning the conditions of the release, and monitoring and remedial plans.[47] In addition, member state authorities were to make their decision-making processes more transparent, holding consultations and making information on all releases and reports publicly available (Article 9).[48] The directive instructed the member states to adapt their laws to comply with its requirements by October 17, 2002, at which time Directive 90/220 would be repealed.

Although touted by the EP's rapporteur David Bowe as "the toughest laws on GMOs in the whole world,"[49] the adoption of Directive 2001/18 did not satisfy a core of member states (in particular Austria, Denmark, France, Greece, Italy, and Luxembourg), which continued to insist on the moratorium's continuation and on the need to impose national safeguard bans in the absence of still more stringent EU regulations.[50] Unable to obtain the regulatory committee's approval of a legal challenge against these bans, the Commission worked toward passage of yet further EU legislation governing the authorization, labeling, and traceability of GM products. For this reason, only the directive's provisions governing the release of GMOs into the environment remain in effect,[51] while its provisions governing the marketing of GMOs used for commercial crops were replaced within a mere eighteen months by two new EU regulations regarding the labeling and traceability of GM foods and their use in food and feed, respectively. Proposed by the Commission in 2001, these new regulations were finally adopted in September 2003, once again after drawn-out bargaining among the Commission, Council, and European

[47] A simplified procedure can be used where an operator and the member state authority have sufficient experience with the GMO to be released. See article 7 of Directive 2001/18. Commission Decision 94/730 of 4 November 1994 established the simplified procedure.

[48] Similarly, the procedures of Regulation 1829/2003 are to be conducted in a transparent manner pursuant to which the public may provide comments to the Commission. The public is to be granted access to the application file, opinions from EFSA, and all post-marketing monitoring reports, after confidential information is deleted. Compare Scott, 237 (noting the "limited opportunities envisaged for pubic participation"). Article 6.4 of Directive 90/220, in contrast, only provided that member states would consult the public where they consider it "appropriate."

[49] Quoted in Blake Evans-Pritchard, "Vote on GMO Legislation Today," *euobserver.com*, 14 February 2001, accessed on 6 June 2003.

[50] In a joint statement, France, Italy, Austria, Denmark, Greece and Luxembourg "reaffirm[ed] their intention… of ensuring that the new authorizations for cultivating and marketing GMOs are suspended pending the adoption" of new provisions on traceability, labeling, and environmental liability. Quoted in Michael Mann, "Six EU States Refuse to Lift Block on New Modified Crops," *Financial Times*, 16 February 2001, p. 8.

[51] Part B of the directive covers the "deliberate release of GMOs for any other purpose than for placing on the market" that go beyond the "contained use" of GMOs (i.e. it addresses the testing of GMOs in pilot plots). Directive 90/219, as amended, continues to govern the contained use of GMOs. Council Directive 98/81/EC of 26 Oct. 1998 amended Directive 90/219.

Parliament.[52] Both legislative instruments took the form of regulations, and not directives, placing authority predominantly in the hands of Community institutions. Regulation 1829/2003, regarding the authorization of GMOs in food and feed, replaced the provisions of Directive 2001/18 governing the authorization for marketing of GMOs as or in products,[53] and the labeling provisions of the Novel Foods Regulation. Regulation 1830/2003, in turn, created new rules on the traceability of GM products throughout the production and distribution process. Since Regulation 1829/30 involved authorizations for both food and feed, its legal basis (which the member states contested)[54] rested on three separate Treaty provisions: Article 37 (common agricultural policy), Article 95 (internal market), and Article 152(4)(b) (public health). Both regulations became effective on April 18, 2004. (The revised EU regulatory scheme is summarized in Box 2.)

Box 2. EU Legislation Governing GMOs and GM Products as of May 2004

Step-by-step Activities in the Production Process	*Applicable EU Legislation*
GMO research in laboratories	Contained Use Directive 90/219
All GMO experimental releases (trials)	Directive 2001/18
GMO environmental releases and marketing authorizations for non-food or feed seeds and crops (such as flowers)	Directive 2001/18
GMO environmental releases and marketing authorizations for seeds and crops for food or feed	Regulation 1829/2003 and Directive 98/95/EC (common seed catalogue)

[52] The Commission initiated its original proposals in 2001. See Commission of the European Communities, "Proposal for a Regulation of the European Parliament and the Council on Genetically Modified Food and Feed," COM(2001)425 final of 25 July 2001; and Commission of the European Communities, "Proposal for a Regulation of the European Parliament and the Council 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," COM(2001)182 final of 25 July 2001. For the Commission's amended proposal, see COM(2002)559 final.

[53] Article 5.5 of Regulation 1829/2003 provides that articles 13-24, constituting Part C of Directive 2001/18, "shall not apply," but rather be replaced by the new, more centralized authorization procedures. Note that, in order to be marketed in the Union, GM seeds must also meet the standard requirements for all seed varieties to be placed in the Union's "common catalogue of agricultural plant species." See e.g. Council directive 98/95/EC of 14 December 1998 (concerning requirements for such listings). DG Sanco was "chef de file" for Regulation 1829/2003 and DG Sanco and DG Environment were joint "chefs de file" for Regulation 1830/2003.

[54] The UK had pressed for including article 308 of the Treaty (the so-called "implied powers" clause) as a legal basis, which would have required unanimous approval of the regulation (Scott 217). Regulation 1830/2003's primary legal basis was article 95, the internal market provision. As is common practice, the preambles to both regulations 1829 and 1830 also referred to the Treaty as a whole.

Authorization for marketing of GM food and feed	Regulation 1829/2003
Labeling of GM food and feed	Regulation 1829/2003
Traceability and labeling of GM food and feed products	Regulation 1830/2003

Importantly, Regulation 1829/2003 broadened the definition of legitimate objectives that may be pursued in determining whether to approve a GM food or feed variety. The range of objectives is expanded to include not only the protection of the environment and of human life and health (as under the 2001 deliberate release directive), but also "consumer interest in relation to genetically modified food or feed."[55] Moreover, in preparing its draft decision over the authorization of a GM variety, the Commission is to take into account not only EFSA's scientific opinion, but also "other legitimate factors relevant to the matter under consideration."[56] It is unclear whether these other legitimate factors will only include the identified "objectives" listed in article 1, including consumer protection, or whether the Commission can also take into account other objectives such as ethical ones, especially given that the new regulation specifically provides for Commission consultation with the "European Group on Ethics in Science and New Technologies."[57]

The regulation also broadened the scope of product coverage. First, the regulation's authorization and labeling requirements cover GM animal feed for the first time, in addition to food for human consumption. Second, the regulation covers food and feed that do not contain or consist of GMOs, but nonetheless are "derived, in whole or in part, from GMOs" or contain ingredients that are "derived, in whole or in part, from GMOs." [58]

Regulation 1829/2003 created a more centralized authorization procedure to regulate the placing of GM food and feed on the market. With a more centralized procedure, the Commission hopes to better manage countervailing member-state and US challenges to the EU's regulatory regime. The application process still begins when an operator submits an application file to the

[55] Compare article 1 of Regulation1829/2003 with article 1 of Directive 2001/18.
[56] Article 7(1).
[57] See article 33; and discussion in Scott 2004 (who notes the contrasting, and limited, legal basis of the regulation, which is based primarily on the Treaty's internal market provision, and does not expressly refer to the Treaty's environmental and consumer protection provisions).
[58] See articles 2.10 and 3.1 (defining the scope of coverage).

competent authority of one of the member states.[59] That member state authority, however, now immediately provides the file to the new European Food Safety Authority, which, in turn, provides a copy to the other member states and the Commission, and makes a summary of the file publicly available. EFSA is to issue its opinion, based on risk assessments, within six months from its receipt of the file, subject to extensions if further information is needed. EFSA submits its opinion to the Commission, the member states, and the applicant, and, after the deletion of any confidential information, makes it publicly available. The Commission is then to issue a draft decision, which may vary from EFSA's opinion. The Commission's draft decision is again provided to the regulatory committee consisting of member state representatives. If the committee supports the Commission's proposed decision by a qualified majority vote, then the decision is approved. If the committee fails to approve it by a qualified majority, then the Commission must submit its proposal to the Council. Unless the Council, in turn, opposes the Commission's proposal by a qualified majority vote, then the proposed decision "shall be adopted by the Commission," unless of course the Commission independently withdraws its proposal.[60] These voting rules represent a significant change compared to those applicable under Directive 90/220, under which the member states could only overturn a Commission decision by a unanimous vote. As noted earlier, since one member state supported the Commission's proposal to approve a variety of bt-maize in January 1997, the member states could not block it. Any authorization of a GM variety is now limited to a term of ten years, although it is subject to renewal.

Box 3. Authorization Process for GM Food and Feed under Regulation 1829/2003

Operator	An operator submits an application to the competent authority from one of the member states.
Member State	The member state provides the file to the new European Food Safety Authority (EFSA).

[59] The application requirements are quite detailed. In the case of GMOs and food or feed containing GMOs, the application must include an environmental risk assessment, informational requirements concerning the conditions of any release, and a monitoring plan for environmental effects. For these products, as well as food derived from (but not containing) GMOs, the file must include a post-market monitoring plan, and such additional information as studies showing that the food will not "have adverse effects on human health, animal health or the environment, mislead the consumer, [or] differ from the food which it is intended to replace [in a manner that] would be nutritionally disadvantageous to the consumer" (articles 4 and 5).

[60] See Articles 7, 19 and 35 of Regulation 1829/2003 which, in turn, refer to the operation of the Standing Committee on the Food Chain and Animal Health, pursuant to article 5 of Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (known as the "comitology" decision)..

EFSA	The EFSA provides a copy to the other member states and the Commission, and makes a summary of the file publicly available.
EFSA	Within six months, the EFSA submits its opinion, based on risk assessments, to the Commission, the member states, and the applicant, and, after the deletion of any confidential information, makes it publicly available.
Commission	The Commission is then to issue a draft decision, which may vary from EFSA's opinion, to the regulatory committee consisting of member state representatives.
Regulatory Committee Council Commission	The regulatory committee is to deliver its opinion on the Commission's draft decision. If the committee does not support the proposal by a qualified majority, the Commission must submit its proposal to the Council. If the Council does not oppose the Commission's proposal by a qualified majority vote, then the proposed decision "shall be adopted by the Commission."

Although the procedural scheme at the EU level is somewhat similar to that provided under Directives 90/220 and 2001/18, it became more centralized in two primary respects. First, EFSA, a centralized EU agency, oversees the application file and works in conjunction with member state competent authorities and a Community reference laboratory to conduct risk assessments and product evaluations.[61] Second, the regulation restricts the grounds on which member states may ban GMOs unilaterally as a "safeguard" measure. A member state may adopt "interim protective measures… where it is evident that products authorized…. are likely to constitute a serious risk to human health, animal health or the environment," provided that it first informs the Commission of the "emergency" situation and the Commission does not act.[62] The Commission's original proposal provided for no member state safeguard powers, but the Parliament and Council succeeded in including this clause. The European Parliament, however, preferred to grant greater autonomy to member state authorities (Scott 2003: 224).

One of the most controversial elements of the new regulation was the establishment of a set of thresholds for permitted traces of genetically modified ingredients, provided their presence is "adventitious." Recognizing that it is practically impossible to ensure that any shipment is entirely free of GM material because of the way crops are threshed, stored, and transported, the

[61] EFSA has a specific Scientific Panel on Genetically Modified Organisms that issues opinions on the risks of GMOs and products derived from them. Compare articles 4-6 of the Novel Foods Regulation and article 13 of Directive 2001/18 (where the member state competent authority conducted the initial risk assessment and made the initial authorization decision). Nonetheless, under article 6.3 of Regulation 1829/2003, EFSA "shall ask a national competent authority to carry out the risk assessment… if the application concerns GMOs to be used as seeds."

[62] Article 34 of the directive provides that articles 53 and 54 of Regulation (EC) No 178/2002 (that established EFSA) will apply in such a situation. Compare article 16 of Directive 90/220 and article 23 of Directive 2001/18. Scott points out that the regulation appears to take the form of "an exhaustive harmonization measure," so that article 95 of the EC Treaty, that might otherwise permit a member state to restrict trade on the grounds of major needs or the exceptions listed in article 30 of the Treaty, would not apply. See Scott at 225-226.

Commission initially proposed a threshold of 1% GM material, below which any crop would not have to be labeled as containing GM foods. The Commission's proposed threshold was contested, however, by environmental groups such as Greenpeace and the European Consumers Organization (BEUC), by the European Parliament, and by several member governments in the Council, all of which called for lower thresholds. European biotech companies and the United States government, by contrast, criticized a one percent threshold as unrealistic, unnecessarily costly and scientifically unjustified. These divisions were mirrored in the Council, where the United Kingdom favored the Commission's proposed 1% threshold, while Austria at the other extreme favored thresholds as low as 0.1%.[63] The final regulation represents a compromise among these member state positions, and establishes two distinct thresholds. First, it provides that food products will not violate its labeling requirements if they contain material consisting of or produced from EU-approved GMOs "in a proportion no higher than 0.9% of the food ingredients considered individually… provided that this presence is adventitious or technically unavoidable." Second, however, the regulation establishes a second and stricter threshold of 0.5% for GMOs not yet approved for environmental release in the EU, provided that they have received a favorable EU scientific risk assessment. It also establishes a three-year window after which no residues of such non-approved GMOs will be allowed in food or feed product unless new regulations are enacted. The regulation provides that the Commission may further lower these thresholds over time. The regulation's authorization and labeling requirements nonetheless do not apply to food produced with the aid of GMOs, such as meat, milk, and eggs produced from animals fed with GM feed.[64] The European Parliament had wanted the labeling requirements to cover these products, but did not prevail (Scott 2003: 215).

Regulation 1830/2003, finally, complemented the new authorization and labeling rules with a more centralized framework for tracing genetically modified products, as Directive 2001/18 had left this responsibility to the member states. The new regulation required the Commission to establish a system of unique identifiers for each genetically modified organism in order "to trace GMOs and products produced from GMOs at all stages of their placing on the

[63] "Biotechnology: Member States Agree on GM-Labelling of Food," *European Report,* 4 December 2002. For other good accounts of the debate over thresholds in Regulation 1829/2003, see e.g. "Biotechnology: MEPs Draw Inspiration from Hearing on Labeling and Tracing GM Food," *European Report*, 1 May 2002; Bettina Berg, "GMO Proposals Adopted in European Parliament," *euobserver.com*, 3 July 2002.

[64] Similarly, cheese is not covered by the regulation's authorization and labeling requirements when a GM enzyme is used, to the extent that the enzyme is only a processing aid so that no GM source material is in the cheese.

market through the production and distribution chain." More specifically, the regulation requires producers to collect and retain for five years data regarding the GM content of foods and crops one step backward and one step forward in the distribution chain. These strict traceability requirements have been bitterly criticized by many US producers (whose commodity system does not require and is not designed for tracing GMOs through the distribution chain), as well as by some European producers, but has been justified by the Commission as vital to the EU labeling system as well as for any future recalls of GM foods or crops.[65]

The Commission and biotech companies tried to step up enforcement against member state non-compliance with some EU regulatory requirements in 2003, although they have not been nearly aggressive as they could be.[66] In April of that year, the Commission issued a "letter of formal notice" to twelve member states that had failed to implement Directive 2001/18, as required.[67] It initiated a lawsuit against eleven of them in July pursuant to Article 226 of the Treaty. When Austria proposed to make the region of Upper Austria a GM-free zone in March 2003, the Commission (following an opinion from EFSA)[68] ruled that Austria's general ban would be illegal since GMO restrictions should be based on attributes of specific GMOs. Concurrently, three biotechnology companies (Monsanto, Syngenta, and Pioneer) challenged Italy's ban of food products containing authorized GM maize before the Italian courts. An Italian lower court referred the matter to the European Court of Justice for an interpretation of EU law pursuant to Article 234 of the Treaty. In September 2003, the European Court of Justice ruled that Italy must conduct "a risk assessment which is complete as possible… from which it is apparent that, in light of the precautionary principle, the implementation of such measure is necessary in order to ensure that novel foods do not present a danger," which Italy had so far failed to show.[69]

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[65] See e.g. the comments of Tony Van Der Haegen, minister counselor at the EU Delegation in Washington, D.C., who referred to the US grain handling system as "very efficient, but … totally incompatible with the traceability system." Quoted in "US Grain System Said Incompatible with EU Rules," *Reuters*, 13 July 2001.

[66] As Scott (2004) writes, the Commission's reticence to use the law "has served to allow the law to stand aside, pending political resolution."

[67] Joe Kirwin, "EU Formally Warns 12 States for Failing to Conform to GMO Licensing Directive," 20:16 International Trade Reporter (BNA) 671 (April 17, 2003).

[68] See The EFSA Journal 2003 (opinion of 4 July 2003).

[69] The matter then returned to the Italian courts to apply the ruling based on Italy's presentation of any studies supporting its restrictions. See Judgment of the Court, Case C-236/01 (reference for a preliminary ruling from the Tribunale amminstrativo regionale del Lazio): Monsanto Agricoltura Italia SpA and Others v Presidenza del Consiglio dei Ministri and Others (Sept. 9, 2003). Similarly, the Court of Justice ruled in March 2000 that France could not ban the sale of GM crops that had been approved at the EU level without producing new information

Finally, the EU tentatively resumed approvals of new GM varieties in May 2004. By early 2004, the Commission had received twenty-two notifications for approvals of genetically modified varieties – eleven involving import processing only, and eleven for cultivation (Commission 2004b). With the completion of the new regulatory framework, the Commission moved to resume approvals of new GM varieties. In November 2003, it proposed to approve the importation of a variety of GM maize (Bt-11 sweet corn), for which EFSA had delivered a favorable opinion. This was the first time that the Commission had initiated a GM approval since 1998. The regulatory committee, however, again refused to approve the Commission's proposal so that the matter was referred to the Council, which was given until the end of April to act.[70] On 26 April, a divided Agriculture Council failed to reach agreement on the Commission's proposal.[71] In the absence of a decision by the Council, the Commission was free to adopt the proposal – the first new approval of a GM variety in nearly six years. Despite this apparent breakthrough, US officials noted that the Commission's decision – greeted by a chorus of condemnation among European environmentalists and consumer groups – was taken over the objections of a bloc of implacably hostile member governments, with no guarantee that additional approvals were to follow or that EU risk managers would continue to be guided by the scientific risk assessments carried out by the EFSA.[72] In addition, the Commission's approval applied only to importation and not cultivation, and was subject to the full range of EU regulations regarding traceability and labeling, with all their attendant costs. Under the circumstances, Syngenta, the crop's manufacturer, indicated that it had no immediate intention of marketing Bt-11 sweet corn in Europe (Meller and Pollack 2004; Pollack 2004a; European Report 2004).

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regarding health and environmental risks. The case was referred to the Court of Justice by a French court following a challenge by Greenpeace of France's initial approval of a GM maize variety. See Judgment of the Court, Case C-6/99 (reference for a preliminary ruling from the Conseil d'Etat): Association Greenpeace France and Others v French State, Ministere de l'Agriculture et de la Peche and Others, In the presence of Novartis Seeds SA and another (March 21, 2000).

[70] Austria, Denmark, France, Greece, and Luxembourg voted against the proposal, while Germany, Belgium, and Italy abstained. See Bridges BioRes, "European Food Committee Fails to End de facto Biotech Moratorium," vol. 3, no. 22, Dec. 15, 2003, at http://www.ictsd.org/biores/03-12-15/story1.htm.

[71] Six states (Ireland, Italy, the Netherlands, Finland, Sweden, and the UK) voted in favor of the Commission proposal, six others (Denmark, Greece, France, Luxembourg, Austria, and Portugal) voted against, and three states (Belgium, Germany, and Spain) abstained. Commission 2004c: 4.

[72] As one US official put it, "The approval of a single product is not evidence that applications are moving routinely through the approval process in an objective, predictable manner based on science and EU law, rather than political factors." Quoted in Anthony Browne, "Protests after Europe Ends GM Food Freeze," *The Times*, 20 May 2004, p. 18.

Subsequent approval procedures appeared to support this cautious interpretation of the "end" of the moratorium. One month following the approval of Bt-11 sweet maize, a regulatory committee of member-state representatives from the now-enlarged EU failed to agree on the Commission's proposed approval of a genetically modified rapeseed (or canola). Significantly, six of the ten new member states (Cyprus, Estonia, Hungary, Malta, Lithuania, and Poland) joined six existing members (Austria, Denmark, Greece, Italy, Luxembourg, and the UK) in voting against the approval, which was then scheduled for decision by the Council of Ministers.[73] A similar pattern emerged later that month when the Environment Council met to consider the Commission's recommendation to approve another Monsanto variety, the NK603 genetically modified corn. Here again, the Council was divided, with nine member states (including four of the new members) reportedly voting against, nine in favor, and seven abstaining.[74] Although the Commission again approved the variety in July 2004 in the absence of Council agreement, this case once more demonstrated the persistent divisions in the Council on new approvals.[75] Significantly, these two cases also seemed to dispel some initial concerns that the new member states – most of which were already engaged in the cultivation of GM crops, often without adequate controls – might serve as a "Trojan horse" for the United States and the biotech industry.[76] Ensuring adequate testing facilities in the new member states remains a challenge for the EU post-accession, but it seems clear that the ambivalence toward agricultural biotechnology in the "old" EU is reflected in the public opinion and governmental positions of the new members as well.[77]

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[73] For good accounts of the debate over the approval of the GT73 rapeseed, see "Biotechnology: EU Member States Fail to Agree on GM-Rape GT-73," *European Report*, 19 June 2004; and Andrew Beatty, "Majority of New EU States Block GMO Approval," *euobserver.com*, 21 June 2004.

[74] The member states voting against approval were Denmark, Luxemboug, Austria, Italy, and Greece (old members), and Cyprus, Latvia, Lithuania, and Malta (new members). See "EU Governments Deadlocked over Monsanto's Genetically Modified Corn Product," *Associated Press*, 28 June 2004; Sharon Spiteri, "Member States Split on GM Maize Approval," *euobserver.com*, 29 June 2004; and Joe Kirwin, "Old, New EU States Block Authorization to Cultivate Gene-Engineered Corn NK603," *International Trade Reporter (BNA)*, vol. 21, p.1234 (July 22, 2004).

[75] See Bridges BioRes, "EU Approves Another GM Import as WTO Dispute Drags On," vol. 4, no. 14, July 23, 2004, at http://www.ictsd.org/biores/04-07-23/inbrief.htm#4. (noting that "The approval only applies for the use of corn as feed—not for cultivation—and imports will only be allowed once the maize also has been approved for food use").

[76] On the new members as a "Trojan horse," see Paul Brown, "EU Races to Thwart Influx of GM Food from East," *The Guardian*, 14 February 2004. A more detailed but equally critical study is Thomas Schweiger, *EU Enlargement: The Introduction of GMO's by the Backdoor of EU Accession?* (Northern Alliance for Sustainability and Friends of the Earth Europe, May 2003).

[77] A survey of citizens of the EU's ten new members conducted in November 2002 showed that sixty-eight percent held negative views toward GMOs, a result roughly similar to surveys of citizens of the "old" Europe. "Genetically Modified Food," *Economist*, Apr. 3, 2003, at 5. A second major change in the Union, the constitutional treaty agreed

The future of biotechnology regulation in the EU thus appears unclear. The EU Commission has underlined the "completion" of the EU regulatory framework and the resumption of approvals as major steps forward, yet a careful examination of the approval process reveals continuing opposition to GMOs among EU member governments as well as in the European Parliament and in European public opinion. Some member states are now insisting on the establishment of an EU liability regime and EU rules on the coexistence of GM and non-GM crops. They are responding to concerns that GM seeds grown on a neighboring field could contaminate a conventional farmer's crop, making it impossible for that farmer to meet EU purity obligations. The Commission held a roundtable about the issue in April 2003 with a range of "stakeholders."[78] In July 2003, it issued guidelines on coexistence, but left rulemaking to the member states on the grounds of "subsidiarity"—the EU principle that regulation should be left to the national level where practicable.[79] Likewise, both of the regulations enacted in 2003 provided that "the member states shall lay down the rules on penalties applicable to infringements."[80] Despite these efforts, the continuing approval of new GM varieties – and, even more so, the cultivation and marketing of these varieties within the Union – remains in doubt.[81]

The Commission thus remains concerned about Europe's loss of competitiveness in the agricultural biotech sector. A 2004 Communication from Romano Prodi, the Commission's President, noted the "exodus of researchers and rapid decline in GMO field research in the EU and the consequent negative repercussions in innovation and competitiveness."[82] Prodi similarly remarked in 2002 that Europe's biotech industry lagged "four or five years" behind and was

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in Brussels in June 2004, does not alter the substance of EU policy or policy-making with regard to agricultural biotechnology, and is therefore unlikely to affect policy toward GMOs if and when it is ratified and comes into force.

[78] See Commission Recommendation of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming, OJ L 189, p. 0036-0047, 29/07/2003 (par. 1.3, noting discussion with "a range of stakeholders representing the farming sector, industry, NGOs, consumers and other players").

[79] Article 43 of Regulation 1829/2003 added an article 26a to Directive 2001/18 to provide that "Member States may take appropriate measures to avoid the unintended presence of GMOs in other products."

[80] See article 45 of Regulation 1829/2003 and article 11 of Regulation 1830/2003 (noting that the penalties "must be effective, proportionate and dissuasive").

[81] GM foods could continue to face significant regulatory obstacles, especially in light of the elimination of the exception that genetically modified foods may be marketed if they are "equivalent" to conventional foods in quality, given that no GM products were ever authorized under the Novel Foods Regulation except pursuant to this exception. Products from sixteen GMOs that were deemed "equivalent" to traditional foods could be legally marketed under the exception set forth in the former regime. Commission 2004a, at 4.

[82] Communication to the Commission (from the President in association with Mrs Wallstrom, Mr Byrne, Mr Fishcler, Mr Lamy, Mr Likanen and Mr Busquin) For an orientation debate on Genetically Modified Organisms and related issues, January 28, 2004, available at: http://www.eurunion.org/news/press/2004/20040010.htm (visited March 18, 2004).

worth "roughly one-third as much as its U.S. counterpart" (Skogstad 2003a: 336). The Commission's 6th Framework Programme for research, technological development and demonstration activities proposed that the area of life sciences and biotechnology was its "first priority" (Communication 2002).[83] In light of the European public's continued skepticism, however, the EU's promotion of this technology continues to face considerable obstacles.

6. The International Context

As we have noted, EU regulatory policy for GMOs faces external challenges as well, and in particular from the United States which has exercised bilateral pressure in the shadow of the rules of the World Trade Organization. The WTO Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) places the onus on the EU to demonstrate that its regulatory measures pertaining to GM products are based on scientific risk assessments and are not otherwise disguised restrictions on trade.[84] In the earlier US-EU dispute over the EU's ban on hormone-treated beef, the WTO Appellate Body held that the EU had violated the SPS because it had failed to base its ban on a scientific risk assessment. When the EU did not comply with the ruling, the WTO Dispute Settlement Body authorized the United States and Canada to prescribe retaliatory tariffs against EU products, which they continue to apply in 2004.

Starting in 1997-1998, when the EU tightened labeling requirements for GM foods, stopped approving new GM varieties, and effectively shut down the marketing of varieties that had been approved, the United States threatened to bring a complaint before the World Trade Organization. It nonetheless hesitated to initiate legal proceedings for years (Pollack & Shaffer 2001; Shaffer and Pollack 2003). In part, the United States was preoccupied with the EU's ability to retaliate against the United States' non-compliance with other WTO rulings.[85] In part, it was

[83] Similarly, in a 1994 White Paper, the Commission remarked, "biotechnology has emerged as one of the most promising and crucial technologies for [the twenty-first] century." In a 1996 report, however, the Commission expressed its concern over the low rates of approvals of GM products in Europe compared to the United States (1996 Report).

[84] The SPS Agreement is concerned with food safety regulatory measures that can serve as non-tariff barriers to international trade. The SPS Agreement does not establish binding international standards, nor does it automatically preempt the adoption of nondiscriminatory national food safety regulations that might inhibit international trade. However, it does privilege international standards determined by Codex-Alimentarius, a joint venture of the Food and Agricultural Organization and the World Health Organization, in which the United States and European countries actively participate.

[85] When the United States failed to comply with a WTO decision in 2000 involving U.S. tax legislation permitting companies to shield taxable income through the use of "foreign sales corporations," the WTO authorized the EU to sanction the United States by withdrawing trade concessions in an amount of US$ 4.043 billion dollars per year. See

concerned with larger systemic challenges to the international trade regime that such a controversial case could trigger. In part, it hoped that the dispute would subside once Europeans learned to accept genetically modified products under a reformed European food safety regime. Yet because the EU moratorium continued and because affected U.S. commercial interests became increasingly frustrated, the United States finally stepped up the pressure by filing a WTO complaint in May 2003 against the EU moratorium and the member state "safeguard" bans.[86] On February 23, 2004, the United States, Argentina, and Canada asked the WTO Director-General to appoint a panel to rule on their complaint, which was formed in March. The complainants appeared poised to challenge new EU labeling rules under another WTO agreement, the Agreement on Technical Barriers to Trade, as well.[87] If the United States proceeds with the lawsuit, and if the WTO judicial bodies rule against any of the EU's restrictions and the EU does not comply with the ruling, the United States and other complainants could once again retaliate by raising tariffs on EU products. They likely would target sanctions to spur European industries to pressure member-state and EU authorities to act more flexibly toward genetically modified products.

WTO rules, and the threat of an adverse WTO judicial ruling, have influenced EU decision-making in two primary ways. First, EU authorities would like to tailor the EU's regulatory regime in a manner that will survive a challenge under WTO rules. In order to fend off a U.S. challenge, European public officials have been pressed to set up a system where they do not simply ban GMOs without justification and without examining regulatory alternatives.[88] They rather must conduct risk assessments on a case-by-case basis, explicitly justify their decisions on the basis of these assessments, and take account of alternative measures that could accomplish the same regulatory goals in a less trade-restrictive manner. Second, many European constituents, and, in particular, the European biotechnology sector, favor a more flexible European legal

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Dan Pruzin, "WTO Gives EU Green Light in Sanctions against United States over FSCs," *International Trade Reporter (BNA)*, Vol. 19, September 5, 2002, p. 1484; and "European Commission News Release on Request to WTO Compliance Panel for Imposition of Sanctions in US, FSC Dispute, with Indicative Product List," *International Trade Reporter (BNA)*, Vol. 17, November 23, 2000, p. 1792.

[86] Argentina, Canada, and Egypt simultaneously filed complaints against the EU.

[87] See e.g. Gary Yerkey, "U.S. Firms Urge Administration to Move against EU in WTO over new Labeling Rules," 20:48 International Trade Reporter (BNA) 1991 (Dec. 4, 2003); and "Argentina Seeks U.S. Help in Challenging EU's Labeling, Traceability Rules for GMOs," 21:2 International Trade Reporter (BNA) 61 (Jan. 8, 2004). For an analysis of WTO claims, see Howse and Mavroidis 2000; and Macmillan & Blakeney 2001).

[88] See Scott 2003: 223 (concerning the impact of WTO rules and decisions on the Commission and Court of First Instance concerning the application of the precautionary principle); and Young and Holmes 2003.

regime toward GMOs. They have allies at different levels of government who wish to facilitate the EU's development of this technology. WTO rules offer these advocates a further rationale to press for a more conducive EU agricultural biotech legal regime.

The EU has not accepted passively the influence of WTO rules on its regulatory system, however. Instead, the EU has sought actively to export its precautionary approach to the international trade, environmental, and food safety regimes, and thus help shield the EU from a WTO legal challenge (Skogstad 2001). During the late 1990s, the EU worked with other countries to press for a new international environmental treaty governing genetically modified organisms. The treaty was eventually signed in January 2000 as a protocol to the 1992 Convention on Biodiversity, after the United States failed to block it. The protocol, known as the "Biosafety Protocol" or "Cartagena Protocol," entered into force in June 2003.[89] The Biosafety Protocol expressly incorporates the precautionary principle, providing that a country may reject the importation of a GMO for release into the environment where there is "lack of scientific certainty regarding the extent of the potential adverse effects... on biological diversity in the Party of import, taking also into account risks to human health" (Article 10). A similar provision applies to a country's rejection of bulk genetically modified commodities (such as soybeans, wheat, corn, and cotton) for food, feed, or processing (Article 11). In February 2004, the parties to the protocol agreed to stricter labeling requirements for trade in genetically modified seeds and bulk crops.[90] The EU can now cite the protocol as evidence of international consensus (involving over 130 signatory countries) regarding the application of the precautionary principle. No such treaty could be cited in the earlier meat-hormones case.

The EU has used a similar strategy before the international food standard setting body, Codex Alimentarius, but with less success. Nonetheless, it was able, after a seven year period, to have Codex adopt new "Principles and Guidelines on Foods Derived from Biotechnology" in

[89] The protocol entered into effect on June 11, 3003, ninety days after fifty signatories had ratified it. By early August 2004, 106 parties had ratified it. See the Protocol website at http://www.biodiv.org/biosafety/, accessed 12 August 2004. Not surprisingly, DGs Trade and Industry supported DGs Environment and SANCO regarding the protocol, in large part because the protocol can help shield the EU from legal challenge before the WTO. However, Trade Commissioner Pascal Lamy was forced to back down from his agreement at the Seattle WTO ministerial meeting in December 1999 to create a WTO working group to address GMO issues. See Frances Williams, "Europeans block biotech move," *Financial Times*, 13 (Dec. 3, 1999).

[90] International Conference Deals Blow to US on labeling of gene modified food," *Financial Times*, 8 (Feb. 28, 2004).

July 2003.[91] Among other matters, the Principles acknowledge the use of "tracing of products" as a risk management tool, although noting in a footnote that they "should be consistent with the provisions of the SPS and TBT Agreements."[92]

In sum, international law pertaining to GMOs is also multi-sectoral, cutting across the global trade, environment and food-safety regimes and raising analogous issues of policy coordination at the international level. By internationalizing its precautionary approach to GMOs through the Biosafety Protocol, the EU has helped shield itself from attack under international trade-law disciplines. In modifying the international environmental and food safety legal regimes, the EU hoped to influence the WTO Appellate Body's interpretation of WTO rules. Indeed, the Appellate Body already had exhibited a trend toward providing more policy space for WTO members' domestic regulations (Young & Holmes 2003). The EU also hoped to influence how foreign (and particularly U.S.) producers and distributors operate, so that they segregate and label genetically modified products for export markets.[93] If commercial enterprises adapt to the EU's regime, they will be less likely to press their governments to initiate legal challenges under WTO rules.

This internationalization of GM regulation also represents a further centralization of powers within the Commission, which is responsible for coordinating member state positions in these fora, and, as regards the WTO and now Codex Alimentarius, formally speaking and voting on behalf of the member states. In November 2003, the EU acceded to the Codex Alimentarius Commission so as to ensure the coherence between EU and member state biotech regulations and the EU's and member states' international obligations.[94] The Commission now speaks and votes on behalf of the EU "where an agenda item deals with matters of exclusive Community

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[91] The principles were formally adopted in July 2003. See Codex Alimentarius Commission, Report of the Twenty-sixth Session (Rome, 30 June-7 July 2003), par. 52, document available at ftp://ftp.fao.org/es/esn/food/princ_gmfoods_en.pdf. See also Anne Mackenzie, "The Process of Developing Labelling Standards for GM Foods in the Codex Alimentarius," 3 *Agbioforum* 203 (2000); and Sara Poli, "Setting Out International Food Standards: Euro-American Conflicts within the Codex Alimentarius Commission," Giandomenico Majone, ed., *Risk Regulation in the European Union: Between Enlargement and Internationalization* (Florence: European University Institute, 2003), pp. 125-147.

[92] See Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology, *Codex Principles and Guidelines on Foods Derived from Biotechnology*, par. 21, available at http://www.bgvv.de/cm/208/codex_principles_and_guidelines_on_foods_derived_from_biotechnology.pdf (last visited Aug. 13, 2004).

[93] Young (2003: 468-469) explains how the U.S. grain industries have worked to segregate crops.

[94] See Council Decision (2003/822/EC) of 17 November 2003 on the accession of the European Community to the Codex Alimentarius Commission (OJ L309, 26.11.2003, page 14).

competence."[95] In practice, this means that the Commission will almost always represent the member states in Codex on biotech matters, since annex II of the Council Decision provides: "As a general rule, the European Community has exclusive competence for agenda items dealing with harmonization of standards on certain agricultural products, foodstuffs…., including labeling, methods of analysis and sampling, as well as codes and guidelines."[96]

Overall, in light of the multi-sectoral, multi-level nature of GM risk regulation, international rules have both constrained and offered opportunities for EU authorities. The Commission, in particular, can refer to WTO rules to further its policy goals in EU internal debates so as to end member state safeguard bans and the moratorium on new approvals of genetically modified products. The Commission has also acted as an international policy entrepreneur by working to export the EU's precautionary regulatory approach for GM products to the world. Once the Biosafety Protocol was adopted, the Commission then incorporated these international environmental obligations into the EU's internal legislation governing GMOs.[97]

7. Conclusions

The regulation of biotechnology has presented the Union with a number of challenges. Many of these challenges are common to all EU regulations, but others relate specifically to the nature of biotechnology as a highly politicized case of risk regulation, a multi-sectoral challenge requiring cross-sectoral coordination, and a multi-level concern in which EU regulations must respond to both national fears and international disciplines. In the introduction to this paper, we noted that the policy process for biotechnology regulation most closely approximates Hellen Wallace's "regulatory mode" of governance.[98] To generalize, this traditional form of EU governance is characterized by the following features:

- The Commission is the primary architect and defender of regulatory objectives and rules, in particular, by referring to market criteria.

[95] Id., Annex III, Agreement between the Council and the Commission regarding preparation for Codex Alimentarius Meetings and statements and exercise of voting rights.
[96] Id. Annex II, par. 1. Single Declaration by the European Community on the exercise of competence according to Rule VI of the Rules of Procedure of the Codex Alimentarius Commission.
[97] See e.g. Article 44 of Regulation 1829/2003 and Article 32 of Directive 2001/18.
[98] Helen Wallace, William Wallace, and Mark Pollack, eds., *Policy-making in the European Union* (5th edition) (Oxford University Press) (2005).

- The Council constitutes a forum through which member states agree to minimum standards and thereby direct harmonization efforts, mostly upwards toward higher standards. These harmonized standards are complemented by member state enforcement and member state agreement to mutually recognize each other's national preferences, provided that agreed minimum standards are met.

- The EP has become a primary means for prompting the consideration of non-economic factors (environmental, social, regional, and so forth), and has had increasing impact as its legislative powers have grown.

- The ECJ's role is to ensure that the rules are applied reasonably evenly. It is backed by national courts that oversee national application of the rules and that grant private parties redress where a member state misapplies the rules or discriminates against non-nationals.

- Overall, there are extensive opportunities for economic actors, and sometimes other societal actors, to be consulted about and to influence the shape, content, and application of European single market rules.

We indeed find all five of these features in the case of biotechnology regulation, albeit to differing degrees and with some policy-specific exceptions.

The Commission has acted as the primary entrepreneur in the development and implementation of EU policies. However, member governments retain important prerogatives, including the power to regulate trial releases of GMOs in the environment, to determine liability and coexistence rules, and to impose safeguard bans on GM seed, feed, and food. The creation of the EFSA in 2002, in addition, has resulted in a separation of executive functions at the EU level, with the EFSA taking primary responsibility for risk assessment, while risk management continues to be shared between the Commission and the member states.

The Council of Ministers has played the dominant role in the adoption of framework directives and regulations, with an increasing role for the EP. In the implementation of EU regulations, and the approval (or blockage) of new GM varieties, regulatory committees of

officials representing member states have played at least as important a role as the Council meeting at ministerial level. The Parliament has been essentially an onlooker regarding the implementation of EU legislation—albeit an approving one since the moratorium on new varieties has dragged on from year to year. The ECJ, by contrast, has not yet been a major player in the enforcement (or the challenging) of EU agricultural biotech regulation, which would involve the Court in some of the most sensitive and politically charged areas of EU policy. There are signs, however, that the Court may play a greater role insofar as citizens, interest groups, grain traders, and biotech companies seek to challenge, clarify, and enforce the growing corpus of EU biotech regulation in the courts.

Although the EU has been a pioneer and a laboratory for international regulatory harmonization, it is joined in this endeavour by other international organizations, such as the WTO, to the disciplines of which EU regulation is increasingly subject. Indeed, we suggest that a central lesson of the biotech case is that EU policy-making is no longer simply above the nation-state, but instead lies *between* the nation-state and the growing imperatives of global governance. Paradoxically, the Commission's perception of a need to manage challenges to the legitimacy of EU decision-making both from above and from below over the perceived risks of GMOs has led to greater centralization of EU policymaking in this domain, further raising the stakes for EU authorities.

Finally, we re-emphasize the special challenges posed to the EU by biotechnology as a question of risk regulation. As we have seen, national governments and publics have repeatedly questioned the legitimacy of EU regulations in this area, prompting root-and-branch reform of the policy in the early 2000s. In addition to these reforms, the Commission has experimented with two alternative modes of governance.

First, and in common with other areas of EU regulation, it has moved toward a system of 'structured transgovernmentalism' in which EU regulatory committees and the new EFSA bring together a community of scientists from throughout the Union that specialize in GMOs. Many EU authorities hope that this 'epistemic' community can reach common accord and help structure European political and social understandings of GM products.[99]

[99] In a constructivist vein, Chalmers stresses the "normative authority" that EFSA can have in that its decisions "structure individual and institutional choices on food safety within the EU." Chalmers 540. Chalmers notes how knowledge is not just information but "a process" that organizes "belief." At 543. Epistemic communities have been defined as social groups that Ahave (1) a shared set of normative and principled beliefs . . .; (2) shared causal beliefs

Second, the EU has also moved toward 'new governance' mechanisms with the holding of numerous 'stakeholder forums' on GMO-related issues, and Commission officials speak of the need to 'democratize expertise' and to 'expertise democracy.[100] The adoption of these governance modes, however, has been quite limited, with the EFSA providing only risk regulation and stakeholder forums having only a limited impact on EU decision-making. References to these governance modes appear primarily as responses to legitimacy challenges to EU decisions about risk management, as opposed to genuine alternative modes of governance.

Most importantly, the case of agricultural biotech regulation in the EU points to the limitations of EU supranational policy-making when regulatory issues become highly politicized. Neither the adoption of a more centralized regulatory model, nor attempts to complement it with transgovernmental and stakeholder modes of policy-making, have shielded EU risk-management decisions on GMO approvals from public challenge. In the area of GMOs, member state politicians, reacting to their public's lack of acceptance of EU decision-making, have thwarted numerous attempts to implement a harmonized EU approach, and, in the process, ratcheted up the stringency of EU-level requirements. This dynamic between member state publics, their national representatives, and EU authorities appears to best explain the gap to date between the Union's law-in-the-books for GMOs and its law-in-action. Disputes over risk regulation in this domain risk becoming disputes over the legitimacy of EU law itself.

References

Ansell. Chris, Rahsaan Maxwell, and Sicurelli (2003). "Protesting Food: NGOs and Political Mobilization in Europe," in Ansell & Vogel 2003.

. . .; (3) shared notions of validity . . .; and (4) a common policy enterprise . . . .@ *See* Peter Haas, *Introduction: Epistemic Communities and International Policy Coordination*, 46 INT=L ORG. 1, 3 (1992).

[100] See e.g., Christoforou 2003 on "democratizing expertise, expertising democracy." Christoforou is a legal advisor in the Commission's Legal Service. See also, at the national level, the UK Agriculture and Environment Biotechnology Commission, whose role is to advise the government on GMO regulation, "taking ethical and social issues into account as well as the science," operating with "maximum openness and transparency," and building on "public dialogue." The commission's home page is at http://www.aebc.gov.uk/. As regards EFSA's efforts at greater transparency, see Press release, European Food Safety Authority, "European Food Safety Authority Plans Greater Public Involvement in its Work," (Dec. 3, 2003), available at http://www.efsa.eu.int/press_room/press__release/31_en.html. ("The most significant recommendation accepted by the Board today will be to involve consumers and other stakeholders in the Authority's work, including setting up a stakeholder forum, and to hold public hearings on significant scientific issues.").

Ansell, Chris, and David Vogel, eds. (2003). *Why the Beef? The Contested Governance of European Food Safety (MIT University Press, under review),* draft available at http://www.polisci.berkeley.edu/Faculty/bio/permanent/Ansell,C/FoodSafety/HY.pdf.

Beck, Ulrick, (1992). *Risk Society: Towards a New Modernity,* translation by Mark Ritter (London: Sage).

Bernauer, Thomas and Ladina Caduff. (2003). "The European Union's Food Safety Trilemma," in Ansell & Vogel 2003.

Bodansky, Daniel (1991). "Scientific Uncertainty and the Precautionary Principle," *Environment*, Vol. 33, pp. 4-5, 43-44.

Bradley, Kieran St C. (1998). "The GMO-Committee on Transgenic Maize: Alien Corn, or the Transgenic Procedural Maize," in M.P.C.M. Van Schendelen ed. EU Committees as Influential Policymakers (Ashgate: Aldershot UK).

Buonano, Laurie (2003). "Politics versus Science: Apportioning Competency in the European Food Safety Authority and the European Commission," in Ansell & Vogel 2003.

Buonanno, Laurie, Sharon Zablotney, and Richard Keefer (2001). "Politics versus Science in the Making of a New Regulatory Regime for Food in Europe," *European Integration online Papers*, Vol. 5, No. 12: http://eiop.or.at/eiop/texte/2001-012a.htm.

Cameron, J., and J. Abouchar (1991). "The Precautionary Principle: A Fundamental Principle of Law and Policy for the Protection of the Global Environment," *Boston College International & Comparative Law Review*, Vol. 14, pp. 1-27.

Cantley, Marc (1995). "The Regulation of Modern Biotechnology: A Historical and European Perspective: A Case Study in How Societies Cope with New Knowledge in the Last Quarter of the Twentieth Century," in H. J. Rehm and G. Reed (eds.) in cooperation with A Pühler and P. Stadler, *Biotechnology, Volume 12: Legal, Economic and Ethical Dimensions* (Weinheim, [Germany]: VCH), pp. 506-681.

Chalmers, Damien (2003). "Food for Thought: Reconciling European Risks and Traditional Ways of Life," *Modern Law Review*, Vol. 66, No. 4, pp. 532-564.

Christoforou, Theofanis (2003). "The Precautionary Principle and Democratizing Expertise: A European Legal Perspective, *Science and Public Policy*, 30:3, 205-211

Communication to the Commission (from the President in association with Mrs Wallstrom, Mr. Byrne, Mr Fischer, Mr Lamy, Mr Liikanen and Mr Busquin) (2004). "For an orientation debate on Genetically Modified Organisms and related issues," IP-04-118 (Jan., 28, 2004), available at http://www.eurunion.org/news/press/2004/20040010.htm.

Commission of the European Communities (1988). "Proposal for a Council Directive on the Deliberate Release to the Environment of Genetically Modified Organisms," COM(88)160 final – SYN 131 of 4 May 1988.

Echols, Marsha A. (1998). "Food Safety Regulation in the European Union and the United States: Different Cultures, Different Laws," *Columbia Journal of European Law*, Vol. 4, pp. 525-543.

European Commission (1994). White Paper—Growth, Competitiveness, Employment: The Challenges and Ways Forward into the 21st Century.

European Commission (1996). Report on Directive 90/220/EEC on Genetically Modified Organisms, ip/96/1148 (Dec. 10, 1996).

European Commission (2000). Commission Communication on the Precautionary Principle, COM (2000) 1 final.

European Commission (2002). Communication from the Commission to the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions, Life Sciences and Biotechnology—A Strategy for Europe, COM(2002) 27 final.

European Commission (2004a). Question and Answers on the regulation of GMOs in the EU, MEMO/04/16 (Jan. 28, 2004).

European Commission (2004b). State of Play on GMO authorizations under EU law, MEMO/04/17 (Jan. 28, 2004).

European Parliament (1989). "Report drawn up on behalf of the Committee on the Environment, Public Health, and Consumer Protection on the proposal from the Commission to the Council (COM(88)160 final – Doc. C 2-73/88) for a directive on the deliberate release to the environment of genetically modified organisms," PE Doc A 2-142/89. Rapporteur: Mr Gerhard Schmid.

European Parliament (1990). "Recommendation of the Committee on the Environment, Public Health and Consumer Protection on the COMMON POSITION of the Council for a directive on the deliberate release to the environment of genetically modified organisms (C3-228/89), Doc A3-0049/90 of 23 February 1990. Rapporteur: Mr Gerhard Schmid.

European Report (2004). "Biotechnology: Contrasting Reactions to Authorisation for Bt11 Transgenic Corn," *European Report*, 29 May.

Gaskell, George, Allum, Nick, and Stares, Sally (2003) Eurobarometer 58.0: A Report to the EC Directorate General for Research from the project 'Life Sciences in European Society' QLG7-CT-1999-00286.

Giddens, Anthony, (1991) *Modernity and Self-Identity: Self and Society in the Late Modern Age* (Stanford University Press).

Gold, Richard E. and Alain Gallochat (2001). "The European Biotech Directive: Past as Prologue," *European Law Journal*, Vol 7, No. 3, pp. 331-366.

Greven, Michael Th. (2000). "Can the European Union Finally Become a Democracy?" in Michael Greven and Louis Pauly (eds), *Democracy Beyond the State? The European Dilemma and the Emerging World Order* (New York: Rowman and Littlefield).

Henley, Jon (1999). "McDonald's Campaign Spawns French Hero: Political Activist Turned French Peasant Has Fast Food on the Run," *The Guardian*, 11 September, p. 14.

Hill, Lowell B., and Sophia C. Battle (2000). *Search for Solutions in the EU-US GMO Debate*," proceedings of a conference–*GMO Regulations: Food Safety or Health Barrier?*, held at the Wyndham Hotel in Chicago, Illinois, October 22 and 23, 1999 (Department of Agricultural and Consumer Economics, Agricultural Experiment Station/Office of Research, College of Agricultural, Consumer and Environmental Sciences, University of Illinois as Urbana-Champaign, AE-4731).

Howse, Robert & Petros Mavroidis (2000). "Europe's Evolving Regulatory Strategy for GMOs—The Issue of Consistency with WTO Law: Of Kind and Brine," *Fordham International Law Journal* 24, 317 (Nov/Dec).

Hunter, Rod (1999). "European Regulation of Genetically Modified Organisms," in Julian Morris and Roger Bate, eds., *Fearing Food: Risk, Health, and Environment* (Oxford: Butterworth Heineman), pp.189-230.

Joerges, Christian (2001). "Law, Science and the Management of Risks to Health at the National, European and International Level – Stories on Baby Dummies, Mad Cows and Hormones in Beef," *Columbia Journal of European Law,* Vol. 7, pp. 1-19.

Lepage, Corinne and Francois Guery (2001) *La Politique de Précaution* (Paris: Presses Universitaires de France).

Macmillan Fiona & Michael Blakeney (2001). "Genetically Modified Organisms and the World Trade Organization," *Tulane Journal of Technology and Intellectual Property*, Vol. 3, pp. 93-116.

Majone, Giandomenico (2002). "What Price Safety? The Precautionary Principle and its Policy Implications," *Journal of Common Market Studies*, Vol. 40, No. 1, pp. 89-109.

Majone, Giandomenico (2003). "Foundations of Risk Regulation: Science, Decision-Making, Policy Learning and Institutional Reform," in Giandomenico Majone, ed., *Risk Regulation in the European Union: Between Enlargement and Internationalization* (Florence: European University Institute).

Meller, Paul, and Andrew Pollack (2004). "Europeans Appear Ready to Approve a Biotech Corn," *The New York Times*, 15 May, pp. B1, B3.

Moravcsik, Andrew (2002). "In Defense of the Democratic Deficit: Reassessing Legitimacy in the European Union," *Journal of Common Market Studies*, Vol. 40, No. 4 (November), pp. 603-624.

National Corn Growers Association. 2003. USGC pleased US pursuing case against EU moratorium (press release). May 13, available at http://www.ncga.com/news/releases/2003/may/news051303.htm

Patterson, Lee Ann (2000). "Biotechnology," in Helen Wallace and William Wallace, eds., *Policy-Making in the European Union* (Oxford: Oxford University Press), pp. 317-43.

Patterson, Lee Ann and Timothy Josling (2002). "Regulating Biotechnology: Comparing EU and US Approaches," available at http://www.agtrade.org/consumer_issues/research.htm.

Pollack, Andrew (2004). "Narrow Path for New Biotech Food Crops," *The New York Times*, 20 May, pp. C1, C3.

Pollack, Mark, and Gregory C. Shaffer (2001). "The Challenge of Reconciling Regulatory Differences: Food Safety and GMOs in the Transatlantic Relationship," in Pollack and Shaffer, eds., *Transatlantic Governance in the Global Economy* (Lanham, MD: Rowman & Littlefield), pp. 153-178.

Scharpf, Fritz W. (1999). *Governing in Europe: Effective and Democratic?* (New York: Oxford University Press).

Scott, Joanne (2004). "European Regulation of GMOs: Thinking about Judicial Review in the WTO" (draft manuscript).

Scott, Joanne (2003). "European Regulation of GMOs and the WTO," *Columbia Journal of European Law*, Vol. 9, pp. 213-239.

Shaffer, Gregory and Mark Pollack (2004). *Dealing with Regulatory Differences: Global Markets, International Institutions and the Dispute over Agricultural Biotechnology* (draft manuscript).

Siedentop, Larry (2000). *Democracy in Europe* (Hammondsworth: Penguin).

Skogstad, Grace (2001). "The WTO and Food Safety Regulatory Policy Innovation in the European Union," *Journal of Common Market Studies*, vol 39: 3, 485-505 (Sept).

Skogstad, Grace (2003a). Legitimacy and/or policy effectiveness?: network governance and GMO regulation in the European Union, *Journal of European Public Policy* (June) 10:3, 321-338.

Skogstad, Grace (2003b). Regulating Food Safety Risks in the European Union and North America: Distinctive Regulatory Policy Styles, in Ansell & Vogel 2003.

Stewart, Terence P., and David S. Johanson (1999). "Policy in Flux: The European Union's Laws on Agricultural Biotechnology and their Effects on International Trade," *Drake Journal of Agricultural Law*, Vol. 4, pp. 243-295.

Tiberghien, Yves & Sean Starrs (2004). "The EU as Global Trouble-Maker in Chief: A Political Analysis of EU Regulations and EU Global Leadership in the Field of Genetically Modified Organisms," paper presented at 2004 Conference of Europeanists, Chicago.

Vogel, David (2003). "The Politics of Risk Regulation in Europe and the US," *The Yearbook of European Environmental Law*, Vol. 3; page citations from unpublished manuscript.

Vos, Ellen (2000). "EU Food Safety Regulation in the Aftermath of the BSE Crisis," *Journal of Consumer Policy*, Vol. 23: 227-55.

Wallace, Hellen, William Wallace, and Mark Pollack, eds. 2005. *Policy-making in the European Union* (5th edition) (Oxford University Press).

Wiener, Jonathan B., and Michael D. Rogers (2002). "Comparing Precaution in the United States and Europe," *Journal of Risk Research*, Vol. 5, No. 4, pp. 317-349.

Young, Alasdair R. (2003). "Political Transfer and 'Trading Up'? Transatlantic Trade in Genetically Modified Food and U.S. Politics," *World Politics,* Vol. 55, pp. 457-84.

Young, Alasdair R. & Peter Holmes (2003). "Protection or Protectionism? EU Food Safety Rules and the WTO," in Ansell & Vogel 2003.