A Comparison of Biotechnology Regulatory Policy in the United States and the European Union

Lee Ann Patterson
Institute for Health Policy Studies
University of California at San Francisco
Box 0936, Laurel Heights
San Francisco, CA 94143-0936

lapat@ibm.net
Tel. (650)949-1419
Fax (415) 476-0705

Abstract

Polities are increasingly faced with competition in the regulatory arena as well as the market place. Several authors have argued that regulatory competition leads to regulatory harmonization or convergence. However, significant differences in biotechnology regulations in the United States and the European Union remain. These differences have resulted in profoundly different technology trajectories. This paper compares the historical development of guidelines and regulations in the US and the EU. Specific attention is paid to 1) differing philosophies of regulation, 2) the affect of varying societal views of the technology on the regulatory structure, 3) the degree of inter-agency or inter-Directorate General coordination in the policy making process, and 4) the ability of both regulatory systems to adapt to new scientific information. Finally, the impact of these different regulatory structures on the technology trajectory of bio-industries in the US and the EU is examined.

Prepared for the Biennial Conference of The European Community Studies Association, Pittsburgh, PA, 2-6 June 1999.

A Comparison of Biotechnology Regulatory Policy in the United States and the European Union[1]

Introduction

In a globalized economy, regulatory frameworks, once considered the exclusive domain of the nation state, must be assessed in comparative perspective. The increase in capital mobility and foreign direct investment allows firms to make autonomous decisions and find ways to circumvent state rules. Consequently, states are increasingly faced not only with competition in the market place but with competition in the regulatory arena as well.

One might expect this competition to lead to regulatory harmonization in the area of biotechnology, or, at a minimum, to regulatory convergence since the United States and Europe share the goal of simultaneously protecting the public and the environment and allowing bio-industries to flourish.[2] However, significant differences in biotechnology regulations between the United States and the European Union remain. These differences have resulted in profoundly different technology trajectories. This paper addresses the question of how the US and the EU came to develop very different biotechnology regulatory regimes by looking at the historical development of these guidelines and regulations. Special attention is paid to the emergence of differing philosophies of regulation, the affect of varying societal views of biotechnology on the regulatory structure, the degree of inter-agency or inter-Directorate General coordination in the policy making process, and the ability of both regulatory systems to adapt to new scientific

[1]I would like to thank the Fulbright Foundation, the Social Sciences Research Council, the European Community Studies Association, and the UNiversity of Pittsburgh's Provost Development Fund for funding this research.

[2]For instance, McCraw argues that the inherent characteristics of given industries or sectors seem much more important than different legal systems or different national cultures in determining the size and organizational structure within those communities. See T. McCraw "Rethinking the Trust Question" in *Regulation in Perspective.*, ed. T. McCraw (Cambridge: Harvard University Press, 1981). Also see Organization for Economic Cooperation and Development, *Regulatory Co-operation for an Interdependent World* (Paris: OECD, 1994)

information. Finally, the impact of these different regulatory structures on the technology trajectory of bio-industries in the US and the EU is examined.

The Historical Development of Biotechnology Guidelines and Regulations in Europe and the US

The Role of the International Scientific Community

The placing of biotechnology on the policy agendas of both the US and the EU was largely exogenously determined by the international policy network of biological scientists. In June 1973, the annual session of the Gordon Conference on Nucleic Acids held in New Hampton, New Hampshire was devoted to the problem of hazards in rDNA research. The co-chairs of the Conference drafted a letter to the National Academy of Sciences asking them to undertake a study of the possible risks involved in rDNA research.[3] In February 1974, the National Academy of Sciences formed a committee to explore the risks involved in utilizing this new technology. This committee was composed of 11 members who were all actively involved in rDNA research. In July 1974, the committee's report was published in *Science* and *Nature*. The report stated that "although [rDNA experiments] are likely to facilitate the solution of important theoretical and practical biological problems, they would also result in the creation of novel types of infectious DNA elements whose biological properties cannot be completely predicted in advance."[4] There was, therefore, some concern that the artificial recombinant DNA molecules could prove to be biologically hazardous. In light of this, the committee recommended that an international meeting of involved scientists from all over the world should be convened early in the coming year to review scientific progress in this area and to further discuss appropriate ways to deal with the potential biohazards of recombinant DNA molecules.

---

[3]See Maxine Singer and Deiter Soll letter reproduced in James Watson and John Tooze, *The DNA Story: A Documentary History of Gene Cloning* (San Francisco: W.H. Freeman and Co., 1981), 5.

[4]Paul, Berg, Chairman and Committee "Potential Biohazards of Recombinant DNA Molecules," *Science* 185, (July 26, 1974), 303.

The International Conference on Recombinant DNA Molecules was held at the Asilomar Conference Center in California in February 1975. The Asilomar conference influenced the discussion about whether genetic engineering was a problem which required regulation in three main ways. First, and foremost, it raised governmental awareness of both the potential benefits and potential risks involved in biotechnology. This, in turn, raised questions about societal values and scientific experimentation and set the stage for an intense debate on the type and extent of regulation required to monitor new scientific technologies. As Cantley notes,

> The developments in genetic engineering to which Asilomar drew attention catalyzed a fundamental debate about the control of science and technology; or, insofar as such a debate was already in progress, extended and amplified it to all areas of the life sciences and technologies, their applications and implications. [5]

Second, the open environment in which the conference was held not only allowed but encouraged a public debate on the pros and cons of biotechnology research. And third, somewhat surprisingly, the initial willingness of scientists to place a self-generated moratorium on themselves created a policy environment of trust in the US and fear and distrust in Europe. In general, Americans focused on the positive behavior of the scientists while Europeans focused on the potential harms that had caused the scientists to invoke a moratorium to begin with.

Biotechnology Policy Making in the 1970s

Despite the Asilomar conference, the EU was slow to initiate regulatory action on biotechnology throughout the 1970s for several reasons. First, there was widespread disagreement about whether regulation was needed. Second, integration of the common market was proceeding slowly. And finally, there was no real legal basis for the EU to engage in social regulation. Nevertheless, DG XII (Science, Research, and Development) advocated a community-wide research and development program in molecular biology. As Cantley reports, in 1978, DG XII formulated a "Proposal for a Council Directive establishing safety measures against

---

[5]Mark Cantley, "The Regulation of Modern Biotechnology: A Historical and European Perspective: A Case Study of How Societies Cope with New Knowledge in the Last Quarter of the Twentieth Century" in *Biotechnology*, eds. H.J. Rehm and G. Reed (Weinheim, Germany, VCH, 1995),513.

conjectural risks associated with recombinant DNA work." The proposed directive would require notification and authorization by national authorities prior to all research or other work involving rDNA. National authorities would develop categorization procedures for rDNA experiments, keep track of those experiments, report them to the Commission, and finally report on their experiences and problems annually. The directive was to be reviewed and revised at intervals not to exceed two years.

However, with the accumulation of additional experimental evidence in the United States and the United Kingdom that indicated that some of the initial fears related to rDNA research had been overblown, the Commission withdrew their proposed directive and replaced it with a non-binding Council Recommendation. This Recommendation required notification, not authorization, of rDNA work so that in the unlikely event of a problem, the origin of the contamination could be traced. The recommendation was approved by the European Parliament after a lengthy debate and adopted by the Council in June 1982. Key European science organizations including the European Science Foundation (ESF), the European Molecular Biology Organization (EMBO), and the European Federation of Biotechnology (EFB) agreed with this approach.

This initial regulatory approach closely mirrored that which was being developed in the United States. Shortly before the Asilomar conference, the director of the National Institutes of Health (NIH) formed a committee known as the Recombinant DNA Molecule Program Advisory Committee (RAC) to evaluate potential biological and ecological hazards of various DNA recombinations, develop procedures to minimize the spread of such molecules, and devise guidelines to be followed by investigators working with these molecules. After the Asilomar conference, the NIH RAC decided to devote the vast majority of its time to developing guidelines for conducting rDNA research.

The NIH RAC approached the regulatory process by outlining a hierarchy of conjectural hazards, developing a hierarchy of physical and biological containment procedures, and finally matching the conjectural risks with containment procedures thus establishing a draft set of research guidelines. These guidelines went through two major revisions before the final version was

published on July 7, 1976. Each attempt to draft appropriate guidelines was carefully documented in the popular media in forums such as *Science* Magazine and the *New York Times.*[6] In addition, many issues were discussed at public meetings of the NIH RAC. In the end, the final guidelines were relatively stringent and reflected much of the conservative thinking at Asilomar.

The NIH RAC guidelines were, however, just that - guidelines. They did not have the statutory force of regulations. They spelled out four graduated levels of physical containment and three levels of biological containment and they assigned specific safety levels to various types of experiments on the basis of their potential hazards.[7] Experiments thought to entail the most risk were reviewed by the NIH RAC and those that were thought to be less risky were reviewed by local institutional bio-safety review committees.

From the start, it was recognized that the guidelines should be dynamic and should be easy to amend in light of new scientific evidence. In fact, the first major revision of the guidelines took place in 1978 after extended public consultation. At that point, a procedure for amending the guidelines was introduced. Any proposal to modify any section of the guidelines or to introduce new provisions had to be published for public comment in the *Federal Register* at least 30 days prior to a RAC meeting. The proposal and any public comments would then be discussed by the RAC in an open session. The Director of the NIH would make a final decision on the proposal after taking into consideration the RAC recommendations.[8] According to this procedure, the guidelines were revised approximately every three months.

---

[6]See for instance, "Recombinant DNA: NIH Group Stirs Storm by Drafting Laxer Rules" in *Science*, 190 (November 21, 1975):767; "Recombinant DNA: NIH Sets Strict Rules to Launch New Technology" *Science* 190 (December 19, 1975). In fact, from 1978 to 1993, the NIH RAC published the *Recombinant DNA Technical Bulletin* which recorded the formal business of the RAC and served as a source of information and debate relevant to the development of rDNA research, development, and applications.

[7]Physical containment refers to the physical characteristics of laboratories which prevent organisms from escaping from the lab while biological containment refers to techniques which cripple the vector or the host organism so that they can not survive outside the lab (e.g. making them hyper sensitive to ultraviolet light).

[8]Mark Cantley, "The Regulation of Modern Biotechnology" 567.

The openness of the NIH RAC process and the ability of the public to express their concerns to policy makers enhanced the public's confidence in the government's attempts to provide appropriate guidelines, allowed the public to discuss issues of concern with scientists actively engaged in biotech research, and allowed high level bureaucrats to take into account a wide variety of views. As Mark Cantley states, "The early establishment of NIH RAC, its openness of debate, and the participation in its discussion of scientists, federal officials from all agencies concerned and activists, built credibility and confidence in the integrity of the process."[9] There was no similar mechanism for public discussion in the EU.

The NIH RAC guidelines were not the perfect solution, however. The problem was that they applied only to NIH funded research projects. However, private industry, in most cases, chose to voluntarily comply with the guidelines. Cantley argues that industry's motivations for doing so were primarily defensive. By following the guidelines, they hoped to prevent the need for further legislation and they could defend themselves if taken to court by activists' groups protesting a particular experiment.[10]

Biotechnology Policy Making in the 1980s

By the mid-1980s biotechnology policy in the US and the EC began to diverge. Three factors contributed to this divergence: 1) the emergence of opposing philosophies and methods of biotechnology regulations, 2) the influence of different societal views of biotechnology, and 3) the existence of different capacities for inter-institutional coordination.

The biotechnology policy debate in the EC did not end with the adoption of DG XII's non-binding Council recommendation in 1982. Several important events occurred between 1982 and 1990 that led the EC to adopt a restrictive set of community-wide biotechnology regulations. First, there was pressure from within the EC Commission and from the EC Parliament for some sort of community-wide biotechnology regulatory framework to be adopted. The Commission

---

[9]Mark Cantley, "The Regulation of Modern Biotechnology," 567.

[10]Mark Cantley, "The Regulation of Modern Biotechnology," 567.

was mainly concerned about the EC's global competitiveness in the area of biotechnology. In 1983, the Commission submitted a communication to the Council in which they outlined their priority objectives for overcoming the perceived weaknesses in the Community's biotechnology policy. These objectives included: 1) developing clear regulatory regimes at all stages from laboratory testing to marketing and post-market monitoring; 2) creating inter-service, international, and Community-Member State concertation of biotechnology policy; 3) taking into account the social dimensions of biotechnology policy; and 4) providing protection for intellectual property. However, the report did not specify whether biotech products or rDNA as a process should be the subject of regulation. (The important distinction between process-based legislation and product-based legislation will be dealt with below.) In 1986, the European Parliament produced an 'own initiative' report in which they recognized the vast potential of biotechnology to contribute to socially useful products in medical, agricultural, and environmental areas. However, the report also called for biotechnology-specific (i.e. process-specific) regulations to minimize risks.

Second, the Commission was under growing pressure to develop a Community-wide regulatory framework because individual member states were developing their own sets of guidelines by the mid 1980s. These regulatory frameworks varied tremendously and ranged from the very strict, process-driven, Gene Technology Act passed in Denmark to different sorts of systems of monitored self-regulation in the UK and France.[11] This led to the unpleasant possibility of a highly fragmented system of regulations within the Common Market.

Finally, the EC was under international pressure to follow the guidelines for biotechnology research established by the OECD's Group of National Experts (GNE) in 1986. The GNE was composed of 80 experts from a wide variety of academic and professional backgrounds. In 1986, the GNE reached a consensus on guidelines to be used in biotechnology research based on the widely agreed rationale that there was no scientific basis to regulate on the process (rDNA) by

[11]For more on this see Mark Cantley, "The Regulation of Modern Biotechnology" Chapter 5 and Lee Ann Patterson, "EU Biotechnology Policy: Regulating Risks and Risking Regulation" in Policy-making in the EU, 4th ed. Wallace and Wallace, eds. (Oxford: Oxford University Press, forthcoming, 2000).

which a product was produced. (It should be noted that the OECD approach stood in direct contrast to the approach being taken by Denmark).

As a result of this multi-level pressure for some sort of policy to be adopted at the EC level, the Commission stated its intention to introduce proposals for Community regulation of biotechnology in a November 1986 Communication from the Commission to the Council.[12] These proposals would address levels of physical and biological containment, accident control, and waste management in industrial applications (eventually this would become directive 90/219 on the Contained Use of Genetically Modified Micro-organisms), and the planned release of genetically engineered organisms into the environment (eventually this would become Directive 90/220 on the Deliberate Release of Genetically Modified Organisms into the Environment). The rationale for these new directives was to provide a high and common level of environmental protection throughout the Community and to prevent market fragmentation by the separate unilateral actions of the Member States. It is important to note, however, that by framing the regulatory debate in these terms the Commission was essentially advocating a process-based approach to biotechnology regulation.

At the same time that the EC began to move towards a more centralized, process-based biotechnology regulatory policy, the US NIH RAC began to move towards a dispersion of regulatory responsibility across federal agencies based on product regulations. The NIH RAC was very involved in monitoring the first rDNA experiments, but as more knowledge was gained and as more experiments were proposed in the late 1970s, the NIH RAC began to shift responsibility to other federal agencies. These agencies included the Food and Drug Administration (FDA), the Environmental Protection Agency (EPA), and the USDA's Food Safety Inspection Service (FSIS) and Animal Plant Health Inspection Service (APHIS). In general, the NIH RAC tended to agree with the OECD Group of National Experts which stated that there was no justification for

[12]European Commission. A Community Framework for the Regulation of Biotechnology, Communication form the Commission to the Council, Com (86) 573 Final. (Brussels: CEC, 4 November 1986).

regulations based on rDNA as a process. Consequently, the NIH RAC believed that biotech products could best be regulated by various agencies who had experience regulating like products produced by a wide variety of techniques. Hence the policy divergence between the US and the EC in the mid 1980s reflected the emergence of two different philosophies of biotechnology regulation.

Opposing Methods and Philosophies of Regulation. The two major opposing methods and philosophies of biotechnology regulation that became prevalent in the mid 1980s are juxtaposed in Table 1. The column on the left represents a more traditional product-based, vertical, preventive approach to regulation. The column on the right calls for a regulatory paradigm shift to a process-based, horizontal, precautionary approach.

Table 1 about here

Prior to the widespread utilization of recombinant DNA (rDNA) techniques in a variety of industries, most products were evaluated on the safety, quality and efficacy of the final product not on the process by which the product was produced. The widespread use of rDNA , however, led some policy makers to advocate regulations based on the process by which products were produced. The rationale for this new regulatory approach as described by DG XI in a widely distributed pamphlet was the following:

> the new techniques of genetic engineering allow the identification of many useful genes and their transfer to other organisms which didn't possess them before. Biological barriers are by-passed and new organisms are created with novel properties not previously existing in nature. Micro-organisms with novel properties could cause adverse effects in the environment if they survive and establish themselves, out competing existing species or transferring their novel traits to other organisms. (European Commission, DG XI/A/2, n.d.)

If the traditional method of regulating on the basis of product safety, quality, and efficacy was to be utilized, biotech products could be regulated in a vertical manner. In this way all tomatoes, for instance, whether they were produced by genetic modification, cross-breeding, chemical mutagenesis, or radiation mutagenesis would be evaluated for human and environmental

safety using the same criteria. On the other hand, process-based regulation would require a new horizontal approach to regulation. Under this approach all rDNA products including food products, livestock, drugs, pesticides, decontamination products and medical devices would be subject to the same set of safety regulations.

Finally, and most importantly, there were two main philosophies of regulation: the precautionary approach and the preventive approach. The precautionary principle is derived from German socio-legal tradition and gained recognition in the 1980s with the rapid development of environmental laws. The purpose of the principle is to guide political and regulatory action. The principle is based on 1) preventive action, 2) safeguarding of ecological space (even in advance of scientific proof or need), and 3) duty of care (or onus of proof on those who propose change).[13] Les Levidow and Joyce Tait summarize the precautionary principle as a conservative approach to risk in which regulation anticipates the sort of environmental harm which has not already been documented for a given category of products and which does not take into consideration the relative costs and benefits of regulation to industry and the public.[14] In contrast to this, a preventive approach seeks to respond to "scientifically proven adverse impacts that have arisen in earlier generations of products. New products and processes are screened to ensure that they do not give rise to any similar hazards. The regulatory system is built up slowly... Decisions about the need for regulation and the level of regulation required are taken in relation to the relevant benefits and costs."[15]

The result of taking a precautionary approach is that researchers and producers are subject to a strict set of regulations. Those advocating a precautionary approach argue that this is

---

[13]The EC Committee of the American Chamber of Commerce. *The EU Environment Guide*, (Brussels: EC Committee of the American Chamber of Commerce, 1994): 70.

[14]For more on this see Les Levidow and Joyce Tait "Release of Genetically modified organisms: precautionary legislation" in *Project Appraisal*, 7 (June 1992): 1993 and Joyce Tait and Les Levidow "Proactive and Reactive Approaches to Risk Regulation: The Case of Biotechnology" *Futures*, April 1992: 219-231.

[15]Joyce Tait and Les Levidow "Proactive and Reactive Approaches to Risk Regulation: The Case of Biotechnology" *Futures*, April 1992: 221.

necessary to protect the environment from potentially catastrophic events. The possibility of the occurrence of such an event is heightened by 1) the complexity of eco-systems which preclude unambiguous identification of cause-effect relations, and by 2) our lack of experience with genetically modified organisms (GMOs) and therefore our uncertainty about what their impact on eco-systems will actually be.[16] In addition, they argue that a precautionary approach is necessary to allay public fears about new technologies, generally, and about the desire of industry to capitalize on these technologies, specifically.[17]

Opponents of the precautionary approach argue that while caution is certainly necessary, most experiments fall into the low risk category anyway. Furthermore, it is logically impossible to prove that "no risks" exist. They argue that establishing a precautionary set of regulations would stifle important life-enhancing research and industrial competitiveness by creating unnecessary bureaucratic delays or even moratoriums. Advocates of the preventive approach prefer a case-by-case and step-by-step approach where regulations are based on proven harmfulness, different experiments are assessed on the basis of different risks, and different steps in the research and production process are examined according to the specific risks involved in that step.[18] In this way, scientists can proceed and in the process accumulate knowledge which will help clarify what the risks actually are.

The US and the EC ultimately pursued different regulatory approaches. The US adopted a product-based, vertical, preventive approach while the EC adopted a process-based, horizontal, precautionary approach to regulation. Two major factors contributed to the different regulatory

---

[16]Ibid: 223.

[17]See Les Levidow "A precautionary science for GEMs? Reflections on the Second International Conference on the Release of Genetically Engineered Microorganisms (REGEM 2)" *Microbial Releases* (1992): 55-60 for an analysis of some of the scientific problems in pursuing a precautionary approach and the tension between ecological and commercial considerations.

[18]This would still introduce a large degree of bureaucratic delay as compared to no regulations but at least it would guarantee some degree of flexibility.

approaches adopted by the US and the EC: differing societal views about the potential harmfulness of biotechnology products and differing degrees of inter-institutional policy coordination.

Science and Society in the EC and the US. One reason the EC adopted a more conservative, process based approach to regulation was that the biotechnology revolution has been greeted with far more skepticism in Europe than in the United States. Several things account for this. First and foremost, Europeans tend to be more dubious of scientific findings that the vast majority of biological experimentation involves "little or no risk." This is based upon their experience with thalidomide, nuclear energy, and more recently 'mad cow' disease. Thalidomide was widely accepted as 'safe' until countless Europeans developed devastating birth defects. Likewise, in the case of nuclear energy, Europeans were promised a clean, safe, relatively low cost form of energy. The meltdown of the Chernobyl plant in 1986 and the intractable problem of disposing of nuclear waste has led to a deep distrust of both scientists and science-related policy in general.[19] Finally, any lurking distrust of science and science policy has been inflamed again by the existence of 'mad cow' disease. Originally, scientists claimed that 'mad cow' disease could not pass from cows to humans. This is now known to be untrue. The US, on the other hand, never embraced nuclear energy to the same extent as Europe. Thalidomide had not cleared the FDA process by the time the negative results from Europe became apparent and Americans have suffered no major threat to their food supply equivalent to mad cow disease. In general, US citizens are much more likely to give the benefit of the doubt to government regulatory agencies.[20] On the

---

[19]For an excellent discussion of how biotechnology differs from nuclear energy see Martin Bauer. "Resistance to new technology and its effects on nuclear power, information technology, and biotechnology" in *Resistance to New Technology, nuclear power, information technology and biotechnology*, ed. Martin Bauer (Cambridge: Cambridge University Press, 1995), 7-11.

[20]This is not to say that there are not pockets of dissent and protest. For instance, a citizens' group in Maine has tried to win a five-year moratorium on the approval of any additional genetically-modified food in the state. In addition, the International Center for Technology Assessment has fled a lawsuit against the EPA claiming that its' approval of "Bt crops"(engineered to carry internal insect resistance) had been unlawful. *Financial Times.* "Comment and Analysis: All the Food that's fit to eat: John Willman analyses the media panic surrounding the introduction of genetically modified foods in the UK" 20 February, 1990. Also, Jeremy Rifkin and his colleagues have published

other hand, as Tony Burke of the New Statesman points out: "Under resourced regulators, operating at the boundaries of the known, driven on all sides by deregulatory pressures, command no public confidence [in Europe]."[21]

Second, Europeans are suspicious of politicians who base regulatory decisions on scientific evidence which appears to favor industry over consumers. Given the vast, and seemingly endless, problems with the Common Agriculture Policy, Europeans are dubious of embracing any new technology which would increase production and profits for big agri-business at the expense of consumer safety. Monsanto's failure to understand the concerns of the European citizen in combination with their high profile advertising campaign to promote biotech foods has only inflamed consumer attitudes especially in the UK.[22]

Third, biotechnology has been portrayed differently in the media in Europe and the US. Most media coverage of biotechnology products and innovations in the US focuses on the positive health and environmental benefits to be gained from specific rDNA products. In Europe, however, there is a tendency especially in the UK and Germany, to focus on "Frankenstein Foods." Many of these articles do not hold up to scientific scrutiny but they are quite successful at stirring up fear and distrust in the general population. In fact, the underlying theme of many media articles written in the EU is the problematic relationship between technology, society, and the state. In the US, the theme tends to be oriented towards solving specific health, agricultural, or environmental problems.

Finally, the policy making process in the US has been far more open and transparent than that in Europe. As mentioned above, the Federal Register process guarantees a venue for opposing voices to be heard and requires the agency involved in drafting the regulations or guidelines to

---

extensively on the dangers of genetic modification. See Jeremy Rifkin, *Harnessing the Gene and Remaking the World: The Biotech Century* (Jeremy P. Tarcher/Putnam a memeber of Penguin Putnam Inc.: New York, 1998).

[21]Tom Burke. New Statesman. "Bananas are only the Warm-up Act" 12 March 1999.

[22]Financial Times, "Monsanto Admits Promotion of Modified Foods has Backfired" 15 March 1999.

address these concerns. While this is not always done to the satisfaction of those opposing certain proposed regulations, it has contributed to a far more open policy making process in the US.

Internal Policy Coordination. In addition to differing levels of societal trust in science, in general, and the lack of a Federal Register type process, the EC failed to establish an internal policy coordination mechanism which would allow a variety of perspectives to be considered in the policy making process. Tables 2 and 3 show the vast number of EC Directorates General and US departments and agencies who are interested in some area of biotechnology policy. Each of these DGs or agencies tends to be concerned with a unique product or problem related to biotechnology. They often operate in different policy networks, have different standard operating procedures and even different regulatory philosophies. Thus inter-agency coordination is critical to avoid problems of redundancy, incoherence, and lacunae. Furthermore, inter-service coordination provides a forum to discuss policy objectives and new policy initiatives, to solve problems of interservice overlap, and to coordinate standpoints to be taken at meetings with other countries and organizations. While the US was successful at establishing internal coordination from an early date, the EU was not. This can be explained largely by the fact that US administrative and regulatory agencies were well established by the mid 1980s while the different DGs within the EU were still trying to carve out policy territory.

Tables 2 and 3 about here

The EU engaged in two rather unsuccessful attempts to horizontally coordinate biotechnology policy between 1984 and 1990. In early 1984, Vice President Davignon (Research and Development and Industrial Affairs), together with Commissioners Dalsager (Agriculture) and Narjes (Internal Market) put forward a Commission paper calling for internal coordination for biotechnology. The paper was accepted and the Biotechnology Steering Committee (BSC) was formed. The BSC was comprised of DG III (Industry), VI (Agriculture), XII (Science, Research, and Development), and XIII (Information Market and Innovation) and was to be open to other Directorates General where their interests were concerned. The mandate of the BSC was to

establish internal communication and concertation on biotechnology policy and it was to provide a forum for discussion at the Director General level. However, as Mark Cantley notes "the time pressures on senior staff in the Commission made them reluctant to devote time to a mere 'debating club'. The consequence was the dilution of participation to a more junior level as the years went by and a declining frequency of meetings: the numbers of meetings in the five years from 1984-1988 were 3,3,2,1,1."[23]

By July of 1985, pressure was mounting for the EU to take some sort of regulatory action in the field of biotechnology as mentioned above. The BSC knew that consideration of regulatory options would involve a highly technical discussion which was outside the purview of the Directors General. Consequently, in July 1985, the BSC agreed to establish the Biotechnology Regulations Interservice Committee (BRIC). BRIC thus served as a technical agent for the BSC.

BRIC was composed of DGs III (Industry), V (Employment, Social Affairs, and Education), VI (Agriculture), XI (Environment, Consumer Protection and Nuclear Safety), and XII (Science, Research and Development) and became the center of biotechnology regulations within the Commission. As mentioned above, in November 1986, the Commission submitted a Communication to the Council entitled "A Community Framework for the Regulation of Biotechnology" in which they stated their intention to introduce proposals for Community regulation of biotechnology by the summer of 1987. The proposals would deal with 1) levels of physical and biological containment, accident control, and waste management in industrial applications and 2) authorization of planned release of genetically engineered organisms into the environment.[24] DG III and DG XI were appointed *co-chef de file* for the directive on contained use and DG XI was appointed *chef de file* for the directive on planned (or deliberate) release.

---

[23]Mark Cantley, "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 *Biotechnology*, eds. H.J. Rehm and G. Reed in cooperation with A Pühler and P. Stadler. 2nd completely revised edition. (Weinheim, Germany: VCH, 1995): 534.

[24]European Commission, *Communication from the Commission to the Council, A Community Framework for the Regulation of Biotechnology* Com 86(573) final.

The term *chef de file* refers to the service which is given primary responsibility for drafting a directive. The role of *chef de file* is extremely important for two reasons. First, the *chef de file* drafts the directive and in so doing sets the terms of the debate. Second, the service which is *chef de file* presents the directive to the Council of Ministers. DG XI, who was in the policy network of ecologists and environmental interest groups preferred a process-based, horizontal, and precautionary set of regulations. This approach was opposed by DGs III, VI, and XII. DGs III and VI viewed rDNA as simply a different technology for producing products which would fall under their long-established domains. In general, DGs III and VI do not believe that a technology is something which exists on its own, but rather its relevance is in its utilization as a new and improved route to the manufacture of products.[25] From a regulatory point of view, it was the product rather than the technology which was important. DG XII, which was in the policy network of scientists and microbiologists, believed that the vast majority of rDNA experiments could be classified as low risk and that these risks could be controlled by the application of good microbiological practice. Furthermore, they argued that treating rDNA technologies as unique and different from all other technologies by regulating on the basis of the production technique rather than the final product would unduly stigmatize biotechnology and contribute to the already negative public perception of the technology.[26]

Unfortunately, the inter-DG coordination procedure failed for two main reasons. First, DG XI did most of the drafting on the Directives because DG III was too busy working on legislation related to the impending passage of the Single European Act to participate in either the drafting sessions or the Council meetings. In addition, DGs VI and XII were marginalized in the drafting process. Second, the draft directives went before the Council of Environment Ministers.[27] These

---

[25] Information gathered from interviews with several DG VI and DG III officials from September 1994 through June 1995.

[26] For a more detailed discussion of the inter-DG debates about biotechnology and the ways in which DG XI and the Council of Environment Ministers worked to overturn the few inter-DG compromises that were made see Lee Ann Patterson, "EU Biotechnology Policy: Regulating Risks and Risking Regulation" in Policy-making in the EU, 4th ed. Wallace and Wallace, eds. (Oxford: Oxford University Press, forthcoming, 2000).

ministers, in general, shared the same philosophical outlook on biotech regulations as DG XI and were able to overturn all the compromises that DG XI had originally made with the other DGs within BRIC.[28]

The EU's approach as embodied in Directives 90/219 on the Contained Use of Genetically Modified Microorganisms and Directive 90/220 on the Deliberate Release of Genetically Modified Organisms into the Environment meant that all products produced via genetic modification including plants, drugs, pesticides, food products, or medical diagnostics were subject to the same set of regulations under the directives. Furthermore the directives were to be administered by DG XI and the Competent Authorities established by DG XI. Finally, the regulations made little attempt to balance the costs and benefits of research and product development with potential environmental risks. Consequently, the regulations were very restrictive and administratively burdensome.

The US took a somewhat different approach. To facilitate coordination in the US, two important working groups were convened, the White House Cabinet Council on Natural Resources and the Environment (CCNRE) in 1984 and the Biotechnology Science Coordinating Committee (BSCC) in 1985. The CCNRE was a working group established to consider whether the regulatory framework that pertained to products developed by traditional techniques was adequate for products obtained with the new rDNA technologies and whether the review processes for research conducted for agricultural and environmental applications was sufficient. The stated goal of the CCNRE was to "achieve a balance between regulation adequate to ensure health and

---

[27]Interview with former DG III official February 24, 1995.

[28]For more on this see Lee Ann Patterson, "Regulating Biotechnology in the European Union: Institutional Responses to Internal Conflict Within the Commission" unpublished paper presented at the 1997 ECSA Conference in Seattle, Washington and Lee Ann Patterson "EU Biotechnology Policy: Regulating Risks and Risking Regulation" in Policy-making in the EU, 4th ed. Wallace and Wallace, eds. (Oxford: Oxford University Press, forthcoming, 2000).

environmental safety while maintaining sufficient regulatory flexibility to avoid impeding the growth of an infant industry."[29]

Upon examination of the existing laws, the CCNRE determined that for the most part, current laws were adequate to address regulatory needs. The group also found that because of the rapid growth in scientific knowledge, federal agencies needed to have an interagency mechanism for sharing scientific knowledge. Consequently, the BSCC was formed.[30] This working group will be discussed in greater detail below.

In December of 1984, the CCNRE published a proposal called a "Coordinated Framework for Regulation of Biotechnology" in the *Federal Register* and called for public comment. The final policy statement, which was refined in light of public comments on the 1984 proposal, was published in the *Federal Register* on June 26, 1986.

The CCNRE, whose name was changed to the Domestic Policy Council Working Group on Biotechnology, announced in the 1986 Coordinated Framework that for the most part, the existing laws would address regulatory needs adequately. In the case of a few microbial products, some additional regulatory requirements needed to be established under existing statutory authority.[31] The regulatory framework for biotechnology products would thus be composed of a mosaic of existing federal law including the USDA's Federal Plant Pest Act (PPA) and Plant Quarantine Act (PQA), EPA's Toxic Substances Control Act (TSCA) and Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and FDA's Federal Food Drug and Cosmetic Act and Public Health Services Act (PHSA) among others. (See Table 4) Furthermore, the Coordinated Framework stated that there appeared to be no alternative unitary approach since "the very broad

---

[29]Executive Office of the President, Office of Science and Technology Policy, "Coordinated Framework for Regulation of Biotechnology" *Federal Register* 51, no. 123 (26 June 1986):23303, microfiche.

[30]Executive Office of the President, Office of Science and Technology Policy, "Coordinated Framework for Regulation of Biotechnology," 23303.

[31]See footnote 4 on page 12 of The President's Council on Competitiveness, *Report on National Biotechnology Policy* (Washington, DC: Department of Commerce, February 1991).

spectrum of products obtained with genetic engineering cut across many product uses regulated by different agencies."[32] This was exactly the opposite approach from that being taken in the EC. Thus the US pursued a vertical approach rather than a horizontal approach to regulation.

In the area of research, the Coordinated Framework stated that the Center for Disease Control's (CDC) publication *Biosafety in Microbiological and Biomedical Laboratories* and the NIH's publication *NIH Guidelines for Research Involving Recombinant DNA Molecules* provided adequate guidelines for research. For contained federally funded research, research approval must be granted by the funding agency. For non-federally funded research, the Coordinated Framework stated that appropriate agencies would conduct voluntary reviews. It was determined that EPA would have authority over all research on microbial pesticides, whether research was federally funded or not, and nonpesticide microorganisms released into the environment would fall under the jurisdiction of USDA, NSF or EPA depending on the source of the funding and the purpose of the research. The framework also stated that not all experiments involving the environmental release of genetically engineered organisms required prior federal approval. For instance, it stated that there was a substantial body of research in the area of plant applications that indicated that such experiments were of low risk.

The Coordinated Framework also stated that to the extent possible, responsibility for product use would lie with a single agency. In cases of overlap, the Framework established a lead agency. (See Table 5 for an outline of agency responsibilities). In the EU there is still a dispute about who should be the lead regulatory agency. Directive 90/220 states that consent may only be given for the placing on the market of products containing or consisting of GMOs provided that... the products comply with the relevant Community product legislation and the products comply with this part of the directive, concerning the environmental risk assessment." However, it also states that "In the future, Part C would not apply to any products covered by Community

[32]Executive Office of the President, Office of Science and Technology Policy, "Coordinated Framework for Regulation of Biotechnology," 23303.

legislation which provides for a specific environmental risk assessment *similar to that laid down in the Directive*." (author's emphasis).[33] Consequently, *all products* containing GMOs have to meet the Community's relevant product legislation, but they also have to meet technology based environmental risk assessment requirements similar to those laid down in 90/220. Now DGs III and VI and the European Medicines Evaluation Agency (EMEA) are engaged in a heated debate with DG XI about what constitutes a 'similar' risk assessment. This has led to a great deal of regulatory confusion and added an extra component of uncertainty for EU biotech companies which are trying to figure out which regulations they must meet.

In addition to using a mosaic of already existing federal laws to regulate on a product basis, the attitude towards regulatory reform in the US was very different from the attitude in the EU. In both directives 90/219 and 90/220, certain amendments to the annexes could be made by a committee composed of representatives of the Member States. (This committee is called the Committee of Competent Authorities.) These annexes, however, only pertained to the classification of genetically modified organisms and notification procedures. Amending the directives themselves required a new Commission proposal, agreement in the Council, and approval of the Parliament as defined by the legal basis of the directives. This process was unwieldy and time-consuming and industry languished while political/regulatory battles were being fought out in the various institutions of the EU. In the US, the framework was expected to evolve in accord with the experience of industries and the agencies, and thus modifications could be made through either administrative or legislative action.[34]

Tables 4 and 5 about here

The second important US working group which grew out of a need to coordinate scientific information was called the Biotechnology Science Coordinating Committee (BSCC) and was

---

[33]Council Directive of 23 April 1990 on the deliberate release into the environment of genetically modified organisms. (90/220/EEC) (Official Journal No. L 117/15)

[34]Executive Office of the President, Office of Science and Technology Policy, "Coordinated Framework for Regulation of Biotechnology," 23302.

established as part of the Federal Coordinating Council for Science, Engineering and Technology (FCCSET).[35] Members consisted of senior policy officials of agencies involved in the oversight of biotechnology research and products. The BSCC established two critically important principles. First, they stated that agencies should seek to adopt consistent definitions of those genetically engineered organisms subject to review. This they believed was critical to a coordinated federal regulatory framework. Second, they stated that agencies should utilize scientific reviews of comparable rigor.

In general, the regulatory approach taken in the Coordinated Framework was to focus on the safety of new products or microbial releases into the environment whereas the general approach of the EU was to monitor products produced via biotechnological processes regardless of whether or not these products were generally considered to be safe. See Table 6 for a comparison of the US and EU approaches.

Table 6 about here

The existence of the Coordinated Framework does not mean that everyone is in agreement that this is the approach that should be taken. The American regulatory system is far more nuanced than a cursory look at the Coordinated Framework might imply. In fact, there are two major and related areas of conflict. First, there has been an ongoing disagreement between federal agencies regarding the scope of biotechnology legislation. This disagreement reached a climax in 1988. The 1986 Coordinated Framework recognized that because of the statutory differences in the laws that individual agencies administered, agencies would have to adopt the definitions outlined by the BSCC in ways consistent with their existing legislation. However, no interagency agreement could be reached on the precise definition of organisms that would be subject to EPA regulations. The issue was turned over to the Biotechnology Working Group of the President's

[35]The FCCSET was a statutory interagency coordinating mechanism managed by the Office of Science and Technology Policy, Executive Office of the President. Its mission was to coordinate federal science activities among federal agencies.

Council on Competitiveness, chaired by Vice President Dan Quayle.[36] Consequently, the EPA rules for regulation of microorganisms under TCSA and FIFRA were not published until 1993.

Second, the relative freedom given to different agencies in the United States in adapting their statutory legislation to the Coordinated Framework allowed them to adopt different philosophical approaches to regulating biotechnological products. As Henry Miller states, "federal regulatory agencies have jumped on the biotechnological bandwagon with different and sometimes incompatible, if not downright contradictory regulatory approaches."[37] For instance, the FDA did not establish new administrative procedures to deal with biotechnologically derived products. Instead, they declared that each new product developed using biotechnological processes would be treated on a case-by-case basis and evaluated for safety, quality, and efficacy in keeping with existing requirements or procedures.[38] This means that new biotechnological drugs will be subject to the same requirements as all new drugs. The same applies to biotechnologically derived foods and biologics. Similarly, OSHA decided that no new guidelines were necessary and FSIS decided that it would treat genetically engineered food animals in exactly the same way that they treated new breeds.

On the other hand, EPA and APHIS both announced their intention to modify old legislation to take into account the new characteristics of genetically modified organisms.[39]

---

[36]U.S. Congress, Office of Technology Assessment, *Biotechnology in a Global Economy* (Washington, DC: U.S. Government Printing Office, October 1991), 176.

[37]Henry I. Miller, *Policy Controversy in Biotechnology: An Insider's View* (Austin: R.G. Landes Company, 1997), 80.

[38]See Henry I. Miller, "Policy Controversy in Biotechnology," 95-101 for a description of FDA'a attempts to overturn its own policy on biotech food in the mid 1990s.

[39]See Executive Office of the President, Office of Science and Technology Policy, "Coordinated Framework for Regulation of Biotechnology," 23315, 23342. Specifically, the EPA reviews and registers chemical pesticides under FIFRA and reviews chemical substances (except those used for pesticides, foods, food additives, cosmetics, drugs and medical devices) under TSCA. Under FIFRA, all pesticides whether chemical, microbial or genetically engineered must be registered with EPA before being sold and can only be distributed and used under the conditions approved in the registration. The EPA also grants experimental use permits (EUP) which allow limited use of unregistered pesticides for pre-market testing. In general, EUPs are not required for new pesticides used on less than 10 acres. However, the EPA did conclude that evaluation of small scale testing of certain genetically engineered microorganisms was needed. Consequently, they stated their intention to amend the rule to require that the EPA be

Scientists argued that the EPA had thus made an arbitrary distinction between GMO pesticides and chemical pesticides on the basis of production process rather than the inherent risk of the product.

In light of the EPA's reforms to TCSA and FIFRA, DG XI (Environment, Consumer Protection, and Nuclear Safety) argued that there is very little difference between the operation of TCSA and FIFRA with respect to micro-organisms and the operation of Directive 90/220. They stated that "extensive discussions with EPA and a comparison between the US and the EU systems concerning a number of basic issues of assessment and approval have shown a remarkable similarity in approach and practice."[40] What is different, however, is that TCSA and FIFRA apply to a limited number of products, while Directive 90/220 applies to the deliberate release of all genetically modified organisms. In addition, it is far easier to grant exemptions under TCSA and FIFRA than under 90/220.

Nevertheless, there is an interesting parallelism between the precautionary approaches pursued by the US EPA and Europe's DG XI. It is also interesting to note that both EPA and DG XI have assumed a sort of bunker mentality at various times and have on several occasions dropped out of, or ignored, attempts at interagency coordination. This implies a sort of functional similarity in philosophy and operationalization of notification procedures across environmental agencies in Europe and the United States. Freeman argues that "policy making in a particular sector, will exhibit strong similarities whatever its national context... The policy sector approach...

---

notified of all small scale testing of certain categories of micro-organisms. TSCA gives the EPA authority to screen chemicals that will not be reviewed under other statutes for health hazards. This includes, for example, pollution control, waste degradation, energy and mineral recovery, and nitrogen fixation. The EPA announced in its policy statement in the Coordinated Framework that it considered certain types of micro-organisms to be chemical substances subject to regulation under TCSA. Under TCSA, the EPA issues consent for new substances or new uses of substances. These consents are called Pre-Manufacturing Notices and Significant New Use Notices. TCSA applies only to commercial manufacturing, not academic research, and does not apply when small amounts of chemicals are produced for research or analysis. The consent orders are issued after an environmental risk assessment has been carried out. The EPA reformed TCSA to apply differently to GMOs. First, they announced that they would amend the regulations so that the research and development exemption would not apply to field releases of microorganisms. Second, they stated their intention to develop a significant new-use rule for pathogenic micro-organisms.

[40]Commission of the European Union, "Background Paper for the BCC: Overview of US Legislation on Biotechnology - Existing and Proposed Legislation" (DG XI, Brussels, Belgium, DG XI, 14 May 1992, photocopy), 8.

predicts differentiation within individual countries across sectors and convergence across nations within sectors."[41] It is difficult to support this hypothesis when one studies biotechnology policy as a whole because there are profound differences between US and EU biotechnology policy. However, at a more micro level, it is interesting to note the similarity in approaches taken by environmental agencies in both the US and the EU particularly with respect to policy goals.

Within the Coordinated Framework, APHIS (the Animal and Plant Health Inspection Service) is responsible for regulating plants, plant products, and plant pests under the PPA and PQA. These laws also give it authority to regulate import, interstate movement, and release of genetically engineered organisms derived from plant pests into the environment.[42] APHIS operates by using a permit system to control the release of plant pests. Permits are required for any organism that has been genetically altered using rDNA techniques which is being imported, moved interstate, or released into the environment. To receive a permit for a small scale planned introduction into the environment of a GMO, applicants must submit details about how the organism was produced, a description of changes in the organism resulting from the introduction of new genetic material, a statement of the purpose of the introduction and details of the experimental protocol including a description of methods to prevent dissemination beyond the test site. Before a permit is issued, APHIS prepares an environmental risk assessment based on this information.[43] DG XI has also claimed that the systems administered by APHIS and DG XI are remarkably similar.[44]

There is, however, one major difference. Under the APHIS system, individuals may submit petitions to amend lists of organisms regulated as plant pests by adding or deleting any

---

[41]Gary P. Freeman, "National Styles and Policy Sectors: Explaining Structured Variation," *Journal of Public Policy* 5, no. 4: 486-487.

[42]'Plant pest' is defined as any organism that directly or indirectly causes disease or damage to plants.

[43]U.S. Congress, Office of Technology Assessment, "Biotechnology in a Global Economy," 180.

[44]Commission of the European Union, "Background Paper for BCC," 5.

genus, species, or subspecies. After publication in the *Federal Register* and an opportunity for public comment, the Deputy Administrator of APHIS can approve or deny the petition.[45] No similar procedure exists under Directive 90/220.

Policy Reform in the 1990s

In general, the US has continued to refine the regulatory framework to reflect new scientific evidence. The EU has also been engaged in reforming directives 90/219 and 90/220. Immediately after the passage of the two directives there was a huge public outcry form European businesses, European scientists, and Europe's trade partners. Business groups claimed that the directives were so administratively burdensome that they would seriously thwart innovation and investment in Europe.[46] European scientists claimed that there was no scientific justification for regulating on the basis of a production technique rather than product safety.[47] The US argued that a process-based regulatory system would result in trade disputes.[48] To address these concerns, President Delors and the College of Commissioners established a new inter-DG coordinating body called the Biotechnology Coordinating Committee (BCC) in 1990. Since then, the BCC has tried to reform Directive 90/219 to bring the risk classification more in line with internationally accepted risk classification schemes. Some reforms were finally passed in 1998, a mere eight years after the passage of the original directive. However, the horizontal, process-based approach of the initial directive was left in tact. The Commission is now engaged in reforming Directive 90/220 but the path dependency established by the original directive and the public outcry against the import of

---

[45]U.S. Congress, Office of Technology Assessment, "Biotechnology in a Global Economy," 180.

[46]Senior Advisory Group on Biotechnology. Letter from the Senior Advisory Group on Biotechnology to Jacques Dlors. 24 August 1989. Photocopy.

[47] Open Letter of Nobel Laureates to EC Commission, Council, and Parliament. May 18, 1989.

[48]US Government. "International Harmonization in the Biotechnology Field" (July 7, 1989) reprinted in Cantley, "The Regulation of Modern Biotechnology," 559.

genetically modified maize and soya have slowed the reform process and led to small incremental reforms to the directive rather than allowing for a major overhaul of the directive.

Meanwhile in the US, the EPA has published exemptions to TSCA based on new scientific information and APHIS has made tremendous strides in simplifying the requirements for the planned introduction of modified plants into the environment. In 1993, APHIS announced that six crop species were no longer considered to present a plant pest risk based on extensive experience with field tests and hence no longer required a permit for introduction into the environment. Thus genetically modified corn, cotton, potato, soybean, tobacco, and tomato were made eligible for introduction by notification only.[49] On June 2, 1997, APHIS again simplified their regulations. Under the new system, 99% of all field trials will be conducted under notification procedures. No similar provision for the release of genetically modified organisms into the environment exists or is even under consideration in the EU. In addition, the amount of time required to petition for a determination of non-regulated status in the US was reduced by about three-fourths. This was accomplished by allowing determinations of non-regulated status to be based on establishing similarity with an antecedent organism.[50]

The Impact of Different Regulatory Schemes on Bio-Industries

The impact of these different regulatory structures on bio-industries has been profound. First there has been a net outflow of biotechnology capital investment from the EU to the US. The line-up of European companies investing in the US biotechnology companies and research facilities is astounding. Since 1987, Novo Nordisk (Denmark) has invested at least 29 million ECU in the United States to support the production of insulin, Factor VIII C, and enzymes.[51] BASF

---

[49]Animal Plant Health Inspection Service, "Genetically Engineered Organisms and Products; Notification Procedures for the Introduction of Certain Regulated Articles; and Petition for Nonregulated Status" *Federal Register* 58, no. 60 (31 March 1993):17044-17046, microfiche.

[50]Animal Plant Health Inspection Service, "Genetically Engineered Organisms and Products; Simplification of Requirements and Procedures for Genetically Engineered Organisms" *Federal Register*, 62, no. 85 (2 May 1997): 23945-23958, microfiche.

[51]Factor VIII C is a blood clotting protein for hemophiliacs.

(Germany) has invested 81 million ECU for research on cures for cancer. Bayer (Germany) has invested 109 million ECU for genetic engineering and cell biology. Rhone Poulenc (France) has invested over 111 million ECU in the area of agricultural research, seeds, and food additives. Glaxo (United Kingdom) has invested at least 428 million ECU for research in cell and molecular biology applied to cancer, connective tissues diseases, metabolic disorders, bone diseases, AIDS research and gene therapy. And SmithKline/Beecham (United Kingdom) has invested at least 120 million in biomedicine, human and veterinary vaccines, and immunoglobulins. Many other European companies have also made investments in the United States. In sum, the European Commission estimated that as of 1994 EU companies have invested at least 2.7 billion ECU in the US in the area of biotechnology.[52] By 1990, the US was filing 50% more biotech patents than the EC and in the area of bio-pharmaceuticals 67% of the patents were held by US companies and only 15% by Community-based companies.[53] Furthermore, as of 1997, the US had conducted 69.94% of the field trials of genetically modified plants while the EU had conducted only 15.87%. Even allowing for some discrepancies in the way that field trials are counted, the US has an indisputable global advantage in this area of biotechnology research.[54] Although, the current biotechnology regulatory structure in the EU may meet the social goals of some groups, the economic impact on a knowledge-based economy attempting to create high value added jobs has been profound.

Conclusions

The objective of both the United States and the European Union is to protect human health and the environment, while simultaneously promoting the competitiveness of industries using biotechnological processes and developing biotechnological products. Despite this shared goal, the US and the EU have adopted dramatically different regulatory policies. There are several reasons

---

[52]European Commission, DG III, "Draft report on the International Competitiveness of Biotechnology in the EU, November 11, 1994" (Directorate General III, Brussels, Belgium, photocopy).

[53]White Paper p.116-117

[54]Data taken from BioTrack Data Base of Field Trials, OECD.

for this. First, the American public in general tends to be relatively pro-science and consequently they tend to trust regulators and politicians who base regulations on scientific findings. Europeans on the other hand, through experience, are very dubious of scientific findings and advice and are more distrustful of politicians and regulators who base policies on scientific evidence alone.

Second, one might expect the existence of entrenched statutory regulatory bodies in the US to pose a greater coordination problem than would be experienced in the fairly fluid organizational structure of the European Commission. However, coordination was more easily achieved in the US for several reasons. The scale of the conflict in the US was limited by pre-existing institutional structures which compartmentalized the debate. The existing division of regulatory responsibility in the United States set a precedent both for the involvement of multiple actors in the interagency process and for limiting the range of their authority. While there was, and still is, some conflict about how each agency will regulate the biotech products which fall under its supervision, the EPA never attempted to capture the regulatory process for foods, drugs, or agricultural products.

On the other hand, the scope of conflict, or the number of people involved in the conflict, in the United States was very large. The Administrative Procedures Act of 1946 requires agencies to announce proposals for regulations in the *Federal Register* and then to address the public comments registered in the final notice. This system ensures that a wide variety of viewpoints can be expressed and requires that they be taken into consideration in the regulatory process. This allows business, scientists, environmental groups, and concerned citizens to be engaged in the process and it decreases the amount of uncertainty faced by research scientists and product developers by allowing them to anticipate future regulations and plan accordingly.

In the European Union, however, DG XI, created in 1981, was relatively new and anxious to establish itself as a key part of the Commission. Consequently, rather than looking at biotechnology as it applied to research efforts or specific product categories, DG XI successfully generalized the scale of the conflict so that all biotechnological products and processes were lumped together and the process of using rDNA technologies was viewed in juxtaposition to the

protection of the environment and human health at large.[55] Various DGs who had some previous experience regulating similar products were not able to limit the scale of the debate.

Curiously, however, the generalization and consequent enlargement of the scale of the debate was accompanied by limiting the scope of the debate in Europe. (See Table 7)

Table 7 about here

There are no requirements for public comment on proposed regulations in the EU. Furthermore, prior to the establishment of the BCC, DG XI was very successful at dismissing conflicting scientific views primarily by marginalizing DG XII and leaving DGs III and VI out of the policy drafting stage. Consequently, DG XI was able to engage in a very narrow debate with the Council of Environment Ministers and a few environmental interest groups and scientists who supported its position. This led to the adoption of significantly different biotechnology policies in the US and the EU.

Finally, the ability to deal with a cross cutting policy area was enhanced by the built-in flexibility of the American regulatory system. As our knowledge about genes and rDNA technologies grows, adjustments to the system of biotechnology regulations in the US can be made. In some cases, this means shifting responsibility from one agency to another as was done by the NIH. In other cases, this means limiting the regulatory burden placed on researchers and industry by decreasing the administrative procedures necessary to conduct research or develop products which are generally considered to be safe. DG XI, on the other hand, failed to build in adequate mechanisms for adjusting its regulatory structure to new scientific evidence. It is not impossible to reform the directives, but the process is slow, and unwieldy and because of this, regulatory reform in the European Union never seems to keep pace with scientific developments

[55]As mentioned in other chapters, DG XI was able to do this because of the procedures by which directives are initiated in combination with a more general leaning towards environmentalism in Europe in the late 1980s. Part of the environmental movement reflected a high degree of disillusionment with the ability of scientists to control the adverse impacts of modernization on the environment. This disillusionment resulted partially from the many problems of dealing with nuclear waste and the melt down of the Chernobyl nuclear reactor.

and is almost always out of date by the time it is passed. As a result, the EU's horizontal, precautionary, regulatory policy has stifled biotechnology research and innovation in a wide variety of EU industries.

Table 1

Conflicting Positions On How Biotechnology Should Be Regulated

Basis of Regulation	Regulation based on safety, quality, and efficacy of product.	Regulation based on process by which product is produced.
Type of Regulation	Vertical Regulation - Existing sectoral regulations can be modified to insure human and environmental safety of new biotech products.	Horizontal Regulation - New cross-cutting regulations need to be adopted to insure a basic level of human and environmental safety.
Philosophy of Regulation	Preventive - Less conservative regulatory approach which attempts to minimize environmental harm only after existence of harm has been scientifically proven.	Precautionary -Conservative regulatory approach in which regulation anticipates environmental hazards which have not already been documented but which could conceivably occur.

Table 2
Biotechnology Related Responsibilities and Interests in the Commission Services

Directorate General	Areas of competence related to biotechnology
DG I - External Relations	OECD Trade Group; GATT negotiations; international agreements, trade issues
DG III- Industry	Industrial affairs in bio-tech related sectors: agro-food, chemicals, pharmaceuticals, veterinary medicines, timber and wood products; related regulatory regimes; international/bilateral discussions
DG V-Employment, Social Affairs and Education	Use of Social Fund; worker safety in biotech industries and agriculture; employment impact of biotech
DG VI-Agriculture	Current or potential impacts on practically all aspects of plant and animal production; inputs to agriculture; impacts of substitution conversion technologies on competition and trade; agricultural legislation (crop products, animal nutrition, veterinary and zoological legislation, crop regimes, quotas, prices, disease control)
DG XI- Environment, Consumer Protection and Nuclear Safety	Impact of biotechnology on environment; contained use and deliberate release of GMOs
DG XII - Science, Research and Development	Research programs in biotechnology and in many areas of applied life sciences; science and technology for development; rDNA registration; bio-ethics; international scientific relations
DG XV-Internal Market	Intellectual Property Rights
DG XXIV-Consumer Policy Service	Consumer Protection

Information from "Biotechnology at the Community Level: Concertation" Concertation Unit for Biotechnology in Europe, DG XII, 7 October 1985: 13-14 and updated to reflect recent changes in the Commission.

Table 3
Biotechnology-Related Responsibilities and Interests of US Departments and Agencies

Department or Agency	Area of Interest or Competence Related to Biotechnology
Agency for International Development (AID)	Specific products or systems with the potential to improve human health, make agriculture more productive, and enhance the environment in the developing world
Department of Health and Human Services (DHHS)	Basic and applied research directed at the diagnosis, prevention, and treatment of disease
Department of Commerce (DOC)	Basic and applied research to accelerate the commercialization of biotechnology -derived products to enhance US competitiveness
Department of Defense (DOD)	Biomaterials, bioprocesses, and biosensors
Department of Energy (DOE)	Improving the production and utilization of energy and energy supplies, environmental remediation and restoration, genome mapping and sequencing technologies, new industrial biochemicals, elucidation of biomolecular structure and function, molecular nuclear medicine
Department of the Interior (DOI)	Fisheries and environmental contamination
Department of Justice (DOJ)	Forensic DNA analysis
Department of Veterans' Affairs	Disease-oriented Research
Environmental Protection Agency (EPA)	Application of biotechnology for protecting or improving the environment and safety of biotechnology products
National Aeronautics and Space Administration (NASA)	Space biology, microgravity sciences, and space life support systems
National Science Foundation (NSF)	Environmental technology, bioprocessing, bioconversion, bioelectronics, bionetworks, biomolecular materials, plant biology, marine biology, social and economic dimension of biotechnology, databases, research resources, and training
Department of Agriculture	Genome mapping and genetic enhancement, safe and effective pest management, animal health and welfare, biomass energy production, new processing technologies, consumer foods, waste management
Department of State	Trade agreements and trade issues
Food and Drug Administration	Safety, Quality and Efficacy of Food and Drugs

Taken largely from the Executive Summary of *Biotechnology for the 21st Century: Realizing the Promise* A Report by the Committee on Life Sciences and Health of the Federal Coordinating Council for Science, Engineering, and Technology. Available on the internet at http://www.nal.usda.gov/bic/Federal_Biotech/biotech94.fccset.html.

Table 4
Important Laws Affecting Biotechnology in the US

Agency	Law	Acronym
FDA	Federal Food Drug and Cosmetic Act	FDCA
	Public Health Services Act	PHSA
EPA	Toxic Substances Control Act	TCSA
	Federal Insecticide, Fungicide, and Rodenticide Act	FIFRA
APHIS (USDA)	Federal Plant Pest Act	PPA
	Plant Quarantine Act	PQA
	Virus-Serum-Toxin Act	VSTA

Table 5
Agencies Responsible for Approval of Commercial Products

SUBJECT	LEAD AGENCY	SECONDARY AGENCY
Human Drugs, Medical Devices, and Biologics	FDA	
Foods/ Food Additives	FDA	FSIS[1]
Animal Drugs	FDA	
Animal Biologics[2]	APHIS[1]	
Other Contained Uses	EPA	
Plants and Animals	APHIS	FSIS and FDA
Pesticide Microorganisms Released in the Environment	EPA	APHIS

[1]FSIS is the Food Safety Inspection Agency and APHIS is the Animal and Plant Health Inspection Agency. Both are part of USDA.
2 Biologics generally include any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product applicable to the treatment, prevention, or cure of diseases or injuries to man.

This table is derived from Chart 1 found in the *Federal Register*, June 26, 1986. Vol. 51, No. 123. p.23304.

Table 6

Comparison of the EU and US Biotechnology Regulatory Process

Area of Comparison	United States	European Union
Administration of Regulation	Wide variety of agencies. When two or more agencies have jurisdiction, the 1986 Coordinated Framework establishes a lead and secondary agency.	DG XI. In specific cases such as novel foods and pharmaceuticals DG III or the EMEA administer regulation but in all cases, products must conform to an environmental risk assessment equal or similar to that prescribed by DG XI.
Ability to Adapt to new Scientific Information	Regulations are easy to revise in light of scientific evidence and both research and product regulations have been revised many times. Exemptions are possible.	Regulations are difficult to revise. Major revisions to 90/219 have taken place once. Major revisions to 90/220 are still being discussed. (Some minor revisions to 90/220 have been made.) No exemptions are possible.

Effective Interagency Coordination	Interagency coordination began in 1984 prior to passage of the Coordinated Framework .	Effective interagency coordination occurred only after the passage of Directives 90/219 and 90/220.
Rule Making Consultation Process	Open. Scientists, business, special interest groups and other agencies are free to comment through the Federal Register process.	Closed. Consultation occurred primarily between DGs and their specific clients or occasionally among DGs. There was no public record or open comment period prior to the formulation of the regulatory framework. Since the formation of the BCC, interest groups are consulted on an ad hoc basis.
Input from Scientific Community	Extensive.	Marginalized. Communicated primarily with DG XII.

Table 7
Characteristics of the Policy Debate in the US and the EU

	SCOPE OF DEBATE	SCALE OF DEBATE
UNITED STATES	**Wide**	**Compartmentalized**
EUROPEAN COMMUNITY	**Narrow**	**Generalized**