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A Conflict of Legitimate Concerns or Pandering to Vested Interests?

Conflicting Attitudes Towards the Regulation of Trade in Genetically Modified Goods – The EU and the US

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The success of multilateral negotiations in reducing explicit trade barriers has focused the attention of policy makers and other interest groups on the impact domestic policies and attitudes may have on trade flows. In the area of genetically modified goods the principal area of dispute between the U.S. and the EU involves fundamental differences in the perception of these goods and consumer attitudes towards them. The current dispute settlement mechanisms do not provide a way of dealing with this type of issue. Existing bodies were designed to deal with “producer vested” interests and so cannot deal with “legitimate” consumer concerns. The paper concludes that a new body should be established to deal with these within the ambit of the WTO.

Keywords: conflicts; EU; GMOs; trade; U.S.

Introduction

It is generally agreed that the multilateral trade negotiations carried out under the auspices of the World Trade Organization (WTO) have had a considerable impact on the reduction of trade barriers. Tariffs in particular have been reduced considerably, allowing

a great deal of trade in manufactures to be conducted between WTO members almost tariff free. Substantial progress has also been made in the area of non-tariff barriers, particularly quotas. Many of these have been converted into tariff equivalents and then *bound*. As a consequence of this success national policy makers, no doubt pressured by business lobbies, have increasingly begun to consider the effect that trading partners' domestic regulations have on trade. When put in place, these domestic regulations may not have had any protectionist intent. In a world, however, where traditional trade barriers are either non-existent or have little effect on trade, their impact may become important. What becomes even more important for policy makers is not just the individual regulations but the principle that underlies them. Once the principle is breached, then a whole raft of regulations can be undermined in one go. The consequences of this outcome are not lost on the nations defending the rationale behind their domestic regulations. Damaging trade disputes are likely to arise between nations that not only have different domestic regulations but also have different sets of principles that underlie the regulations. It is within this context that one has to see the U.S. objections to the European Union's application of the *precautionary principle* that underlies its regulations regarding public health and environmental protection.

In this paper we will examine the EU's *precautionary principle* and how it applies to the regulation of the development and trade in genetically modified products. We will also examine the U.S. objections to this principle and how the United States perceives the way the principle can operate as a trade barrier. The latter part of the paper will concern itself with the issues that may need to be addressed by the WTO regarding the underlying principles nations can apply.

European Union Regulation of Genetically Modified Products and Biotechnology

Current regulations in the EU pertaining to biotechnology apply to two specific areas of policy: environmental protection and food safety. In both these areas the EU's competence is derived from treaties and laws establishing its common market and, in particular, the internal market. There are additional regulations that apply to the production of all agricultural products and, hence, encompass genetically modified foods.

In the area of environmental protection three directives apply. Directive (90/219/EEC) deals with micro-organisms that have been modified during research trials. Directive (90/679/EEC)—the Biological Agents at Work Directive—deals with the protection of workers from risks associated with exposure to biological agents while at work. While it applies only to micro-organisms, their definition is broad enough to encompass animal and plant cells in tissue culture.

Where the organisms in question are destined for deliberate release into the environment, Directive (90/220/EEC) applies. Part B of the Directive outlines the modification requirements and procedures that the release has to abide by and follow and the information it has to provide the competent national authority. The information that must be passed on includes a technical analysis of the product to be released and an assessment of the potential environmental and health risks.

The European Union's procedures regarding the authorisation for marketing genetically modified products are covered in Part C of Directive (90/220/EC). Part C also requires a complete risk assessment to be carried out before products are marketed.

In the area of food safety, specific legislation exists for novel foods and food ingredients as well as for products that are to be used as or incorporated into medicines for both humans and animals. Here national legislation is supplemented by EU regulations—in particular EC Regulation No 209/93 and EC Regulation 258/97. The latter regulation, which is substantially based on UK national legislation, requires a mandatory premarket approval system for novel foods throughout the European Union. This regulation's scope covers all foods and food ingredients which have been derived from genetically modified organisms. Regulation 258/97 has been, in turn, supplemented further by a Council Regulation (EC) 1139/98 and deals with the compulsory labelling of foodstuffs produced from genetically modified organisms. In particular, the regulation requires that foods derived from genetically modified soya and maize be labelled as genetically modified if either the protein or DNA *resulting from genetic modification is present*.

To gain approval for the commercial release of genetically modified products, a company has to apply to a competent authority. A competent authority is the national body in any one of the member states charged with the responsibility to oversee regulations in this area. This body has to examine the application and a decision has to be made within 90 days of its receipt. This time period can be extended if further information is required from the applicant. If a recommendation is made to approve the application, the EU Commission is informed, and it, in turn, forwards the recommendation to the other member states and their competent authorities. Objections to adopting the recommendations have to be made in 60 days. If no objections are raised or registered within this period, it is taken as an indication that all member states are willing to accept the product. The country in which the application originated then issues approval on behalf of all the member states.

If there are objections, even by one EU member country, then the Commission has to accept the responsibility to resolve the matter; until it does, approval cannot be granted. The Commission will have to draft and table proposals to resolve the issue under Article 21 of the Treaty. It can set a time limit but the time limit is not specified. All that is required is that the Commission's *committee* decides timing according to the urgency of the matter.

If the committee approves the application, albeit by a qualified majority vote, then the Commission has to accept approval and authorise the originating country to grant consent. If the relevant committee fails to agree or does not take any action to resolve conflict, then the Commission itself has to take charge. It has to then present its proposals to the Council of Ministers for adoption. If this is accepted, the relevant country grants approval. If not, the application is rejected.

As one can see, in this procedure once the competent authority has examined the application and approved it, the whole process can be influenced by non-scientific factors.

The process is complicated further when one considers that the individual member states of the EU can defy the Commission's decisions. Despite the EU approval gained by some genetically modified products, countries such as Denmark, Britain and France have effectively called a partial halt to approvals. Austria, France and Luxembourg have banned new genetically modified crop strains and along with Greece have imposed import bans on genetically modified maize and rapeseed. This is despite these crops having received EU approval; therefore, the countries are in contravention of EU trade and domestic policies.

The Background to EU Regulations

In 1986, the Organisation for Economic Co-operation and Development (OECD) group of national experts suggested that there was no reason for specific legislation to deal with genetically modified organisms. In spite of this, the EU has put in place the special regulatory framework outlined above. There are several reasons for this (OECD, 1986).

The first, and most straightforward, is that the OECD's recommendation presupposes that there already exists a body of law or regulations that can deal with genetically modified products. Since there was no EU-wide legislation in existence, only national law, it was necessary to have a harmonised regulatory framework if for no other reason than the *single market* required it.

The second reason, which is linked to the first, is that in seeing the gap in this area the EU institutions saw the opportunity to promote further the need for even closer integration. It has been suggested that this constitutes the establishment of a federal European state by stealth (Cantley, 1999).

A third reason for the development of EU-wide legislation is the growing and widespread concern that consumers have regarding the long-term impact that genetically modified products will have on human health and the environment. While a great deal of scientific evidence suggests that genetically modified foods are safe to humans, there is still enough uncertainty within the scientific community to raise doubts, if not alarm, in consumers' minds.

There is a similar issue surrounding the environmental impact of genetically modified organisms. While conventional science suggests that it is unlikely that genetically modified

plant varieties can cross over and affect traditional varieties, other groups of scientists are not so sure. Certainly, studies suggesting that there is some effect on fauna and flora add weight to the opposition.

Ethical issues also have played their part in promoting legislation. These range from the *one should not interfere with God's work* variety to the effect genetic modification will have on consumer choice. Far from increasing consumer choice, genetic modification could reduce it if, as some suggest, natural products are invaded by genetically modified pollen.

Given that it is impossible to limit the movement of birds, insects and other vectors that carry pollen at national frontiers, it is sensible for the EU to have a common policy regarding the regulation of genetically modified goods since releases in one country will offend another. Undesirable externalities can, therefore, be limited by a common policy.

While some view the development of the EU's policy towards genetically modified goods as unwarranted pandering to consumers and environmental lobbies (Cantley, 1999), others do not. For some, the uncertainties surrounding the underlying science and current testing abilities are enough to warrant a high degree of caution (Consumer Association, 1999).

Underlying Principles of EU Regulation

What governs the EU's attitude to all environmental policy issues is its desire to prevent damage occurring from a particular action rather than letting it arise and then dealing with the consequences. The approach is summed up in the phrase *precautionary principle* and is enshrined in Article 130 (2) of the EC Treaty.

In the area of genetically modified organisms, this *precautionary principle* is embedded in all the directives and regulations mentioned above. Directive 90/220/EEC is the first piece of international legislation in which the principle has been translated into practice.

The *precautionary principle* has a long legal heritage and can be found in the law regulating food in most European countries (Streinz, 1998). While its interpretation varies between member states, the application of the *precautionary principle* at the European Union level is clear. It is to be applied in areas or situations where uncertainty as to outcome exists. In other words, in areas where risk assessments have been carried out but the limitations of the science underlying the assessments are obvious, the *precautionary principle* should apply. What is suggested is that even though scientific procedures have been carried out, the results cannot be taken as conclusive due to the limitations of the current state of science. Under these circumstances, it not only becomes right, but also proper, for another authority to rule on whether a procedure, process or good should be carried out, integrated or released (Streinz, 1998).

The U.S. System of Regulation

In the United States, four agencies are responsible for ensuring the safety of genetically modified products for humans and the environment. The National Institutes of Health looks after the safety aspects of dealing with genetically modified goods in laboratories and factories. The remaining three agencies deal with the release of genetically modified products into the environment or market.

The leading institution in this area of regulation is the United States Department of Agriculture (USDA), in particular its Animal and Plant Health Inspection Service (APHIS). As long as genetically modified plants and micro-organisms meet the APHIS safety criteria, they are granted the status of non-regulated goods. This allows these goods to enter the marketplace without restriction. APHIS can use its powers under the Federal Pest Act and the Plant Quarantine Act to prevent the introduction and dissemination of plant pests. In other words, if genetically modified products constitute potential pests, APHIS has the power to stop their release. Another branch of the USDA, the Food Safety Inspection Service, looks after the area concerned with the slaughter of research animals for human consumption.

The second body involved with regulating genetically modified goods is the Environmental Protection Agency (EPA). It is charged with assessing the impact that genetically modified products will have on the environment and on food safety for humans. It is specifically involved in the regulation of inter-generic micro-organisms under section 5 of the U.S. Toxic Substance Control Act. Prior to their commercial importation, notice must be submitted to the EPA.

Finally, the U.S. Food and Drug Administration is involved in the process of regulation. Its remit covers the safety of food for human consumption as well as drugs for both human and animal use. The range of products its powers cover is very wide. The main exclusions are meat and poultry products. Its powers, however, embrace substances added to food, such as vegetable oils, sweeteners, spices, enzymes and additives (colour, etc.). The FDA can take regulatory action against any food that might contain adulterated material that may be injurious to human health. Producers of genetically modified foods are, therefore, likely to seek consultation with the FDA before their products are placed on the market.

Depending on which agency is regulating or being consulted, the average product approval time is between six and eight months, although the range varies between two and twelve months. The EPA, for example, can take up to twelve months from the receipt of the application to reach a decision. Where approval from research and development activities is being sought, or the commercial application of genetically modified goods, this can be granted in sixty to ninety days. The speed by which these agencies can grant approval

is highly dependent on the completeness of the information and data supplied. Incomplete information can lead to delays.

The background to the regulation of agricultural biotechnology products in the United States dates back to the Co-ordinated Framework for Regulation of Biotechnology of 1986. Prior to that, regulations largely dealt with the laboratory testing and development of products.

The framework dealt very precisely with the form and extent of regulation. Regulation in the United States was based on existing health and safety laws. There was a pragmatic reason for this. Existing legislation provided a swifter means for regulation than could be provided by new legislation. New legislation would have had to go through all the constitutional processes with their attendant uncertainties.

Another, and perhaps more fundamental, reason the existing legislative framework was used was that genetically modified goods and organisms are not perceived as new goods. In the United States, they are perceived as being extensions of existing products. Most field trials are, hence, subject only to notification of the relevant authorities and not to assessment. It has to be borne in mind that the agencies involved, especially APHIS, do not consider themselves to be guardians of the environment. APHIS sees its role as that of a protector of agriculture. As a result, it is more concerned with the possible adverse effects of genetically modified products on agriculture—the problems of crossovers for example.

U.S. Objections to the EU Regulatory System

The United States has two major objections to the EU regulatory system for biotechnology. The first deals with the way the system of regulation operates while the other has to do with the underlying principles on which that system is based.

U.S. objections to the operation of the system include the length of time it takes to seek approval, the influence that politics play in regulatory decision making and, finally, the unpredictability and lack of transparency of the system. There are also specific objections regarding labelling requirements.

Certainly, the EU's review process is long compared to that of the United States and other countries such as Canada. The EU process can take up to two years or more, much longer than in North America. From the U.S. perspective, the reason for the extended approval process is not that the EU carries out more vigorous procedures. It has more to do with the role of the EU approval bodies. The conclusions of these largely science-based institutions are not regarded as final. It is the political institutions of the EU, namely, the Commission and the Council of Ministers, that have the final say in the process of approval. This contrasts with U.S. practice whereby the regulatory institutions come to independent conclusions which cannot be challenged by political institutions.

The United States is also concerned about the way procedures are conducted. While Directive 90/220 does not require scientific reviews for genetically modified product varieties, the EU Commission has requested these to be carried out. Several ad hoc changes have been made to the operation of procedures laid out in 90/220, yet these were never made explicit or announced. The lack of transparency and the inability to predict the outcomes of the approval procedures increase the uncertainties facing the producers of genetically modified goods. Delays in the granting of approval can have serious consequences for companies contemplating, or already in, production.

The EU's labelling requirements also raise objections in the United States. Labelling is not objected to on the basis of providing scientific information regarding the product's composition, nutritional value or effect. What is objected to is that labelling to EU standards signals that genetically modified goods are new or in some way different from their *conventional* counterparts. It is for this reason that producers in the United States view the EU's labelling requirements as constituting a technical barrier to trade (Caswell, 1999).

The U.S. authorities and U.S. producers are also objecting to the basis on which the EU's regulations are founded. The *precautionary principle* is based on the premise that genetically modified goods are new goods, not extensions of their natural counterparts. As seen above, this approach places an onus on the authorities not to approve or release products until there is conclusive proof that they will not damage humans, animals or the environment. The U.S. approach is the opposite. Genetically modified goods are accepted as being extensions or enhancements of existing (natural) products and, therefore, unlikely to harm humans, animals or the environment. The United States thus perceives that the Europeans cannot be taking a scientific approach and are allowing other political factors, and hence interest group pressure, to influence policy making and formulation. As a result, the United States refuses to accept the EU's *precautionary principle* as a legitimate barrier to trade both within the WTO and elsewhere.

Are the U.S. perceptions correct? Is the EU merely protecting the home market for its domestic producers? Does the EU have a legitimate viewpoint which is being ignored by the United States? Is the United States not just promoting the interests of U.S. companies at the long-run expense of the environment and consumers worldwide? These are the questions raised by the differences in regulatory approach.

The first thing that can be said regarding domestic protection is that EU legislation impinges equally on both U.S. and EU producers. In their written evidence to the British House of Lords select committee investigating EU regulations in this area, EU companies are highly critical of the existing legislation. The companies see the legislation as having both short- and long-term detrimental effects on both their profitability and capacity to undertake production and conduct research and development in this promising area of new

technology. One company in particular raised the possibility that research and development activities could be transferred from Europe to locations where the regulatory climate was more conducive. It is clear that the European companies involved in research, development and production in this area are not seeking protection.

It is also clear that the groups that are seeking protection are consumer and environmental groups. Their wide ranging concerns are well documented. The European Public Concerted Action Group survey of public attitudes to genetic modification with regard to food is highly instructive (European Public Concerted Action Group, 1999). It found that 74 percent of those surveyed believed that genetically modified foods should be labelled. Another 60 percent believed that there needed to be public consultation regarding new developments, and 53 percent felt that existing regulations were insufficient to protect individuals.

A MORI (UK) poll conducted in June 1998 found that 77 percent of the public questioned believed there should be a ban on genetically modified crops and food. As far as eating such foods was concerned, 61 percent did not want to.

A survey carried out by the National Federation of Women's Institutes (265,000 members in 8,000 branches across England and Wales and the Channel Islands) amongst its members showed that 98 percent wanted more debate and 93 percent wanted all genetically modified foods labelled (NFWI, 1998). These attitudes to genetically modified foods are also reflected in the rest of Europe. For example, in the Netherlands the Dutch Association of Housewives signed a petition requesting a moratorium on field trials and the cultivation of genetically modified foods. The Dutch Consumers Union also wanted to see a ban on their cultivation.

The U.S. attitude towards the *precautionary principle* would certainly hold if one could resolve the issue by appealing to science. The problem is that science does not have a definite answer regarding the long-term safety of genetically modified goods. There have also been some scientific studies that question the long-term safety of consuming genetically modified foods. While the majority of scientists may scorn these results, the sight of scientists arguing publicly over the safety of these products does not help consumer confidence. It does, furthermore, weaken the view that consumers should defer to scientists over such matters. There is a growing body of evidence which suggests that consumers are no longer willing to accept scientific evidence used by scientists charged with ensuring human, animal and plant health (Fraver et al., 1996). The BSE crisis in Europe, and particularly the UK, has further hardened European consumers' views.

There is an additional issue that merits consideration and that concerns the appropriateness of risk assessment. When a product is to be placed on the market, it is customary to carry out a risk assessment to determine whether the product is safe for humans to use,

consume, etc. Risk assessment, even when non-quantitative aspects are allowed in the calculations, presupposes the existence of statistically determinable probabilities. If there is little or no information, then it is impossible to establish probabilities and one is operating in a world of uncertainty (Knight, 1921). This point is highly relevant when considering genetically modified goods. The potential problem with genetically modified goods is their long-term effects. Currently, there is insufficient information regarding these effects, and as a result, it is not possible to establish probabilities. Under this situation of uncertainty, it is not surprising that one country's authorities will not accept another's conclusions regarding scientific results. If risk cannot be assessed, then it can be argued that it becomes legitimate for non-scientific bodies such as political institutions not only to have a view, but also to decide outcomes. While this approach may not be universally accepted, it is nonetheless a legitimate viewpoint. This approach also has major implications for the conduct of trade policy and the institutions established to deal with trade conflicts.

Reforming WTO Institutions to Defuse Potential Conflicts

As currently constituted, conflicts over food issues between signatories of the GATT and members of the WTO are dealt with under two agreements. The first is the agreement regarding Sanitary and Phytosanitary (SPS) issues; the second is the agreement regarding Technical Barriers to Trade (TBT).

The SPS agreement was established to prevent countries from protecting their domestic food producers by using spurious evidence and discriminatory procedures. In other words, if a country wished to protect its consumers from harmful products, it would first have to justify its actions on the basis of scientific evidence. Second, it would have to apply whatever rules and regulations it had adopted equally to both domestic and foreign producers. In this way politicians would be inhibited from supplying protection to domestic producers on dubious grounds.

The TBT agreement works on similar lines. It ensures that, whatever regulations are placed on importers, the cost of implementation must be proportional to its purpose. For example, if labelling is needed it must not be unduly onerous relative to the benefits consumers receive from the labelling of the products.

In the case of the SPS agreement, the WTO does not judge what constitutes appropriate or best available scientific evidence. This function has been devolved to independent standards agencies. Food safety is covered by the Codex Alimentarius Commission, animal health comes under the International Office of Epizootics, and the International Plant Protection Convention covers plant health. These organisations are staffed by individuals who possess the necessary scientific training and skills to come to a judgement. They are not noted for their haste in reaching decisions, preferring long consultation and delibera-

tion to build a consensus (Kerr, 1999).

The SPS agreement does allow individual countries to impose domestic regulations and trade measures on a temporary basis when they feel that sufficient evidence does not exist. The imposing countries are, however, required to gather the necessary information quickly, because *temporary* really means precisely that (Roberts, 1998).

Is it possible to use these existing WTO structures to deal with the potential conflicts over genetically modified goods? The answer must be no. The SPS and TBT agreements were established to deal with fairly straightforward issues. Was a regulatory measure based on appropriate scientific evidence and did it apply equally to domestic as well as foreign suppliers? Were the costs of complying with the regulation proportionate to the benefits to be derived by consumers? If the answers to these questions were affirmative, then the regulations imposed were legitimate. If scientific evidence was lacking or there were doubts, then temporary restrictions could apply but only for a short while. If the independent standards agencies found against the country imposing the regulations, then it would have to either withdraw these or face retaliatory action from other WTO members.

What the existing WTO arrangements cannot do is deal with the issues raised by genetically modified goods. As pointed out above, in cases where uncertainty exists, differing interpretations can prevail and be legitimate grounds for choosing different policy solutions. Further, if ethical issues also arise, there is no forum within which they can be discussed—let alone resolved. If the existing structures are inappropriate for handling genetically modified goods, what should be done? Should one reform the existing SPS and TBT agreements to take these issues into account or should new bodies be established?

It is generally accepted that you do not fix things that are not broken. The same is true for international agreements and institutions. The existing SPS and TBT agreements work well where the science is straightforward or where evidence can be easily accumulated and interpreted. These existing agreements ensure that national politicians are forced to think through the consequences of promoting domestic producer interests under the guise of protecting the consumer against inferior foreign products. They ensure that political actions come at a price. Should these existing agreements be modified to include legitimate consumer concerns and to recognise that, in areas of uncertainty, differing policy interpretations are valid? The answer to this question is probably no; far better to keep the existing structures and agreements for the work for which they were intended. In these new areas, which need to focus on the principle on which regulations are based, new institutions or agreements need to be put in place.

If new agreements are established to monitor and decide on the legitimacy of consumer fears, they too will have to be based on internationally agreed principles. They will have to be seen to be open and transparent. The way these new agreements and institutions oper-

ate will be very important to ensuring international confidence in their operations. Their deliberations should be based on thorough investigation by an independent body of people appointed for their expertise. They should not be drawn from the ranks of “industry” or “pressure group” experts, so that conclusions can be as free as possible from the influence of vested interests. The penalties for non-compliance with the findings of the institution should be made high so as to prevent spurious requests for protection. If the costs of protection are high, then domestic politicians will think twice before embarking on such a course of action. There are several ways that non-compliance can be made costly. Paying compensation to injured third parties is one way. Another would be to allow retaliation involving the imposition of trade sanctions, akin to the current system. Whichever way is chosen as a deterrent, it has to be enforced effectively and consistently.

Summary and Conclusions

As international negotiations have successfully reduced the traditional barriers to trade, the effect that domestic regulations have on trade has become more apparent. These regulations may never have been intended as protectionist devices, but their impact may be just as real.

The current problem facing international trade negotiators is that domestic regulations are the result of a mixture of domestic prejudices and biases as well as reflections of genuinely held differences in perceptions. In this paper, it has been argued that the EU’s regulatory framework regarding genetically modified products and the *precautionary principle* on which it is based are examples of a legitimate point of view.

The United States sees genetically modified products and their impact in a different light than Europe does and regards the EU’s response as protectionist. This view has been well expressed by U.S. officials (*Inside US Trade*, 1998). It is clear that the potential exists for a damaging trade dispute to take place between the EU and the United States.

The current international agreements—those dealing with SPS and TBT—are not able to provide the framework to defuse such a dispute. To burden them with the extra function of determining the legitimacy of consumer concerns and the underlying principles on which regulation is based would be burdensome and possibly dilute their effectiveness in other areas. It is considered better that a new agreement/institution be established to deal with this aspect of international trade relations. This new body would be charged to adjudicate in areas where regulatory systems differed and these differences were claimed to be the result of legitimate differences in principles and attitudes.

It is essential, if the present trading system is to remain acceptable and open, that an institutional framework to handle these issues be established. Unless policy makers are allowed some leeway in meeting consumer needs and formulating policies along domesti-

cally accepted lines, the trading system will be questioned. While the current system is open to criticism, it is at least open. The alternative, a more closed system, would endanger the further expansion of world trade and prosperity. Will national trade negotiators move in this direction? Certainly there is some evidence from the United States that something needs to be done to accommodate consumer interests and alternative viewpoints (Manning, 1999). In Europe as well, there is an acceptance that the regulatory system for genetically modified products needs revision and that it should become transparent and open (Smith 1999). What has to be accepted by all parties is that consumer issues are different in character from the trade issues of the past. Consumer interests are not served simply by denying domestic producers protection from foreign competition; the acceptability of products to consumers also needs to be taken into account.

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