REGULATING BIOTECHNOLOGY: COMPARING EU AND US APPROACHES

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ABSTRACT

The United States and the European Union share a common desire to provide a safe food supply and credible regulatory systems. However, they have adopted two very different regulatory approaches to deal with the increasing numbers of GM (genetically modified) food and feed products coming to market. Consequently, the transatlantic relationship has become fraught with conflict over the issue of GM foods. This paper explores the nature of the two regulatory systems and the underlying social, political, and institutional factors that contributed to the development of these systems. It then explores the potential impact of these two regulatory systems on international trade. We distinguish between producer protectionism, a commonly recognized trade impediment, and overprotection of consumers that can also have trade implications. Because the potential for trade conflicts over GM foods could result in serious consequences for both the transatlantic relationship and the multilateral system of trade rules, various attempts at bilateral and multilateral reconciliation have been made. Unfortunately, most of these attempts have stalled or failed. Finally, the paper explores product labeling as a possible solution to the conflict. We distinguish between positive and negative labeling and positive and negative attributes. The paper concludes that leaving the labeling to producers and retailers of food would allow the market to work effectively and could allow the EU and the US to reach consensus without resulting in major trade disruptions.

BACKGROUND

The introduction of transgenic crops into the food supply has highlighted both the successes and the failures of the international trade system. On one hand, the GATT and the WTO have ensured that domestic and international markets have become ever more entwined, thus allowing producers and consumers alike to benefit from competition and economies of scale. On the other hand, such institutions are not well designed to mediate political disputes between domestic players arising from the application of trade law. The introduction of new technologies for food products illustrates this dilemma. The present open trade environment allows domestic political and regulatory differences to spill over into the international arena, with serious and detrimental effects on trade relations. This was the case in the beef hormone dispute between the EU and the US. While this dispute remains unresolved, it pales in comparison to the looming dispute over the introduction of transgenic crops into the food system.

To date, the US and the EU have taken very different approaches to the introduction of genetically modified (GM) crops. Trade tensions have been brewing for some years. But these differences do not have to lead to conflicts if the parties can recognize common ground and can see the issue as an opportunity for transatlantic cooperation. Both the EU and the US face essentially the same challenges with respect to the health and safety of the food supply and the credibility of the regulatory system. The farm sectors on both sides of the Atlantic have similar incentives to make use of scientific advances that allow new characteristics to be inserted into plants and animals to improve productivity and enhance utility. The medical biotech industry has achieved widespread public support with no apparent negative publicity in the EU. Perhaps time will mellow the European reaction to transgenic crops and the market will take care of any residual concerns through labeling. Or perhaps the US consumers will acquire some of the same sensitivities as their EU cousins and demand an end to the use of such new varieties. Either would illustrate an important process of convergence. If public opinion and the regulatory approach in the US and the EU converge, then trade conflicts will fade away. On the other hand, if the trajectories diverge there is little hope of preventing a serious disruption in transatlantic relations however much governments may wish otherwise.

The issue is, in fact, inherently one about regulation, not about international trade: it arises from consumer sensitivities, not from producer protectionism. The implication is that we should look closely at administrative and political structures and consumer attitudes. We therefore examine, first, differences in regulatory assumptions and procedures on either side of the Atlantic; secondly, at explanations for these differences; thirdly, at the consequences of these differences, especially for trade; and, fourthly, at possible resolutions.

I. TRANSATLANTIC DIFFERENCES IN BIOTECH REGULATION

Substantial regulatory differences between the US and the EU in the area of biotechnology have been apparent for some time. Vogel has described the US as moving from a strict regulatory stance in the early 1980s to one that is now more permissive, while the EU has changed over the same period from a less to a more conservative and cautious approach (Vogel, 2001). This "crossover" is evidence of the dynamic nature of regulatory policy faced with a rapidly developing technology and growing political pressure, and incidentally casts doubt on too rigid a cultural explanation for transatlantic differences. Whether the EU was ever more permissive than the US in its treatment of biotech depends on how one interprets the diverse regulations in the member states before the Single Market program. It is clear, however, that a major split between the US and the EU happened in the mid-1980s in the approach to biotechnology regulation. Divergence and polarization characterized the decade of the 1990s.

Underlying this divergence are two different models of biotechnology regulation

(Patterson, 2000), which are juxtaposed in Table 1.

TABLE 1

Alternative Models of Biotechnology Regulation

Philosophy of Regulation	Precautionary: Proactive regulatory approach anticipates environmental hazards that have not already been documented but which could conceivably occur.	Preventive: Reactive regulatory approach attempts to minimize environmental harm whenever the existence of harm has been scientifically demonstrated.
Basis of Regulation	Regulation based on process by which product is produced.	Regulation based on safety, quality, and efficacy of product regardless of method of production.
Type of Regulation	Horizontal Regulation: Cross-cutting regulations need to be adopted to insure a basic level of human and environmental safety.	Vertical Regulation: Existing sectoral regulations modified to insure human and environmental safety of new biotech products.

Source: Adapted from Patterson, 2000.

The first model represents a regulatory paradigm that is process-based, horizontal, and precautionary. The second represents a more traditional product-based, vertical, preventive approach to regulation. Most countries employ a combination of the two paradigms depending on the aspect that is being regulated and the political and other pressures on the regulators. The clash between the two different philosophies of regulation, the *precautionary* approach and the *preventive* approach, often appears to be at the root of transAtlantic biotechnology tensions. But aspects of both models have played a role in the development of biotechnology regulations in the US and the EU.

The precautionary philosophy of regulation is usually associated with the "precautionary principle" of risk management, which puts a priority on anticipating and guarding against environmental damage. This 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 preventive action to safeguard ecological space (even in advance of scientific proof or need), and places the duty of

care (or onus of proof) on those who propose change. (See EC Committee of the American Chamber of Commerce, 1994, p.70) Levidow and 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. (Levidow and Tait, 1992 and Tait and Levidow, 1992).

A precautionary approach tends to impose stricter regulations on researchers and producers. Those advocating a precautionary approach to biotech 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 the complexity of eco-systems which preclude unambiguous identification of cause-effect relations. Lack of experience with genetically modified organisms (GMOs) increases the degree of uncertainty about what their impact on eco-systems will actually be. (Tait and Levidow, 1992 p. 223) In addition, proponents argue that a precautionary approach is necessary to allay public fears about new technologies, and about the desire of industry to capitalize on these technologies.

Opponents of the precautionary approach, on the other hand, argue that while caution is certainly necessary, most experiments fall into the low-risk category. Majone has argued that the precautionary approach suffers from a number of shortcomings such as the lack of a sound logical foundation, the potential for it to distort regulatory priorities and the relative ease with which it might be used to justify protectionist measures. (Majone, 2001) Furthermore, establishing a precautionary set of regulations could stifle important life-enhancing research and industrial competitiveness by creating unnecessary bureaucratic delays or even moratoria.

In contrast to this, a preventive approach concentrates on identifying the damage and risk associated with particular products. As Tait and Levidow remark, the approach seeks to respond to

> "scientifically proven adverse impacts that have arisen in earlier generations of products. New products and processes are screened to ensure that they do not give rise to any similar hazards. The regulatory system is built up slowly ... Decisions about the need for regulation and the level of regulation required are taken in relation to the relevant benefits and costs." (Tait and Levidow, 1992, p.221.)

Consequently, advocates of the preventive approach prefer a case-by-case and step-by-step approach to regulation, where rules are based on demonstrated harmfulness, different experiments are assessed on the basis of different risks, and different steps in the research and

production process are examined according to the specific risks involved in each step. In this way, scientists can proceed and in the process accumulate knowledge that will help to clarify what the risks actually are. This approach still introduces bureaucratic delay as compared to no regulations but at least it guarantees some degree of flexibility.

The EU followed the product-based model in the early 1980s. Prior to the widespread utilization of recombinant DNA (rDNA) techniques in a variety of industries, most products were evaluated according to the safety, quality and efficacy of the final product, not according to the process by which the product was produced. The widespread use of rDNA, however, led some policy makers to advocate regulations based on the process by which products were produced.

The rationale for this new regulatory approach as described by DG XI (Environment and Nuclear Safety) in a widely distributed pamphlet was the following:

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

If the traditional method of regulating on the basis of product safety, quality, and efficacy were to be utilized, biotech products would be regulated in a vertical manner. In this way all tomatoes, for instance, whether they were produced by genetic modification, cross-breeding, chemical mutagenesis, or radiation mutagenesis would be evaluated for human and environmental safety using the same criteria. On the other hand, process-based regulation would require a new horizontal approach to regulation. Under this approach all rDNA products including food products, livestock, drugs, pesticides, decontamination products and medical devices would be subject to the same set of safety regulations.

In the US, by contrast, the precautionary approach reigned at least until 1984. In case after case regulatory decisions emphasized precaution and minimal risk to consumers and the environment. It reached its peak in the Delaney Clause to the Food, Drug and Cosmetic Act, which banned the use of any food additive if tests revealed that it caused cancer in either laboratory animals or humans (Vogel, 2001). Air quality standards, pesticide restrictions, drug safety tests and ground water contamination rules all focused on the “potential” rather than the “probable” findings of hazards. Consistent use of scientific risk assessment was not a hallmark of

US regulation. Yet by the mid-1980s, the positions were reversed: the US adopted a product-based, vertical, preventive approach, while the EC adopted a process-based, horizontal, precautionary approach to biotech regulation. This set the stage for the trade tensions that emerged at the end of the 1990s.

II. REASONS FOR DIFFERENCES IN REGULATION OF BIOTECH

Observers have suggested many reasons for the differences in regulatory approach and policy in the US and the EU. Some stress social and philosophical differences that have arisen from different historical experiences, along with differences in culture. For instance, consumers in the EU seem to have a greater mistrust of science and scientists based on the negative experiences they have had with thalidomide, nuclear energy, and more recently "mad cow" disease (see Echols 1998 and Nelson, etal 2001). The US escaped the worst of these "technological" crises. In the US, thalidomide had not cleared the FDA process before negative reports from Europe began to surface. Likewise the US did not experience the strong public reaction against nuclear energy to the same extent as several European countries (the meltdown of the radioactive core at the Three Mile Island nuclear plant notwithstanding). And there has been no large-scale threat to the food supply equivalent to mad cow disease. These, along with other public policy scandals such as tainted blood and adulterated wine and olive oil, have resulted in a greater distrust of both public and private policy makers in Europe. Perhaps as a result, the media portrayal of biotechnology in the EU has differed significantly from that in the US. In the US, the focus has been primarily on the positive health and environmental benefits to be gained from specific rDNA products. In Europe, especially in the UK and Germany, the focus has been on "Frankenfoods" and the problematic relationship between technology, society, large corporations, the environment, and the state.

Political differences may also be significant. In particular, environmental groups have been more active in European politics than in American politics. The Green Party has been strong in both individual Member States and in the European Parliament. The Green Party's influence was felt as early as 1983 when it won 5.3% of the national vote in Germany and secured 27 seats in the German Parliament. A major component of the Green Party's platform has been to promote the idea that GM foods may have a deleterious impact on the environment and human health. The Greens have also played an important role within the Parliament at the EU level. While the Green Party in the US has gained some momentum over the last few years, its influence with respect to actual biotech policy has been minimal.

Institutional differences between the two transAtlantic trade partners are also important. Table 2 summarizes the main differences in US and EU biotech-related regulatory processes.

TABLE 2

Comparison of the EU and US Biotechnology Regulatory Process

Area of Comparison	**United States**	**European Union**
Administration of Regulation	Wide variety of agencies (FDA, USDA, EPA and others). When two or more agencies have jurisdiction, the 1986 Coordinated Framework establishes a lead and secondary agency.	DG XI (Environment). In specific cases, such as novel foods and pharmaceuticals, DG III (Industry) or the EMEA administer the regulation, but in all cases products must conform to an environmental risk assessment equal or similar to that prescribed by DG XI.
Ability to Adapt to new Scientific Information	Regulations are easy to revise in light of scientific evidence and both research and product regulations have been revised many times. Exemptions are possible.	Regulations are difficult to revise. Major revisions to 90/219 have taken place once. Major revisions to 90/220 are still being discussed. (Some minor revisions to 90/220 have been made.) No exemptions are possible.
Effective Interagency Coordination	Interagency coordination began in 1984 prior to passage of the Coordinated Framework	Effective interagency coordination occurred only after the passage of Directives 90/219 and 90/220.
Rule Making Consultation Process	Open. Scientists, business, special interest groups and other agencies are free to comment through the Federal Register process.	Closed. Consultation occurred primarily between DGs and their specific clients or occasionally among DGs. There was no public record or open comment period prior to the formulation of the regulatory framework. Since the formation of the BCC, interest groups are consulted on an *ad hoc* basis.
Input from Scientific Community	Extensive.	Marginalized. Communicated primarily with DG XII (Research).

Source: Adapted from Patterson, 1998

The administration of the regulations is more dispersed in the US. In the EU, the Directorate-General for the Environment takes the lead and sets the standards that must be met for the release or use of biotech products. Regulations are difficult to revise in the EU, and exemptions are not possible. In spite of (or perhaps because of) the dominance of DGXI in the EU regulatory process, interagency (or inter-DG) coordination is not as effective in the EU as in the US. For instance, the EU only established an internal policy coordination mechanism that would allow a variety of perspectives to be considered in policy making after adopting Directives 90/219 and 90/220, the seminal pieces of biotechnology legislation in the EU. The lack of a Federal Register type process limited the input of scientists, special interests, other agencies and the public in general in the EU. Because the rule-making is more open and input from the scientific community is easier to obtain in the US, the system allows for a flexible response to new knowledge.

On both sides of the Atlantic, there are a considerable number of official bodies involved in some area of biotechnology policy. Each of these bodies tends to be concerned with a specific product or problem related to biotechnology. Agencies and directorates generally operate in different policy networks, have different standard operating procedures and even different regulatory philosophies. Thus inter-agency coordination is critical to avoid problems of redundancy, incoherence, and lacunae. Furthermore, inter-service coordination provides a forum to discuss policy objectives and new policy initiatives, to solve problems of inter-service overlap, and to coordinate standpoints to be taken at meetings with other countries and organizations. While the US was successful in establishing internal coordination from an early date, the EU was not. This might be explained in part by the fact that US administrative and regulatory agencies were well established by the mid-1980s while the different DGs within the EU were still trying to carve out policy territory at that time.

The EU did engage in two rather unsuccessful attempts to coordinate biotechnology policy horizontally between 1984 and 1990. In early 1984, the Biotechnology Steering Committee (BSC) was formed but it was mainly meant to provide a forum for discussion rather than being given a policy mandate. Poor attendance resulted in its eventual disintegration. However, by July of 1985, the BSC agreed to establish the Biotechnology Regulations Interservice Committee (BRIC). BRIC was to serve as a technical agent for the BSC in the drafting of biotechnology legislation. BRIC was composed of DG III (Industry), DG V (Employment, Social Affairs, and Education), DGVI (Agriculture), DG XI (Environment, Consumer Protection and Nuclear Safety), and DG XII (Science, Research and Development) and became the center of biotechnology regulations within the Commission. In November 1986, the Commission submitted a Communication to the Council in which it stated its intention to introduce proposals for Community regulation of biotechnology by the summer of 1987. The proposals would deal, *inter alia*, with levels of physical and biological containment and the authorization of planned release of

genetically engineered organisms into the environment (European Commission, 1986). DG III and DG XI were appointed *co-chef de file* for the directive on contained use (later Directive 90/219) and DG XI was appointed *chef de file* for the directive on planned (or deliberate) release (later Directive 90/220). In fact, DG XI (Environment) did most of the drafting on both directives with very little input from any other DG. Only after the directives were passed, and in response to wide-ranging criticisms from scientists, industry, and even some Member States, did President Delors agree that better coordination was needed and created the Biotechnology Coordinating Committee (BCC).

In the US, by contrast, it became clear in the early 1980s that coordination was necessary to resolve interagency debates about the scope and boundaries of regulatory authority. Consequently, two important working groups were established, the White House Cabinet Council on Natural Resources and Environment in 1984 and the Biotechnology Science Coordinating Committee in 1985. Out of these groups came the Coordinated Framework for the Regulation of Biotechnology that was published in the *Federal Register* in 1986. The Coordinated Framework found that, for the most part, existing laws would address biotechnology regulatory needs adequately. No over-arching horizontal legislation such as in Directives 90/219 and 90/220 was deemed necessary. Instead, a mosaic of existing laws and agencies was utilized to regulate different aspects of biotechnology. In this way, the agencies that were most familiar with the new products were able to regulate them according to extensive information about like products (see Patterson, 1998).

III. THE CONSEQUENCES OF TRANSATLANTIC REGULATORY DIFFERENCES

Differences in regulations can cause trade impediments, in areas of food law as in other sectors of commerce. Some of these impediments reflect different circumstances and different attitudes toward food safety. But many of the differences in food law are arbitrary, reflecting the action of separate legislatures writing regulations in various ways to the same end. Some of these differences are significant enough to generate strong vested interest in their perpetuation. Trade policy issues arise when regulatory differences both interfere with trade and are less-than-obviously justified by diverse circumstances (see Josling, Roberts, and Orden).

Under the international trading system, domestic producers must not receive preferential treatment over foreign producers. The principle - that of “national treatment” - is enshrined in Article III of the GATT, now a part of the rules of the World Trade Organization (WTO). Most trade policy disputes that involve regulations arise because this fundamental precept is thought to have been broken. However, biotechnology differs from other traded products in one crucial respect: its regulation is concerned more with consumers than with producers. Many GATT and

WTO cases have involved an attempt by one party to provide protection to its domestic *producers*, often as a result of the "capture" of the domestic regulatory process. The SPS Agreement negotiated in the Uruguay Round of GATT negotiations introduced the science test as a way to be able to distinguish such cases from genuine protection of animal, plant, and human health. Biotechnology policy, on the other hand, reflects a relatively new phenomenon, that of protecting domestic *consumers* from hazards real or imagined. This has been referred to as "consumer capture" (see Josling and Patterson, 2002). This form of capture has very different implications for trade.

The essence of consumer capture is that it is largely a domestic matter. Trade effects are of marginal importance to the protagonists. The debate on the adoption of the hormone that increases milk yields, Bovine Somatotropin (BST, also known as rBGH), has been largely about the effect on domestic milk markets, though some trading firms have been affected.[1] The irradiation of food is also a domestic issue, though some irradiated foods cross borders. The debate in the US has not been about whether to allow in irradiated foreign food, but rather about whether to allow the sale of such food on the domestic market regardless of its provenance. Seen in this light, the GMO conflict between the US and the EU is not primarily about trade but about the adequacy of domestic food safety and environmental regulations themselves. The "producer protection" problem becomes a trade issue directly, as the producer is seeking protection from foreign suppliers. The "consumer protection" problem affects all producers alike, and its influence on trade is less direct. Tight consumer regulations put up the cost of products on the domestic market but do not necessarily disadvantage the imported good relative to the domestic product.

Attempts by governments to discriminate against foreign suppliers can obviously be challenged under trade rules. But this has not happened in the GMO dispute, nor indeed was it a factor in the beef hormone case. Attempts to discriminate against domestic suppliers, not implausible if the fear is one of environmental impacts associated with the production of GMO foods, would be challenged immediately by domestic producer interests.[2] Thus the political economy of consumer capture is noticeably different from that of producer capture. This has been reflected in the transatlantic debate. Cooperation among producer groups has been a feature of the transatlantic dialog: in fact such cooperation may have been easier than among consumer interests on each side of the Atlantic.

IV. ATTEMPTS AT COOPERATION

The potential for trade conflicts between the EU and the US over GM foods and the serious consequences that such conflicts could have for the transAtlantic relationship and the multilateral system of commercial rules have spurred attempts to coordinate regulatory policies and reconcile differences. These attempts have been at both the bilateral and the multilateral

levels. So far, any success has been overshadowed by the opportunity that such attempts offer for confrontation. Each new forum provides another stage for confrontation. Little reduction in tension has been evident, though the wider spread of information could have prevented even more serious conflicts.

A. BILATERAL ATTEMPTS AT COOPERATION

The transatlantic commercial relationship has been on a roller coaster ride for much of the postwar period. Intensive involvement through trade and investment has gone along with noisy conflicts over relatively minor trade flows. During the Cold War, the economic conflicts were subordinated to the general shared goals of the containment of communism and the defense of democracy. By 1990, it was clear that this justification for the transatlantic relationship was being rendered ineffective by events and that it could usefully be supplemented by a renewed mutual commitment to common political and economic values. The Transatlantic Declaration of 1990 attempted to create some high-level political cover for the discussion of trade and other differences between the US and the EU. This interaction at the official level included six-monthly summits for heads of government and periodic meetings at the cabinet and sub-cabinet level. These meetings helped to advance the discussions leading up to the conclusion of the Uruguay Round of trade talks and to defuse some otherwise disruptive conflicts. The meetings held under the banner of the Transatlantic Declaration led in turn to the New Transatlantic Agenda (1995), including an Action Plan that promised action on economic as well as security issues. From that emerged the program that governs the present talks among diplomats and officials, the Transatlantic Economic Partnership (TEP) of 1998.

One of the most elusive tasks for the Transatlantic Economic Partnership has been to improve commercial relationships in the area of agriculture and food trade between the US and the EU. It was not certain that such discussions could ever include anything meaningful on agricultural trade. In agriculture, any discussion of US-EU relations carries with it the fear of failure and frustration, borne of the experience with the Uruguay Round and the previous twenty years of tension (see Josling, 1996 and Tangermann, 1999). However, the parties felt that they should not lose the opportunity for an improvement in trade relations in such an important area as food safety. An agreement on the mutual development of quality and health standards and on mutual recognition of each other's sanitary and phytosanitary measures perhaps was not beyond the realm of possibility. The key to such an outcome lay in the development of relations among regulatory agencies. If the transatlantic partnership could encourage a spirit of cooperation rather than confrontation among these agencies, this would offer an alternative to the prospect of endless conflicts over food standards across the Atlantic. Several bodies have been set up which bring together regulators from each side of the Atlantic, but to date there has not yet been the required political will to make such cooperation a natural way of defusing tensions.[3] Attempts to craft "mutual recognition agreements" to recognize each other's testing have proved difficult, in

part because of the reluctance of the relevant agencies to change established ways.

Several private sector or civil society structures have been set up in parallel to the intergovernmental processes noted above (see Cowles, 2001 and Bignami and Charnovitz, 2001). These have included the Transatlantic Business Dialogue (TABD), which emerged in 1995 as a private sector initiative to facilitate commerce and investment between the EU and the US; the Transatlantic Consumer Dialogue (TACD), a forum of US and EU consumer organizations that came together in response to the activities of the TABD to make policy "consumer-friendly" recommendations to the leaders of the EU and US; and the Transatlantic Environmental Dialogue (TAED) that was set up in 1998 by environmental organizations from the EU and the US in response to a request by the EU Commission and the US government to have an ongoing and structured discussion between officials and environmentalists. The TABD has been successful in advocating and monitoring work on the mutual recognition of conformity assessments in a number of areas. The TACD has been particularly concerned with public health issues, including food safety. In particular they have given strong support to the mandatory labeling of genetically-engineered food. The TAED was also originally intended to provide some balance to the TABD. However, it has not been notably successful and apparently suspended its activities in November 2000 due to lack of financial support from the US.

EU-US Biotechnology Consultative Forum

One concrete manifestation of the attempt to explore broad public consensus in biotech policy (as opposed to regulatory cooperation among government agencies) was the decision at the May 2000 US-EU Summit to create a EU-US Biotechnology Consultative Forum comprised of an "independent group of experts representing diverse views on the two sides of the Atlantic." The Forum, comprised of ten "experts" from the US and an equal number from the EU, met four times and produced a report that was presented to the Summit in December 2000. The group focused on the use of transgenic crops or foods, and thus did not consider medical biotech or even animal products that may involve the fruits of biotechnology.

The Forum provided a convenient opportunity for a review of the concerns and the hopes for the new technology in the area of foods. The debate did not yield any surprises and the report covers most sides of the argument with some attempt at even-handedness. It is replete with worthy admonitions such as the statement that "scientists have the obligation to evaluate possible long-term consequences of new technologies and to inform policy makers honestly." But it also concludes with the more contentious statement that "the biotechnology debate is also a debate over the role of the citizen." It endorses "public responsibility for global governance of biotechnology", at least in the area of sustainable agriculture, but it also asserts that "biotechnology holds the promise of dramatic and useful advances in some of the areas of greatest challenge for humankind during the 21st Century."

Such comprehensive statements act as a prelude to some more concrete suggestions: that all products should be subject to mandatory pre-market examination (Recommendation 1); that "substantial equivalence" should not be taken to relieve new foods from additional testing (Recommendation 5); that processes should be introduced to make it possible to trace all foods derived from GMOs (Recommendation 8); that regulatory procedures, including risk-assessment, should include, *inter alia*, representatives of civil society (Recommendation 14); and that the EU and the US should establish content-based mandatory labeling requirements for finished products containing GMOs (Recommendation 15) (Anon, 2000). No action has followed the submission of the report, but it will no doubt be cited, in particular by the EU, as support for its own position on many of the issues raised. The US agencies are less likely to be drawn to the conclusions of the Forum.[4]

B. COOPERATION IN PLURILATERAL AND MULTILATERAL INSTITUTIONS

Biotechnology regulation appears on the agenda of a number of multilateral institutions. Consequently, tensions between the US and EU positions are often projected onto these bodies. Differences between the EU and the US can have a negative impact on those institutions. On the other hand, collaboration can strengthen those institutions and make them more effective. The question is whether the institutions themselves offer the hope of avoiding trade conflicts across the Atlantic or whether they provide just another platform for the disagreements. The most important multilateral institutions dealing with issues of biotechnology are currently the OECD, which has taken on a major role in the discussion at least on a plurilateral level; the WTO, which finds itself reluctantly in the hot seat on issues of trade impediments arising from national policies; and the CODEX, which has responsibility for international standards on several aspects of food safety.

The OECD

The OECD has played an extremely important role in the formation of biotechnology policy since the early 1980s. Very early in the biotechnology policy debate, key policymakers from several countries recognized that biotechnology had the potential to harm the global commons. Biotech presented a policy environment characterized by high levels of risk and uncertainty; it raised concerns about competitiveness; and it would possibly require raising the debate above the realm of domestic politics. Consequently, the OECD has acted as a policy coordinator, information broker, and forum for policy learning in the emerging field of biotechnology. Two units of OECD are specifically related to biotechnology: the Directorate for Science, Technology and Industry, and the Environment Directorate. In addition, the Agriculture

and Trade Directorates include a biotechnology component.

An early and very influential attempt to agree to some guidelines for biotechnology research was achieved by the OECD's Group of National Experts (GNE) in 1986. The GNE (organized as part of the Committee for Scientific and Technology Policy) was composed of 80 experts from a wide variety of academic and professional backgrounds. In 1986, the GNE reached a consensus on guidelines to be used in biotechnology research based on the widely- agreed rationale that there was no scientific basis for specific legislation to regulate the use of recombinant DNA organisms (OECD, 1986, pp.7-8). In other words, they came out against process-based regulation. Since then the OECD has published a number of books relating to different aspects of biotechnology including studies of bio-remediation, food safety, and biotech and developing country agriculture.

The work of the OECD has been well regarded. In June 1999, the G8 Heads of Government invited the OECD Working Group on Harmonization of Regulatory Oversight of Biotechnology and the OECD Task Force for the Safety of Novel Foods and Feeds to undertake a study of the implications of biotechnology for food safety. They also asked the OECD to report on ways to improve the approach to these issues through international and other institutions. At a Conference on the Scientific and Health Aspects of Genetically Modified Foods held in Edinburgh in February 2000, the OECD called for the establishment of an independent, international panel on food safety.[5]

WTO (GATT, SPS, and TBT Agreements)

At the international level, the issues of regulatory differences have posed problems for the GATT for many years. Under the 1947 GATT agreement, sanitary and phytosanitary measures which impinged on trade were covered by Article XX (b). This provision allows countries to employ trade barriers "necessary to protect human, animal or plant life or health" which would otherwise be illegal so long as "such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or as a disguised restriction on international trade" (Josling, Tangermann and Warley, 1996, p.209). But Article XX had no teeth: there was no definition of the criteria by which to judge "necessity", and there was no specific procedure for settling disputes on such matters. The attempt in the Tokyo Round to improve on this situation through the Agreement on Technical Barriers to Trade (1979) (TBT), known as the Standards Code, also failed. Though a dispute settlement mechanism was introduced and countries were encouraged to adopt international standards, relatively few countries signed the Code, and a number of basic issues were still unresolved.[6]

Intensive negotiations in the Uruguay Round led eventually to a new SPS Agreement that tried to repair the faults of the existing code. This Agreement defined new criteria that had to be met when imposing regulations on imports more onerous than those agreed in international standards. These included scientific evidence that the measure was needed; assessment of the risks involved; and recognition of the equivalence of different ways of testing and sampling. In addition, the dispute settlement mechanism was considerably strengthened under the WTO to make it easier to obtain an outcome that could not be avoided by the losing party.[7]

The force of the SPS Agreement comes in part from the more precise conditions under which standards stricter than international norms can be justified and partly from the strengthened dispute settlement process within the WTO. In this regard, much was expected of the panel report in the Beef-Hormone dispute between the EU on the one hand and Canada and the US on the other. This was widely seen as a test case for the new SPS Agreement. Though the panel and the subsequent appellate body reports did indeed clarify the scope and interpretation of the SPS Agreement, transatlantic trade tensions have not receded.

Although the new SPS Agreement represents a significant advance in rule-making, it is difficult to say how effective it will be in curbing trade disputes arising from biotechnology. Many environmental and consumer groups fear that there will be an erosion of health and safety standards in the name of freer trade. The significance of these trade rules is becoming apparent. And the question of genetically-modified foods poses a particularly emotional challenge to the SPS system.

Often overlooked in the focus on the SPS Agreement with its science-test is the scope of the TBT Agreement, originating in the Tokyo Round but modified somewhat in the Uruguay Round to ensure that it covers process-based regulations. This Agreement is, in fact, more likely to be the basis for a challenge to biotech food regulations than is the SPS Agreement. The SPS Agreement only covers regulations that are explicitly designed to protect plant, animal and human health. Any regulation that is not specified in these terms necessarily falls under the TBT Agreement (Heumeuller and Josling, 2001). Thus it is likely that a WTO action against a trade barrier arising from a technical regulation, standard or conformity assessment procedure will be judged by compliance with the TBT Agreement. This agreement is not quite as strict in some respects as the SPS Agreement. It does not require a risk assessment and does not insist on scientific evidence as the main criterion for justification of a measure. But it is not by any means without constraints. It provides that technical regulations should be applied in a non-discriminatory way, should be used only in pursuit of legitimate objectives, and should be least trade disruptive, taking into account the risks of not fulfilling the objective of the regulation. Risks should therefore be assessed, but in the broader context of a set of objectives that is not limited to health and safety issues. These legitimate objectives could include national security considerations and prevention of deceptive practices, as well as environmental protection. Indeed the list is open

ended, implying that countries might argue that such concerns as a consumer's right to know could be a legitimate objective for a technical regulation. Thus a TBT case involving GM labeling might hinge on whether there are less trade disruptive alternative ways of informing consumers than a particular mandatory labeling regime.

Underlying the tensions between the US and the EU in the discussions about both the SPS and TBT Agreement are the different regulatory philosophies and practices described earlier in this paper. The translation of these differences onto a multilateral stage mainly serves merely to emphasize them. Neither the SPS nor the TBT Agreement have caused a major change in domestic regulations in the US and the EU, though they could have made domestic regulators a little more circumspect.[8]

CODEX and labeling

The Codex Alimentarius Commission (a joint FAO/WHO body) has played an important role in setting many international food standards including acceptable levels of pesticide residues; food labeling; standards on fish and fishery products, fruits, vegetables, processed foods, vegetable proteins, animal feeding and nutrition and foods for special dietary uses. CODEX is a widely recognized and highly respected organization. CODEX has formed an Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology and the task force held its first meeting in March 2000. The meeting was attended by a wide variety of public officials from over 33 countries, five international governmental organizations, and about 14 international non-governmental organizations. The purpose of the meeting was to identify the work priorities and key concepts and definitions to be developed by the task force. At that meeting, the task force decided that it would proceed with the elaboration of two major texts. The first would address broad general principles for risk analysis of foods derived from biotechnology. This would include matters such as science-based decision-making, pre-market assessment, transparency, and post-market monitoring. The second text would provide specific guidance on the risk assessment of foods such as food safety and nutrition, "substantial equivalence," potential long-term health effects, and non-intentional effects. In addition, the Task Force agreed that a list of available analytical methods for the detection and identification of foods or food ingredients derived from biotechnology should be prepared. The committee prepared a preliminary report that was submitted to the 24th session of the CODEX Alimentarius Commission on July 2-7, 2001.[9]

Another important CODEX Committee that has become involved in the debate over biotech policy is the Committee on Food Labeling. This committee has established a set of proposed draft guidelines for labeling food and food ingredients obtained through genetic modification. In general, the committee advocates labeling when food and food ingredients are no longer equivalent to their conventional counterparts, and/or when they are composed of or contain a genetically-modified organism or protein or DNA resulting from gene technology,

and/or when they are produced from but do not contain genetically-modified organisms, protein or DNA resulting from gene technology.[10]

The importance of CODEX was undoubtedly enhanced by the SPS and the TBT Agreements, the former specifying that countries using CODEX standards were *de facto* in conformity with the WTO. However, once again the differences between the US and the EU regulatory policy towards biotech have led to conflicts. It may not be any easier to get the US and the EU to agree within the confines of a CODEX task force than in the Transatlantic Dialogues.

V. THE SEARCH FOR A SOLUTION

Given the fundamental differences in approach between the EU and the US, is trade conflict inevitable? Do grounds for cooperation exist and can a trade war be averted?

A total ban on GM products would result in consumer overprotection because consumers who might want to purchase GM products (which have not been scientifically proven to be harmful to humans or the environment) because they are either cheaper or because they have been positively enhanced would be unable to do so. It would also be challenged in the WTO, under either terms of the SPS or TBT Agreements (Sheldon and Josling, 2001)

Labeling offers one possible solution. The international demand for some form of labeling of GM foods is growing stronger (See Phillips, 2000; Sheldon 2001, and Sheldon and Josling, 2001). Although EU directive 90/220 as amended by directive 2001/18 already required traceability and labeling of some GM products, in July 2001 the Commission proposed two new regulations (49/2000 and 50/2000) that will require all food to be labeled, irrespective of whether DNA or protein of GM origin is in the final product. But the demand for some sort of labeling extends beyond the EU. In January of 2000, 130 countries ratified the Cartagena Protocol on Bio-safety which calls for bulk shipments of GMO commodities, such as corn or soybeans, that are intended to be used as food, feed or for processing, to be accompanied by documentation stating that such shipments "may contain" living modified organisms and are "not intended for intentional introduction into the environment."

Labeling, however, is no panacea. The extent to which it facilitates trade and avoids friction depends on the nature of the label and who provides or requires it. Two distinctions are important: whether the attribute that appears on the label is seen as positive by the consumer (such as a nutritional attribute) or negative (in effect, a warning label). The label itself can either contain a positive statement (“does contain”) or a negative claim (“does not contain”). The

incentives generated by the combinations of these factors are shown in Table 3.

TABLE 3

Relationship between Attributes and Label Claims

	Positive Attribute as seen by consumer (price premium)	*Negative Attribute as seen by consumer (price discount)*
Positive Label *(" does contain")*	Likely to be provided by private sector: government mandate not necessary	Unlikely to be provided by the private sector: government mandate may be needed
Negative Label *(" does not contain")*	Unlikely to be provided by the private sector: government mandate may be needed	Likely to be provided by private sector: government mandate not necessary

Claims for positive attributes require no particular mandate: the role of government is to prevent fraud. Similarly, claims for negative attributes should be in the interest of the private sector, with the authorities merely making sure that the claims are true. The more contentious cases are the requirement of a positive label for a negative attribute and a negative label for a positive attribute. The private sector has no incentive to provide information that is contrary to its commercial interest.

This account conveniently summarizes the nature of the debate on labeling between the US and the EU. The EU has instituted positive labeling for what is perceived in Europe as a negative attribute (For example, "This product has been genetically modified.") The US broadly recognizes (though it might regret) the demands of EU consumers for GMO labels, but argues that they should be of the negative kind and hence likely to be introduced voluntarily. (For example, "This product has not been genetically modified.") When the biotech sector brings to market GM food products that are recognized as having a positive attribute, the private sector will wish to switch to positive labeling. Thus the issue is not so much whether to label, but whether to mandate positive labels in markets that treat GM ingredients in foods as a negative attribute (in the absence of any evidence of actual health consequences). In sum, leaving the labeling to producers and retailers of food may be a way in which to reach consensus between the US and the EU without resulting in huge trade disruptions. Precedent exists for this approach and

it has been rather successful. Both Sainsbury's and Marks and Spencer's pledged that their store chains were GMO-free. Gerber, Heinz, Unilever, Nestle and McDonald's (for their French fries) have done the same thing. This allows the market to work and does not impose consumer overprotection.

VI. CONCLUSIONS

Why do the differences among biotech regulations seem to be such a contentious transatlantic issue? One explanation seems to dominate others. The EU has yet to come to grips with the phenomenon of "consumer protectionism," the capture by consumer and environmental groups in some European countries of the regulatory system in an attempt to avoid the risks of modern technology and society. The US at present reacts to this phenomenon as if it were a case of "producer protectionism" such as has been evident in food and agricultural markets over the past forty years. But whereas overprotection of producers harms trade, consumer overprotection can offer commercial opportunities.

The costs of producer protection in commodity markets are generally borne by exporters who have a clear incentive to ensure that importing countries base their regulations on "science". However, in the case of consumer protection the situation is not so clear. By voluntarily expressing strong feelings in the marketplace in favor of particular attributes of his or her food, the consumer is in a position to be targeted by retailers and food manufacturers. The market should return premia adequate to make market segregation worthwhile. Rather than cause a trade conflict, such market differentiation offers profitable openings. The US should encourage its exporters to exploit the regulations of the EU and only to challenge them when they discriminate against foreign supplies. But the US should also push the EU toward the type of labeling (negative claims on a perceived negative attribute) that it is in the interest of the private sector to introduce and that conforms to multilateral rules and standards.

The role of the government in biotech regulation, and in labeling of biotech foods, is still evolving. The main dangers lie not so much within the biotech sector but in the wider trade system. A clash over the EU labeling system could precipitate a serious systemic trade conflict. Within the EU, politicians are unwilling to grant food consumers the ability to make choices between biotech and non-biotech foods. Politicians are the servants of the public and not answerable to trade dispute panels. The attempt to impose the use of scientific evidence as a basis for regulating what governments can do in responding to fears about biotech foods may be at best controversial and at the worst counterproductive. A favorable panel ruling could be a hollow victory for US exporters. Transatlantic cooperation to prevent such a conflict could be in the interests of all the governments concerned.

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Footnotes

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[1] It is perhaps not a coincidence that the firm that introduced BST was Monsanto, now the major player in the introduction of transgenic crops. Monsanto clearly did not learn the lesson of the problems with the acceptability of BST, but the opponents of the use of this product put their experience to good use in marshalling the opposition to GM foods.

[2] But it may be that some producers feel that they have a better chance to be competitive under the "old" technology, and may resist the introduction of biotechnology if all competing producers are allowed to use it. Thus some link between consumer capture and producer protectionism could exist.

[3] See Pollack and Shaffer (2001) for a more comprehensive account of the various attempts at US-EU management of the regulatory conflict over GMOs, including the High Level Environment Consultation Group, the Agrifood Biotech Group, and the US-EC Task Force on Biotechnology Research. None of these has notably altered the regulatory divergence in this area.

[4] For a discussion of the Forum in comparison with other Consultative Councils on biotech see Heumeuller (2001).

[5] Compare with the suggestion for an International Panel on Genetically Engineered Foods that is presented in Heumeuller (2001).

[6] One such issue was whether international obligations extended to regulations dealing with methods of production (Production and Processing Methods, or PPM) or just with the nature of the product (Product Standards, or PS).

[7] The Decision on the Application and Review of the Understanding on Rules and Procedures Governing the Settlement of Disputes (the Dispute Settlement Understanding) provides a framework for the better enforcement of panel rulings. To block the adoption of a Report from a Panel now requires consensus. Any party may appeal the ruling (on issues of law), but the Appellate Body Report is final unless overturned by consensus.

[8] The SPS Agreement does, however, seem to have influenced the domestic regulation of smaller countries and in particular developing countries, who need to be seen to be following international rules with assiduity (Roberts, *et al*., 2001)

[9] The report can be located at the following internet address: ftp://ftp.fao.org/codex/ALINORM01/al0134Ae.pdf

[10] The full proposed draft recommendation can be found at: ftp://ftp.fao.org/codex/ALINORM01/al0122ae.pdf