# **Robert Schuman Centre for Advanced Studies**

Trading Up or Trading Blows?
US Politics and Transatlantic
Trade in Genetically Modified Food

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**BP CHAIR IN TRANSATLANTIC STUDIES** 

# **EUI WORKING PAPERS**



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#### **ABSTRACT**

The simmering dispute between the European Union and United States over trade in agricultural biotechnology is worthy of study for several reasons. First, it is a potentially significant source of tension in one of the world's most economically and politically important trade relations. Second, it hinges on different approaches to regulating risk, and thus is particularly difficult type of trade dispute to resolve. Third, the dispute appears to be affecting regulatory policy on both sides of the Atlantic.

This paper focuses on this reappraisal of domestic political decision in the light of international pressure. I argue that while one would not expect the United States government to 'trade up' – strengthen its domestic regulations – and would expect it to 'trade blows' – prosecute the European Union's rules through the multilateral trading system – we observe the opposites. particular, trading up is taking place in response to the learning by and mobilization of US consumers and to business adaptation to the EU's rules and changing domestic market conditions. There are limits to this process, however, and limited 'trading up' by the US (even combined with reform in the EU) is insufficient to end the dispute. There are also political and legal limits to 'trading blows,' which mean that further, externally driven reform of the EU's procedures is highly unlikely. Consequently, barring any biotechnology disasters and pending any breakthroughs with direct and evident benefits to consumers that would shift the balance decisively in either direction, the likely scenario is one of protracted tension. The two sides will therefore likely seek to minimize (at the margins) the disruptive effects of continuing regulatory differences.

#### I. Introduction<sup>1</sup>

"Sound Science, Not Political Science"

- National Food Processors Association, Annual Report, 1999-2000, p. 21

I cannot pretend to be able to address the hard science aspects of agricultural biotechnology. In contrast to the National Food Processors Association, however, I think that while politics are very much in evidence in the transatlantic dispute concerning agricultural biotechnology, political science has largely been absent. This paper seeks to illuminate the dispute by bringing a political science perspective to bear and by situating it in the broader context of the political interaction between international trade and domestic regulation.

The simmering dispute between the European Union and United States over agricultural biotechnology is worthy of study for several reasons. First, it is a potentially significant source of tension in one of the world's most economically and politically important trade relations, and it is one with ramifications for the rest of the world as well. Second, the dispute hinges on different approaches to a new technology and the risks associated with it. As such, it represents a particularly difficult type of trade dispute to resolve and one that arguably is becoming increasingly salient in international trade. Third, there are indications that the dispute is affecting regulatory policy on both sides of the Atlantic. Thus, international pressures are prompting a reappraisal of domestic political decisions. This last aspect is the main focus of this paper.

I argue that while one would not expect the United States government to 'trade up' – strengthen its domestic regulations – and would expect it to 'trade blows' – prosecute the European Union's rules through the multilateral trading system – we observe the opposites. In particular, 'trading up' is taking place in response to the learning by and mobilisation of US consumers and to business adaptation to the EU's rules and changing domestic market conditions. There are limits to this process, however, and limited 'trading up' by the US (even combined with reform in the EU) is insufficient to end the dispute. There are also political and legal limits to 'trading blows,' which mean that further, externally driven reform of the EU's procedures is highly unlikely. Consequently, barring any biotechnology disasters and pending any

<sup>&</sup>lt;sup>1</sup> This highly derivative subtitle combines David Vogel's *Trading Up: Consumer and Environmental Regulation in a Global Economy* and Stephen Woolcock's *Market Access Issues in EC-US Relations: Trading Partners or Trading Blows?*. Early versions of this paper was presented to the Robert Schuman Centre's Transatlantic Seminar on 7 March 2001 and the University of Glasgow's Department of Politics on 9 May 2001. I am grateful to the participants for their comments. I am particularly grateful to Mark Pollack for his comments on an earlier version of this paper. I am also indebted to the practitioners who discussed these issues with me.

breakthroughs with direct and evident benefits to consumers that would shift the balance decisively in either direction, the likely scenario is one of protracted tension. The two sides will therefore likely seek to minimize (at the margins) the disruptive effects of continuing regulatory differences.

I begin by discussing the interaction of international trade and domestic (regulatory) politics (Section II). I then describe the US approval process for genetically modified (GM)<sup>2</sup> crops and contrast it with the EU's (Section III). This discussion sets up an analysis of the contours of the dispute, which summarizes the main differences in the two approaches and spells out their impact on trade (Section IV). In Section V I reverse the focus and describe how US regulatory policy is changing and in Section VI analyze the impact the dispute has had on that change. In the next section (VII) I pull back from the focus on the domestic level to examine EU-US cooperation in bilateral and multilateral fora. In the final section (VIII) I draw out some of the implications of my analysis both for how the dispute might develop and for our understanding the dynamic interaction between international pressures and domestic politics.

# **II. International Trade and Domestic Regulatory Politics**

The interaction between international trade and domestic politics hinges on the obstacles to trade posed by differences between national regulations. Because all products sold in a country must comply with its domestic regulations, any products not complying with those rules are excluded. Such technical barriers to trade (TBTs) have become increasingly significant as domestic regulation has expanded and as other trade barriers, notably tariffs, have fallen (Hocking, 1999; Vogel, 1995).

How significant the export market is (economically and as a policy exemplar) relate to the aggrieved country's 'sensitivity' interdependence – how much changes abroad inflict cost/change at home (Keohane and Nye, 1989). The greater a country's 'sensitivity' interdependence the stronger will be domestic political mobilization. To the extent that Country B's firms can adapt to Country A' rules, that mobilization will be damped. The harder it is for Country B's producers or government to respond effectively to the challenge posed by Country A's rules, however, the greater Country B's 'vulnerability' interdependence and the greater its incentive to reach a cooperative solution to

technology of agricultural biotechnology.

A wide variety of adjectives - including transgenic, genetically engineered and bioengineered – is used to describe to organisms that have had genes inserted from another organism using recombinant DNA technology. Although genetic modification can occur through selective breading. I use the term here as it is commonly applied to refer to the new

its problem. Asymmetries in interdependence, however, structure the power relationship between partners, and the country that has higher levels of sensitivity and vulnerability interdependence will be in a weaker negotiating position. Any compromise would therefore favor the other partner.

When domestic producers' access to another country's market is restricted by TBTs, a government, therefore, has essentially four possible political responses: 1) trying to force the other government to change its rules to eliminate the barrier ('trading blows'); 2) changing its own rules to match those of the importing country ('trading up'); 3) seeking a cooperative solution; and 4) doing nothing. The first three policy options are not mutually exclusive. Further, the attractiveness (or unattractiveness) of one option may affect the attractiveness (or unattractiveness) of the others. As my focus is the impact of international trade on domestic politics, I focus on the second option – the adoption of stricter domestic rules, <sup>3</sup> what David Vogel (1995) has called 'trading up.' The other options, however, are necessarily part of the story.

According to Vogel (1995: 8), 'trading up' is most likely to occur when: 1) the countries in question are parties to an international agreement aimed at eliminating technical barriers to trade and 2) when the most economically important participating country has strict consumer and environmental protection standards. Thus trade among the member governments of the European Union is most likely to lead to 'trading up,' and a number of studies have found evidence of such a dynamic (Peterson, 1997; Sbragia, 1993; Scharpf, 1996; Vogel, 1993, 1995; Young and Wallace, 2000).

The simmering transatlantic dispute over genetically modified food, however, presents a 'hard case' for 'trading up.' First, the 1995 New Transatlantic Agenda and, more specifically, the 1998 Transatlantic Economic Partnership, which structure the bilateral EU-US relationship, do not provide a strong impetus for eliminating regulatory barriers, although they do provide a framework for diffusing disputes (Egan, 2001; Peterson, 2001). In addition, the multilateral trading system that frames the transatlantic relationship is better suited to eliminating national rules that obstruct trade than to promulgating common approaches.

Second, although the EU is generally a large market, in 1999 it was only the third largest US agricultural export market (after Japan and Canada) accounting for 14 percent of exports (USDA, 2000a). Further, even though the US is a major agricultural exporter, domestic consumption is much more

<sup>&</sup>lt;sup>3</sup> I use stricter standard although 'more risk averse,' a formulation suggested by David Vogel in a talk to the Robert Schuman Centre on 12 December 2000, might be more accurate (if more cumbersome) as it avoids the connotation that stricter standards are objectively better.

important than exports. In volume terms, the US exports 25 percent of its grain production<sup>4</sup> and 29 percent of its soybean production (USDA, 2000b).<sup>5</sup>

Two additional (and related) reasons why the agricultural biotechnology is a 'hard case' for trading up are linked to the fact that genetically modified foods are subject to an approval process rather than having to comply with a particular standard. First, as imported products will still require the approval of the importer, domestic regulatory reform is not sufficient to secure access to the foreign market. This means that there is little incentive for domestic producers to advocate policy change, which neutralizes one of the key mechanisms of 'trading up'; the formation of 'Baptist and bootlegger' coalitions between firms seeking competitive advantage through stricter regulations and civic interests<sup>6</sup> pursing higher levels of protection (Vogel, 1995).

Second, domestic policy change is likely to be very difficult because instead of trying to change a specific standard (the outcome of the regulatory process), as is usually the case, one is seeking to change the process itself. In other words, one needs to change domestic institutions, not just outcomes. Institutions are resistant to change because the political hurdles to reforming them are high (Hall, 1986; Krasner, 1982; North, 1990; Thelen and Stienmo, 1992). As will become clear in the following section, the institutions involved are rooted in deep-seated features of the respective regulatory systems, such as the role of science, attitudes to risk and the political independence of regulatory agencies. To the extent that there is change, therefore, it is unlikely to be radical and it is most likely to occur if it is along the same 'trajectory' as the existing institutions.

Despite these reasons not to expect it, at least limited 'trading up' has occurred in the United States, as Section V demonstrates. The following sections contrast the two approval processes, mapping the point of departure for US reform, and examine the economic implications of the differences between them.

<sup>5</sup> Together these account for 80 percent of US bulk commodity exports (USDA, 2000a).

<sup>&</sup>lt;sup>4</sup> Wheat, rice, corn, oats, barley, sorghum grain, and feedstuffs.

<sup>&</sup>lt;sup>6</sup> Helen Wallace and I introduced the term 'civic interests' to embrace 'those interests other than those of producers that are relevant to both individual items of market regulation and the broad policy impact.' The term captures the notion that there are distinct interests that most members of a polity all else being equal would prefer but that societal preferences often differ as to what price is warranted to realize those interests (Young and Wallace, 2000: 2, 11).

## III. Approving Biotechnology Products: Why? Versus Why Not?

In order to set the scene for both the trade dispute and the policy changes underway in the US, it is necessary to survey the origins and characteristics of both regulatory systems. I begin with a discussion of the US regulatory regime prior to the reforms initiated in May 2000. I shall return to these reforms in Section V when I examine in detail the impact of the trade dispute on US domestic regulatory politics. My discussion of the EU's regime will focus on the system in place, but will include a summary of new procedure adopted in March 2001. In the following section I will identify the principal differences, both in terms of procedures and outcomes, between two regulatory regimes and draw out the implications for trade in agricultural products.

Three issues are the focus of regulation of agricultural biotechnology:

- 1. Whether and under what conditions may a genetically modified crop be grown (environmental protection);
- 2. Whether food produced from genetically modified crops is safe for human (or animal) consumption (consumer protection);
- 3. What information should consumers be given about a genetically modified food (consumers' right to know).

Although the US and EU regulatory systems address these same issues, they do so very differently. This UK's House of Lords Select Committee on the European Communities pithily characterized the difference as 'Why not?' versus 'Why?' (House of Lords, 1998: para 44).

# The United States: Why not?

The US framework for regulating biotechnology, the Coordinated Framework for the Regulation of Biotechnology, was established in 1986 the White House's Office of Science and Technology at the height of deregulation in the United States (Shapiro, 2000; Vogel, 2000). The centerpiece of this framework was the 'substantial equivalence' of products developed using biotechnology and those produced using traditional means; genetically modified foods are not considered inherently different from other foods. This implied that no special regulatory mechanisms were needed, and responsibility for overseeing agricultural biotechnology was apportioned among the agencies already responsible for food safety: the United States Department of Agriculture (USDA), the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA).

Before addressing the specifics of the regulation of biotechnology in the US it is, therefore, necessary to sketch some key features of broader food-safety framework. US regulatory agencies must follow procedural requirements laid down by Congress. In particular, the Administrative Procedure Act specifies that final regulations must be justified by policy rationale, scientific bases and legal authority (US, 2000). In addition, US regulatory decisions are subject to legal review and often end in litigation (Jasanoff, 1987). These two features combine to lead agencies to base decisions closely on scientific evidence so that they can withstand legal challenge and judicial scrutiny (Andersen, 1999; Vogel, 2000). This approach has been labeled 'sound science' by its proponents (e.g., Andersen, 1999; White House, 2000). Industry's legal responsibility to produce safe food and the attendant producer liability are also crucial elements of the US food safety system (US, 2000: 282).

The **USDA** is responsible, under the Federal Plant Pest Act (FPPA) for protecting plants and for safeguarding US agriculture. As such, it is the lead agency for the oversight of environmental release of genetically modified plants and animals (McCammon, 1999). If, however, the crop is going to be planted on more than 10 acres the EPA must also give its approval. Following field trials a company can apply to the USDA for non-regulated status, which means that the crop can be grown without site-specific permits. Such approval is thus effectively necessary for commercial production.

Field tests of GM crops began in the US in 1988, and the first GM crop was commercially planted in 1995. As of early 2001 the USDA had approved 54 of 76 petitions submitted for non-regulated status, and nearly 75 million acres of GM crops were growing in the US (out of 109.2 million acres worldwide) (James, 2001). In 1999 GM varieties accounted for half of all soybean acreage in the US, 55 percent of cotton acreage and 33 percent of corn acreage (James, 2000). Although overall acreage of GM crops grown in the US increased in 2000, with a particularly large increase in GM cotton, the area of GM corn in the US decreased (James, 2001).

The **EPA**'s responsibility for GM crops is related to its responsibility for regulating pesticide residues in food under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA) and microorganism products under the Toxic Substances Control Act (TSCA) and to its oversight of the National Environmental Policy Act (NEPA). It sets acceptable limits for pesticide residues in food and is responsible for assessing whether plants genetically modified to be pest resistant exceed these

Current Status of Petitions, http://www.aphis.usda.gov/biotech/petday.html, visited 8 February 2001.

limits. It also assesses the impact of exposure and toxicity of the plant-pesticide to non-target organisms, such as wildlife and beneficial insects.

As of early 2001 the EPA had registered 21 plant-incorporated protectants<sup>8</sup> (ten of which are products for a *Bacillus thuringiensis* (*Bt*) protein/gene complex). The *Bt* registrations initially are for a limited time. <sup>10</sup>

The **FDA** has primary responsibility for regulating foods derived from GM crops. According to the FDA's 1992 policy, foods developed through genetic modification are not inherently dangerous and, except in rare cases, should not require extraordinary premarket testing or regulation. In essence, genetically modified foods should be regulated as ordinary foods unless they contain substances or demonstrate attributes that are not usual for the product Premarket approval is required only if there is scientific (Levitt, 2000a). uncertainty about safety, that is if the substances intentionally introduced by genetic engineering are not functionally very similar to others commonly and safely consumed, and thus generally recognized as safe (GRAS) (Maryanski, 1999). Until 2001 even prior notification was voluntary, but was sought in practice (Maryanski, 1999). Labeling is required only if the composition of the genetically modified product differs significantly from what is expected (e.g., in nutritional value) or if it contains potential allergens (Levitt, 2000a; Maryanski, 1999).

The first commercialized GM food product, fermentation-produced chymosin (FPC), which is used in making cheese, was approved by the FDA in 1990. By November 2000 the FDA had approved 48 foods derived from new plant varieties derived through genetic modification.<sup>11</sup>

# The European Union: Why?

EU rules on biotechnology were developed as part of the project to create the single European market. The objective is thus to have a common approval for all biotechnology products grown or sold in the EU's 15 member states. Crucially, however, the member governments do not fully trust each other or the

<sup>&</sup>lt;sup>8</sup> Previously called 'plant-pesticides' but Congress thought that the term would put consumers off.

<sup>&</sup>lt;sup>9</sup> 'EPA Plant Pesticide Regulatory Decisions' at <a href="http://www.aphis.usda.gov/biotech/EPA/index.html">http://www.aphis.usda.gov/biotech/EPA/index.html</a> accessed on 8 February 2001.

The registrations for Bt corn and cotton were due to expire in April and January 2001, respectively, but have been extended until September 2001, while the agency revises its approval procedures.

<sup>11 &#</sup>x27;Foods Derived from New Plant Varieties Derived through Recombinant DNA Technology: Final Consultations under FDA's 1992 Policy,' November 2000, http://vm.cfsan.fda.gov/~lrd/biocon.html

European Commission to regulate such products properly. <sup>12</sup> As a result, any member government can impede the approval of any product. In addition, the EU's rules on biotechnology include safeguard clauses, which permit member governments under certain circumstances to exclude from their territories biotechnology products that have been approved for sale in the EU.<sup>13</sup>

The EU's approach to agricultural biotechnology and particularly how the rules are implemented also reflect a more general (and relatively recent) emphasis on the 'precautionary principle' as an important tool of risk management (Vogel, 2001). The precautionary principle emphasizes a cautious approach when existing scientific understanding is incomplete or when there is not a consensus about the nature of a threat (PIU, 2000). The increased emphasis on a 'precautionary' approach to agricultural biotechnology has its roots in a number of recent regulatory failures concerning consumer safety in Europe: Bovine Spongiform Encephalopathy (BSE, or 'mad cow' disease) in the UK and now elsewhere; HIV-tainted blood in France; and dioxin-contaminated food in Belgium (Pollack and Shaffer, 2001; Vogel, 2001).

The EU's approach differs in four fundamental and crucial differences from the US system. First, in effect biotechnology products are considered inherently different from those produced via other means; 'substantial equivalence' is rejected.<sup>14</sup> Second, the European approval process provides much greater scope for the consideration of non-scientific factors. Third, consumers' right to know is given greater weight. Fourth, there are many more veto points in the approval process.

The approval of agricultural biotechnology in the EU is governed by: *Directive 90/220/EEC* on the deliberate release into the environment of genetically modified organisms (field trials; commercial crops; foods containing genetically modified organisms; e.g., tomato); and *Regulation 258/97* on novel

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<sup>&</sup>lt;sup>12</sup> The Commission (1998: 3) has noted that assessments by one member government are 'usually' not accepted by other member governments. For a discussion of how the lack of trust affects the single market, see Previdi, 1997.

<sup>&</sup>lt;sup>13</sup> Such safeguard clauses are not uncommon in EU law. Most prominently, Article 95(5) of the Treaty of Rome provides the right of member governments to exclude products so long as it has scientific reasons for doing so.

<sup>&</sup>lt;sup>14</sup> This was a source of contention within the Commission when Directive 90/220 was being developed. The Directorates General responsible for agriculture, industry and research favored regulation based on safety, quality and efficacy. The Directorate General responsible for the environment, however, favored regulation based on the process by which the product is produced (Patterson, 2000).

foods (foods derived from biotechnology, e.g. tomato paste or ketchup). <sup>15</sup> These correspond roughly to the two main regulatory concerns about agricultural biotechnology identified earlier: its environmental impact and its implications for food safety, respectively.

#### Deliberate Release

The deliberate release directive was adopted in 1990 (a replacement directive was adopted in March 2001) and has been the principal focus of the transatlantic trade dispute. It requires that a manufacturer or importer of a genetically modified product seek the prior approval of the government of the member state in which the product is first going to be grown or sold. If that government evaluates the submitted information favorably, the dossier is forwarded to the Commission and to the other member governments for consideration. If none of the other member governments raise an objection, the product may then circulate freely throughout the EU. Only three varieties of GM carnations have been approved by this procedure.

If, as has been much more common, any member government raises an objection, a decision has to be taken at the EU level through a centralized procedure. The Commission, in the light of scientific advice, makes a proposal to a Regulatory Committee (composed of representatives of the member governments). If the Committee does not give a favorable opinion (by qualified majority vote), the proposal is forwarded to the Council, which can adopt the Commission's proposal by qualified majority. It can reject the Commission's proposal only by a unanimous vote. If the Council does not take a decision within three months, the Commission decides. Thus the Commission is obliged to authorize a genetically modified organism, if the application complies with EU rules and is not unanimously rejected by the Council within the fixed deadline. This is what happened in 1997 when the Commission approved a variety of *Bt* corn developed by Ciba-Giegy (now Syngenta) (Stewart and Johanson, 1999).

Since Directive 90/220 entered into force in October 1991, 18 authorizations for the commercial release of GM crops have been approved, only two of these are food crops (8 are feed crops). There have been no approvals since October 1998, however. This situation was politically if not

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<sup>&</sup>lt;sup>15</sup> A third measure, Directive 90/219/EEC governs the contained use of genetically modified micro-organisms. The European Medicines Evaluation Agency is responsible for evaluating all medicines derived from biotechnology.

<sup>&</sup>lt;sup>16</sup> Two varieties of genetically modified carnation were approved by member state consent in October 1998. The most recent food/feed crops were approved (by the centralized procedure) in April 1998.

legally formalized in June 1999 when the Danish, French, Greek, Italian and Luxembourg governments adopted a declaration suspending new authorizations pending the adoption of a revised directive (Council, 1999).

Although the Commission has proposed the authorization of five additional crops – two cotton, two rape seed (canola), and one fodder beet – the member governments, operating through the Regulatory Committee, have not approved their authorization. In the case of the two cotton crops the Council failed to act, but the Commission, in the light of the hostile response to its authorization of Ciba-Geigy's *Bt* maize, has not approved the cotton varieties. With respect to the other three crops, the member governments postponed consideration pending additional information from the companies concerning how they would respond to new tracability and labeling requirements begin developed as part of the revised directive (*Agence Europe*, 11/3/00).

Further, a number of member governments are refusing to accept GM crops that have been authorized. The Austrian, French, German, Greek and Luxembourg governments have invoked the 'safety clause' (Article 16) of Directive 90/220 to ban temporarily varieties of GM maize and canola (oilseed rape). The Commission is currently pursuing eight cases against these member states. In each case the Commission's Scientific Committee on Plants has deemed the bans unjustified. Member governments, however, have been reluctant to condemn others' measures, leaving the ball in the Commission's court (*Agence Europe*, 13/1/98; 16/4/98; 12/9/98). The Commission, however, has thus far not proceeded further.

# The Revised Directive (2001/18/EC)<sup>18</sup>

Motivated by concern for the implications of the EU's slow approval process for the competitiveness of the European biotechnology and agriculture industries and frustration at the fragmentation of the single market caused by governments' invoking the 'safeguard clause,' the Commission proposed amending directive 90/220/EEC in February 1998 (Commission, 2000a). The new directive places greater emphasis on precaution and environmental risk assessment based on common principles; limits consents to 10 years (which may be extended upon review); and requires tracability, monitoring, and labeling throughout the production process. It also makes more of the importance of the principle of free circulation and tightens the conditions under which the 'safeguard clause'

<sup>18</sup> Official Journal, L 106, 17 April 2001.

<sup>&</sup>lt;sup>17</sup> Interview with a Commission official, San Domenico, 4 Dec. 2000.

can be invoked.<sup>19</sup> There is also a slight, but potentially important change in the decision rules in the event that an EU decision is required. If the Regulatory Committee votes against a Commission proposal by a qualified majority, the Commission will re-examine its proposal.

Whether the stricter rules will clear the way for new approvals, however, is unclear. When the Council reached its political agreement on the directive in June 1999, the Austrian, Belgian, Dutch, Finnish, German, Spanish and Swedish governments attached a declaration stating their intention to take a 'thoroughly precautionary approach' in authorizations and noting the possibility for member governments to introduce stricter measures in conformity with Article 95 of the Treaty of Rome (Council, 1999). Further, the Austrian, Danish, French, Greek, Italian and Luxembourg governments have apparently indicated that, although they did not block the new directive, they would like the moratorium to remain in effect (*New York Times*, 15 Feb. 2001).

# *The Novel Food Regulation (Regulation 258/97)*

The authorization procedure for GM foods is broadly similar to that in Directive 90/220/EEC. The most significant difference is that the Regulation provides for a simplified procedure for foods derived from genetically modified crops but no longer containing genetic modification and which are 'substantively equivalent' to existing foods with respect to composition, nutritional value, metabolism, intended use and the level of undesirable substances. In such cases, a company need only notify the Commission when placing a product on the market and provide either scientific justification that the product is substantively equivalent or an opinion to that effect from the competent authority of a member state. Eleven such products have been notified to the Commission (Commission, 2000a). The Italian government, however, considers that some of these products are not 'substantially equivalent.' In August 2000 it invoked the 'safeguard clause' (Article 12) and suspended trade and use of products derived from four varieties of GM maize (SCF, 2000). In September 2000 the EU's Scientific Committee on Food issued its opinion that the ban was not justified by the evidence provided by the Italian authorities (SCF, 2000).

Two genetically modified food plants – a variety of soy and a variety of maize – were approved under Directive 90/220/EEC prior to the entry into force of the Novel Foods Regulation. To date no products consisting of or containing live GM crops have been authorized under the Novel Food Regulation (Commission, 2000a), although nine applications are pending.

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<sup>&</sup>lt;sup>19</sup> From having 'justifiable reason' to consider a product a risk, the member government must have 'new or additional information' affecting the environmental risk assessment or reassessment of existing information on the basis of new or additional scientific knowledge.

#### Labeling

Labeling is mandatory for all authorized genetically modified products in which DNA or protein resulting from genetic modification is present.<sup>20</sup> This applies to seeds, plants and foods. Commission Regulation 49/2000 requires labeling if genetically modified content exceeds 1 percent ('adventitious' or accidental presence). Specific labeling requirements (under Commission Regulation 50/2000) apply to foods and food ingredients containing additives or flavorings derived from genetic modification.

## **IV.** The Contours of the Dispute

As the preceding discussion illustrates there are significant philosophical and institutional differences between how the EU and US approach the approval of agricultural biotechnology products. These are summarized in Table 1.

Table 1. Summary of US and EU approaches to the regulation of biotechnology

Aspect	US	EU	
Philosophical			
View of biotech	'Substantially equivalent'	Inherently different (de facto)	
Approach to risk management	'Sound science'	'Precautionary principle'	
Consumers' right to know	No	Yes	
Institutional/Regulatory			
Decision-making style	Administrative	Political (de facto)	
Pre-release notification	Field tests – mandatory		
	Pesticides - mandatory	Mandatory	
	Foods – Voluntary if GRAS		
Approval required	Field tests – yes		
	Pesticides – yes	Yes	
	Foods – no if GRAS		
Labeling	Only in specific instances	Mandatory	

Source: augmented and adapted from McGarity and Hansen, 2001.

Not surprisingly, these differences have produced significantly different outcomes in terms of crops approved. The US authorities has approved the commercial growing of 54 varieties of genetically engineered crops and 48 foods derived from these new plants. The EU has approved 11 genetically engineered crops, only 3 of which (including a variety of tobacco) are for human consumption. Two of the 11 can only be used in breeding activities and three are approved only for importation and processing (Commission, 2000a).

<sup>&</sup>lt;sup>20</sup> The Novel Foods Regulation requires labeling of all processed foods and food ingredients derived from GM crops (among others). Council Regulation 1139/98 extended that requirement to the two GM crops approved before the Novel Food Regulation was adopted.

The trade dispute began to simmer during 1997 when US companies began to complain about the EU's slow and opaque approval process (USTR, 1998a). The banning of some EU-approved GM products by some EU member governments also prompted concern. The dispute, however, really intensified when the EU adopted its rules on mandatory labeling and burst into flame with the announcement of a *de facto* moratorium on approvals by five member governments in June 1999.

Table 2 compares the US and EU approvals for the crops in which biotechnology is most used and reports the importance of US exports to the EU. Box 1 chronicles the key events in the dispute.

**Table 2. Comparison of approvals** 

	US		EU		
Crop	GM varieties	GM as % of	Exports to	GM varieties	GM varieties
	approved	production	EU as %	approved	with MS bans
	$(2000)^a$	$(1999)^{b}$	production	$(2000)^{c}$	(2000)
Corn	15	33%	1.5% <sup>d</sup>	4	4
			Feed: 63% e		
Soybeans	5	50%	15% <sup>f</sup>	1	0
Cotton	4	55%	clothing only	0	0
Canola	2	15% <sup>g</sup>	oil only	2	2

#### Sources:

Although many more varieties of genetically modified corn and soybean are approved in the US than in the EU, less than 5 percent of US GM corn production is of varieties not yet approved in the EU<sup>21</sup> and virtually all US GM soybean production is of the one variety approved in the EU and is kept separate from that which is not (ASA, 2000).

Because corn gluten feed, the major corn-derived product exported to the EU, has been processed and cannot grow, it is not affected by differences in approvals.<sup>22</sup> The processed oil from six varieties of GM oilseed rape have been approved in the EU under the notification procedure of the Novel Foods Regulation (Commission, 2000a). Likewise, clothing produced from GM cotton is not affected, and the US does not export raw cotton to the EU.<sup>23</sup>

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<sup>&</sup>lt;sup>a</sup> Wallace Center (2000)

<sup>&</sup>lt;sup>b</sup> James (2000)

<sup>&</sup>lt;sup>c</sup> Commission (2000a)

<sup>&</sup>lt;sup>d</sup> 1995 FAO (data for subsequent years incomplete)

<sup>&</sup>lt;sup>e</sup> Interview, former representative of the Corn Refiners Association, 8/1/01.

<sup>&</sup>lt;sup>f</sup> 1997 ASA (1998)

g Commission (2000b)

<sup>21</sup> http://www.ncga.com/11biotechnology/know\_where/statement.htm

<sup>&</sup>lt;sup>22</sup> Interview with a former representative of the Corn Refiners Association, Washington, DC, 8 Jan. 2001.

<sup>&</sup>lt;sup>23</sup> Interview with a USDA official, Washington, DC, 11 Jan. 2001.

Box 1. Key events in the transatlantic biotechnology dispute

Date	EU	US	International
2/96	First food crop approval		
2/97	Aust. and Lux. ban GM corn		
5/97	Novel Foods Regulation		
2/98	-		Negotiation of Biosafety Protocol starts
4/98	Insufficient support for action against Aust. & Lux. bans		
	4 food crops approved		
5/98	Commission proposal		
7/98		Raised EU labeling in WTO TBT Committee	
9/98	Greece bans 1 GM oilseed rape		
10/98	Last approvals before moratorium		
11/98	France bans 2 GM oilseed rapes		
2/99	Regulatory Committee not approve 2 GM cottons		1st meeting of TEP Biotechnology Group Cartagena meeting on
2/00		House bearing on biotech	Biosafety Protocol
3/99		House hearing on biotech. regulation	
1.10.0		Bipartisan warning against excessive EPA regulation	
4/99			TACD position on GM foods
5/99		Nature letter on Monarch butterfly	Codex meeting on labeling TAED position on GM foods
6/99	Council common position Moratorium	,	
7/99		USDA policy initiative	Montreal meeting on Biosafety Protocol
10/99		Senate hearing on biotech. regulation	Clinton-Prodi agreement TABD position on GM foods
11/99		House bill on mandatory labeling 1st FDA public hearing	
12/99		130 1 D11 puone neuring	EU-US agree 2-track approach
			WTO Ministerial
1/00	1% threshold set for labeling		Biosafety Protocol agreed
2/00		Senate bill on mandatory labeling	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
3/00	Reg. Committee postpones decisions on 3 GM varieties	House and Senate bills calling for mandatory	1 <sup>st</sup> session of the Codex biotech task force
	Germany bans GM corn	FDA approval	
4/00	Austria bans another GM corn	NRC Report	
5/00		White House initiative	<b>EU-US Summit Statement</b>
8/00	Italy bans foods derived from 4 varieties of GM corn		
9/00		StarLink found in human food	
12/00			EU-US Biotech. Consultative Forum Report
1/01		FDA proposals EPA final rule (withdrawn)	•
3/01	Revised directive adopted	` '	

The impact of any differences in approvals, however, is greatly amplified by US's commodity-based agricultural system in which crops are gathered together from farms and transported in bulk to grain elevators for subsequent distribution. The possible presence of non-approved variety of a genetically modified crop, therefore, threatens the export potential

of the entire crop. Establishing a system that keeps genetically modified and non-genetically modified crops separate ('segregation' or 'identity preservation') increases costs an estimated 12 percent over the farm price (Lin et al, 2000).

The main commodity to have been affected by the differences in EU and US approvals, therefore, is corn. US exports, estimated to be worth \$200 million per year, have essentially stopped because US producers cannot guarantee that shipments contain only EU-approved varieties.<sup>24</sup> The impact of this impediment, however, is relatively small as US corn exports to the EU were very small (less than 5 percent of all corn exports in 1995) even before the differences in approvals became a problem.<sup>25</sup>

# V. The Response in the US

The actual and potential barrier to US agricultural exports presented by the differences between EU and US approvals of GM crops has triggered a variety of commercial and political responses within the US. This section describes those responses, while the following section analyses why the political responses have taken the form they have.

# Commercial adjustment

Adaptation: Give the Europeans what they want

A number of US agricultural producers have sought to mitigate the impact of fewer EU approvals. US corn refiners have established an identity preservation system that enables them to reassure their European customers that they make every effort to use only EU-approved varieties of corn.<sup>26</sup> The American Soybean Association has worked with the biotechnology industry to ensure that the one US-approved variety of soybean (High-Oleic) that is not approved in the

<sup>&</sup>lt;sup>24</sup> Interview with a USDA official, Washington, DC, 11 Jan. 2001.

<sup>&</sup>lt;sup>25</sup> The US has a quota that secures historical US exports to the Iberian peninsula as the result of a trade dispute following Portuguese and Spanish accession to the EU in 1986. In 1995, the last year for which FAO statistics are complete Spain accounted for 62 percent of US corn exports to the EU; Portugal for 17 percent and Austria for 13 percent.

<sup>&</sup>lt;sup>26</sup> Interview with a former representative of the Corn Refiners Association, Washington, DC, 8 Jan. 2001.

EU is grown on a small scale and kept separate from the rest of the crop (ASA, 2000). The US wheat industry, half of whose production is exported, is pursuing a similar line, insisting that Monsanto put in place a system to strictly segregate GM wheat from ordinary varieties even before the company has secured regulatory approval in the US (US Wheat Associates, 2001).

The National Corn Growers Association (NCGA) has established a 'Know before you grow/know where to go' program that provides information on companies selling only those GM corn hybrids approved for import into the EU.<sup>27</sup> Manufacturers of processed foods have sought to eliminate non-EU approved GM ingredients by changing the sourcing of certain ingredients, transferring production of some product lines (i.e., those involving corn) to the EU, and by refraining from introducing new products on the EU market. <sup>28</sup> De facto *trading up* 

More profoundly, some US farmers organizations, particularly those that are particularly export dependent, are effectively complying with EU approvals. The American Soybean Association, for example, has asked that one variety of soybean (LibertyLink) not be grown commercially until it has received regulatory approval in major export markets (ASA, 2000). In addition, the area of GM corn planted in the US decreased sharply in 2000 (James, 2001). Although there are a number of factors at play in this decrease, at least some of it is attributed to farmers' concern about access to export markets (James, 2001). The National Corn Growers Association (NCGA, 2001) says that it supports the commercial release of GM corn varieties that have been fully approved in the US and Japan (its most important export market) and for which approval is being 'aggressively' pursued in every other export market. It 'insist(s)' on due diligence in bringing products to market in a manner that does not disrupt domestic or international trade.

In addition, number of major US food companies – including, Gerber, Heinz, McGain and Frito Lay – have announced that their products will be GM free in response to the increased concern of US consumers (Pollack and Shaffer, 2001). For the same reason US sugar refiners have asked farmers not to grow genetically modified sugar beets (*Wall Street Journal*, 27 April 2001).

The various commercial responses are summarized in Table 4.

<sup>28</sup> Interview with representatives of the National Food Processors Association, Washington, DC, 9 Jan. 2001.

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<sup>&</sup>lt;sup>27</sup> http://www.ncga.com/11biotechnology/know\_where/statement.htm

<sup>&</sup>lt;sup>29</sup> Interview with a former representative of the American Corn Growers Association, Washington, DC, 11 Jan. 2001.

Table 4. Commercial responses to differences in EU and US approvals.

Commercial response	Industry
Provide information on EU-approved varieties	Corn growers
Established identity preservation system	Corn refiners
	Wheat growers
	Soybean growers
Non-commercialization of non-EU-approved varieties	Soybean growers
Not accept GM ingredients	Sugar refiners
Change sourcing of ingredients	Food manufacturers

# De jure Trading Up: Incremental Reform

The initial US response to the EU's new rules was incomprehension and irritation. Until mid-1999 Congressional testimony by Clinton Administration officials and industry representative and statements by Congresspeople of both parties repeatedly depicted the EU's approval process as at best over politicized and at worst protectionist (see, for example, Barshefsky, 1999; Dykes, 1998; Eisenstat, 1999, Johnson, 1999; Lugar, 1999, Smith et al, 1998). In addition, the US regulatory system was generally up-held as appropriate, and certainly adequate. The 3 March 1999 hearing of the House Committee on Agriculture's Subcommittee on Risk Management about agricultural biotechnology, which did not include testimony from any civic interest groups, did not hear one word of criticism of the US regulatory system.<sup>31</sup> Later that month Republican and Democratic Representatives cautioned the EPA against tightening its regulation of biotechnology on the grounds that it was unnecessary and that it might harm the industry.<sup>32</sup> In October 1999 representatives of the EPA (Andersen, 1999), FDA (Maryanski, 1999), USDA (McCammon, 1999) and industry (Barach, 1999; Giddings, 1999; Kushner, 1999) all assured the Senate Committee on Agriculture, Nutrition and Forestry that the US regulatory approach was appropriate.

During the second half of 1999, however, things began to change. In July 1999 US Secretary of Agriculture Dan Glickman announced a new policy initiative on agricultural biotechnology. In November 1999 the FDA held the first of three public meetings on its procedures for approving and labeling

http://commdocs.house.gov/committees/ag/hag1066.000/hag1066\_0.htm.

http://commdocs.house.gov/committees/ag/hag1066.000/hag1066\_0.htm.

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<sup>&</sup>lt;sup>30</sup> See also House of Representatives, Committee on Agriculture, Subcommittee on Risk Management hearing on Agricultural Biotechnology,

<sup>&</sup>lt;sup>31</sup> House of Representatives, Committee on Agriculture, Subcommittee on Risk Management hearing on Agricultural Biotechnology,

<sup>&</sup>lt;sup>32</sup> Republican, Democrat Committee Leaders Urge Caution in New Plant Regulations, Request EPA Re-propose Plant-Pesticide Rule,' http://agriculture.house.gov/106/pr990324a.html.

genetically modified foods. In May 2000 the Clinton Administration announced agricultural biotechnology initiatives to 'strengthen science-based regulation and consumer access to information' (see Box 2).

#### **Box 2 May 2000 White House initiatives**

- an interagency assessment of federal environmental regulations pertaining to agricultural biotechnology;
- mandatory prior notification to the FDA of agricultural biotechnology crops or products to be introduced into the food supply;
- public access to information submitted to the FDA and the agency's conclusions;
- an expanded program of research focusing on current and future safety issues;
- the FDA to develop guidelines for voluntary efforts to label food products;
- USDA to work with farmers and industry to facilitate the creation of reliable testing procedures and quality assurance programs for differentiating non-GM products;
- USDA and the State Department to provide farmers with timely information on oversees markets; and
- USDA, FDA, EPA and the State Department to enhance domestic and foreign public education and outreach activities to improve understanding of the US regulatory process.

Source: White House, 2000.

The USDA moved first. On 13 July 1999 then Secretary of Agriculture Dan Glickman (1999) acknowledged that biotechnology raises a number of questions that have not been adequately addressed. In particular he warned that if consumers do not trust the regulatory process they would not accept agricultural biotechnology. In response he announced a new approach to biotechnology based on five principles: arm's length regulation, consumer acceptance, fairness to farmers, corporate citizenship and free and open trade. Among the specific initiatives that accompanied this policy statement were a review of the USDA's approval process by the National Academy of Sciences (due in autumn 2001); a review to reinforce the separation between the Department's regulatory and promotion functions; and the establishment of an Advisory Committee on Biotechnology to address social and economic implications of agricultural biotechnology.

The FDA's public meetings during late 1999 and early 2000 produced what the Agency heard as three clear messages: 1) that there is no new scientific information that raises concern about the safety of foods already on the market; 2) that some of public is not convinced that the FDA's regulatory approach is adequate; and 3) that there is divided opinion on whether GM foods should bear special labeling (FDA, 2001a). Although it stands by its policy of assuming that genetically modified foods are safe when the proteins and other substance s involved do not differ significantly from those commonly occurring in food, the FDA acknowledges that breeders utilizing genetic engineering can introduce genetic material from a much wider range of sources, which may require the

they be regulated as food additives (which would require premarket approval), and that the increasing introduction of multiple genes may cause unintended effects to become more common (FDA, 2001a).

Consequently, the FDA proposed introducing a system of mandatory premarket *notification* of foods (and animal feed) derived from GM crops, whether produced in the US or imported. If a product that the FDA is not convinced is safe is marketed, the FDA will take legal action, however, the FDA says it does not have the legal authority under its current statutes to require premarket *approval* (unless it is classed as a food additive) (Jacobson, 2001). The FDA is also proposing to increase the availability of information about notifications, but within the limits of commercial confidentiality set by the Freedom of Information Act.<sup>33</sup>

The FDA (2001b) contends that under its historical interpretation of the Federal Food, Drug and Cosmetic Act (Section 403) it can require labeling only when it contains information that is 'material' with respect to the consequences that may result from the use of the food. The FDA, therefore, does not consider that it has the power to require labeling of genetically modified foods beyond what is already required, and advanced draft guidelines for only voluntary labeling. In October 2000 the US District Court for the District of Columbia accepted the FDA's view that special labeling for genetically modified foods as a class is not required solely because of consumer demand or because of the process used to develop them (FDA, 2000). Consumer organizations, however, contend that the FDA could require mandatory labeling by changing its interpretation of the 'materiality' concept in the Federal Food, Drug and Cosmetic Act (see, for example, McGarity and Hansen, 2001).

There is also some reason to question the constitutionality of requiring labeling of GM foods.<sup>34</sup> A 1996 Second Circuit Court ruling in *International Dairy Foods v. Amestoy,*<sup>35</sup> overturned, on the grounds that it contravened the First Amendment, a Vermont law requiring manufacturers to identify products that were or might have been derived from dairy cows treated with rBST because it required companies to 'speak' when they would rather not. Some (see, for example, McGarity and Hansen, 2001) contend that if labeling measures were justified on health and safety grounds rather than just the consumers right to know (as was the case in Vermont), the constitutionality problem would be defused.

<sup>35</sup> International Dairy Foods v. Amestoy, 92 F.3d 67 (2d. Cir. 1996).

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<sup>&</sup>lt;sup>33</sup> The FDA's view is that most of the data submitted as part of a pre-market biotechnology notice (PBN) would not constitute trade secrets and so could be made public.

<sup>&</sup>lt;sup>34</sup> For a discussion see McGarity and Hansen, 2001.

On 17 January 2001 the EPA adopted final rules on plant-incorporated protectants (PIPs) (previously 'plant-pesticides'). These rules largely formalized the EPA's existing process (EPA, 2001), which was laid out in a 1994 proposed rule. The EPA is also considering whether to finalize exemptions for three categories of PIPs<sup>36</sup> from regulatory oversight, which were included in the 1994 proposal. The elimination of these exemptions was advocated by a April 2000 National Research Council report (NRC, 2000). This report, among other things (see below), recommended strengthening the EPA's regulatory role.<sup>37</sup> The EPA has invited comment on National Research Council report. On 20 January 2001, at the White House's request, the proposed rule was withdrawn while the new administration studies it.

#### Other Initiatives

In addition to the changes to administration policy, there have been a number of legislative initiatives at the federal (see Table 4) and state levels since late 1999 (see Table 5). These initiatives have tended to take a much more skeptical line towards biotechnology and a more favorable approach to consumers' right to know. Given the predominance of Democratic sponsors of federal legislation and Bush Administration's generally hostile attitude towards regulation (see, for example, *New York Times*, 23/5/01), it is highly unlikely that the legislative initiatives that go beyond what is already in train will have much impact. There may be more movement at the state level where eight states are considering requiring mandatory labeling (Maine is to hold a referendum on the issue in November 2001).

<sup>&</sup>lt;sup>36</sup> These exceptions are: PIPs derived through genetic engineering from sexually compatible plants; PIPs that act primarily by affecting the plant (e.g., thicker wax cuticles); and PIPs based on viral coat proteins (substances that encapsulate and protect the genetic material of certain plant viruses).

<sup>&</sup>lt;sup>37</sup> Interview with an EPA official, Washington, DC, 9 Jan. 2001.

**Table 4 Federal Legislative Initiatives** 

Date	Bill	Aim	Sponsor(s)
11/99	HR3377	Mandatory labeling	Kucinich (OH), Metcalf, Bonior (MI),
			Defazio (OR), Smith (NJ), Doyle (PA),
			Lipinski (IL), Brown (OH), Hinchey
			(NY), Schakowsky (IL), Norton (DC),
			Stark (CA), Woolsely (CA), Mink
			(HI), Martinez, McDermott (WA), Lee
			(CA), Waters (CA)
2/00	S2080	Mandatory labeling	Boxer (CA)
3/00	HR3883	Treat as food additives	Kucinich (OH), Metcalf, Hinchey
			(NY), Conyers (MI), Sanders (I-VT),
			Woolsely (CA), Lee (CA)
3/00	S23115	Treat as food additives	Moynihan, Reid (NV), Boxer (CA).
10/00	S3184	Mandatory FDA pre-market	Durbin (IL)
		approval, more research,	
		increased access to information	
1/01	HR115	Education about and further	Holt (NJ)
		research on agricultural	
		biotechnology	

*Notes*: Unless otherwise noted sponsors are Democrats. Absence of state denotes not reelected in 2000.

**Table 5 Active State legislative initiatives** 

Aim	State(s)
Mandatory labeling	CA; CO; MA; ME; MI; NH; PA; VT
Mandatory environmental assessment	HI; MN, TX (adopted 1/95)
Moratorium on planting GM	MA, MN; NY, VT; MD (terminator gene)
Higher standard of legal liability	MA
Legal liability for contaminating non-GM	MN, NB
Mandatory labeling of rBST milk products	NY
Consider ban in school food	OK
Protection of GM crops	CA, SD

Source: adapted from Grimm, 2001 and <a href="http://www.bio.org/govt/testimony2001.html">http://www.bio.org/govt/testimony2001.html</a>.

Note: Unless otherwise stated all legislation are bills.

## VI. Explaining Observed Change

Although the changes in US policy are modest they are changes, and the changes in US *politics* are substantially more pronounced. The timing of the changes, starting in mid- to late-1999, suggests a link to EU policies, particularly the adoption of mandatory labeling in February 1998 and the announcement of a de facto moratorium in July 1999. There appear to be two main impacts of EU policies: 1) to heighten the awareness of US civic interest organizations to the potential pitfalls of biotechnology and 2) to provide an exemplar that is deployed by US civic interest organizations when arguing for domestic regulatory change. These impacts have had knock on effects on US consumer attitudes to biotechnology and, consequently, on how some industry organizations view stricter regulation.

#### The Mobilization of Civic Interests

US government (Levitt, 2000b)<sup>38</sup> and European Commission officials,<sup>39</sup> and representatives of industry associations<sup>40</sup> and civic interest organizations (Tucker Foreman, 1999)<sup>41</sup> attribute the greater mobilization of civic interest groups in the US at least in part to the publicity surrounding the EU-US trade dispute (see also Pollack and Shaffer, 2001). The impact seems to have been most pronounced on the US consumer organizations.

Prior to the trade dispute with the EU and their engagement in the Transatlantic Consumer Dialogue (TACD), which brought together consumer organizations from the EU and US, US consumer groups did not campaign on agricultural biotechnology, even though they had been very involved on food safety issues, including pesticide residues. In December 1998, for example, a representative of Public Citizen addressing the FDA Science Forum on Biotechnology explicitly left aside food safety issues to concentrate on the regulation of biologics and drugs (Wolfe, 1998). Although the Consumers Union participated in the 'Global Days of Action against Gene Foods' in April 1997, it did not issue an independent news release on agricultural biotechnology until August 1999 in conjunction with the first *Consumers Report* (September 1999) article on the subject, while the Consumer's Choice Council did not do so

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<sup>&</sup>lt;sup>38</sup> Interview with a USDA official (Washington, DC, 12 Jan. 2001).

<sup>&</sup>lt;sup>39</sup> Interview with a Commission (Washington, DC, 10 Jan. 2001).

<sup>&</sup>lt;sup>40</sup> Interview with representatives of the European-American Business Council (Washington, DC, 8 Jan. 2001) and National Food Processors Association (Washington, DC, 9 Jan. 2001).

<sup>&</sup>lt;sup>41</sup> Interviews with representatives of the Centre for Food Safety (Washington, DC, 10 Jan. 2001) and the (UK) Consumers' Association (Florence, 2 Apr. 2001).

until November 1999.<sup>42</sup> The Consumer Federation of America's first independent statement came at the FDA's hearing in November 1999.<sup>43</sup>

In fact, the main US consumer organizations first formal contribution to the policy debate on agricultural biotechnology was the Transatlantic Consumer Dialogue's statement adopted in April 1999 (see Box 3). Apparently, during the discussions within the TACD that led to the statement the US consumer organizations became sensitized to the concerns of their European counterparts.44

#### Box 3 TACD Statement on Genetically Modified Organisms, April 1999

'Since consumers are concerned about risks, the environment, socio-economic factors, ethical issues and the lack of benefit for consumers, the TACD calls upon the governments of the US and the EU to establish effective and mandatory government approval systems of human health, safety and environmental protection.

'Genetically modified (GM) foods should provide a clear showing of consumer benefits and present no harm to human or animal health or the environment.

'In order to ensure consumers' right to choose and to be informed, governments *must require* mandatory labeling of all genetically engineered foods and ingredients based on complete traceability of GMO's throughout the entire production, processing and distribution chain.'

Source: TACD, Doc No. Food-5-99 (emphasis added).

Some environmental organizations – such as the Center for Food Safety, Jeremy Rifkin's Foundation on Economic Trends and the Union of Concerned Scientists - had been active on agricultural biotechnology issues for much longer. Some of the more prominent environmental organizations – such as Friends of the Earth USA, Greenpeace USA, the Sierra Club and the US Public Interest Research Group – however, did not start actively campaigning on the issue until 1998/1999 (PBS, 2001). 45 Friends of the Earth USA, for example, did not write to US corporate executives to ask them to go GM-free until 6 August 1999,46

(http://www.consumerunion.org/news/news.html) and Consumer's Choice Council (<a href="http://www.consumerscouncil.org/ccc/gmo/gmo.htm">http://www.consumerscouncil.org/ccc/gmo/gmo.htm</a>) websites.

43 Based on a search of the Consumer Federation of America's website

46 http://www.foe.org/safefood/companyletter.html.

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<sup>&</sup>lt;sup>42</sup> Based on a search of the Consumer Union's

<sup>(</sup>http://www.consumerfed.org/releases.html)

<sup>&</sup>lt;sup>44</sup> Interviews with a Commission official (Washington, DC, 10 Jan. 2001) and representative of the (UK) Consumers' Association (Florence, 2 Apr. 2001).

<sup>&</sup>lt;sup>45</sup> Interview with a representatives of the Centre for Food Safety (Washington, DC, 10 Jan. 2001) corroborated by extensive searches of the organizations' web pages. The earliest document on GM food on the Greenpeace website

<sup>(</sup>http://www.greenpeaceusa.org/ge/gereleasestext.htm is December 1999; the earliest on USPIRG's site (<a href="http://www.pirg.org/ge/press/">http://www.pirg.org/ge/press/</a> is mid-2000; the earliest document on the Sierra Cub's website (http://www.sierraclub.org/biotech/) is August 1999; and the earliest document on Friends of the Earth's website (http://www.foe.org/safefood/) is June 1999.

more than 18 months after a its sister organization in the UK had launched a similar campaign. Although Greenpeace participated in the April 1997 'Days of Action,' it did not join a May 1998 lawsuit against the FDA's GM food policy, although it was a party to a February 1999 lawsuit against EPA approval of Bt crops (CFS, 2000).

The EU, however, was not the only, perhaps not even the major, motivator for the environmental organizations. In February 1999 negotiations began in earnest on a protocol to the 1992 Convention on Biodiversity to establish procedures for the safe transportation, handling and use of living GM organisms that might adversely affect biodiversity. Apparently more important, however, was a letter in the May 1999 issue of *Nature* that reported the findings of a laboratory study that suggested pollen from Bt corn could adversely affect the caterpillar of the Monarch butterfly. This letter sparked widespread press coverage and galvanized the US environmental movement (Pollack and Shaffer, 2001). Friends of the Earth, for example, in its letters to President Clinton and food industry CEOs urging them to go GM-free focused heavily on the implications for the Monarch (FoE, 1999a, 1999b). Although the publication of the *Nature* letter coincided with the adoption of the Transatlantic Environment Dialogue's (TAED) position on GM foods, none of the major US environmental organizations participated in the working group that produced the statement.<sup>47</sup> European and other environmental organizations apparently did, however, participate in a meeting in October 1999 to plan a campaign against agricultural biotechnology in the United States (Wall Street Journal, 12 October 1999).

Whatever the impact of the EU's policies in mobilizing US civic interest organizations, it is evident that they serve as exemplars in the ensuing policy debate. Although not entirely uncritical of the EU's regulatory regime (see, for example, McGarity and Hansen, 2001), US civic interest organizations are united in their support for two key elements of the EU regime that are lacking in the US: mandatory approval and mandatory labeling of all GM foods.<sup>48</sup> Consequently, they regularly cite what the EU is doing in support of their desired policy changes (see, for example, McGarity and Hansen, 2001; Hansen, 2000; FoE, nd; Consumer Reports, September 1999).

<sup>47</sup> http://tiesweb.org/taed/wg/agriculture/concerns gmo.html

<sup>48</sup> It should be noted that although US civic interest organizations share these reform aims they have different overarching objectives. The consumer organizations for the most part acknowledge potential benefits from biotechnology but want to ensure that is safe and advocate the consumer's right to know as a point of principle (Silberberg, 1999; Tucker Foreman, 1999). The environmental organizations tend to be much more hostile to the technology and see labeling as a means of killing the technology through market means (implication of interview of a representative of the Center for Food Safety, Washington, DC, 10 Jan. 2001).

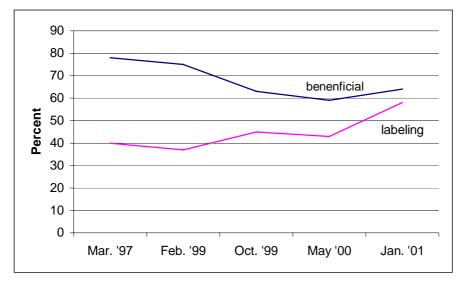
It is important to note, however, that while US consumer and environmental organizations advocate similar policy reforms, their aims are not identical. The environmental organizations tend to be much more hostile toward the new technology; seeing stricter standards and heightened consumer awareness as means of stifling it. The consumer organizations, by contrast, tend to perceive potential benefits from the technology, but demand safety and the right to choose.

## **Changing Consumer Preferences**

Following the mobilization of US civic interest organizations there appears to have been a marked decline in public support for biotechnology in the US (see Figure 1). This decline was sharpest during mid-1999 when the campaign was just beginning. The discovery in September 2000 that a variety of GM corn (StarLink) that had been approved for use only in animal feed had found its way into the human food chain appears to have had less impact on attitudes toward biotechnology, but a greater impact on consumers' desire for mandatory labeling.

Although American consumers' concern about genetically modified food appears to have increased since the trade dispute with the EU really started to simmer (see also NSF, 2000), they still tend to be less worried about the technology than their European counterparts (NSF, 2000 and see Table 6). In addition, some of the more sophisticated studies of US consumer attitudes reveal that they are at least if not more concerned about the use of pesticides than they are about genetic modification (CSPI, 2001; PIFB, 2001). Although many surveys (CSPI, 2001; PIFB, 2001) show large majorities (greater than 60 percent) of Americans favor labeling, some indicate that whether a product contains genetically modified ingredients is not their chief concern or they only favor labeling if it does not cost too much (PIFB, 2001). There are also real doubts about how much US (and European) consumers understand about genetic engineering, which makes their opinions malleable when presented with additional information (NSF, 2000; PIFB, 2001). For example, after US consumers were informed that genetically modified foods are already widely available, 19 percent of consumers who had initially indicated that GM foods are unsafe changed their answers to 'safe,' as did 37 percent of those who originally said they did not know (PIFB, 2001). In part this appears to reflect a high degree of public confidence in the key US regulatory agencies (Jenkins-Smith, cited in PBS, 2001).

Figure 1. US consumer attitudes to biotechnology<sup>49</sup>



Notes:

'beneficial' answered positively when asked if biotechnology (including in pharmaceuticals) will provide benefits to you or your family within the next five years;

'labeling' denotes support for mandatory labeling

Source: International Food Information Council (http://www.ific.org).

Table 6 Consumer understanding of agricultural biotechnology

	Percentage agreeing	
	US	EU
Eating genetically modified fruit can cause your genes to be modified	14	24
Ordinary tomatoes do not contain genes, only genetically modified ones do	14	35

Sources: Horning Priest, 2000 (US); Eurobarometer, 2000 (EU)

# **Changing Producer Views**

Despite the relatively modest (at least compared to Europe) opposition of US consumers to genetically modified foods, US agricultural producers at least are not taking any chances. In addition to the sugar refiners who are telling farmers not to grow GM sugar beets (Kilman, 2001), others are seeking policy changes. The Illinois Farm Bureau, for example, in December 2000 called for legislation requiring that GM crops must be approved for all uses (a reference to StarLink) and in all export markets before being sold (IFB, 2001). The American Soybean Association (ASA), while expressing confidence in the existing regulatory

<sup>49</sup> This data should be treated with caution as fewer people reported having heard about genetic engineering in 1999 than in 1997.

framework, would endorse requiring mandatory FDA approval of products if that would reassure consumers (ASA, 1999).

Others favored only modest reforms, and even then only since October The American Farm Bureau (AFB),<sup>50</sup> the Biotechnology Industry 1999. Organization (BIO) 51 and the Grocery Manufacturers of America (GMA) 52 supported mandatory pre-market notification to the FDA and only voluntary labeling. This is the modest reform that has been adopted so far. The National Corn Growers Association also favors voluntary labeling guidelines, but also urges biotech providers to avoid using antibiotic markers because they 'unnecessarily raise consumer concerns' (NCGA, 2001).

# More than a Response to Just the EU

Although the EU's policy seems to have acted as a catalyst to the policy debate in the US, it has not been the sole driver. As mentioned earlier, several environmental organizations had opposed agricultural biotechnology from the outset. It would also appear that concern surrounding the impact of Bt corn on the Monarch butterfly was crucial to galvanizing other US environmental organizations (PBS, 2001).

In addition, the regulatory process has not been static and has been subject to periodic review and assessment. In September 1998, for example, the FDA issued a draft guidance asking developers of biotechnology to think carefully about using antibiotic resistance markers <sup>53</sup> and stating that some markers should not be used (FDA, 1998). The development of the technology is also influencing the regulatory process. The FDA (2001) justified its heightened oversight of agricultural biotechnology on changes in techniques (increasing introduction of multiple genes and more traits intended to modify the food itself) and because foreign producers might not voluntarily consult with the FDA as US-based producers are believed to do.

In March 1999 the National Research Council (2000: xii) – in response to concerns voice by professional societies, members of Congress and others – initiated a study of the 'risks and benefits of genetically modified pest-protected plants and the coordinated Framework for Regulation of Biotechnology affecting the use of these plants.' Although generally supportive of the US regulatory regime, it found room for improvement. Its recommendations included eliminating categorical exceptions from the EPA's final rule; finalizing

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<sup>&</sup>lt;sup>50</sup> Compare Whisenhunt, (1999) and AFB (2000)

<sup>&</sup>lt;sup>51</sup> Interview with a BIO representative, Washington, DC, 9 Jan. 2001.

<sup>&</sup>lt;sup>52</sup> Compare Kushner (1999) and GMA (2001).

<sup>&</sup>lt;sup>53</sup> Antibiotic resistance genes are used to mark select transform plant cells.

an FDA guidance on the assessment of potential food allergens; expanding the quantity, quality and public accessibility of information; clarifying the scope of USDA's coverage so as to capture all GM pest-protected plants; and improving coordination among the three agencies.

In addition, as alluded to above, the StarLink episode also heightened consumer awareness of the presence of GM foods and concern about the regulatory framework. It, however, seems to have provided as an additional push to an already moving process.

In addition to additional internal dynamics, the EU is not the only export market whose rules have an impact on US producers (see Table 7). Japan, as the US's largest agricultural export market, including for corn, is particularly significant. Although Japan requires pre-market approval of GM products it has approved many more than the EU and its mandatory labeling requirements kick in only above the 5 percent threshold, which is much easier to meet than the EU's 1 percent. In addition, the concern started in the EU and spread to other countries. In many respects, it is this 'contagion' that concerns and angers US producers most about the EU's policy.<sup>54</sup>

Table 7 Mandatory labeling requirements around the world

Country	Status of rule
Australia	Pending implementation
Brazil	In force (12/00)
Czech Republic	In force (1/01)
Chile	In force (5/01)
Indonesia	In force (1/01)
Japan	In force (4/01)
Korea	In force (commodities 3/01; packaged food 7/01)
Mexico	Legislation being debated
New Zealand	Pending implementation
Taiwan	Legislation proposed
Turkey	In force (1/01)
Saudi Arabia	In force (1/01)

Source: NFPA Journal, December 2000

Further, the EU's policy has the potential to chill more directly the adoption of agricultural biotechnology in other, particularly developing, countries. Other countries that grow GM varieties of crops will face the same problem exporting to the EU that the US does and may be even less able to segregate and test their

<sup>54</sup> Interviews with representatives of the National Food Processors Association (Washington, DC 9 Jan. 2001) and US Grain Council (Washington, DC 11 Jan. 2001).

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exports to the standard demanded by the EU.<sup>55</sup> Consequently, countries that export heavily to the EU may be reluctant to grow any non-EU-approved GM crops.

#### **Constraints on Alternatives**

Part of the explanation for the change in US domestic policy is tied to the limits on other policy alternatives. The incentive for US producers to contemplate domestic policy reforms would be even lower if there were a strong prospect of forcing their trading partners to change their rules so as to eliminate the trade barriers. There are a number of reasons why this many not be a viable proposition with respect to the EU's rules.

First, although the multilateral trading system is essentially designed to remove national rules that unnecessarily restrict trade, it also imposes limits on those seeking action. Prior to the conclusion of the Uruguay Round the United States government periodically unilaterally imposed trade sanctions on countries in an attempt to get them to change their policies (see, Woolcock, 1991). The establishment of the World Trade Organization (WTO) and the introduction of binding dispute settlement, however, have introduced curbs on such unilateral action. This constraint was underlined by the EU's successful case against the US concerning Sections 301-310 of the Trade Act of 1974, which resulted in the US undertaking to act in compliance with its WTO obligations. In other words, rather than acting unilaterally, the US government would take its trade grievances to the WTO.

Consequently, it is up to the WTO's dispute settlement body to determine whether a member's policies contravene WTO rules. Only if a government is found to be in violation of WTO rules and fails to comply with the ruling, can the plaintiff government impose sanctions. Crucially, the WTO does not unequivocally favor free trade. Rather it sets limits on the exceptions to free trade. Article XX of the General Agreement on Tariffs and Trade (incorporated into the WTO) recognizes the protection of human health and safety as legitimate objectives for government action so long as the measures in question are not a means of arbitrary discrimination between countries or disguised restrictions on trade. The WTO's Technical Barriers to Trade (TBT) Agreement – which covers, *inter alia*, labeling – and the Sanitary and Phytosanitary (SPS) Agreement – which applies to the approval process of GM

<sup>&</sup>lt;sup>55</sup> The impact of EU food safety standards on developing country exports concerns the World Bank (see, for example, Otsuki, et al, 2001).

Comment by Ellen Frost at the 'The New Transatlantic Agenda at Five: A Critical Assessment' workshop, European University Institute, 20 Apr. 2001.

<sup>&</sup>lt;sup>57</sup> I am grateful to Peter Holmes for putting this insight so succinctly.

foods – also recognize protecting consumers and the environment as a legitimate reasons for a government to adopt trade-impeding regulations, although subjecting them to procedural disciplines.<sup>58</sup> The SPS Agreement requires that measures be based on an 'appropriate' assessment of the 'risks to human, animal or plant life or health' and 'taking into account risk assessment techniques developed by the relevant international organizations.' The TBT Agreement, meanwhile, only incorporates a voluntary 'Code of Good Practice for the Preparation, Adoption and Application of Standards.' Thus multilateral rules allow governments a fair degree of leeway in pursuing their policy objectives, particularly with respect to the level of risk that they are willing to accept (PIU, 2000). Consequently, it is not clear that the US would win a case before the WTO.

Several other factors further call into question the likelihood of a successful prosecution. First, the EU has not yet actually rejected any GM products, it has just not approved them. It is consequently harder to argue that the EU is taking arbitrary decisions, although there is an issue of timeliness.<sup>59</sup> Second, the EU's rules are non-discriminatory in letter and in practice; 60 more EU than US firms have products held up in the regulatory process (Commission, 2000a). Third, the EU's deliberate release directive, the focus of most concern, was being revised for much of the period of the dispute (May 1998 – March 2001), which meant that it was a moving target and might be irrelevant by the time a judgement was issued. Fourth, due to adjustment by US producers, the only product currently affected is corn, worth about \$200 million per year and accounting less than 1 percent US production. Further, strictly speaking, the EU does not prohibit corn imports from the US, but US producers are reluctant to export because of the difficulties of ensuring that no un-approved GM corn is in the shipment.<sup>61</sup> These factors are important because to bring a case the US government would want to be confident of winning and therefore would want a clear cut and important case.<sup>62</sup>

In addition, even if the US were to win the case it is unclear whether the EU's policy would change.<sup>63</sup> To start, with any change would be a long time coming. It is common for WTO cases to take two years from the time a request for a panel is filed to the adoption of the Appellate Body's report. A losing

<sup>&</sup>lt;sup>58</sup> For a fuller discussion, see PIU (2000).

<sup>&</sup>lt;sup>59</sup> Interview with a representative of the European-American Business Council, Washington, DC, 8 Jan. 2001.

<sup>&</sup>lt;sup>60</sup> Interview with a Commission official, San Domenico di Fiesole, 4 Dec. 2000.

<sup>&</sup>lt;sup>61</sup> Interview with a Commission official, Washington, DC, 10 Jan. 2001.

<sup>62</sup> Interview with a USDA official, Washington, DC, 11 Jan. 2001.

<sup>&</sup>lt;sup>63</sup> Interviews with representatives of the European-American Business Council (Washington, DC, 8 Jan. 2001), the National Food Processors Association (Washington, DC, 9 Jan. 2001); and the US Grains Council (Washington, DC, 11 Jan. 2001).

defendant then has a 'reasonable' period in which to bring its rules into compliance. The EU, in particular, has been slow change its rules in response to WTO judgements. For example, five years after the WTO Appellate Body found against the EU's ban on hormone-treated beef the EU still has not changed it rules. Given the depth of consumer opposition in Europe governments would be unlikely to act quickly on an issue even more sensitive and wide-ranging than the hormone-treated beef ban. In addition, for much of the period of the dispute the French, German and Italian (until June 2001) governments had Green Party coalition partners, which makes such policy changes even less likely.

Even if the EU were to change its rules, it is far from clear that it would improve the situation on the ground. A number of major European food retailers have moved to meet and shape the demand for non-GM food (Commission, 2000b). For example, a consortium of seven European supermarkets — Carrefour (France), Delhaize (Belgium), Esselunga (Italy), Marks and Spencer (UK), Migros (Switzerland), Sainsbury (UK) and Superquinn (Ireland) — are organizing their supply chains in order to eliminate GM ingredients from their own-label products. Other supermarkets — including Pryca (Spain), Spar (Germany), Iceland (UK) and Tesco (UK) — have undertaken individual actions to eliminate GM ingredients from their own-brand products.

In such circumstances, some US producers are concerned that an aggressive approach might be counter productive, both economically and politically. European consumers would probably not react well to US multinationals forcing them to eat food they consider unsafe and therefore might vigorously resist the next generation of GM foods, which is expected to bring direct benefits to consumers, such as enhanced nutrition. In addition, too aggressive a stance might have interfered with the reform process underway in the EU, which held out the possibility of resolving much of the dispute. Thus for a host of reasons, none of the US agricultural industry associations have (yet at any rate) aggressively pushed the US government to pursue a formal dispute through the WTO, although some on the total dispute through the WTO, although some on the total dispute through the WTO, although some on the total dispute through the WTO, although some of the US government to pursue a formal dispute

<sup>&</sup>lt;sup>64</sup> Interviews with representatives of the European-American Business Council (Washington, DC, 8 Jan. 2001) and the US Grains Council (Washington, DC, 11 Jan. 2001).

<sup>&</sup>lt;sup>65</sup> Interview with a former representative of the Corn Refiners Association, Washington, DC, 8 Jan. 2001.

<sup>&</sup>lt;sup>66</sup> Interviews with a former representative of the Corn Refiners Association (Washington, DC, 8 Jan. 2001) and representatives of US Grains Council (Washington, DC, 11 Jan. 2001)

<sup>&</sup>lt;sup>67</sup> Interview with a representative of the Biotechnology Industry Organization, Washington, DC, 9 Jan. 2001.

There are some additional, broader considerations that also influence First, a number of politically influential firms with government policy. extensive operations on both sides of the Atlantic dislike trade disputes between the EU and US because even when they are not directly affected they suffer from the poisoned atmosphere. 68 Second, there is a strong disincentive to unsettle unnecessarily relations with an important political ally and economic partner (Shaffer, 2001). Third, a finding by the WTO's dispute settlement body sets precedents, and government officials have to be alert to the implications of an apparently favorable ruling for domestic regulators (Shaffer, 2001).<sup>69</sup> A successful case that establishes a precedent that undesirably constrains domestic policy might be considered a pyretic victory. Lastly, there is a desire not to further strain the WTO dispute settlement mechanism by giving it another politically charged case that whether the US wins or loses might further undermine the already challenged legitimacy of the multilateral trading system (Holmes and Young, 2001).

## VII. Cooperation: Middle Path or Road to Nowhere?

This discussion suggests that unilateral action by the US – 'trading up' or 'trading blows' – is unlikely to overcome the trade barriers posed by the EU's rules. 'Trading up' in the US may be reaching its limits, and thus far adjustments to the US approval process have only nudged it towards the EU system. Although the new administration might be inclined to take a more aggressive stance than its predecessor with the EU over GM foods, there are a number of reasons to think that the US government will not pursue a complaint before the WTO. Even if it does, several years would elapse before a judgement is issued, and even that would be unlikely to result in a swift (if any) change in EU policy.

The EU's new directive may help, but even if it leads to a renewal of approvals, the approval process will almost certainly be much slower than in the US resulting in a persistent disjuncture between products approved in the two markets. If there is no resumption of approvals, the dispute could well escalate as US producers, particularly the biotechnology companies, lose patience. In addition, EU labeling requirements are unlikely to ease.

http://www.eucommittee.be/pop/pop1997/Agf/agf4.htm, 1 December 1997. One of the TABD's priority issues for 2001 is 'Dispute Management', which includes resolving existing disputes and avoiding new ones (TABD Newsletter, February/March, 2001).

<sup>&</sup>lt;sup>68</sup> Comment by Sir John Browne, European University Institute, 10 November 2000. See also the 'EU Committee Position Paper on the Implications of Agro-Food Developments on International Trade and Transatlantic Relations,'

<sup>&</sup>lt;sup>69</sup> Interview with a USDA official, Washington, DC 11 Jan. 2001.

Consequently, there is likely to be a protracted period of trade tension. Given that there are limits on what the US government can achieve unilaterally, there are incentives for it to seek a negotiated solution. Significantly, as most of the apparent economic cost of the conflict fall on the US, the US government is more likely to compromise than is the EU; its 'cost of no agreement' is higher (Keohane and Nye, 1989; Milner, 1997; Moravcsik, 1998; Young and Wallace, 2000).

The extent of the differences between the EU and US, however, may be such that no compromise acceptable to both sides is possible. In particular, the persistent underlying differences of approach (as manifested by the lack of mandatory prior approval for food products in the US) makes conclusion of a true mutual recognition agreement (ASA, 1999; NCGA, 1999/3; US Grains Council, 2000) or creation of a centralized approval process, <sup>70</sup> both of which have been proposed by firms as ways of overcoming the approval disjuncture, unthinkable. <sup>71</sup> The adoption of mandatory labeling, along with the attendant segregation and identity preservation, in the US along the lines required in the EU would go along way to facilitating trade. The costs entailed, however, are significant and given the Republican Party's and especially Bush Administration's ideological hostility to social regulation adoption of the necessary legislation seems improbable.

Therefore, cooperation has focused on reducing friction where possible and increasing understanding. Such bilateral cooperation and exchanges in other international fora (see below) has contributed significantly to taking the heat out of the conflict by helping the US protagonists to understand that the EU's policy is not just disguised protectionism, as many at first thought. Most now view the EU's policy as a (rather cowardly) political response to real (if unfounded) public concern about the safety and environmental consequences of GM foods <sup>72</sup>

The most concrete cooperation has taken place within the Transatlantic Economic Program's Biotechnology Working Group, which was set up in February 1999. It has worked on developing GM testing protocols and procedures for corn exports to the EU and has initiated a pilot project on

<sup>&</sup>lt;sup>70</sup> See the TABD's October 1999 'Berlin Recommendations', reproduced in the mid-year report 2000 (http://www.tabd.com/about/mym2000.html).

Witness the difficulties the EU and US have had in concluding agreements on the mutual recognition of certifications (see Egan, 2001).

<sup>&</sup>lt;sup>72</sup> Interviews with representatives of the EPA (Washington, DC, 9 Jan. 2001); the European-American Business Council (Washington, DC, 8 Jan. 2001); National Food Processors Association (Washington, DC, 9 Jan. 2001); USDA (Washington, DC, 11 Jan. 2001); US Grains Council (Washington, DC, 11 Jan. 2001).

simultaneous filings for approval in the EU and US, which focuses on harmonizing data requirements.<sup>73</sup> There have also been more political discussion within the US-EU Senior Level Group since early 2000 although they have not led to substantive outcomes. An EU-US Biotechnology Consultative Forum of independent experts was set up by US President Clinton and Commission President Prodi in May 2000. Its report in December 2000 largely supported the EU's cautious approach to regulating biotechnology, but also stressed the potential of the technology, particularly for developing countries.<sup>74</sup> There has been no evident policy response to the report.

Discussions are also under way in broader international fora, most notably the Codex Alimentarius Commission and the Organization for Economic Cooperation and Development (OECD). The Codex Ad Hoc Intergovernmental Task Force on Food Derived from Biotechnology met for the first time in March 2000 and again in March 2001. The taskforce is pursuing two tracks, both limited to food safety considerations: Proposed Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology and Proposed Draft Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant DNA Plants. Progress on both texts has apparently been good, although a number of important issues are outstanding (FSIS, 2001). The risk management portion of the Principles Document – particularly whether requiring tracability is an appropriate risk management tool and what other factors can legitimately be taken into consideration when deciding approvals – appears to have been the principle focus of disagreement. It is clear, however, that even if they are agreed and adopted, the Codex principles and guidelines will still leave governments with a significant degree of latitude.<sup>75</sup>

While Codex is a relative new comer to the issue, regulators have been discussing agricultural biotechnology within the OECD for much longer. The OECD's Task Force for the Safety of Novel Foods and Feeds began working on the issue in late 1990 and its Working Group on Harmonization of regulatory Oversight in Biotechnology, which focuses on environmental aspects of regulation, was established in 1995 building on work dating back to the mid-1980s (OECD, 2000a, 2000b). Both groups have made some progress in defining some basic parameters for safety assessment. In 1993 the Task Force established that an assessment of 'substantial equivalence' is the most 'practical approach' to determining the relative safety of a new food (OECD, 2000a: 6).

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<sup>&</sup>lt;sup>73</sup> 'Report of the Transatlantic Economic Partnership Steering Group' <a href="http://www.useu.be/SUMMIT/tep1200.html">http://www.useu.be/SUMMIT/tep1200.html</a>, 18 December 2000.

<sup>&#</sup>x27;The EU-US Biotechnology Consultative Forum Final Report,' http://www.useu.be/ISSUES/biotreport2000.htm, 19 December

<sup>&</sup>lt;sup>75</sup> It has been agreed, for example, that the purpose of the principles document is to provide a framework for risk analysis rather than to give specific advice (FSIS, 2001).

The Working Group has sought, with a fair degree of success, to harmonize the information and methods used in risk/safety assessments (OECD, 2000b). Despite this progress, however, differences in regulatory outcomes persist because governments differ in how they manage risk and take other factors (such as ethical and socio-economic concerns) into account (OECD, 2000a, 2000b). Confronted with these more intractable differences, both OECD groups advocate information exchanges and increased transparency.

These multilateral efforts rather than promoting true regulatory approximation appear to be setting limits on differentiation. Consequently, while perhaps establishing boundaries for the transatlantic dispute, they are unlikely to resolve it.

In the end, time and continued technological development may ease the problem. The longer GM foods are around without causing environmental or health problems, the more consumer fears will fade. In addition, as the next generations of agricultural biotechnology products, which deliver concrete and direct benefits to consumers, 76 become available, consumers may become more willing to consume them and companies will become more willing to label them as part of their marketing campaigns. This, of course, assumes that no harmful effects of GM food are found. If they are, then the trade dispute may be resolved through abandonment of the technology. As one representative of a US agricultural trade association said, if a problem is discovered with biotechnology his association would 'flip-flop in a heart beat.'77

### **VIII. Conclusions**

# **Implications for the Dispute**

This analysis suggests that the transatlantic dispute over genetically modified will simmer for some time to come. If the EU's new directive results in a resumption of approvals, however, it also seems unlikely that the dispute will burst into flame. While there has been policy reform in the US, sparked in part by the EU's policy, there are still profound differences in regulatory approach and policy substance between the EU and US. Because the EU insists on approving all GM varieties itself, 'trading up' by the US was never going to be sufficient to end the dispute, however, the extent of the persistent differences is such that there is still no foundation on which a cooperative arrangement – such as a mutual recognition agreement – could be built. Although a solution is not imminent neither is an all-out trade war, as a number of factors – not least that

<sup>&</sup>lt;sup>76</sup> Such products could include crop varieties delivering better flavor or with improved levels of specific nutrients.

<sup>&</sup>lt;sup>77</sup> Interview, Washington, DC, 11 Jan. 2001.

the case might not be winnable before the WTO – mitigate against the US pursuing an aggressive strategy.

While there is some scope for cooperation, the focus is more on managing friction than on resolving the dispute. Perhaps the most significant benefit from cooperation – increased understanding – has already been reaped. Further benefits could come from agreeing procedures and protocols for testing for GM and for managing identity preservation systems. An agreement covering mutual recognition of such tests would greatly amplify the benefits of such an agreement.

In these circumstances, the most significant steps toward easing the dispute have been market-driven adjustments by US producers (*de facto* trading up). By accepting only GM varieties approved in the EU (and other markets) a number of US producers have lessened the commercial implications of the policy discord for them. This adjustment, however, has exacerbated the commercial implications of the dispute for the agricultural biotechnology companies, which are finding harder to sell their seeds in the US, as well as abroad.

## **Broader implications**

Although the US reforms have been limited, the preceding analysis stresses that 'trading up' occurs even when international institutions do not favor it and that it is a phenomenon that affects actors even as economically and politically powerful as the United States. There are two key aspects to this conclusion. The first is the importance of the transmission of political mobilisation as a mechanism for 'trading up.' By raising the awareness of US consumers and consumer and environmental organisations, the EU's rules on GM food provided a catalyst to political mobilization and limited policy change. An important caveat, is that domestic institutions play a pivotal role in shaping how political mobilisation translates into policy change. In this instance, the prevailing approach to regulation and the legal framework in which it is situated dampened the impact of political mobilisation. The second aspect, is the importance of exceptions to multilateral trade rules to diffusing 'trading blows.' The acceptance in multilateral rules of legitimate obstacles to trade undermines aggressive trade policies and creates incentives for cooperative solutions.

There are, however, some trade disputes that are largely intractable, at least without exogenous change. This situation is likely to occur where there are profound differences of approach between the protagonists and where multilateral trade rules permit governments to exercise discretion; neither 'trading up' nor 'trading blows' is likely or adequate. These circumstances

appear to arise most frequently when it comes to regulating under scientific uncertainty. As many of these issues touch on safety, particularly food safety, they tend to be highly politically sensitive, and therefore harder to resolve. We may therefore have to accept a perpetual level of (background) trade friction.

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