RESEARCH AT A GLANCE

Biotechnology and Genetic Resource Policies

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Policy, National Regulation, and International Standards for GM Foods

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The introduction of biotechnology into the agri-food world in the 1990s complicated an already difficult regulatory and trade system. At one level, biotechnology and genetically modified (GM) foods increase the potential for trade and the need for a fully functioning international trading system. At another level, the products of this new technology have precipitated a large and difficult debate about the structure and effectiveness of national food safety regulations and the appropriate role for international institutions. A number of national and international efforts are underway to manage these pressures, but prospects for early resolution are not great.

Biotechnology, Production, and Agri-food Trade

Biotechnology is inextricably linked to international trade. The technology has been globally developed and is being applied to research programs in more than 30 countries around the world. Biotechnology has had the greatest effect on the most heavily traded agri-food commodities in the global trading system.

Although the first biotechnology-based agri-food product entered the market only in 1994, by 2001 more than 50 modifications involving 13 crops had been approved and produced on more than 52 million hectares in at least 14 countries. Commercial production of GM foods has been concentrated in canola, corn, cotton, and soybeans, which are extensively traded internationally. Perhaps most important, GM production has been concentrated in countries that are the traditional and dominant exporters of those crops (particularly Argentina, Canada, China, and the United States). Up to 88 percent of trade in some of the products with GM varieties comes from the key GM-adopting countries (Table 1). For the most part, GM products have been marketed as commodi-

Table 1—Production and trade of GM agri-food products, 2000

Crop	Number of producing countries	Percent of global exports from GM producers	Number of importing countries
Maize/corn	8	85	168
Soybeans	6	88	114
Canola	2	50	68

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ties and mixed with batches of GM and non-GM products as they flow into the international marketplace and then to many countries around the globe. Once in these markets, the commodities are extensively processed, and their components (edible oils, corn meals, soybean proteins, and so on) are fundamental ingredients in more than 70 percent of the processed foods available in most developed-country markets.

GM products appear to simply raise new concerns about access to international markets. Those few countries producing and exporting the products seek to be able to continue their business unimpeded. Yet GM varieties tend to exacerbate the debate about market access because almost all the biotechnology traits in commercial production—herbicide tolerance, insect resistance, and viral resistance—lower production costs or increase yields. Those countries adopting these technologies, which also tend to be traditional exporters, thereby increase their exportable surpluses, depressing world prices and making nonadopting importing producers less competitive. As a result, disadvantaged farmers may join with consumers in importing countries concerned about the safety of these products in calling for increased controls on these products.

The Domestic Regulatory Response

A number of factors have made this issue hard to handle. Uncertainty about the food and environmental safety of new GM foods has led to different responses in different markets. Those markets lacking domestic regulators that command the confidence of consumers have tended to act in a "precautionary" way, either reviewing the products more slowly or imposing temporary bans on the introduction of the new products. This is a sharp break from the international food safety system that evolved over the past 100 years, where importers tended to accept the food and environmental safety judgments of regulators from those countries developing and exporting the products. One result of this "renationalization" of agri-food safety regulation is that national systems have tended to diverge. Canada, Japan, Mexico, and the United States, among others, generally make similar rulings and have approved most of the new GM products for production and consumption. Regulators in Australia, the European Union (EU), and New Zealand, in contrast, have postponed approvals in recent years, reflecting the concerns of their citizens. Another 20 or so countries have developed domestic regulatory systems consistent with one or other of these approaches.

The diverging domestic systems are most evident when one looks at the labeling systems being proposed or developed in various countries (Phillips and McNeill 2001). So far more than 26 countries have either adopted provisions or announced plans for rules to help the market develop and deliver labeled products. At one extreme, Argentina, Canada, Hong Kong, and the United States have adopted a voluntary labeling strategy that will likely allow labels for either GM or GM-free products, with only 1–5 percent tolerances for comingling. At the other extreme, 22 countries and the EU have adopted or announced plans to implement mandatory labeling systems. As of June 2002, only a handful of these countries had revealed the full structure of the labeling rules they intend to pursue, and only Australia, China, Japan, New Zealand, South Korea, and the United Kingdom have formally implemented labeling systems. A number of other countries have proposed mandatory labeling (for example, Brazil, Czech Republic, Hungary, Indonesia, Poland, Russia, South Africa, and Thailand), but there is little available evidence that these countries have developed domestic systems to manage such regulations or, for that matter, any firm indication of when their systems might be operational.

The key concern about the diverging domestic regulatory systems is that production and trade are shifting. Key GM adopters, especially Canada and the United States, are abandoning or losing key markets and diverting their exports to new markets. U.S. exports of corn to the EU have fallen by 70 percent in recent years, U.S. exports of soybeans to the EU have dropped by 48 percent, and Canadian exports of canola to the EU have dropped 96 percent. Meanwhile, the EU has developed new GM-free sources of soybeans from Brazil and canola from Australia, both markets that have not yet approved GM varieties for those crops. So far these changing trade flows have not significantly affected producer returns—trade has simply been reallocated between adopting and nonadopting countries—but over time such policies have the potential to seriously distort trade flows and offset many of the benefits of recently negotiated international trade agreements for these products.

Most of the rest of the countries in the world do not have any domestic regulatory capacity and are seeking guidance and help from international institutions.

The International Regulatory Response

Nine international bodies are currently vying to coordinate and regulate different aspects of food safety (Table 2). These institutions fall into three types. Five are largely science-based organizations: the International Plant Protection Convention (IPPC), International Epizootics Organization (OIE), Codex Alimentarius (Codex), the Food and Agriculture Organization of the United Nations (FAO), and the World Health Organization (WHO). One, the World Trade Organization (WTO), is a trade-based organization. The three others have broader objectives such as environmental protection and other social or political goals: the Organisation of Economic Co-operation and Development (OECD), Regional Initiatives, and the Cartagena BioSafety Protocol (BSP). These organizations seek to develop standards for health, safety, and labeling for GM foods, establish testing procedures to ensure the standards are met, provide rules for allowable policies, and create systems to manage disputes (see Buckingham and Phillips 2001).

Despite the substantial effort being undertaken, there is no common view on the goal of international regulation. While most agree that safety is the bottom line, few can agree on what that means, whose opinions should hold the most weight (scientists' or citizens'), or how to handle nonsafety issues such as social, economic, or ethical concerns. The FAO and WHO have a long history of multilateral efforts to promote food security and public health and have worked to develop a consensus about the implications of biotechnology for their areas of interest. Meanwhile, the IPPC and OIE are multilateral treaties that seek to protect plants and animals from the spread of pathogens through international trade, thereby providing much of the scientific consensus that underlies domestic food safety systems. Both institutions have their own nonbinding dispute avoidance and settlement systems, but their most important role in international trade is through the WTO Sanitary and Phytosanitary Agreement (SPS), which uses the IPPC and OIE standards as the basis for evaluating SPS disputes. National measures based on international standards from either of these institutions will generally not be open to challenge under the WTO dispute resolution process.

Furthermore, both the IPPC and OIE nominate experts for WTO SPS dispute panels and provide technical background information to the panels based on their standards. As such, they can have far-reaching economic and political consequences on food trade.

The Codex, under the joint FAO/WHO Food Standards Program, provides a similar service related to processed foods. The Codex develops international food standards, which identify the product and its essential composition and quality factors, identify additives

Table 2—International regulatory institutions

Institution	Members	Coverage
Food and Agriculture Organization of the United Nations (FAO)	184	Food security programs
World Health Organization (WHO)	191	Health science and policy
International Plant Protection Convention (IPPC)	107	Pests and pathogens (crops)
International Epizootics Organization (OIE)	155	Pests and pathogens (animals)
Codex Alimentarius (Codex)	165	Food standards and labels
World Trade Organization (WTO)	139	Trade rules for all goods; Dispute Settlement Mechanism
Organization for Economic Cooperation and Development (OECD)	29	Harmonize standards and policies
Regional Initiatives	Various	Harmonize science or processes
Cartagena BioSafety Protocol (BSP)	Minimum 50	Transboundary movements of living modified organisms

and potential contaminants, set hygiene requirements, provide labeling requirements, and establish the scientific procedures used to sample and analyze the product. Each standard normally takes six or more years to develop. Determination of the safety of the food product is based on scientific risk analysis and toxicological studies. Once a Codex standard is adopted, member countries are encouraged to incorporate it into any relevant domestic rules and legislation, but they may unilaterally impose more stringent food safety regulations for consumer protection, provided the different standards are scientifically justifiable. Codex plays an important role in agri-food trade because its standards, guidelines, and recommendations, like the IPPC and OIE provisions, are acknowledged in the SPS and Technical Barriers to Trade Agreements during consideration of trade disputes. There has been an eight-year process to develop a Codex standard for products of biotechnology, but consensus eludes the negotiators.

The OECD, composed of 29 industrial democracies, has actively assisted in harmonizing international regulatory requirements, standards, and policies related to biotechnology since 1985. The OECD has undertaken a number of projects to make regulatory processes more transparent and efficient, to facilitate trade in the products derived through biotechnology, and to provide information exchange and dialogue with non-OECD countries.

A number of bilateral or multilateral regional initiatives have played an increasingly important role in regulating trade in goods and services. These institutions help create the consensus necessary to establish international rules, given that many food safety concerns in trade are bilateral and the knowledge base to develop standards resides in a few countries only. The Trans-Atlantic Economic Partnership (TEP) between the United States and the EU, for example, has undertaken talks in recent years to improve regulatory processes and scientific cooperation through mutual recognition of testing and approval procedures; progressive realignment or adoption of the same standards, regulatory requirements, and procedures; the adoption of internationally agreed upon standards; and dialogue between scientific and other expert advisers in standard-setting bodies and regulatory agencies. The EU has similar trade liberalization initiatives with Canada and Japan. Since 1998 the Canadian Food Inspection Agency and the U.S. Department of Agriculture's Animal and Plant Health Inspection Service have also been studying and comparing the molecular genetic characterization of transgenic plants in search of ways to harmonize their regulatory review processes. Some agreement has already been achieved, although no formal binding bilateral agreement has yet been concluded. Meanwhile, Canada, the EU, and the United States all offer training and support for regulators in key import markets (usually developing countries) in an effort to "export" their regulatory models to other countries. These bilateral processes could be an important way to resolve technically based trade disputes. Regional agreements, memoranda of understanding, mutual recognition agreements, formal dialogues, and joint research projects are mechanisms that can be used to decrease bilateral regulatory barriers to GM food trade.

The WTO has become a focal point for examining and resolving trade disruptions related to GM foods. Although there was a nonbinding agreement on technical barriers to trade in the Tokyo Round of the General Agreement on Tariffs and Trade, the 1995 SPS agreement for the first time extended the newly formalized and binding dispute settlement system to cover trade concerns related to sanitary and phytosanitary rules and technical barriers to trade. The WTO agreement permits national "standards or regulations for the classification, grading or marketing of commodities in international trade" (Article XI) and the adoption or enforcement of measures necessary to protect human, animal, or plant life or health (Article XX(b)), but it sets some rules on when and how they may be used. Specifically, the SPS Agreement requires that measures (1) do not discriminate between member states; (2) conform where possible to international standards developed by Codex, OIE, or IPPC; (3) be based on scientific principles and the completion of a risk assessment study; and (4) do not constitute a disguised restriction on international trade.

Although the WTO is the main locus of dispute resolution for many countries, it has some limitations. As currently interpreted, the SPS Agreement allows regulations based on science but does not permit regulations that restrict trade based on nonscience concerns such as consumer preference, animal welfare, or nonmeasurable environmental risks.

The Cartagena Biosafety Protocol is one effort to

provide a more comprehensive international structure to ensure the protection of biodiversity and to facilitate consideration of nonscientific concerns in food trade. Although the Cartagena Protocol, concluded in Montreal in January 2000, is primarily designed to provide rules facilitating advance informed agreement (AIA) for first-time transboundary movements of living GM organisms intended for environmental release, it also provides for labeling (but not AIA) of GM elements in commodity shipments destined for the food chain. Countries can use this transparency to decide whether to import those commodities, but the current interpretation is that import bans must still be consistent with the WTO principles already noted. It is perhaps too early to make a confident evaluation of the protocol.

The only conclusion one can derive from this survey of international institutions is that no one institution, and perhaps not even the entire array of institutions, is likely to yield an early resolution to concerns about diverging national policies and regulations concerning GM foods.

Concluding Comments

The adoption of biotechnology and the introduction of GM foods into the international marketplace has exacerbated an already difficult area of trade policy. As biotechnology increases productive capacity in various products, it also increases the need to trade. But diverging national regulations are increasingly impeding trade in these products. This situation has begun to create production and trade distortions, which will build over time. Overcoming these distortions is made more difficult by the fact that the recent WTO agreement on agriculture is not yet fully implemented, and many of the issues left to handle are highly contentious. There is little goodwill in the policy community that can be directed to resolving the growing trade irritants caused by GM foods. As a result, a messy trade world is likely to continue. The private sector may find it needs to change how it introduces and markets the new products of biotechnology in order to maintain market access.

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