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Biotechnology: Can We Trade It?

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The question in the title is divided into: (1) Can we trade the current generation of products from biotech or the technology itself? and (2) Can we trade the future generations of products of the technology? Controversy over the first generation of products has resulted in international trade being segmented into two markets: GMO-free and GMO. The first market is supported by voluntary labelling, making mandatory labelling largely unnecessary. While trade flows have been rearranged, markets have been little affected. We conclude that trade in the future generation will be dominated by capital and technology flows, with production for local markets dominating product trade flows.[1]

Keywords: GMO; institutions; investment; labelling; trade

Introduction

This paper divides the question of whether biotechnology can be traded into two somewhat more manageable questions: (1) Can we trade the current generation of products from biotech or the technology itself? and (2) Can we trade the future generations of products of the technology? The first question addresses the ability of biotechnology innovators to trade the technology or its products across national borders. That ability depends on the regulations governing the testing and approval of the technology by national governments

around the globe. This question also addresses trade in the first generation of commercialized products from biotechnology, which are largely crops with improved input traits.

Consumer concerns with intrinsic product attributes—largely issues of food safety—and extrinsic attributes—ranging from environmental impacts of producing genetically modified crops to control of the global food supply—have placed constraints on trade in commodities. The issues are numerous, and many actors are involved, in both private and public sectors. Mandatory and voluntary labelling have emerged as important private and public issues, as have verifiable production and marketing systems that preserve the identity of a product and guarantee its segregation.

Answering the second question requires a prediction of what the next generation of commercialized products from biotechnology will be, and of the trade conflicts that may arise from their commercialization. To narrow the topic, this paper focuses on nutraceuticals and functional foods. As many commentators have reasoned, consumer acceptance will be less of an issue if products have discernible consumer benefits. Regulation and trade of these products will hinge on how they are classified: as food, food additives, or drugs.

Of course, separating the discussion of the paper to deal separately with the two questions is only partially effective. All aspects of trading biotechnology are interrelated and actions taken to resolve conflicts over trade in the technology will clearly affect trade in the first and future generations of products. That said, the separation does provide a convenient way of dividing issues, institutions and institutional developments.

Biotechnology, in this paper, is synonymous with genetically modified organisms, genetically modified microorganisms, and living modified organisms. The European Union offers the following definition: “Genetically modified organisms (GMOs) and microorganisms (GMMs) can be defined as organisms (and microorganisms) in which the genetic material (DNA) has been altered in a way that does not occur naturally by mating or natural recombination. The use of ‘recombinant DNA technology’ or ‘genetic engineering’ allows selected individual genes to be transferred from one organism into another, sometimes between non-related species” (EU, 2000a).

Trade of the Technology and Its First-Generation Products

National Institutional Developments and Innovations

In many developed countries, discussions on appropriate regulatory norms date back to the early 1980s. In 1986, there was an OECD Council Recommendation that the risks of genetically modified organisms were expected to be the same as those of conventional ones and could be assessed in similar ways (OECD, 1986). This notion of “substantial equivalence,” however, has been mirrored in only a few regulatory regimes. In the United States, the Food and Drug Administration (FDA) adopted such a regulatory approach, whereby products of

biotechnology are assessed within the existing framework for food safety and nutritional fitness. A similar approach was adopted in Canada. Therefore, most regulation, including the United States Environmental Protection Agency (EPA) framework regulating environmental release of genetically modified organisms, has focused on the process of biotechnology rather than its products.

In the European Union (EU), a process-specific regulatory framework was also adopted starting with Directives 90/219 and 90/220 on the contained and deliberate release of genetically modified organisms in 1990. Since that time, the regulatory framework in the EU, reflecting vocal consumer concerns with the technology, has been frequently revised and shaped by different legislative bodies.[2] The 1997 revision of Directive 90/220 was particularly important as it installed mandatory labelling for genetically modified organisms. A major revision is also currently in progress to introduce, among other things, "ethical considerations" in the regulation of biotechnology. This later revision has translated into a *de facto* moratorium on new product approvals until 2002 when the new rules are expected to come into effect.

Horizontal legislation in the EU has been complemented by vertical regulations for specific product risks, which have also needed continuous revisions to reflect changing consumer attitudes. Regulation 257/97 on novel foods made labelling of GMOs mandatory in 1997. But it was not until a year later (regulation 1139/98) that the presence of foreign DNA or newly expressed proteins in foods was made the criterion for labelling. A standard was established in 1999 when the threshold of foreign DNA triggering mandatory labelling was set at 1 percent. Further revisions requiring mandatory labelling for food additives and flavourings in processed foods came into effect in April 2000. The animal feed directive is currently under revision to bring feed in line with other novel foods legislation.

Interestingly, regulation and public opinion toward biotechnology have evolved simultaneously. In the United States and Canada, the regulatory regimes have been largely unchanged, paralleled by relatively stable and positive public attitudes toward biotechnology (Gaskel et al., 1998). In the European Union, increased regulatory oversight has coincided with increasingly negative public attitudes toward biotechnology and diminishing trust in public authorities and regulatory agencies (Cantley et al., 1999).

Recently, Japan and Korea also introduced mandatory labelling for biotechnology products.[3] Various other countries are considering labelling regulations, while Canada and the United States have announced their intent to provide guidelines for voluntary labelling. At this time, regulation for biotechnology and the current generation of products seems to be drifting toward labelling. Even under such conditions, the regulatory regime across the globe will remain fragmented for some time, as standards tend to vary significantly from one country to another.

Private Initiatives and Voluntary Labelling

Some consumer advocates have argued that the presence of GMOs in food products is no different from extrinsic attributes such as production processes that encompass animal welfare standards, and that consumers have a right to know about the processes used to produce a product. Some firms, particularly in Europe, have been keen to embrace this distinction and to offer products that are free of GMOs. In the United Kingdom, for example, some food retailers (e.g., Iceland, Waitrose, and Marks and Spencer) have aggressively adopted GMO-free food products as a corporate strategy. These firms, which cater to middle- and upper-income shoppers, include the attribute of GMO-free as one of the intrinsic and extrinsic attribute bundles offered to their customers. Other attributes that are prominent in the corporate strategy are farm quality assured (which includes animal welfare standards), organic, and natural. Products may not be explicitly labelled as GMO-free, but customers know that own-branded products are largely free of GMOs.

Some multinational food firms have also adopted a GMO-free strategy, more as a reaction to perceived consumer concerns than as an aggressive corporate strategy. Gerber for example has claimed GMO-free baby foods worldwide. Nestlé on the other hand has explicitly supported biotechnology while offering GMO-free food products only in geographic markets where consumer response has been negative (e.g., in the EU).

All of these examples fall into the category of voluntary labelling. Voluntary labelling is a "done deal" in most European markets. Mandatory labelling, then, adds little information if private brands are recognized to be products that are free of GMOs.

International Institution Development and Innovations

International attempts to resolve differences in views on trading biotechnology and first-generation products have focused on the World Trade Organization (WTO) and the Cartagena Protocol on Biosafety. The WTO is involved through the application of existing agreements on food and agricultural trade, and through the ongoing negotiations on the Agreement on Agriculture. The Cartagena Protocol on Biosafety, by some accounts, applies labelling requirements for trade in some genetically modified organisms.

World Trade Organization

Stilwell (1999) identifies several agreements in the WTO that govern trade in genetically modified organisms. Article 27.3(b) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) requires patents on GMOs, but allows governments to exclude plants and animals, and to use *sui generis* systems rather than patents to protect plant varieties. Countries with multinational firms creating the technology and whose farmers grow genetically modified crops would like to increase intellectual property protection. Other countries propose to extend the Article 27.3(b) exception, and to leave the meaning of *sui generis* systems undefined.

The Agreement on Technical Barriers to Trade (TBT) includes disciplines on national technical regulations and standards, including the labelling of products. The Agreement on the Application of Sanitary and Phyto-sanitary Measures (SPS) requires the use of science-based disciplines and risk analysis in the application of trade restrictions to protect plant, animal, and human health. Food safety issues arising from genetically modified organisms might be addressed by the SPS Agreement. The Agreement on Agriculture, of course, governs trade in agricultural products, which naturally includes genetically modified agricultural and food products.

Stilwell also discusses proposals made by countries in preparation for the Seattle ministerial meetings. The United States called for the WTO to address "disciplines to ensure trade in agricultural biotechnology products is based on transparent, predictable and timely processes." The U.S. proposal provided little information relating the new disciplines to existing commitments in the Agreement on Agriculture or other WTO agreements. The United States has consistently declared its firm decision not to seek the reopening of the SPS Agreement.

Canada called for the creation of a WTO Working Party on Biotechnology that should "engage in a collective exercise aimed at establishing how trade and investment in biotechnology are covered by existing WTO provisions and whether the latter constitute a sufficiently effective regime from the WTO perspective." This new working party would provide any conclusions it considers appropriate, and its work would "not be prejudicial as to the need, or not, of any future negotiations … ."

Japan proposed that the WTO should "establish an appropriate forum to address new issues, including GMOs." This could take the form of "a subgroup of an independent negotiating group on agriculture to identify topics on food-related matters of GMOs" and, according to Japan, such a group could consider, among other things, whether "the relevant WTO agreements, such as SPS, TBT and TRIPS … are capable of responding to [GMO-related] matters."

Stilwell points out a number of issues surrounding WTO regulation of GMOs, largely of a critical nature and from the point of view of some developing countries:

- New WTO disciplines on trade in GMO products might deregulate, rather than regulate, trade in biotechnology products and limit the authority to set national laws, including national labelling schemes, to control the import of genetically modified food products.
- The proper relationship must be clarified between possible new WTO disciplines and the need to regulate the international movement of GMOs, including, for example, through the effective Biosafety Protocol.

- There is a need to address the proper role and limits of the multilateral trading system and whether the WTO should consider trade in GMOs as a "new issue," including whether its inclusion will unbalance the existing negotiating agenda and whether, on short notice, developing countries have sufficient capacity to adequately represent their interests.
- Broader questions remain about food security, agriculture, environmental protection, human and animal health, and equitable development.

Swinbank (2000) points to three possible concerns that might lead to trade restrictions: the safety of food containing GMOs; a potential detrimental impact on the environment; and ethical concerns with the technology itself. He points out that if scientific evidence can be marshalled for the first two issues, the SPS Agreement could be invoked to support trade restrictions, or to question their application.

Negotiations in the WTO will pit the self-interest of the handful of countries that generate and produce the current generation of genetically modified organisms against the European Union, which is being pushed very hard by vocal consumer interests, and a large number of developing countries. It seems clear that resolution of differences will be difficult, indeed.

Cartagena Protocol on Biosafety

Negotiations in the WTO must, of course, be mindful of agreements reached in other international fora. In late January 2000, more than 130 countries, all of them members of the Convention on Biological Diversity, adopted the Cartagena Protocol on Biosafety. The Biosafety Protocol provides a framework to address the environmental impacts of living modified organisms (LMOs), the technology, and the first generation of products. According to a fact sheet from the U.S. Department of State (2000) "The Biosafety Protocol will help protect the environment without unnecessarily disrupting world food trade."

This will be accomplished by:

- Requiring bulk shipments of LMO commodities, such as corn or soybeans, that are intended for food, feed, or processing to be accompanied by documentation stating that such shipments "may contain" LMOs and are "not intended for intentional introduction into the environment."
- Establishing a process for considering more precise identification of LMO commodities in international trade.
- Establishing a biosafety "clearinghouse" and an advance informed agreement procedure that requires exporters to seek consent from importers before the first shipment of LMOs intended for intentional release into the environment.

The protocol does not address food safety issues, does not require segregation of bulk shipments of commodities that may contain LMOs, and does not change obligations assumed by membership in the WTO. Moreover, it requires neither identity preservation nor consumer product labelling. The protocol will come into force when 50 member countries have ratified it. The United States is not a party to the Convention on Biodiversity, and so presumably is not bound by this agreement.

An important element of the protocol is the acceptance of the "precautionary principle." The precautionary approach, mentioned in the preamble of the protocol and several other sections, holds that even when there is a lack of scientific evidence that products produced through biotechnology are likely to cause harm, a country can take action to ban the import of those products. In the final agreement, specific references to the precautionary approach in operational provisions also were incorporated.

The EU, in a February 2000 communication, provided its interpretation of the precautionary principle. The precautionary principle is to be considered within a "structured approach" to risk management that includes risk assessment, risk management, and risk communication. The precautionary principle may be invoked when "potentially dangerous effects" have been identified, but "scientific evaluation does not allow the risk to be determined with sufficient certainty." Measures taken under the precautionary principle should be proportional to the chosen level of protection, nondiscriminatory, and consistent with measures already in place. Further, an evaluation of costs and benefits, going beyond an economic analysis, "comparing the overall cost to the Community of action and lack of action, in both the short and long term," should be carried out.

Trade of First-Generation Products

Fragmented regulation and lack of standards could encourage market segmentation. In practice, two market segments have already emerged, one where biotechnology products continue to be traded without restrictions and a "non-GMO" market. Commodity markets affected by biotechnology (i.e., corn, soybeans, and canola) have shown little strain from such segmentation, as supply and demand shifts have been limited and gradual (Ballenger, Bohman and Gehlhar, 2000; Kalaitzandonakes, forthcoming).

With the exception of Mexico and Taiwan, all major importing countries have experienced some degree of negative consumer response toward biotechnology and have installed mandatory labelling regulations. Consumers in all major exporting countries have been more accepting of the technology and domestic markets have been largely undisturbed. As domestic consumption in these countries dominates exports, demand shifts have been limited. Demand shifts have also been minimized as feed use dominates both the domestic and international markets in these commodities. Feed markets have been largely

open, though the EU market has been deteriorating. In addition to regulation for mandatory labelling of feed currently being prepared by the EU Commission, a number food merchants in the European Union claimed meats as fed with non-GMO feed as early as 1999.

In the international markets for corn and canola, the EU is a minor player and has little impact on trade.[4] In the soybean market, however, the EU is the primary import market and any shifts can have meaningful impacts on trade flows. At current market conditions, identity preservation will be required to effectively supply the EU market if significant demand for non-GMO feed exists.[5]

Identity preservation implies additional costs. Farmers must be compensated for the direct costs of segregation and for forgone profits from not using engineered crops. Similarly, grain handlers must be compensated for direct logistical costs for segregating, testing, and certifying crops from field to market. Identity preservation costs at the grain handler level can be substantial, especially under strict purity standards (Lin, Chambers and Harwood, 2000). They are much higher when opportunity costs are added to account for capacity under-utilization as well as forgone profits from spread opportunities and other value-added activities (Maltsbarger and Kalaitzandonakes, 2000). As such costs are borne by all food merchants, they will ultimately be passed on to the consumer.

Identity preservation in processed food supply chains is more complex. Complexity increases disproportionately with the number of ingredients and their sources and so do added costs. Accordingly, regionalization of processing could be encouraged, especially for highly processed foods.[6] Bredahl (2000) found that multinational firms tended to produce in one European country and to distribute products to the other countries. This meant that producing GMO-free products for one national market required producing the same product for several markets.

Concentration in food processing markets acts to shield markets from unexpected abrupt shifts (Kalaitzandonakes, forthcoming). In markets with significant supplies of biotechnology products, large buyers cannot shift from one market segment to the other without significant risks of supply disruptions and increased liability. Therefore, any such market shifts will likely come only under deteriorating consumer response and with advance notice to suppliers. These conditions help markets adjust without major disruptions. In markets with consumer preferences for non-GMO products and adequate supplies of conventional crops, food processors have typically pre-empted suppliers.

Overall, with the EU soybean (oil) market being a possible exception, little in the way of major short-term market shifts should be expected. Consumer attitudes will dictate whether key markets, such as the United States and Asian feed and processed food markets, remain open to biotechnology products. However, markets have the mechanisms to accommodate any demand shifts without major or unexpected disruptions.

Trading the Future Generation of Products

Biotechnology's next quest, to provide field crops with value-enhanced qualities for end-user output traits is underway. Biotechnology's first stage featured crops with improved agronomic qualities, for example, input traits valued by farmers, such as resistance to pests. Second-generation biotechnology products make possible a system where farmers grow crops designed for the specific needs of end-users in food manufacturing, the livestock sector, and even the pharmaceutical industry (Kalaitzandonakes and Maltsbarger, 1998). Regulating such products will prove challenging.

Uncertainty over the regulation of nutraceuticals and functional foods illustrates the upcoming challenges for second-generation biotechnology products. Nutraceuticals enjoy a broad acceptance driven by the increased awareness among consumers of the connection between diet and disease. This newest offspring in the world of "high-tech" food products is currently so cutting edge that there is neither a concrete definition for nutraceuticals nor legislation to regulate these products. Whether nutraceuticals are to be considered drugs, foods, or food additives could determine how governments apply existing policy and develop future legislation. Like most countries, the United States has laws in place that regulate drugs and food additives separately, but when food manufacturers make health or medical claims about the function of their product, the line between drugs and food additives becomes blurred. The idea of "food as medicine and medicine as food" challenges the archetypal paradigm most consumers have had for food.

National Regulation of Nutraceuticals

United States

Not all nutraceuticals are products of biotechnology. Nutraceuticals are generally regarded as products for final consumption. Food safety is generally regulated by the FDA post market, which follows the FDA's traditionally "hands-off approach" to regulations (Echols, 1998). A new food, be it genetically modified or otherwise, must be established as having "substantial equivalence" to a traditional counterpart; it is thereafter regarded as safe for consumption and no further review of the food is required.

A "drug" is defined as: (1) an "article recognized in the official United States Pharmacopoeia, the official Homeopathic Pharmacopoeia of the United States, or the official National Formulary, or any supplement to any of them; (2) an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) an article (other than food) intended to affect the structure or any function of the body of man or other animals" (21 USCS § 321, 1999). New drugs must be shown, through clinical trials, to be safe for their intended purposes prior to being released onto the market. Drugs, unlike foods, can make "disease claims" indicating their specific effect on a disease or diseases.

The FDA has a separate designation for food additives. According to the FDA, "Food additives include all substances not exempted by section 201(s) of the act, the intended use of which results or may reasonably be expected to result, directly or indirectly, either in their becoming a component of food or otherwise affecting the characteristics of food" (21 CFR 170.3(e)(1), 1992). Food additives are significantly different in function, nutritive value, or amount than the typical components of food.

The term nutraceutical describes many different kinds of products, from pill-form crushed cranberries to edible vaccine potatoes and genetically engineered rice with an improved protein profile. The most encompassing and accurate description is:

> Nutraceuticals are foods or food ingredients that provide medical or health benefits, including disease prevention and treatment. This emerging class of products blurs the line between food and drugs (Adelaja and Schilling, 1999).

With this definition in mind, several questions may be raised. How will the federal government regulate such products? When will legislation be passed to regulate such products? How will regulation affect producers and consumers of nutraceuticals?

Nutraceutical regulation could ultimately consider such products as food additives or as drugs. The primary laws that regulate products that are similar to or are nutraceuticals come under the Federal Food, Drug, and Cosmetic Act and the U.S. Food and Drug Administration (FDA) regulations. Although these laws have been around since the 1990s, nutraceuticals are as of yet not mentioned directly by the FDA in any U.S. legislation (Rodriguez, 1998).

For nutraceuticals that are food additives as a result of genetic modification, the FDA's biotechnology policy "treats substances intentionally added to food through genetic engineering as food additives if they are significantly different in structure, function, or amount than found in food" (FDA/Center for Food Safety and Applied Nutrition, 2000a). This seems to indicate that in the future the FDA could view nutraceuticals as food additives. Should the FDA decide to apply existing food additive legislation found in the Federal Food, Drug and Cosmetic Act to nutraceuticals, such regulation will go the way of dietary supplements and a statute will be passed to address nutraceuticals specifically. Many nutraceuticals already fall under the classification of dietary supplements. There is legislation that specifically addresses this class of products without directly naming nutraceuticals as such.

The Dietary Supplement Health and Education Act of 1994 (DSHEA) was the first real step toward installing specific legislation relevant to nutraceuticals. According to the DSHEA, "dietary supplement ingredients may not be regulated as food additives" (Council for Responsible Nutrition, 2000). This act, which received strong support from Congress, seeks to protect the public against products that may pose a risk to consumer health. It pro-

vides procedures for the regulation of new products and approval of health claims for supplements, a definition of a dietary supplement, and labelling requirements. It also requires that manufacturers follow special Good Manufacturing Practices (GMP).

Health claims are regulated under the Nutrition Labeling and Education Act. This act limits the kind of claims that nutritional supplements and foods can make about their effect on the human body. Health claims may tout nutritional benefits and demonstrate nutritive value to consumers. But to maintain the distinction between foods and drugs, the FDAdoes not allow health claims to declare therapeutic, medicinal, or pharmacological effects on the body. Health claims are not appropriate when they imply that a food is able to diagnose, cure, treat, or mitigate a disease. The FDA has sanctioned certain kinds of health claims, such as structure/function claims like, "calcium builds strong bones" (Rodriguez, 1998). The FDA also remarks that, "the relationship of a food or food component to a disease is different from that of a drug because of genetic, environmental, and behavioral factors that effect the development of chronic disease in addition to diet, and because of the complexity of foods themselves" (65 FR 14219, 2000). In an effort to be consistent the FDA authorizes health claims to keep up with the rapidly evolving nature of food science. It is possible to petition the FDA to approve a health claim, but there is a rigorous scientific approval process that must be completed before the health claim is accepted (Rodriguez, 1998).

Building on the work accomplished by the Dietary Supplement Health and Education Act in June of 1999, the Food Advisory Committee (FAC) developed further plans for the regulation of supplements. A major concern of the FDA is the correct identification and testing of the ingredients of dietary supplements. To guard against misidentification of ingredients the FAC plans to help firms better comply with GMP. The FAC wishes to define what constitutes "adequate testing" of supplement components for firms. The FAC has also developed an outline of the kinds of records firms must maintain in order to insure quality and safety standards are met.

The federal government is not likely to regulate nutraceuticals as drugs. Nutraceuticals are more like food than they are like drugs. In the eyes of the U.S. government they are perceived to be "encompassing food specially formulated to provide one or more dietary ingredients that can be expected to improve long-term health to reduce the risk of chronic disease" (Rodriguez, 1998). To date, the terms "nutraceuticals" and "functional foods" have been used to describe food "that is distinct from the traditional or 'conventional'types of foods that would customarily be found in retail stores. The terms are generally not applied to a product used primarily for characteristics such as taste, aroma, or basic nutrition." These terms are typically used in reference to food products designed to provide some specific health benefit or provide a preventive health measure to the consumer. This seems to indicate that although a nutraceutical is not a traditional food, it is a kind of food

with a unique function. Such foods may be eaten for sustenance as well as for their health benefits. "Nutraceutical" does not refer to a drug that will cure a disease (Rodriguez, 1998). A nutraceutical would be regulated as a drug should the manufacturer make any claims that the food product is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man" (21 U.S.C. § 321, 2000). Claims such as these would be grounds for regulation under United States Code as a drug instead of as a food or food additive.

Obviously producers of nutraceuticals wish to steer clear of allowing their products to be labelled as drugs and consequently regulated as such. This is an industry concern that will not disappear until clear legislation is in place. A recent case of a new product introduction illustrates this point. McNeil Pharmaceuticals introduced a new kind of margarine claiming that not only was it a margarine spread, but it also lowered cholesterol levels. The FDA claimed that the firm must first show scientific data that supported the safety of the product because their claim indicated that it could cure the problem of high cholesterol. When the FDA attempted to block this product from entering the market, McNeil claimed that it didn't need FDA approval. It maintained that the margarine was actually a dietary supplement, and therefore no preliminary regulatory oversight from the FDA was warranted (Adelaja and Schilling, 1999). This uncertainty has prompted many manufacturers to engage independent third parties to perform experimental trials for scientific proof of the safety of their product. This strategy reduces the chance of future unexpected holdups should there be a change in regulation, but in the short run it increases costs.

European Union

Regardless of how world trade standards for nutraceuticals develop, the first concern for the United States is the European Union. Of all the trade relationships the United States shares, by far its largest is with the European Union. It fact, it is the largest trade relationship in the world. For all the benefits both stand to gain from trade, there is a fundamental difference between these two partners: the United States is interested in the safety and quality of the product, but the EU is interested in the safety of the underlying process as well. The marketing of nutraceuticals in the European Union could be at the same time straightforward and problematic. It would be straightforward in the sense that the European market is already familiar with nutraceutical-type products. Europeans have been aware for many years of the health benefits associated with certain foods and dietary supplements. But with that prior knowledge coexists skepticism for U.S. genetically modified products, meaning that genetically modified versions of nutraceuticals may be difficult to market.

Obviously, nutraceuticals will receive some kind of labelling in the EU due to their added nutritional value, and producers of nutraceuticals will want this, but the question is one of how the regulatory framework will evolve. Currently there exist two laws in the EU that govern agricultural biotechnology products and that are of concern to the United

States: Council Directive 90/220/EEC and Regulation 258/97. The difference between a directive and a regulation is that a directive requires each member state to amend its current laws to conform to the directive. A regulation has the direct force of law in every member country. The Council Directive 90/220/EEC gives member countries the power to "provisionally restrict" the entrance of a product into the country.

The Council Directive deals with agricultural commodities and controls the release of GMOs into the environment. The Directive has official control over GMO foodstuffs and is designed to protect the environment from the introduction of unknown potential risks within the European Community. Its effect on nutraceuticals could be significant should the nutraceuticals be in the form of agricultural commodities. Otherwise, Regulation 258/97 is more likely to have an effect on imports of nutraceuticals.

Regulation 258/97 is the more applicable of the two laws since it deals primarily with biotechnology foods or novel foods. It also takes a more restrictive approach to regulation. Since it was developed through co-procedure, the European Parliament had a hand in deciding how GMOs were to be regulated. The Parliament decided that GMOs should be subject to mandatory labelling. It is therefore clear that nutraceuticals that have been developed through genetic modification will be subject to similarly restrictive labelling laws.

Implications for Trade

Trade in inputs to the food processing sector tends to be based on flows of goods, while trade in processed foods (and drugs) tends to be dominated by investment, rather than product flows. This reflects general market characteristics. First, cultural and economic differences vary greatly across countries and so product attributes must be rather carefully targeted to local markets. Second, products need to meet often widely varying regulatory requirements across countries.

As discussed above, differences in regulatory conditions and consumer preferences have induced market segmentation in commodities for first-generation biotechnology products. In the EU, commodities and derivatives with potential GMO origin that are inputs to food markets have been sourced internally or substituted away. Commodities directed to the unaffected feed markets, however, have continued to be traded without interruption. Markets, unlike institutions, have adjusted quickly to the realities of various market segments.

Such general conditions are expected to continue well into the future. Second-generation biotechnologies will continue to challenge the boundaries of the regulatory framework for some time to come. Accordingly, markets and market participants will shoulder the task of bringing relevant products to the various segments.

Summary and Implications

Trade will happen. As long as feed markets remain unaffected in Europe, trade in the products of the first generation of biotechnology will be largely unaffected by disputes over the technology or by differences in consumer values and attitudes. This paper expresses the view that institutional developments, such as agreement on labelling standards in CODEX, will be so slow and any outcome so ambiguous that reducing risk and transaction costs will fall to the private sector, which may well be the most efficient and economically desirable outcome.

Voluntary labelling and branding of proprietary products with desired consumer attributes will overwhelm mandatory labelling. Labelling will either state that the product is GMO-free, or that the GMO adds some discernable consumer benefit to the product.

Trade in future generations of biotechnology will likely occur more in the form of investment flows and production for local markets than it will as trade in products. The market will be differentiated on the basis of consumer attributes that vary across nations, or geographic areas.

Endnotes

1. An earlier version of this paper was presented at the Canadian Agri-Food Trade Research Network Workshop on Agricultural Trade Liberalization: Can We Make Progress? Quebec City, Quebec, October 2000.
2. Several Directives General are involved with shaping biotechnology regulation in the EU. They include: (1) DG III which regulates novel foods; (2) DG VI which regulates feeds and seed; and (3) DG XI which regulates the deliberate releases of GMOs.
3. Mandatory labelling rules in Japan and Korea explicitly exclude feeds, oils, and highly processed foods. Tolerance levels for GMO labels have been set at 5 percent in Japan and 2 percent in Korea.
4. The EU has little impact on commodity corn. It is, however, the world's largest buyer of corn gluten, a by-product used as animal feed. Supplies originate mainly from the United States and at almost $500 million the EU is a significant market.
5. Currently, there are no viable feed substitutes for soybean meal. Some 90 percent of all protein meal fed to animals globally comes from soybeans, canola, and cotton seed, with over 50 percent from soybeans alone. A significant portion of the cotton and canola supplies is also bioengineered. Furthermore, of the three major exporters of soybeans, only Brazil claims non-GMO status and exports to the EU market without significant identity preservation effort. If a significant portion of the current EU imports were to be non-GMO, exports from the United States and Argentina would require identity preservation.

6. A large portion of all processed foods sold by U.S. firms overseas is already produced in U.S.-owned manufacturing facilities in foreign countries close to their destination markets (Henderson et al., 1996). Similar conditions hold for firms from other countries that operate in international markets. Such tendencies could be encouraged in lieu of exports.

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