University of Pittsburgh

Center for West European Studies
University Center for International Studies

4E01 Forbes Quadrangle
Pittsburgh, Pennsylvania 15260 USA
Tel: 412-648-7405
Fax: 412-648-2199
Email: wesp+@pitt.edu

Regulating Biotechnology in the European Union: Institutional Responses to Internal Conflict Within the Commission

Lee Ann Patterson
Graduate School of Public and International Affairs
University of Pittsburgh
Pittsburgh, PA 15260
E-mail: ucis301@pitt.edu

Research for this paper was supported by the European Community Studies Association, the Fulbright Foundation, and the Social Sciences Research Council. This paper was prepared for the bi-annual meeting of the European Community Studies Association, Seattle, May 29-June 1.

ABSTRACT

The European Union has targeted biotechnology as a key technology for future global competitiveness. Unlike traditional sectoral policies, biotechnology policy cuts across several sectors including agriculture, medicine, chemicals, pharmaceuticals, and processed foods and is of interest to environmentalists, ecologists, industry, and researchers at both the pure and applied levels. Consequently, the multi-dimensional nature of biotechnology requires a paradigm shift, for policy-making purposes, from sector specific governance to horizontal governance.

This paper explores successive institutional attempts to overcome the inherent structural fragmentation both among the various Directorate Generals (DGs) and between the political and technocratic levels of decision making within the Commission. This fragmentation is exacerbated by the existence of widely differing beliefs and perceptions about biotechnology and the extent to which biotechnological processes require regulation.

Early attempts at coordination in the form of the Biotechnology Steering Committee (BSC) and the Biotechnology Regulatory Interservices Committee (BRIC) were largely unsuccessful leading to a highly criticized regulatory framework. The Biotechnology Coordination Committee (BCC), however, has been largely successful at coordinating inter-DG biotechnology policy. The paper identifies the existence of a policy arbiter with high level political backing and the ability to move freely between the bureaucratic and political sides of the Commission as a key variable in the successful coordination of biotechnology policy.

Regulating Biotechnology in the European Union: Institutional Responses to Internal Conflict Within the Commission

"Without interest opposition, cooperation would not be necessary and without interest interdependence, it would not be possible."[1]

Bernd Marin

The European Union has targeted biotechnology as a key technology for future global competitiveness. Unlike traditional sectoral policies, biotechnology policy cuts across several sectors including agriculture, medicine, chemicals, pharmaceuticals, and processed foods and is of interest to environmentalists, ecologists, industry, and researchers at both the pure and applied levels. Consequently, the multi-dimensional nature of biotechnology requires a paradigm shift, for policy-making purposes, from sector specific governance to horizontal governance.[2]

Because of the crucial importance of this new technology, the Commission decided in 1986 that a regulatory framework was necessary to both insure the development of an internal market and provide adequate protection throughout the Community for consumers and the environment. Regulation, by its very nature imposes variable costs on different segments of business and society. Consequently, as outlined in Table 1, biotechnology regulatory policy is of considerable interest to a wide variety of Directorates General (DGs) including DGs I (External Relations), III (Industrial Affairs), V (Employment, Social Affairs and Education), VI (Agriculture), XI (Environment, Nuclear Safety, and

---

[1]Bernd Marin, "Generalized Political Exchange: Political considerations" in *Generalized political exchange: Antagonistic Cooperation and Integrated Policy Circuits*, ed Bernd Marin. (Westview Press: Boulder, 1990):60

[2] Recognizing this, the Commission, in its 1983 communication to the Council entitled *Biotechnology in the Community*, stated that although many of the activities in the area of biotechnology are the predominant concern of a particular service within the Commission, "the rich and proliferating interactions arising from biotechnology demand a horizontal view." European Commission. *Biotechnology in the Community* Communication from the Commission to the Council COM (83) 672 final / 2: E8-E9.

Civil Protection), XII (Science, Research, and Development), and XV (Internal Market). Each of these DGs represents a different client base, has a different institutional mandate and different standard operating procedures, and is concerned with a slightly different product or problem area related to the use of biotechnology.

Given the wide range of concerns related to biotechnology regulatory policy, one would expect to find a high degree of horizontal coordination across DGs in framing the regulatory directives. Unfortunately, however, early attempts to achieve internal coordination failed. This failure had a severe impact on European bio-industries in particular. This paper compares early failed attempts at horizontal coordination with later more successful attempts and thereby draws some conclusions about creating successful institutional mechanisms to deal with internal conflict.

The paper identifies the existence of a policy arbiter as a key variable in the successful coordination of biotechnology policy in the European Commission. A policy arbiter engages in both arbitration and interlocution.[3] As an arbitrator he or she has the political authority to simultaneously and iteratively broker deals among the services and among the Commissioners' cabinets. As an interlocutor, a policy arbiter is able to represent the concerns of a wide variety of technocrats to politicians and vice versa. The existence of a policy arbiter is necessary to overcome the inherent structural fragmentation within the Commission and thus to insure effective horizontal governance.[4]

---

[3]Unlike a policy entrepreneur, a policy arbiter does not necessarily advocate a specific policy or position. For a detailed description of a policy entrepreneur see John Kingdon, *Agendas, Alternatives, and Public Policies* (University of Michigan: HarperCollins Publishers, 1984).

[4]See Simon Bulmer. "The Governance of the European Union: A New Institutionalist Approach" *Journal of Public Policy* 13, no. 4. (1994) for a discussion of how thinking in the College of Commissioners is often conditioned by fragmentation within the DGs.

HORIZONTAL GOVERNANCE

Traditionally, governments have pursued a 'divide and manage' approach to improve efficiency in dealing with the scale and diversity of governmental functions. This approach has been widely accepted in the 1990s as well. In fact, one of the primary models for improving bureaucratic performance and efficiency, the market model, calls for establishing even greater autonomy within and between agencies rather than greater coordination. Proponents of the market model focus on the efficiency of markets for allocating resources in society and hence call for advisory, regulatory, and delivery functions to be separated and undertaken by different agencies.[5]

---

[5]Jonathan Boston, "The Theoretical Underpinnings of Public Sector Restructuring in New Zealand" in *Reshaping the State, New Zealand's Bureaucratic Revolution,* eds. Jonathan Boston, John Martin, June Pallot and Pat Walsh (Auckland: Oxford University Press, 1991):4. For more on market models of governance see B. Guy Peters "Models of Governance for the 1990s" in *The State of Public Management,* eds. Donald F. Kettl and H. Brinton Milward (Baltimore: John Hopkins University Press, 1996) and B. Guy Peters, *The Future of Governing, Four Emerging Models* (Lawrence, Kansas: University Press of Kansas, 1996).

Table 1 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
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	Training and education requirements in biotech; 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; possibly hazardous facilities/activities; consumer protection; and waste disposal
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

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.

This system may work well for independent policy fields. However, it creates problems of redundancy, incoherence, and in some cases lacunae in areas where policy problems are interdependent.[6] Interdependence can be defined as a situation in which one actor deliberately or inadvertently interferes with or contributes to the goal achievement of another actor.[7] Thus as Donald Chisholm notes "to say

---

[6]B. Guy Peters, "Managing Horizontal Government: the Politics of Coordination" (forthcoming).

[7]Based on Lindblom's definition of interdependence in Charles E. Lindblom, *The Intelligence of Democracy* (New York: The Free Press, 1965):21-22. Also see Donald Chisholm, *Coordination without*

that a set of organizations is described by interdependence is to claim that the set possesses systemic properties such that it is not immediately decomposable into the individual units of which it is comprised."[8]

Interdependent policy problems require coordination between functionally differentiated ministries, agencies, or directorates general. This coordination is central to horizontal governance and is manifested both in structure and process.[9]

MODES OF COORDINATION

Institutionalists focus on both structure and process as determinants of policy outcomes.[10] Structure refers to the relationship between the various parts of an organization.[11] Process refers to the

---

hierarchy; Informal Structures in Multiorganizational Systems (Berkeley: University of California Press, 1898):43.

[8]Donald Chisholm, "Coordination without hierarchy" :42.

[9]Ernest Alexander, defines coordination as Coordination can be defined as "a deliberate activity undertaken by an organization or an intergovernmental system to concert the decisions and actions of their subunits or constituent organizations." in Ernest Alexander "Interorganizational Coordination: Theory and Practice," *Journal of Planning Literature*, 7 (May 1993): 331.

[10]See Peter A. Hall and Rosemary C.R. Taylor. "Political Science and Three New Institutionalisms" *Political Studies*, 44, (1996): 952-973, Kathleen Thelan and Sven Steinmo, "Historical Institutionalism in Comparative Politics" in *Structuring Politics: Historical Institutionalism in Comparative Analysis,* eds. Sven Steinmo, Kathleen Thelen, and Frank Longstreth (Cambridge: Cambridge University Press, 1992): 1-28, Paul Dimaggio and Walter Powell 'Introduction" in *The new Institutionalism in Organizational Analysis,* eds. Walter W. Powell and Paul DiMaggio " (Chicago: University of Chicago Press, 1991), James March and Johan Olsen, *Rediscovering Institutions: The Organizational Basis of Politics* (New York: The Free Press, 1989).

[11]See B. Guy Peters "The Machinery of Government: Concepts and Issues " in *Organizing Governance, Governing Organizations* , eds. Colin Campbell, S.J. and B. Guy Peters (Pittsburgh, University of Pittsburgh Press, 1988) : 24-46 for a discussion of the ways in which the term structure has been used in referring to government.

formal and informal rules and procedures adopted for communication, consultation, and arbitration in the development of policy initiatives and the passage of various kinds of legislation.

Table 2 outlines a typology of coordination modes. A hierarchical structure is usually associated with top down policy making, rules, red tape, and a direct line of accountability.[12] Horizontal structures usually involve a group of peers, and are less bound by rules and red tape. However, there is also less political accountability since it is often difficult to tell exactly who is responsible for policy decisions.

Coordination activities may take place through formal meetings with mutually agreed procedural rules or they may simply entail an informal exchange of information. There are pros and cons to both approaches. Formal approaches to coordination are often too slow to facilitate timely solutions.[13] On the other hand, informal agreements reached at lower levels where participants do not have the political authority to make decisions may be blocked at higher levels for political or organizational reasons. Informal coordination may facilitate the exchange of substantive information, information about the importance of various policy proposals, and information about strategies.[14] However, where the policy frames of different agencies are extremely different, there may be no communication at all in the absence of a formal mandate.

---

[12]For an extensive discussion on the problems and benefits of hierarchy see Gary Miller, *Managerial Dilemmas: the Political Economy of Hierarchy* (Cambridge, Cambridge University Press, 1992).

[13]Chisholm "Coordination without hierarchy" : 65.

[14]Chisholm "Coordination without hierarchy" : 65-69.

TABLE 2 Typology of Coordination Mechanisms

STRUCTURE / PROCESS	Hierarchical	Horizontal
Formal	Traditional hierarchical structure where communication occurs at the Directorate General level if at all.	Administratively established inter-DG coordination mechanism with mutually agreed procedural rules.
Informal	Authoritatively condoned informal communication and exchange of information.	Laterally initiated informal communication and exchange of information.

The EC has traditionally fallen into the formal/hierarchical category where policy decisions are made within the various DGs. Although there are procedures for interservice consultation, as Simon Bulmer notes, they tend to be ad hoc rather than systematic or continuing.[15] When communication occurs, it tends to occur at the Director General level. In some cases, however, a Director General might encourage staff members to exchange information with their peers in other DGs on an informal basis in order to determine potential areas of conflict. This sort of exchange would fall into the informal/hierarchical category.

Formal/horizontal coordination can occur at any level of the political hierarchy, but it is generally bound by mutually agreed procedural rules. This requires self-conscious organization. Informal horizontal coordination is often laterally initiated. This might occur, for example, when a staff member of DG XII contacts a staff member of DG III to float an idea by them, or to ask for, or offer, some information.

---

[15]Simon Bulmer, "The Governance of the European Union: A New Institutionalist Approach" *Journal of Public Policy* 13, no. 4, (1994): 361. Also see David Spence, "Structure, functions and procedure in the Commission" in *The European Commission*, eds. Geoffrey Edwards and David Spence. (Essex, UK: Longman Group Limited, 1994):105-107 on the lack of interdepartmental coordination despite coordination procedures which are provided for in principle.

Which typology is most appropriate for achieving coordination will depend on the degree of interdependence, the degree of conflict, the level of technical complexity involved, the degree of scientific uncertainty, the degree to which an issue has become politicized, time constraints, and the inherent authority of different levels of managers to make policy decisions. (See Table 3) As Metcalfe notes

> part of the complexity of public management is that spheres of high and low interdependence co-exist: government activities involve both tight and loose coupling among organizations... Where there is limited interdependence, simple co-ordination capacities should suffice. Where the activities of different ministries are closely interdependent more sophisticated and complex co-ordination capacities are needed.[16]

Table 3 Determinants of Level of Coordination

Degree of Interdependence
Level of Conflict
Technical Complexity
Scientific Uncertainty
Degree to which issue has become Politicized
Time Constraints
Managerial Decision making Authority

From a theoretical and often retrospective perspective, it is easier to identify the appropriate level of coordination based on policy success and failure. However, achieving the appropriate level of policy coordination under conditions of incomplete information and political pressure is a much more complex endeavor. In the case of biotechnology regualtory policy, attempts to determine the proper structure and process for inter-DG coordination were exacerbated by widely differing views about the degree of interdependence (focusing mainly on whether existing vertical legislation could be modified or a new horizontal directive was necessary), the degree of technical complexity, and degree of risk

---

[16]Les Metcalfe "International policy co-ordination and public management reform," *International Review of Administrative Sciences*, 60 (1994): 279.

involved in biotechnological processes given the level of scientific uncertainty. Existing disagreements within the Commission became more pronounced as biotechnology became more politicized.

Before proceeding, it is important to make a distinction between horizontal coordination and horizontal policy which can be defined as a policy which cuts across multiple sectors. The outcome of horizontal coordination can be an exchange of information, an agreement to coordinate vertical policy areas, an agreement to introduce a cross-cutting program or piece of legislation, or a grand all-consuming national strategy.

BARRIERS TO POLICY COORDINATION AMONG DIRECTORATE GENERALS

There are both functional and operational barriers to coordination in the biotechnology policy sector. The Commission is divided into 23 Directorate Generals. Table 1 serves as a testament to the all-pervasive nature of biotechnology by outlining the interests and responsibilities of several of these DGs with respect to biotechnology. Functional barriers arise when different DGs, serving different client bases, frame policy questions in different ways. Operational barriers to coordination involve both bureaucratic turf battles and lack of institutional mechanisms to promote coordination.

FUNCTIONAL BARRIERS TO COORDINATION

It is not surprising that different DGs have approached the biotechnology regulatory question from different policy frames. Donald Schön and Martin Rein define frames as "underlying structures of belief, perception, and appreciation." Furthermore they state that "interests are shaped by frames and frames may be used to promote interests... Frames are not free-floating but are grounded in the institutions that sponsor them, and policy controversies are disputes among institutional actors who sponsor conflicting frames.[17]

---

[17]Donald A. Schön and Martin Rein, *Frame Reflection, towards the Resolution of Intractable Policy Controversies*, (New York: Basic Books, 1994):23, 29.

In the case of biotechnology, policy frames and consequently policy initiatives, reflect various beliefs and perceptions about the resilience or fragility of nature. Aaron Wildavsky has identified four models of nature: cornucopian nature, fragile nature, perverse or tolerant nature, and capricious nature. Each model calls for a different type of policy response.

Cornucopian nature knows few limits to human ingenuity.... individuals can always create more of what is wanted and therefore this model justifies bold experimentation... Fragile nature is the opposite. It presumes a terrifyingly unforgiving world, in which the least jolt may trigger a catastrophic collapse.[18] This requires strict regulation and perhaps prohibition. Perverse or tolerant nature assumes the nature can take jolts in moderation but expert knowledge is required to prevent the system from being destabilized by human intervention. Capricious nature views the world as full of totally random surprises both good and bad. It is therefore, futile to try to anticipate and provide contingency plans for all of them.[19] Wildavsky goes on to state that perverse or tolerant nature is the bureaucrats' model since it says to follow the rules and all will be well. (This, of course, begs the question of how the rules are established.) Much of the conflict between the various DGs involved in formulating biotechnology policy can be attributed to their different beliefs about nature.

Determinants of Biotechnology Policy Frames

The various policy frames held by the different DGs can be understood by examining their positions on the following three questions.

1) Do genetically modified organisms (GMOs) require special regulations at either the research or marketing stage because they are unique by virtue of being produced by a unique process? (This is sometimes referred to as a technology-triggered approach to regulation.)

2) If regulation is necessary, should it be conducted via a vertical or horizontal regulatory process?

---

[18]Wildavsky, "Public Policy" : 82-83.

[19]Wildavsky, "Public Policy" : 82-83.

3) Should regulations reflect the precautionary principle or a preventive principle?[20]

The first question underlies what has come to be known as the product / process debate. And it has two components, the research component and the marketing component. From a research perspective, one must ask if there is anything inherently more dangerous about using biotechnological processes in the laboratory than using traditional chemical and radiation processes? From a marketing perspective, one must ask whether there is something inherently unique about products produced via genetic manipulation. That is to ask, do products resulting form genetic manipulation constitute a distinct class of products requiring a separate regulatory framework for marketing? For instance, should there be two distinct sets of regulations for the marketing of tomatoes, one for tomatoes produced as a result of cross-breeding or chemical mutagenesis, and one for tomatoes produced as a result of genetic engineering?

How you answer the first question will affect how you answer the second question. If one believes that tomatoes, no matter how they are produced, should meet the same standards of quality and safety, then all tomatoes can be regulated via a vertical framework administered by a department of agriculture or some other food agency. However, if one believes that genetically manipulated organisms are inherently different and constitute a class of products unto themselves, then one would argue for a horizontal directive which cuts across all sectors and applies to any product utilizing genetic

---

[20]Simon Shackley, Les Levidow and Joyce Tait make a similar argument about what they call contending rationalities between DGs XI and XII. They identify the main points of contention between the DGs as the scope of the EC Deliberate Release Directive, the appropriate regulatory structure (product based or process based) and the interactions of political and scientific considerations in Simon Shackley, Les Levidow, and Joyce Tait "Contending Rationalities and Regulatory Politics" unpublished paper (1990).

manipulation at some point in the production process.[21] Consequently, tomatoes, medical devices, pesticides and vaccines would be evaluated according to the same criteria. In either case, the nature of the evaluation required would rest on some concept of risk to human health and/or the environment.

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 six concepts: 1) preventive action, 2) safeguarding of ecological space (even in advance of scientific proof or need), 3) proportionality of response (or cost effectiveness of margins of error), 4) duty of care (or onus of proof on those who propose change), 5) promoting the cause of intrinsic natural rights, and 6) paying for past ecological debt.[22] 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.[23] 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

---

[21]Alternatively, one could imagine the establishment of a Ministry of Biotechnology that would deal with all biotechnology products in a vertical manner but both the EC and the US have rejected this as being unnecessarily bureaucratic.

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

[23]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.

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."[24]

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 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 GMOs and therefore our uncertainty about what their impact on eco-systems will actually be.[25] In addition they argue that a precautionary approach is necessary to allay public fears about new technologies specifically, and about the desire of industry to capitalize on these technologies in general.[26]

Opponents of the precautionary approach argue that while caution is certainly necessary, it is nearly impossible to establish a precautionary set of regulations without stifling important life-enhancing research and industrial competitiveness by creating unnecessary bureaucratic delays or even moratoriums. Furthermore, they argue that a precautionary approach makes the state an environmental insurer of last resort. Consequently, companies that comply with the regulations may take greater risks than they would if they were forced to assume legal responsibility for the effects of experimental releases.[27] Advocates of a less stringent regulatory framework prefer a case by case and step by step approach where regulations are based on proven harmfulness, different experiments are assessed on the

---

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

[25]Ibid: 223.

[26]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.

[27]Les Levidow and Joyce Tait "Release of Genetically modified organisms": 103.

basis of different risks, and different steps in the research and production process are examined according to the specific risks involved in that step.[28] In this way, scientists can proceed and in the process accumulate knowledge which will help clarify what the risks actually are. (See Table 4)

The main difference between the preventive and precautionary approaches is a difference of emphasis. As Wildavsky states, there is agreement that the chances of inadvertent harm from various applications of biotechnology is remote, even exceedingly remote, given that the genetically engineered organism would have to survive, multiply, disperse, compete and impact others. "Where the sides differ is on the degree of harm that might be done in such an unlikely but still possible event."[29] Those advocating a precautionary approach tend to focus on the mutually agreed remote possibility of an accident, thus arguing that a particular application must be proven safe before it can be tried. While those advocating a preventive approach tend to focus on the fact that the chances of such an outcome are exceedingly remote, thus arguing that opponents of an application must demonstrate that it is harmful before it can be stopped.

---

[28]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.

[29]Aaron Wildavsky "Public Policy": 77-78.

Table 4 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. The level of regulation takes into account relevant benefits and costs. Regulations are therefore based on knowledge gained by taking a step-by-step approach and/or existing knowledge of properties of like organisms.	Precautionary -Conservative regulatory approach in which regulation anticipates environmental hazards which have not already been documented but which could conceivably occur. Emphasis is placed on high level of complexity in the eco-system and uncertainty about effect of new technologies. It does not take into consideration the relative costs and benefits of regulation to the industry and the public.

Various Biotechnology Policy Frames within the Commission

The four Directorates General most involved in biotechnology regulatory policy have taken different positions on the above stated questions. By examining their answers it becomes clear that they are operating on the basis of different policy frames.

In the late 1970s and early 1980s DG XII was primarily responsible for following biotechnological developments in Europe and throughout the world and for proposing guidelines for both bio-safety and Community sponsored research programs. Consequently, DG XII was in close contact with the scientific community composed primarily of biologists and microbiologists who were well versed in the characteristics of specific organisms. These scientists claimed that there were no unique bio-hazards associated with rDNA research. Therefore, the vast majority of scientists argued that genetically modified organisms required no specific regulations at either the research or marketing stage.

This view was advocated by a wide range of scientists in different forums. For instance, in 1981 the European Science Foundation's Liaison Committee on Recombinant DNA stated that

> Extensive information supports the view that recombinant DNA work per se entails no significant biohazards. This is already accepted by some national recombinant DNA committees and in those countries special safety precautions beyond good microbiological practice together with the use of appropriate host organisms are no longer required for recombinant DNA work except when known pathogens or toxin producing organisms are involved.[30]

The OECD had also stated in *Recombinant DNA Safety Considerations* that "there is no scientific basis for specific legislation to regulate the use of rDNA organisms."[31]

On question two, DG XII advocated that at the research level, research utilizing biotechnology processes should follow the traditional standard operating procedures for dealing with microbes

---

[30]Statement of the European Science Foundation Liaison Committee on Recombinant DNA Research, 1981.

[31] Organization for Economic Cooperation and Development. *Recombinant DNA Safety Considerations*, (OECD: Paris, 1986): 8.

including appropriate physical and chemical containment procedures. Large scale industrial applications should follow the Good Industrial Large Scale Practice (GILSP) outlined in the OECD's *Recombinant DNA Safety Considerations*. If it was necessary to pass some sort of EC legislation to assuage public and political concerns, a system of national registration and monitoring with an information exchange at the EC level could be passed as outlined in the 1982 *Council Recommendation concerning the registration of work involving recombinant deoxyribonucleic acid.* DG XII also argued that once a product was developed it should be evaluated on the basis of the qualities of that product not on the basis of how it was produced. This could best be accomplished through the application of vertical legislation. As one DG XII official put it, "The key question is whether the environmental risk assessment for a vaccine is the same as an environmental risk assessment for a degradation bug. I believe that a sectoral approach allows you to take into account all the factors that are involved in placing a product on the market, not just the environmental factors and the safety of human health."[32]

On the basis of scientific research and the OECD's study on bio-safety, DG XII argued that the effects of agricultural and environmental applications of rDNA organisms were expected to be similar to effects that have been observed with introductions of naturally occurring species or selected species used for agricultural applications.[33] Consequently, they advocated taking a preventive approach where accumulated knowledge could be used to predict outcomes.

Using Wildavsky's typology of views about nature, DG XII would fall somewhere between cornucopian nature and perverse, tolerant nature. DG XII argued that, by following the rules of good laboratory practice and notification (not necessarily a Community-wide directive), one could minimize

---

[32]Interview with DG XII official. June 7, 1995.

[33]See Organization for Economic Cooperation and Development. "Recombinant DNA Safety Considerations" : 29.

risk while still garnering the vast benefits to humankind and the environment promised by utilizing rDNA techniques.

DG XI, on the other hand, falls somewhere between fragile nature and perverse or tolerant nature where 'the rules' are the rules outlined by a community-wide directive. Whereas the client base for DG XII is largely biologists and microbiologists, the client base for DG XI is largely ecologists and environmental interest groups. Policy analysts in DG XI tend to agree with DG XII that the risk of some untoward event occurring is small, but it is still possible. In fact, they argue that small genetic alterations can cause large harmful environmental consequences because ecological systems are so complex, and so poorly understood.

DG XI tends to view genetically modified organisms as unique because they have not occurred via natural mutation. In a widely dispersed pamphlet, DG XI justifies the need for Community-wide regulatory directives by stating that

> the new techniques of genetic engineering allow the identification of many useful genes and their transfer to other organisms which didn't posses 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.[34]

DG XI advocated the development of horizontal legislation for several reasons. First, because biotechnological products are unique, cross-cutting legislation to deal with them was necessary. Second, there was an increasing public phobia about the technology. To allay this, DG XI believed it was necessary to pass a special directive which would assure the public that everything was well-regulated, controlled, and contained.[35] In fact, they stated that the OECD study on bio-safety indicated that there was wide spread public concern (or the study wouldn't have been done), and this justified horizontal

---

[34]DG XI/A/2 Biotechnology. "The European Community and the Contained Use of Genetically Modified Micro-organisms" no date : 1.

[35]Interview with DG XI official, May 1995.

legislation. Of course they ignored the fact that the study concluded that no special legislation was required. Finally, DG XI advocated a horizontal approach as a stop gap measure which would fill in the gaps left by the various vertical directives.[36]

Using Levidow and Tait's definition of precautionary and preventive, DG XI leaned more towards a precautionary approach than a preventive approach (although the actual word used in the directive is 'preventive').[37] They argued that because the precise nature and scale of risks associated with genetically modified organisms were not fully known, it was necessary to lay down the regulations rather than simply establish guidelines for environmental risk assessment which would apply to all experiments utilizing genetic engineering. They did, however, acknowledge that there were different types of operations and some were more risky than others. Consequently they advocated a step by step and case by case approach to environmental risk assessment.

DGs III (Industry) and VI (Agriculture) are substantially different from DGs XI (Environment, Consumer Protection and Nuclear Safety) and XII (Science, Research and Development) and therefore took a slightly different approach to regulating biotechnological products. Research and environmental safety are by their nature cross cutting policy areas. DG III and DG VI have a long history of regulating and interacting with producers in specific sectors. To DGs III and VI biotechnology was just a different technology for producing products which would fall under their long established domains. As one DG III official wrote

> It is clear that the industrialization of any new technology which has application over a wide variety of products, has implications for a range of programs and competences within the Commission. Whether it 'cuts across' existing competences is quite a different question. A technology is not something that exists on its own, its significance and its relevance derives from its utilization as a new and improved route to the manufacture of

---

[36]Interview with official in the Office of the Secretariat General, December 13, 1994.

[37]On the other hand, *Fiche #4 Biotechnology* drafted by the Office of the Secretariat General and tabled at the Biotechnology Coordination Committee states that the precautionary principle was a guiding principle underlying the directive: 2.

> products. From a regulatory point of view it is the product rather than the technology which is of relevance.[38]

The memo goes on to state that it is not at all clear that there is a need to develop new regulations for the protection of man and the environment since existing regulations are quite adequate to cope with such products and can be easily adapted as necessary. So in answer to questions one and two above, DGs III and VI did not believe that biotechnologically derived products constituted a new class of products and therefore they argued that they could be regulated under existing vertical legislation.

With regard to a preventive or precautionary approach, both services agreed that it was necessary to protect the environment and human health. They argued that they were in the best position to do this because they could apply the knowledge they had gained through regulating like products to new biotech products. Thus they advocated a preventive approach. In fact, they were quite clear that industry believed that rash and unnecessary regulation would be a major disincentive to increased industrial investment in biotechnology.

In Wildavsky's typology, DGs III and VI fall largely into the category of Cornucopian nature with its emphasis on the power of human ingenuity to overcome apparent limits. Of course, this was precisely what environmentalists who were afraid of the unfettered greed of industrialists were concerned about.[39] The process by which these various sub-cultures were merged (or not merged as the case may be) is critical to understanding the development of European Community biotechnology regulation.

OPERATIONAL BARRIERS TO COORDINATION

Operational barriers to coordination exist alongside functional barriers. One can easily read between the lines of the above discussion an underlying theme of "this is my turf; do not invade it; I will

---

[38]Internal memo from DG III to DG XI dated February 2, 1985.

[39]One DG VI official stated that "DG III is industry's own government" 6/7/95

regulate (or not) as I see fit." This is based on belief held by each of the DGs described above that biotechnology policy falls into the interior heartland, or at a bare minimum, the interior fringe of their territory.[40] Downs states "The interior of the bureau's territory is where it exercises the dominant role over social policy. It consists of two sub-zones: the heartland in which the bureau is the sole determinant of social policy and the interior fringe, where it is dominant but other social agents exert some influence." Each bureau sees attempts by other bureaus to permeate its heartland as a direct threat to autonomy.[41] This is particularly true where regulatory issues are concerned in the European Community since the budget of the European Community is extremely small and very restricted. Consequently Directorate Generals fight not so much over who will administer programs but over who will set regulations.

Territorial claims to biotechnology policy were exacerbated by the passage of the Single European Act which allowed each DG to refer to a different part of the Treaty as the legal basis for their involvement in biotechnology.[42] DG XII and DG III argued that their participation was justified by article 130f which states that "The Community shall have the objective of strengthening the scientific and technological bases of Community industry and encouraging it to become more competitive at international level, while promoting all the research activities deemed necessary by virtue of other Chapters of this Treaty." (DG XII focused on their role in strengthening the scientific base and DG III focused on improving the competitveness of European industry.) DG XI argued that its participation was

---

[40]Linda Chalice also describes the inherent problems of achieving coordination given bureaucratic views of policy ownership in "Policy Coordination: A View of Whitehall" in *Joint Approaches to Social Policy :Rationality and Practice* , eds. Linda Chalice, Susan Fuller, Melanie Henwood, Rudolf Klein, William Plowden, Adrian Webb, Peter Whittingham, and Gerald Wistow . (Cambridge: Cambridge University Press 1988): 106-138.

[41]Anthony Downs, *Inside Bureaucracy*, (reissued by Prospect Heights, Ill.: Waveland Press, 1994): 213.

[42]Prior to the passage of the SEA, there was no legal basis for Community activity in the environmental area.

justified by article 130r (1) which states that "Community policy on the environment shall contribute to pursuit of the following objectives: preserving, protecting and improving the quality of the environment; protecting human health; prudent and rational utilization of resources; promoting measures at international level to deal with regional or worldwide environmental problems." Furthermore, DG XI noted that Article 100A states that "the Commission in its proposals envisaged in paragraph 1 concerning health, safety, environmental protection and consumer protection, will take as a base a high level of protection."[43]

An example of territorial behavior can be found in the DG XI position that the 'heartland' of DG XII's policy was promoting and funding scientific research while the heartland of DG XI's policy was protecting the environment. Consequently, throughout the mid and late 1980s, DG XI believed that it should be responsible for drafting horizontal regulations for biotechnological environmental risk assessment. DG XII, however, considered biotechnology regulations to be at least on the interior fringe of its territory since biotechnological processes were critically important in a wide variety of scientific endeavors and how the guidelines were written would seriously affect the scientific enterprise throughout the Community. What distinguished biotechnology regulatory policy from other examples of bureaucratic politics, however, was that there was little room for compromise, trade-offs, and side payments because of the existence of very strong and widely divergent policy frames.

Despite the differences among the DGs which crystallized in the mid 1980s around the issue of how to regulate the new technology, the communication from the Commission to the Council in 1983 (drafted primarily by DG XII) called for inter-service, international, and Community/Member State concertation of biotechnology policy given its horizontal nature.[44] Unfortunately, the Communication

---

[43]The European Union. *The European Union selected instruments taken from the Treaties Book 1, Vol. 1,* (Luxembourg: Office for Official Publications of the European Community, 1993).

[44]Concertation can be defined as monitoring, cooperation and collaboration.

gave no real indication of how inter-DG cooperation could be operationalized to achieve this horizontal view.[45]

INITIAL ATTEMPTS TO COORDINATE BIOTECHNOLOGY POLICY IN THE EC

Given the barriers to coordination and the need to reduce redundancy, incoherence and lacunae in the area of biotechnology regulatory policy, the question was how the coordination called for in the Commission's 1983 Communication could be operationalized. Unfortunately, neither the Biotechnology Steering Committee (BSC) nor it's offspring the Biotechnology Regulations Interservice Committee (BRIC) were able to achieve a high level of policy coordination.

THE BIOTECHNOLOGY STEERING COMMITTEE

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, VI, XII, and XIII (Information Market and Innovation) and was to be open to other Directorate Generals where their interests were concerned. DG XII was appointed chair; and, the Concertation Unit for Biotechnology in Europe (CUBE), a division of DG XII was appointed secretariat of the BSC.

The mandate of the BSC was to establish internal communication and concertation and the tasks were divided in the following way. DG XII was responsible for establishing communication and concertation in research, training, and demonstration. DGs VI and III were to provide leadership on issues related to raw materials of agricultural origin. And, DG III was to provide leadership on

---

[45]European Commission. *Biotechnology in the Community, Communication from the Commission to the Council* COM(83) 672, 1983: E7.

intellectual property and regulatory regimes in association with DG XIII.[46] DG XI was notably absent in the initial organization of the BSC. At that time there was really no legal basis for environmental regulation and as Hans Brinkhorst, former Director General of DG XI stated, "prior to 1986 environmental policy in the European Community was peripheral, ad hoc, and reactive rather than preventive."[47] However as talk of regulating the contained use and deliberate release of GMOs became more pronounced in 1985, DG XI did start attending the BSC meetings.

The BSC was established to provide a forum for discussion at the Director General level. It was not a decision-making body. Thus the BSC was an example of horizontal/informal coordination. In Stephen Linders' and Guy Peters conceptualization, the BSC fell into the dialogic tradition in which a public space is created for the open deliberation about facts and values. From a governance point of view, the goal of such a body is discursive steering. The decision tradition stands in contrast to the dialogic tradition. The decision tradition focuses on designing institutions to facilitate expert formulation and governance occurs through elite choice making. Davignon had attempted to create a forum for discussion but the BSC failed primarily because the participants in the BSC, Director Generals, were used to working in the decision making tradition. Thus 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."[48]

---

[46]Concertation Unit for Biotechnology in Europe, Commission Decision of 1 February 1984, concerning the establishment of a structure for biotechnology within the Commission services, Annex A to CUBE Report 1984-1988. March 8. 1989. (Available from DG XII, BIODOC)

[47]Lecture given by Hans Brinkhorst at the University of Pittsburgh, March 24, 1997.

[48]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.

THE BIOTECHNOLOGY REGULATIONS INTERSERVICE COMMITTEE

By July of 1985, pressure was mounting for the EC to take some sort of regulatory action in the field of biotechnology. Member Sates and trading partners were developing guidelines and/or regulations. The OECD was conducting a study of the safety aspects of modern biotechnology and the European Parliament was calling for the development of EC regulations. 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 and consequently fell into the hierarchical/informal typology of coordination modes.

Although BRIC was set up as an agent of the BSC to deal with the highly technical aspects of regulation, its mandate indicated that BRIC was more of a decision making body than a dialogic body. (See Appendix 1) This was especially true with respect to mandate (e) which called for BRIC to determine whether current regulations adequately dealt with risks that might be introduced by biotechnology and to initiate specific actions where additional regulatory measures were deemed to be necessary.

BRIC was composed of DGs III, V, VI, XI, and XII. The Committee was to serve a coordinating function, but each of the individual services was to retain their executive function in the examination, initiation, and management of regulations. The chairmanship of the committee was to alternate between DG III and DG XI. DG XII's Concertation Unit for Biotechnology in Europe (CUBE) was to serve as the Secretariat.[49] As Cantley notes the BSC remained, in theory, the parent of BRIC and was to resolve any disputes arising in BRIC. However, this was not workable for two main reasons. First, BRIC met almost every month, totaling about 15 meetings in the first year. The BSC met only three times during this

---

[49]Biotechnology Regulatory Interservices Committee. *The Commission's Approach to the Regulation of Biotechnology* (Brussels: European Commission, DG XII, 28 October 1985).

period. But more fundamentally the structure of the BSC prevented it from resolving very important disputes. DG XII was the chair and secretariat for the BSC and they simply did not have the political power to resolve inter DG disputes. These disputes had to be kicked up to the Commissioner level to be resolved between cabinets or within the Commission itself. Although the Commission meets weekly, they are not really prepared to resolve technical disputes. Thus, issues could be referred up to the Commission, but they required careful preparation and briefing and this could only be done infrequently and on major issues.[50]

Consequently, between 1985 and 1990 BRIC, rather than the BSC, became the center of biotechnology regulations within the Commission. In November 1986, the Commission submitted a Communication to the Council entitled 'A Community Framework for the Regulation of Biotechnology". This document opened with the statement that there was no a priori reason to believe that the use of genetic modification would entail any extra or new risks. Nevertheless, in light of 1) regulatory action being taken by several of the Member Sates, 2) the belief set out in a report by the agrochemical, pharmaceutical and food industries that there was a need for community-wide regulation of biotechnology, and 3) the fact that microorganisms do not necessarily respect national frontiers, the Commission stated their intention to introduce proposals for Community regulation of biotechnology by summer 1987. The proposals would deal with 1) levels of physical and biological containment, accident control, and waste management in industrial applications (which eventually became directive 90/219 on the contained use of genetically modified micro-organisms); and 2) authorization of planned release of genetically engineered organisms into the environment (which became directive 90/220 on the deliberate release of genetically modified organisms into the environment). [51]

---

[50]Mark Cantley: "The Regulation of Modern Biotechnology": 544.

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

Within BRIC, DG V was preparing a general framework directive on worker safety to protect workers form the risks related to chemical, physical, and biological agents. DGs III and XI were co-chef de file for the directive on the contained use of micro-organisms, and DG XI was chef de file for regulating the deliberate release of genetically modified organisms into the environment. DG XII was to provide scientific input into the regulatory debates and DG VI was to provide agricultural input. As Cantley, and many others stated, there was no initial controversy over this division of labor.

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. When DG XII saw DG XI's draft proposal for regulating the deliberate release of GMOs to the environment, they were extremely upset and submitted an alternative draft directive to DG XI focusing on a system of national registration and monitoring with information exchange at the Community level. However, because DG XII was not chef de file, this proposal was ignored. Secondly, the service which is chef de file presents the directive to the Council of Ministers. Because DG XI was chef de file, the directives went before the Council of Environment Ministers. These ministers, in general, shared the same philosophical outlook on the matter as DG XI. Thus while an individual service is supposed to represent the Commission at large to the Council, in reality there is a functional connection across institutions which often supersedes any compromises that may have been made at the interservice level. As one high level official noted, "If you are really eager to change something, you do it in Council. DG III does it all the time. DG XI does it all the time."[52] And as noted below, this occurred with respect to the deliberate release directive and has had lasting consequences.

Within BRIC, DG XI was essentially given free reign to draft the directives with very little input from DG III until the very end. DG III's participation was limited for several reasons. First, the

---

[52]Interview with Dg VI official, 6/7/95.

participation of the DG III official in charge of biotechnology was severely limited by his other responsibilities. In an interview, this official stated that he was the only person responsible for biotechnology legislation in DG III at the time. In addition, he was the only Commission contact point for all questions about food safety arising from the Chernobyl accident which occurred right as DG XI was making a big push for biotech legislation. Finally, he was also responsible for all food legislation much of which was being recast in light of the pending passage of the Single European Act. As this DG III official stated "whereas the FDA had something like 600 people working on food safety, I had 12....and I had less than 5% of myself to think about biotech and that was DG III's effort on biotech." Second, the same DG III official was under pressure from his director who was new and very interested in moving on biotech. Although according to the interviewee, his director did not really understand the ramifications for EC industry of taking a horizontal approach as advocated by DG XI. Consequently, his director had agreed under pressure from DG XI to the communication to the Council which said the Commission was going to develop three horizontal directives. (It should be noted that this director eventually became a Director General of DG XI.) As the former DG III official noted, "Of course, that then became a linchpin for DG XI to push forward... After that it was a question of fighting a rear guard battle to get our philosophy out." After agreeing to introduce horizontal directives, DG III did insist on capturing the legislation on contained use since that was going to affect industry itself most directly. However, the directive on contained use was managed jointly with DG XI and it went before the Council of Environment Ministers. In fact, DG XI did most of the drafting because DG III was too busy to participate in either the drafting sessions or the Council meetings.[53]

Industry, which would be heavily affected by any regulatory framework was curiously absent in the initial stages of policy formation. Justin Greenwood and Karsten Ronit point to several reasons for this. First, companies were slow to identify themselves as bio-industries on the basis of utilizing a

---

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

specific technique. Industry was used to using a variety of techniques and processes and in the past had formed lobby groups which approached the regulatory process on the basis of categories of products not techniques. Consequently there was a significant lag between the formulation of horizontal directives and industry's ability to organize in response to the directives Second, this problem was exacerbated by the existence of many small and medium sized enterprises all of which were at the initial stages of the product innovation cycle. Because of the many firms involved and the high degree of competition between them, there was a significant collective action problem. Third, even among those who realized that there was an attempt to shift from regulating on a product basis to regulating on a process basis, "there was a view among industrial interests that to coordinate too closely by abandoning sectoral representation and using only dedicated bio-industry associations would be a mistake because it would invite industry to be drawn into accepting horizontal regulation." Fourth, the existence of both medium and small enterprises (start-ups) and large chemical and pharmaceutical companies led to a certain degree of fragmentation across companies regarding proper and non burdensome levels of regulation.[54]

In sum, industry was focused on traditional product legislation rather than process driven legislation. They were slow to make the paradigm shift and consequently they were slow to coordinate their efforts with other firms across sectors. In addition, the combination of small and large firms in different sectors made it difficult to develop a coherent industrial strategy. In fact, this was not accomplished until the legislative process was almost complete as will be discussed below. Finally, industry was slow to influence the regulatory process because DG III and DG VI succeeded in having their traditional product areas, including pharmaceuticals, animal feedingstuffs, plant protection products

---

[54]Justin Greenwood and Karsten Ronit, *The Organization of Biotechnology Interests in the European Union, Report to the European Commission from study contract B102-CT93-0603.* (Aberdeen: Robert Gordon University, 1995).

and novel foods, excluded from the draft horizontal directives. Thus industry, within traditional sectors, thought their voice was being heard. However, that was not the end of the story.

DG XII who had very strong reservations against horizontal legislation, as noted above, was not able to sway the debate against introducing horizontal legislation. The CUBE staff believed that horizontal directives were unnecessary and if adopted would unduly stigmatize biotechnology which was a critical research technology for the life sciences. However, as a DG XII official noted "the Director General was not an up front fighter on political matters... While he believed that science should be neutral, he didn't go so far as to fight tooth and nail to say that anything that doesn't have a sensible scientific base should not go forward." Instead he preferred to stay above the political fray and focus on running the EC's research programs.[55] As a former DG XII official noted, "once DG XI became chef de file, we were extremely frustrated because the whole game began to run out of our control."[56]

Directives 90/219, 90/220, and 90/679

DG XI was thus primarily responsible for drafting both the directive on the contained use of genetically modified micro organisms and the deliberate release of genetically modified organism into the environment. While DG VI, DG XII, and some people in DG III were generally opposed to adopting horizontal directives based on a process, their participation in BRIC had little if any influence on the final form of the directives. In fact, if anything, the directives went from bad to worse in three main ways in the Council meeting and there was little that DGs III, VI, or XII could do to stop the process.

First, the original proposal for a Council Directive on the contained use of genetically modified micro-organisms (COM(88) 160 final - SYN 131) had as its legal basis article 100A. Late in the negotiations the legal basis was changed in the Council from 100A to 130S when it became clear that unanimity among the Environment Ministers was possible. This did two things, it shifted the primary

---

[55]Interview with DG XII official, February 24, 1995.

[56]Interview with former DG XII official , June 1995.

reason for the directive from the need to create an internal market to the need to protect the environment and human health (Of course, the need for an internal market remained as a secondary reason for the directive.) This allowed the Environment Ministers to take a more precautionary approach. It also allowed individual Member States to exceed the EC regulation if they wanted. Thus the emphasis shifted from establishing a common level of protection to establishing a floor for protection.

Second, the notification requirements depended on which category of GMOs was being utilized in the research process. In the final directive, the time required for notification under several categories was substantially lengthened.

Third, the final directive also included a new Annex I which provided a list of techniques through which genetic modification occurred. While the other annexes remained subject to change via a vote of the committee composed of representatives of Member States, Annex 1 could not be changed by this procedure. The addition of this annex was critically important because it locked in the concept of process based regulation. In other words, research using genetic modification as defined in Annex 1 was fundamentally different from research using other techniques (conjugation, transduction, transformation or any other natural process) regardless of whether the final products were similar in terms of safety, quality and efficacy. Thus the final directive had an environmental legal basis rather than an internal market legal basis, the notification requirements for conducting research were lengthened, and the directive locked in the concept of process based legislation.

Similar, and in some senses, more startling changes, were made in directive 90/220 on the deliberate release into the environment of genetically modified organisms. Directive 90/220 is divided into four parts. Part A deals with general provisions such as the objective of the directive and relevant definitions, reference to techniques of genetic modification, and establishment of competent authorities. Part B deals with the deliberate release of GMOs into the environment for research and development purposes. Part C deals with the placing on the market of products containing GMOs. Part D deals with

issues of confidentiality and the conditions under which the directive can be modified. The inclusion of Part C was necessary to justify a legal basis of 100A and it has caused the most problems for DGs III and VI.

The original Commission proposal stated that Part C of directive 90/220 "would not apply to medical products; veterinary products; foodstuffs, feedingstuffs and their additives; plants or animals produced or used in agriculture, horticulture, forestry, husbandry and fisheries, the reproductive material thereof and the products containing these organisms, or to any products covered by Community legislation which includes a specific risk assessment."[57] This was an attempt by the Commission to maintain a distinction between vertical and horizontal legislation. As a former DG III official noted, DG III fought bitterly to get this clause placed in the directive and eventually succeeded in forcing it through in Commission over the protest of DG XI. DGs VI and XII were both aligned with DG III on this. When the above noted products were not included in the directive, the directive could be viewed as a stop gap measure that would keep any product not covered under vertical legislation from falling through the cracks. This approach was acceptable to the members of BRIC.

However, the Commission's proposed directive was radically changed in the Council meeting. As with 90/219 an Annex 1 was added which defined what techniques constituted genetic modification. This annex was not amendable by committee decision and thus locked in a process approach which was not easily changed to reflect new scientific evidence. More importantly Part C was changed to read "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. In the future, Part

---

[57]European Community. "Proposal for a Council Directive on the deliberate release to the environment of genetically modified organisms COM (88) 160 final - SYN 131" *Official Journal C* , 198, July 28, 1988:19-27.

C would not apply to any products covered by Community legislation which provides for a specific environmental risk assessment *similar to that laid down in the Directive*." (author's emphasis).[58] Consequently, *all products* containing GMOs had to meet the Community's relevant product legislation, but they also had to meet technology based environmental risk assessment requirements similar to those laid down in 90/220. (A rather heated debate about what constituted a 'similar' risk assessment was to ensue.) In the meantime, both industry and some DG III analysts argued that meeting the requirements of both horizontal and vertical legislation would be extremely burdensome and largely unnecessary.

In practice, however, DG XI had accomplished their goal of extending their influence over all sectoral legislation for products comprising or containing GMOs. This is evidenced in a letter sent by the Director General of DG XI to the Director General of DG VI stating that the Plant Protection Products Directive which was being drafted at the time could apply to GMOs but a new article would have to be added stating that "This directive applies without prejudice to Directive 90/220." The letter goes on to state that "we should keep in mind that under all circumstances, all field tests of GMO products have to receive a clearance under directive 90/220 and that *this is a permanent arrangement*.." (author's emphasis).[59] DG XI would thus set the criteria for the environmental risk assessment of GMOs even when they would fall under sectoral legislation. Further evidence of the influence of DG XI on sectoral legislation can be found in pharmaceutical and novel foods legislation which say that where genetically modified organisms are concerned, Council Directive 90/220 will apply.

Unfortunately, the conflicting policy frames and territorial disputes were not resolved through the BRIC consultation process. The same arguments that were being made by the various services prior to the passage of 90/219 and 90/220 were being made after the passage of the directives.

---

[58]Minutes of Council Meeting of 23 April 1990.

[59]Letter from DG XI to DG VI September, 19, 1990.

A further indication of the failure of coordination can be found in the Workers' Protection Directive, 90/679. This horizontal directive was drafted during the same time period by DG V. Unlike 90/219 and 90/220, the workers protection directive covered all biological agents, including but not limited to, genetically modified micro-organisms. Biological agents were classified into four risk groups. Group 1 is for biological agents unlikely to cause human disease. Group 2 is for biological agents that can cause human disease but are unlikely to spread to the community and for which there is effective prophylaxis or treatment available. Group 3 is for agents that can cause serious disease and might be spread but for which effective prophylaxis or treatment is available. And, Group 4 is for agents that can cause severe human disease and for which there is a high risk of spreading and no effective prophylaxis or treatment. The important point is that unlike 90/219 and 90/220, the directive took a risk based rather than a process based approach.

DG XI strenuously opposed the inclusion of genetically modified micro-organisms in the directive and DGs III and XII fought strenuously to ensure that they were included.[60] DGs III and XII argued that treating genetically modified organisms like other biological agents was better because industry did not want to set up one laboratory for working with unmodified organisms and another lab for working with modified organisms just because of the technique used if the risk levels were the same. Consequently, they argued for consistency between 90/219 and 90/679. The compromise was to include GMOs in 90/679, but because 90/219 and 90/220 had already been adopted by the Council, 90/679 stated that "the directive would apply without prejudice to the provisions of 90/219 and 90/220."[61] While this may have been an acceptable trade-off within the Commission, it was ultimately both confusing and

---

[60]Interview with DG XII official, 6/7/95

[61]European Community. " Council Directive 90/679/EEC of 26 November 1990 on the protection of workers from risks related to exposure to biological agents at work" *Official Journal L,* 374 December 31, 1990.

costly for industry which had to adopt one set of safety and containment measures based on the risk presented to the worker and another set based on whether the research involved genetic modification.

BRIC's failure as a coordinative mechanism

BRIC was plagued by problems and was unable to resolve many of the internal disputes regarding biotechnology policy. Thus it failed as a coordinative mechanism. There are three interrelated reasons for this failure. First, there was not enough political support at the Director General and Commissioner level to overcome asymmetrical power distributions. DG XII, as secretariat, was not powerful enough to influence the debate partially because the Director General preferred to remain out of the political fray. DG III was too understaffed and busy to allocate much attention to the issue. In addition, DG III inadvertently strengthened the position of DG XI because a senior DG III official believed that it was important to move on the issue without fully understanding the ramifications of a horizontal framework for industry. Thus DG XI emerged as the most influential player and DGs III and XII were forced into fighting a rear guard battle within both their own Directorate Generals and within BRIC at the same time.

Second, because of internal weakness within BRIC, DG XI could engage in opportunistic behavior in the Council. A combination of functional alliances and legislative procedure allowed them to overrule important compromises made at the interservice level by accepting changes in the directive at the Council meeting.

Finally BRIC was set up to act as an agent for the BSC. But the BSC itself was not able to achieve a common political position on biotechnology partially because they were never forced to. The institutional structure of the BSC was dialogical not decisional consequently they never resolved any of the philosophical questions swirling around the biotechnology debate. In the absence of philosophical agreement, at a senior political level, it is not surprising that BRIC could reach no agreement on the technical questions.

CALLS FOR REFORM

The ink had not dried on the paper before the Commission fell under heavy criticism from scientists, industry, the European Parliament, and the United States for the regulatory approach they were taking in 90/219 and 90/220. On 18 May 1989, an open letter addressed to the Presidents of the European Parliament, Council and Commission by the European Nobel Laureates in Medicine and Chemistry stated that

> Recombinant DNA is a method in biology, without which modern research in this field is not possible. It allows small and well defined changes to be introduced into the genomic set-up of an organism. More than 90% of research and production use non-pathogenic safe organisms. There are well established and internationally accepted safety standards which have been followed by a community of about one hundred thousand researchers in the past 15 years... In principle there is no scientific justification to single out a technique for regulation instead of basing it on the properties of the generated organisms.[62]

Another scientist stated, "the forward of both directives (90/219 and 90/220) creates an unjustified and scientifically speaking, a nonsense description between organisms which, when derived from rDNA

---

[62]May 18 Open letter of Nobel Laureates to EC Commission, Council and Parliament. There are many, many scientific papers on the various applications of biotechnology but for a sample of papers stating that regulation should be based on the product not the process see John E. Beringer, Mark Bale, Paul Hayes and Colin Lazarus, "Assessing and Monitoring the Risks of Releasing Genetically Manipulated Organisms" Department of Botany, University of Bristol, Woodland Road, Bristol, UK, Presented to the Royal Society of Edinburgh, April 1991; T.G. Kimman, "Safety of Genetically Engineered Vaccines" Department of Virology, Central Veterinary Institute, PO Box 365, 8200 AJ Lelystad, the Netherlands. Contribution to the advanced course "Introduction of Genetically Modified Organisms into the Environment: Biosafety Aspect, December 4-14, 1991 Wagenigen. The Netherlands; Philip Dale, Cambridge Laboratory, AFRC Institute of Plant Science Research, John Innes Center, Colney Lane, Norwich, UK "The Widespread use of Transgenic crops- opportunities and perspectives" presented at EUROCOURSE "scientific-technical Backgrounds for Biotechnology Regulation" ISPRA, June 4-7,1991.

technology, per se and ipso facto need to be regulated."[63] On February 8 1990, the Nobel Laureates wrote the three presidents again to say "Now that the two directives 'contained use' and 'deliberate release' have been carried by EC Council and reviewed by the Environment Committee of the European Parliament, it appears to us that they contain a number of provisions relating to research which are both based on non-scientific criteria and so unduly burdensome as to be discouraging."[64]

When business became aware of the approach being taken by the Commission they decided to form a high level lobby group to specifically address the question of biotechnology regulation. This is consistent with Paul Pierson's observation that "the activity of interests groups often seems to follow rather than precede the adoption of public policies." This occurs because policies provide incentives that may facilitate the expansion of particular groups.[65] In the case of biotechnology, the directives were viewed as so burdensome that they served as a catalyst for collective industry action at the EC level.

The Senior Advisory Group for Biotechnology (SAGB) was created by the European Chemical Industry Foundation (CEFIC) in June 1989 specifically to promote a supportive climate for biotechnology in Europe.[66] The founding members were Ferruzzi Group, Hoechst AG, ICI PLC, Monsanto Europe, Rhône Poulenc, Sandoz, Unilever. In August 1989, they sent a letter to President Delors and all the other Commissioners stating that they were concerned about 1) "the lack of overall

---

[63]DG XII, Biotechnologies, "The Views of the Research Community on the Regulatory Framework: DG XII Survey, Executive Summary." March 1994.

[64]See reference to letters in Cantley, "The Regulation of Modern Biotechnology": 561.

[65]Paul Pierson"When effect becomes cause: Policy Feedback and Political Change" *World Politics*, 45, 4 (1993):598-599.

[66]It should be noted that SAGB is not the only industrial lobby group. There were also national bio-industry associations which were coordinated through The European Secretariat of National Bioindustry Associations (ESNBA). ESNBA tends to represent smaller companies. Nevertheless their aims were often in accordance with those of SAGB. ON September 27, 1996 SAGB and ESNBA merged into one organization. For more on national bio-industry associations see Justin Greenwood and Karsten Ronit, "The Organization of Biotechnology Interests in the European Union".

coordination and resultant confusion in the proposals for regulation of biotechnology", 2) the possible use of ad hoc solutions such as moratoria (being recommended in the Parliament), and 3) the basis of product regulation which they argued should be efficacy, safety, and quality (not the process by which a product was produced). They also called for the development of a relevant 'science based regulatory framework.'[67] They immediately followed up this letter with a report calling for the Community to clearly define and assign regulatory responsibility; apply existing, non-discriminatory approaches for safety in research and industrial processes; regulate products on the basis of their inherent characteristics and intended use; observe common principles for product sector regulation; and, develop regulatory approaches in common with major competitors.[68] Unfortunately, SAGB was not organized in time to effect the initial passage of the directives but they did play an important role in the 1991 decision to reform the directives.

Curiously, Ken Collins, Chair of the European Parliament's Committee on the Environment also stated that "The European Commission, which even now is supposed to be the engine for progress in the Community sees biotechnology through no fewer than six sets of filters... There can be no doubt that if this situation is allowed to prevail the Community will act not as a control on or even guide to the industry but rather as an inhibition or a distortion." Consequently, he called for the Commission to establish a task force to oversee the development of biotechnology "so that industry, consumers, regulators, and legislators will for the first time know where the buck stops."[69]

---

[67]Letter from the Senior Advisory Group on Biotechnology to Jacques Delors 24, August 1989.

[68]Senior Advisory Group on Biotechnology, *Community Policy for Biotechnology: Priorities and Actions*: 12-13. 1990.

[69]Text of address by Ken Collins MEP, Conference on Biotechnology and the Food Supply, Organized by Commission of the EC, Public Voice and European Research in Consumer Affairs, Borschette Center, Brussels May 31, 1990.

A final set of criticisms came from the US government, specifically the US Food and Drug Administration and the US Ambassador to the European Communities. Both expressed concern that the EC's regulations were based on process rather than products and that this approach would hinder research and development, lead to difficulties in attempts to achieve international harmonization and could be used to erect non-tariff trade barriers to foreign products.[70]

THE FORMATION OF THE BIOTECHNOLOGY COORDINATING COMMITTEE

In response to the wide ranging criticisms of 90/219 and 90/220, President Delors asked his chief of staff, Pascal Lamy, to hold a meeting to discuss internal Commission coordination of biotechnology policy in July 1990. At the meeting, agreement was reached that better coordination was needed and could be achieved if there were a single internal coordinating group and if this group held a series of round tables with industry. David Williamson, Secretary General of the Commission, argued that DG III should be the lead directorate general for coordination but given the history of the subject, he acknowledged that perhaps the Secretary General should chair the coordinating group at least in the beginning.

The emphasis on coordination with industry indicated a not so subtle shift in the policy debate. 1985 to 1990 can be characterized by the predominant influence environmental concerns and attempts to deal with scientific uncertainty. From 1990 to the present, the policy debate has been dominated by concerns about maintaining European competitiveness while at the same time sustaining a high level of protection for the environment and human health. This is often referred to as pursuing a strategy of "sustainable development." The shift can be explained by the increased involvement of industry in the policy process, improved scientific information, and a wave of deregulatory initiatives which swept across the industrialized world in the early 1990s.

---

[70]Cantley "The Regulation of Modern Biotechnology" : 559 and F.E. Young and H.I. Miller, "Deliberate releases in Europe: Over-regulation may be the biggest threat of all" *Gene*, 75, (1989): 1-2.

The Biotechnology Coordinating Committee (BCC) was established in November 1990, seven months after the passage of directives 90/219 and 90/220. The BCC was to take over the tasks of both BSC and BRIC. In addition, the mandate of the BCC itself reflects the emphasis placed on coordination. (See Appendix 1) Membership in the BCC was cast at the Director General level although in practice, technical staff often accompany their Director Generals to the meetings. The Secretary General chairs the BCC and the Secretariat General acts as secretary.

Under Williamson's guidance, the BCC has been fairly successful at coordinating inter-DG biotechnology policy. The most influential policy statement was published in April 1991 and was entitled "Promoting the Competitive Environment for Industrial Activities Based on Biotechnology within the Community". The Communication was drafted by DG III but underwent various revisions as requested by the other services.

The 1991 communication set the agenda for the Commission's biotechnology work in the 1990s. Specifically the communication called for new intellectual property legislation, a review of the research and development program with a view to reinforcing the Community's contribution to research and development in biotechnology, the establishment of an advisory structure to deal with ethical questions raised by biotechnology, and improvements to the legal and regulatory framework. Regarding regulations, the communication stated that the Commission would: 1) ensure a coherent regulatory approach and an efficient and simplified interaction between sectoral and horizontal legislation, 2) ensure that existing legislation is kept under review to enable it to reflect rapid developments, and 3) streamline testing and authorization procedures so that one assessment and notification procedure covers all that is required for product authorization. Throughout the 1990s considerable progress has been made in achieving these goals.

Chairmanship by the Secretary General is the institutional key to the BCC's success for three main reasons. First, the role of the Secretariat General is to coordinate between the services. This means

that Williamson has access to information generated by and taking into account the viewpoints of all the services. Because his job is to facilitate agreement between the services in a repeated game type scenario, he is able to encourage cooperation and compromise which would not necessarily occur when each directive is viewed as a single initiative.[71]

Second, Williamson is able to move freely between the bureaucratic and political sides of the Commission.[72] The Secretary General chairs the weekly meetings of the chef de cabinet. This is where many critical political issues are resolved. In fact, only those issues which are truly intractable are referred for decision to the Commissioners. Any single service, or part of a service, only has access to their Commissioner's cabinet. They are therefore dependent on the cabinet to promote their position in the political arena. This may or may not happen. Williamson's job, however, is to coordinate the meetings of the chefs de cabinet. Consequently, he can set the agenda, and, in so doing, insure that political debate occurs when necessary. In addition, Williamson attends the weekly meetings of the Commissioners where he can again encourage compromise based on a more complete and all encompassing knowledge base.

Finally, Williamson had the political backing of the President of the Commission. As Ludlow notes "the Secretary General has always, in one sense, been the President's 'Director General'. In Williamson's case, however, the links have been exploited in quite a new way... In Brussels, Williamson's office has increasingly become the administrative base of the presidential regime."[73] Hence the important influence of the Secretary General and his staff on the policy process should not be

---

[71]See Robert Axelrod, *The Evolution of Cooperation* (New York: Basic Books, 1984).

[72]For more on the tension between the bureaucratization and the politicalization of the Commission see Thomas Christiansen "Tensions of European governance: politicized bureaucracy and multiple accountabliity in the European Commission" in *Journal of European Public Policy* 4:1. (March 1997) 73-90.

[73] Peter Ludlow, "The European Commission" in *The New European Community, Decision making and Institutional Change*, eds. Robert Keohane and Stanley Hoffman (Boulder: Westview Press, 1991):120.

underestimated, nor should their neutrality be overstated despite attempts to portray themselves as apolitical coordinators of policy. In sum, the power and complexity of the Secretary General's job is both immense and necessary for resolving political/technocratic issues.

CONCLUSIONS

Why did the BCC succeed when the BSC and BRIC failed? For policy coordination to take place, the inherent structural fragmentation both among the various DGs and between the political and technocratic levels of decision making had to be overcome. Despite the horizontal nature of both the BSC and BRIC, neither group could overcome this fragmentation. The informal 'debating club' process of the BSC did not require joint decision making. BRIC had a more specific mandate, and consequently a formal set of processes. However, the members of BRIC were technocrats who did not have the political authority to make decisions to resolve conflicting values. Consequently, the members of BRIC were not able to overcome their various policy frames and their loyalties to their Director Generals.

The BCC, on the other hand, has succeeded in generating a variety of compromise positions on several biotechnology policy issues since 1990 including revisions to directive 90/219, two intellectual property directives, and a novel foods directive. A key factor in the BCC's success is the existence of a policy arbiter with high level political backing.

David Williamson, acting as policy arbiter, is able to craft compromises among services with conflicting policy frames largely because the services involved have agreed to submit themselves to a very loose form of binding arbitration under his leadership and in the horizontal format of the BCC. Of course, individual services can, and do, appeal directly to the College of Commissioners via their own Commissioners. But since 1990, many of the interservice disputes have been settled before they reached the level of the cabinets.

High level political backing for both the BCC and Williamson are important factors in the BCC's success. Without a top down impetus for coordination, issues will continue to be dealt with in an

isolated, fragmented and often redundant and contradictory manner. Unfortunately, in the case of biotechnology policy, the political will to design a strong coordinative body was garnered only after the adoption of a highly criticized regulatory framework. When the Senior Advisory Group on Biotechnology, the United States, the chair of the European Parliament's Environment Committee, and European Nobel Laureates began to complain vociferously, the lack of policy coordination captured President Delors' attention.

Another reason that the BCC has been successful is because the process of formulating biotechnology regulatory policy is viewed as an iterative game rather than a single event. This enhances the degree of mutual trust among the services and helps ensure that proper clearance procedures are followed. Failure to abide by the procedural rules and/or attempts to monopolize the policy process may well present a particular DG with serious problems in the future. Furthermore, compromise on conflicting policy frames is easier to achieve if there is an implicit understanding that others will be asked to compromise on issues of specific importance to them in the future.[74] The mandate of the BCC indicates that it will be both ongoing and comprehensive in nature. That is, the BCC will consider all aspects of biotechnology policy and verify specific proposals against policy objectives. Consequently, there are multiple opportunities built into the policy process to express points of view at both the objective setting and policy formulation stages.

Finally, the BCC serves as a technocratic counterpart to the College of Commissioners and their cabinets in the area of biotechnology. As such, the BCC was able to achieve two important things that neither BRIC nor the BSC was able to achieve. First, the horizontal nature of the BCC allowed the individual DGs to reframe their view of who they serve. While the College of Commissioners is viewed as a horizontal body serving the Commission at large, traditionally the Directorate Generals have been policy area specific. This has created a disjunction at the intersection of policy and politics. Policy

---

[74]For more on this see Robert Axelrod, "The Evolution of Cooperation."

alternatives often reflect the narrow view of the Directorate General where they are developed while political decisions must take into account a wide variety of views. The establishment of coordinative institutions at the level of the services helps DGs realize that they, too, are responsible for serving the Community at large. Such an approach taken at the policy formulation stage allows a wider range of interests to be taken into account and limits the number of conflicts to those that are truly irresolvable at a technocratic level

Second, by establishing an ongoing technocratic counterpart to the College, policy games can be played simultaneously. When games are played sequentially, policy outcomes often do not balance the full range of concerns as evidenced by the passage of directives 90/219 and 90/220. A technocratic solution may ignore important political dilemmas and a high level political mandate for a specific policy often does not take into consideration all of the important technical details involved in complex problem solving. The existence of the policy arbiter who can engage both technocrats and politicians in simultaneous problem solving is key.

In conclusion, the evidence in this paper suggests that in the absence of a strong, horizontal, coordinative body with decision making authority, the various services will continue to operate in their relatively isolated vertical traditions. In the case of biotechnology policy in the EC, this fragmented approach to policy making was overcome by establishing the BCC under the chairmanship of a strong policy arbiter with high level political backing and the ability to move freely and simultaneously between political and technocratic games.

Appendix 1

BSC, BRIC, and BSC Mandates

BSC Mandate

Establish internal communication and concertation network

BRIC Mandate

1) review the regulations applied to commercial applications of biotechnology,

2) identify existing laws and regulations that may govern commercial applications of biotechnology,

3) review the guidelines for rDNA research,

4) clarify the regulatory path that products must follow,

5) determine whether current regulations adequately deal with risks that may be introduced by biotechnology and to initiate specific actions where additional regulatory measures are deemed to be necessary; and

6) to ensure the coherence of scientific data which will form the basis of risk assessment and in particular to avoid unnecessary duplication of testing between various services.

BCC Mandate

1) discuss new initiative and prepare policy decisions on all aspects related to biotechnology

2) verify any biotechnology proposal against policy objectives

3) to develop internal guidelines on broad issues to do with biotechnology such as standardization and how to combine the "horizontal with the product by product approach without creating excessive burdens for industry

4) to solve problems of interservice overlap

5) to coordinate Commission standpoints to be taken at meetings held with other EC institutions, third countries and with international organizations

6) to set up if required a system of round tables between representatives of the Commission services and industry representatives.