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The 2006 WTO Ruling on GM Crops: What Impact on the Regulatory Environment?

In 2006, the World Trade Organization (WTO) ruled on a complaint by the United States concerning the failure of the European Union (EU) to lift its moratorium on the approval of genetically modified GM crops (WTO, 2006). Set in the context of the US-EU dispute over trade in GM crops, and their differing approaches to biotechnology regulation, this bulletin provides a review and assessment of the WTO's ruling.

Background to the US-EU Dispute over Trade in GM Crops

Since the mid-1990s, there has been rapid adoption of GM crops. The key commercially available GM crops (corn, soybeans, canola, and cotton) are grown in a concentrated group of agricultural-exporting countries, including the United States, Argentina and Brazil. Of the 246 million acres of GM crops planted worldwide in 2006, 83 percent was planted in these three countries. The most was planted in the United States at 54 percent of the total. Argentina and Brazil accounting for 18 percent and 11 percent respectively (James, 2006).

There has also been widespread public discussion of GM crops, the debate having been most intense, and most publicized in the EU. Consumer surveys there have consistently shown that the public typically has a very negative attitude to GM foods. For example, a poll published by the European Commission in 2006 found that only 27 percent of EU citizens surveyed believe that the technology behind GM crops should be encouraged, the remainder finding it hard to see any clear benefits (Eurobarometer, 2006).

Widespread unease amongst EU consumers about GM crops formed an essential background to the EU placing a moratorium on approvals of genetically modified organisms (GMOs) in 1999. The roots of the moratorium lay in the Novartis Bt-176 corn case, initially notified to the relevant French authority for marketing approval in early 1996. Despite initial French approval, a number of other EU Member States, including Austria, Denmark, Sweden, and the UK argued that the marker gene contained in the corn could be harmful to human health. Then in 1999, Denmark, France, Greece, Italy, and Luxembourg declared they would block future GM crop approvals, which by EU voting rules amounted to a moratorium.

US-EU Regulation of GM Crops

In the United States, the Food and Drug Administration (FDA) has taken the position that recombinant DNA methods of plant development are not "material" information under the Federal Food, Drug, and Cosmetic Act. Essentially, the FDA feels that crop development through genetic modification is simply an extension to the molecular level of traditional plant breeding methods. In addition, the FDA has established the principle that existing GM foods do not differ in any substantial way from those developed through traditional plant breeding methods.

The objective of US regulation is not to establish absolute safety, but to consider whether a GM food is as safe as its conventional counterpart. The focus is on identifying intended and unintended differences between the two types of food, which are then analyzed in a pre-market safety assessment. In addition, labeling is only required if the GM food is substantially different from the conventional version.

Prior to 2003, EU regulation of agricultural biotechnology covered the deliberate release of GMOs, provision of an approval procedure for foods containing or consisting of GMOs, and rules requiring foods that might contain GMOs to be labeled. Between 1992 and 1998, the EU approved 18 GM plants/crops for commercial marketing, including four varieties of GM corn, four varieties of oilseed rape, one variety of soybeans, and one variety of tobacco.

However, in 1999, the European Council formalized a moratorium on GMO approval by recommending to the European Commission an amendment to the existing regulations. The provisions of the recommendation were for the EU to take a thoroughly precautionary approach to future approval of GM crops, and that GM crops should not be placed on the market until it could be demonstrated that there is no adverse impact on human health and the environment, and that principles regarding traceability and labeling be applied. A revised regulatory framework was subsequently approved by the European Parliament and European Council in 2003.

There is clear potential for conflict between the US and EU approaches to regulating GM crops. On the one hand, the US follows a scientific, risk-based assessment appealing to the concept of substantial equivalence, and the notion that zero risk in food safety regulation is not practical, given that conventional foods are already presumed to be safe. On the other hand, the EU follows a more precautionary approach to risk management of GMOs and has abandoned the concept of substantial equivalence. Critics of the EU's adoption of the precautionary principle argue that it has become less of an approach for risk management and more of a tool for NGOs and other lobby groups to influence the regulatory process, undermining the role of science in that process.

GMO Regulations and the WTO

To understand the recent WTO ruling, it is important to show broadly how WTO rules could affect the application of GMO regulations. It should be obvious that most GMO regulation has no direct trade component, both in terms of regulatory process, and the regulations themselves. The WTO, and the General Agreement on Tariffs and Trade (GATT) before it, explicitly recognizes the right of countries to develop policies that protect human, plant and animal health (GATT Article XX). Therefore, the WTO would not get involved in regulations for testing and adoption of GMOs in specific countries. The WTO would, however, be involved in any potential conflict over GMO regulation insofar as there are rules over import restrictions contained in the GATT (94), and the Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) Agreements.[1,2]

Two main principles of the WTO could impinge on the regulation of GMOs in world trade, non-discrimination (GATT Article I), and national treatment (GATT Article III). i.e., it would neither be WTO consistent to ban imports of GM products from one WTO member and allow them from another, nor to impose additional restrictions on GM products once the product had been imported if such restrictions were not imposed on domestic producers of the GM product.

It is unlikely, that the EU would either explicitly discriminate against US exports of GM products, or allow domestic production of a GM product without regulation, but impose regulations on the imported product. However, there might well be a claim of discrimination if the EU, as a deliberate act of trade policy,

[1] The SPS Agreement, agreed on at the end of the Uruguay Round of GATT in 1994, focuses on regulations that are explicitly used to protect human, animal and plant health, the objective being to ensure that such regulations are science-based and do not distort trade.

[2] The TBT Agreement, which originated in the Tokyo Round of GATT, and was subsequently modified in the Uruguay Round, covers technical regulations that focus on non-safety related attributes of all products, such as the characteristics of how a product was produced.

were to ban imports of a GM product but allow imports of the conventional product. GATT Article III states countries cannot discriminate between like goods on the basis of country of origin. So the key issue in any GMO dispute could be the definition of 'like goods', i.e., does either genetic modification or presence of GM ingredients constitute sufficient grounds for differentiation from conventional products?

In terms of risk assessment and labeling of GM foods, the key is how these might be evaluated in terms of the SPS and TBT agreements. The standard interpretation of the SPS Agreement is that an import ban on a GM food would have to meet the risk assessment criteria of the agreement, and scientific justification would have to be made if the risk exceeded international standards. With regards to mandatory labeling, this could be challenged under both the SPS and TBT Agreements. Although application of the TBT Agreement to food products has so far been very limited, it is likely that a case involving labeling of GM foods will provide a test of whether it is legitimate to label a product based on the process by which it was produced. Some observers argue that if GM food labeling is designed to cover a range of issues not explicitly related to health concerns, such as the consumer's right to know, then it could fall under the legal purview of the TBT Agreement and not the SPS Agreement.

The WTO Ruling on GM Crops

The WTO Dispute Panel ruled on three aspects of the EU's regulation of GM crops: first, the EU had acted inconsistently with its obligations under the SPS Agreement by applying a *de facto* moratorium on approvals on new GM crops between June 1999 and August 2003; second, in the case of specific measures delaying the approval of 24 new GM crops, the EU had breached its obligations under the SPS Agreement; and third, safeguard measures implemented by six EU member states against the import and or marketing of specific GM crops were not based on any risk assessment as required by the SPS Agreement, and hence the EU had acted inconsistently with its obligations under that Agreement. The WTO was also extremely clear about what issues it did *not* examine: the safety or otherwise of GM foods; whether GM foods are "like" conventional foods; whether the EU's GMO approval process is consistent with its obligations under the WTO

Despite the narrow context of its ruling, the Panel's report, which runs to over 1,000 pages, contains interesting insights and implications for the debate over GMOs and what might happen in any future complaint about the EU's regulatory regime. In terms of safety, while the Panel concluded that some concerns about GMOs were likely unwarranted, they were very clear that the EU has the right to consider the possibility of such risks prior to giving approval to new GM crops. In addition, the Panel noted that while the EU had subjected GMO approvals to undue delay, this did not mean there would never be circumstances where such delay would be justifiable, stating, "…if new scientific evidence comes to light which conflicts with available scientific evidence…it might, depending on the circumstances, be justified to suspend all approvals pending an appropriate assessment of the new evidence…" (WTO, p.673)

This statement clearly indicates that it would not be WTO-illegal for a country to suspend its GMO approval process in the face of new scientific evidence as regards safety, however, it is also clear from the Panel Report that this does not constitute recognition by the WTO of the precautionary principle, the Panel noting, "…it is clear that application of a prudent and precautionary approach is, and must be, subject to reasonable limits, lest the precautionary approach swallow the discipline…" of the SPS Agreement (WTO, 2006, p. 671).

Although the Panel made no ruling as to whether the EU's GMO approval procedures are consistent with their WTO obligations, there is considerable discussion in the Panel's report of the legal status of these regulations. Importantly, this discussion gives some clue to how the WTO might proceed in any future dispute where the plaintiffs actually file a complaint concerning the EU's GMO approval process. Specifically, the Panel concluded that the relevant EU regulations constitute measures which may affect international trade as determined by the SPS Agreement. The implication of this is that the EU's GMO approval process may subsequently be found

in violation of WTO rules if it can be shown that it does not meet the risk assessment criteria of the SPS Agreement.

The Panel also examined the EU's GM food labeling requirements. Here it concluded that, insofar as these labeling requirements relate to the purpose of protecting human health and the environment from the unanticipated effects of GMOs, the EU's rules on GM food labeling do fall within the scope of the SPS Agreement. However, the Panel also recognized the notion that labeling may be required in order to ensure that consumers who have a preference for non-GM foods are not "misled" into purchasing GM foods. The implication of this would seem to support what was noted earlier – the EU might be able to defend its GM food labeling requirements outside of the SPS Agreement on the grounds of consumers' right to know.

Impact of the WTO Ruling

While it is moot whether the EU's moratorium had already been lifted at the time the US filed its complaint, it is certainly the case that in its ruling on the safeguards implemented by six EU Member States, the Panel clearly asserted that they were put in place without the necessary risk assessment required by the SPS Agreement.

In addition, in its analysis of the EU's regulatory regime, the Panel was also quite clear that it is covered by the SPS Agreement, and therefore might have an effect on international trade. Even though much of the Panel's discussion is both legalistic and even arcane, it would be reasonable to conclude that in any future dispute, the WTO will carefully examine whether the EU's or any other country's GMO regulations are consistent with their obligations under the SPS Agreement. In addition, the Panel's unwillingness to regard the precautionary principle as part of accepted international law suggests that this will not be a defense for implementing trade-distorting regulation of GMOs. The overall conclusion therefore would be that little has been changed by this ruling, although a clearer indication has been given as to how a WTO Dispute Panel might rule in the future.

Bibliography

World Trade Organization. "European Communities-Measures Affecting the Approval and Marketing of Biotech Products." WTO, Geneva, 2006. http://www.wto.org/english/news_e/news06_e/291r_e.htm

Clive James. "Global Status of Commercialized Biotech/GM Crops: 2006." ISAAA *Brief* No. 35-2006. http://www.isaaa.org/resources/publications/briefs/35/executivesummary/default.html

Eurobarometer. "Europeans and Biotechnology in 2005: Patterns and Trends." Brussels, 2006. http://www.gmo-compass.org/eng/news/stories/227.eurobarometer_europeans_biotechnology.html

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