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PART SEVEN: Labeling and Marketing

37. Market Access and Market Acceptance for Genetically Modified Products

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Chapter 37

Market Access and Market Acceptance for Genetically Modified Products

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Introduction

International trade is a vital factor in the continued development and commercialization of agricultural biotechnology products because wide market exposure is required to recoup substantial R&D expenditures. Recent market access difficulties, especially those faced by North American products in the EU, adversely impact the development and commercialization incentives. There has been little success in developing an international regulatory approach to govern the international trade of genetically modified agri-food products (GMPs), as evidenced by the recent suspension of the negotiations to create a Biosafety Protocol. Instead, the rules for market access are based on national regulatory approaches. Divergent levels of consumer acceptance in North America and Europe translate into divergent regulatory approaches which yield regulatory market access barriers.

Unlike traditional trade barriers (e.g. tariffs, quotas), regulatory barriers are deeply embedded in the political economy of the nation and not easily negotiated away. If international market access is a function of domestic regulatory approaches which are, in turn, a function of consumer acceptance, then it is crucial to examine the factors that determine consumer acceptance.

This paper examines the relationship between market access and market acceptance for GMPs. First, it examines the credence nature of GMPs and the implications for consumer acceptance. This is followed by a comparative assessment of the North American and the EU regulatory approaches to GMPs. Finally, conclusions are drawn regarding the long-term role for producers in overcoming the regulatory barriers.

Consumer Theory and GMPs

Using a strict economic definition, we would consider the consumer to be "any economic agent responsible for consuming final goods and services, including individuals, groups of individuals or more formal organizations" (Pearce, 1996). Tirole (1988) identifies three types of goods: search goods where consumers can visually identify attributes before consumption; experience goods, which require consumption to determine the attributes; and credence goods, where the unaided consumer cannot know the full attributes of consuming a good.

GMPs are best characterized as credence goods. The degree of scientific sophistication associated with products of modern biotechnology tends to create an insurmountable information gap between producers (who possess extensive scientific knowledge, some of which is proprietary and not generally available) and consumers (who are generally less scientifically knowledgeable and do not have access to proprietary knowledge).

Due to the information gap, GMPs as credence goods challenge the assumptions of neo-classical consumer theory. According to neo-classical consumer theory the consumer has access to perfect information about all of the attributes of the product being consumed which includes information on the inputs, the processing and production techniques as well as the cost per unit to produce the good and all other substitutes or complements. With access to all relevant information about the product, the consumer is able to make 'rational' consumption choices. The markets provide 'consumer sovereignty'; where the consumer is the best judge of the welfare implications of consumption and does not require market interventions to enhance that judgment. The government cannot make the consumer or society better off than can the self-interested market exchange[2]. With search goods, the independent consumer can fill any information gap and with experience goods, any information gap may be filled by, for instance, a labeling strategy.

With GMPs, however, the information gap is difficult to fill and appears to be widening not narrowing as applications of biotechnologies increase in complexity and sophistication. There appears to be two general problems with GMPs. First, is that consumers have a broad range of legitimate concerns about GMPs that are not being addressed. Consumers are concerned, not just about the price of GMPs, but about the long-term impacts of GMPs on human health and environmental biodiversity and about the moral, ethical or religious implications of both manufacturing and consuming the products. The general second problem is that consumers have not been given the choice to avoid GMPs is they wished to. The nature of the current global agri-food handling and distribution system for bulk commodities makes it virtually impossible to ensure that GM production is fully segregated from non-GM production (Isaac and Phillips, 1999). Given that the first agri-food biotechnology based products are edible oils (corn, soybeans and canola),, that are constituent ingredients in many processed foods, there is a high probability that virtually any processed food product could have been derived from GM crops. Therefore with GMPs consumers face a significant, and growing, information gap, which contravenes their sovereignty and at the extremes takes away their choice. Not surprisingly, the credence nature of GMPs influences consumer acceptance.

Consumer concerns with and acceptance of GMPs varies across products according to two important factors—the perception of primary beneficiary of GMPs and the perception of the control over the GMPs. With respect to the first factor, medical biotechnology targeted at human health has been generally well received because of the obvious consumer benefits, while the application of modern biotechnology to agri-food production is perceived by consumers to yield only supply-side or production gains. Currently approved GM crops involve improved agronomic traits, such as herbicide tolerance and Bt-resistance, which have proven extremely popular with North American farmers (James, 1998). Also, growth hormones are used extensively in the North

American livestock and dairy industries because of the productivity gains that they produce for ranchers, feedlot operators and dairy farmers. Until the productivity gains result in significant price decreases or until applications target attributes desired by consumers[3], they will likely continue to perceive that they don't receive any benefits from these technological adaptations.

With respect to the perceived control over the application of biotechnology, medical research is often seen as less risky because it is done in closed laboratories under 'controlled' circumstances. Many consumers perceive that agricultural biotechnology is done in an 'uncontrolled' manner because the products are released into the environment (Economist, 1998).

Consumer acceptance of GMPs also varies across regions. Because there are no universally accepted norms related to human and environmental safety and product quality, people with different experiences and interests have widely different perspectives. These differences are reflected in a wide range of consumer acceptance as shown in Table 1.

TABLE 1 Consumer Attitudes to Biotechnology Based Foods, 1995 and 1996

Country	Awareness (%)	Willing to buy (%)	Perceive as health risk (%)
Canada	67	74	Na
US	65	73	21
Japan	89	69	Na
Germany	91	30	57
Austria	90	22	60
Denmark	89	55	44
Finland	79	55	41
Sweden	75	51	65
Netherlands	70	64	48
Norway	68	49	28
UK	57	63	39
Ireland	57	50	48
Belgium	57	62	44
Luxembourg	56	43	38
France	55	60	38
Portugal	51	71	62
Italy	47	53	30
Greece	39	60	33
Spain	35	59	49

Notes: Canada, the US and Japan are 1996; the European results are 1995; awareness is the amount heard or read about biotechnology (a lot, some, a little); willingness to buy is the percent likely to purchase produce developed through biotechnology to resist insect damage; and perception of risk is the percent of respondents rating genetic engineering as a "serious" health hazard.
Source: T. J. Hoban (1997).

The industry is indeed aware of the asymmetry in consumer acceptance that exists between North American and European consumers. For instance, in 1998, both Monsanto and EuropaBio launched consumer information campaigns in Europe to address the relatively low level of consumer acceptance among European consumers. Also, in North America there has so far been little pressure to remove or label food products with GM ingredients. In Europe seven large supermarket chains have joined forces to eliminate GM ingredients in their own-label products including Carrefour (France), Delhaize (Belgium), Marks and Spencer (UK), Migros (Switzerland), Sainsbury's (UK), SuperQuinn (Ireland) and Tesco (UK). Carrefour, France's largest supermarket and the world's third largest retailer, has decided to remove GM ingredients from its own-brand products. Of 1,783 products carrying their label, 516 contained GM ingredients. They replaced GM ingredients with non-GM substitutes in 286 of the products; for 221 products where alternate ingredients were not available, Carrefour offers a guarantee of origin and has demanded that its suppliers guarantee and prove their products do not contain GM ingredients. Nine product lines were discontinued because it was impossible to guarantee their GM-free status (Ram's Horn 1999). Meanwhile, Unilever and Nestle in the UK, both large food processors, announced in 1999 that they would remove GM ingredients from their products (Bowditch, 1999).

One striking result of cross-national consumer surveys is that awareness does not tend to translate into acceptance. Table 1 shows that countries with greater consumer awareness tend to have greater concerns with safety (there is a positive 0.335 correlation between awareness and the perception of biotechnology as a serious health hazard) which tends to be negatively correlated (-0.377) with a willingness to purchase a GM food product. Specifically, for European consumers, awareness has not translated into greater confidence. Instead, consumer acceptance would appear to require more than awareness—it may require real and visible transparency aimed at filling the information gap and overcoming the credence nature of GMPs. One can look at the 1998 referendum in Switzerland on a proposal to ban domestic biotechnology R&D for one approach. In the face of low support in opinion polls, the Swiss industry opened up their laboratories to greater public scrutiny during the referendum campaign. This increased flow of information about what was actually being done in the laboratories helped to close the information gap. The result was a 66% vole to reject the ban on domestic biotechnology R&D (European Federation of Biotechnology, 1998).

The key point from this discussion is that acceptance of GMPs is influenced by their credence nature. The use of biotechnology raises consumer concerns about human safety and health, concerns about potential impacts on biodiversity and concerns about the morality or ethics of biotechnology. These concerns are poorly addressed in the market because of the information gap. As well, consumer concerns are non-homogenous and different regions have discernible differences in consumer acceptance. In the next section, we argue that domestic regulatory approaches to biotechnology react to the domestic state of consumer acceptance, often creating regulatory barriers to the international trade of GMPs.

GMPs and Government Regulation

The information gap that characterizes the relationship between producers and consumers with respect to GMPs creates a market failure that justifies government intervention in the market. Governments have jurisdiction over domestic health and safety, the environment and the preservation of social norms. Consumer concerns are the key drivers for government regulatory intervention where the goal of the intervention is to provide the consumer with enhanced market knowledge in order to reduce the information gap and enhance consumer rationality, choice and sovereignty. Therefore, domestic regulatory approaches to GM products are inherently inwardly focused with little attention paid to trade issues and concerns.

Generally, domestic regulations are a function of the traditional role of the state and must be understood in this context. It has been argued that regulatory intervention in North America follows an independence approach, while in Europe it pursues a political-control approach (Woolcock, 1998). The North American approach to regulatory intervention is to correct market failure to ensure market efficiency or effectiveness (Majone, 1990). Discretionary decision-making power wielded by independent regulators is kept in check through the "transparency and openness of the decision-making process" (Woolcock, 1998). This approach, while providing public scrutiny, limits the influence of populist politics and day-to-day public interests on the regulatory system. Without significant consumer concerns over GMPs North American regulations have operated in a supply-push manner focused on removing market failure to enhance research, development and commercialization efforts.

The European political-control approach to government regulatory intervention is dominated by concerns over the democratic accountability of the discretionary decision-making power of regulators (Majone, 1994). In achieving accountability, the objectives of market efficiency and effectiveness tend to be subordinated to broader public interest and regulatory decision-making resides with elected public officials to ensure accountability. As a result, regulatory intervention is subject to the day-to-day public interests which dominate the concerns of elected officials. On one hand, it is positive that market failure is corrected with respect to 'social dimensions' (European Commission, 1983). On the other hand, public concern, which is ever fluid and based on the credence concerns associated with GMPs can result in regulatory intervention impedes the development and commercialization of agricultural biotechnology.

More specifically, domestic biotechnology regulations differ according to four principles. First, domestic regulations on biotechnology focus either on the products created through the use of biotechnology or on the technology (i.e. how the products are made). There are major implications of the focus because biotechnology as a production and processing method cuts horizontally across many areas, such as agriculture, forestry, fisheries, pharmaceuticals, medicine, and the environment. These areas are traditionally regulated vertically according to specific, often divergent mandates. Regulating products of biotechnology allows for preservation of the independent and vertical regulatory

jurisdictions. Regulating the technology requires intervention that cuts horizontally across many applications and divergent mandates.

Second, the decision to regulate biotechnology according to existing, vertical regulations or via new legislation is closely associated with the products vs. process choice. Regulating products of biotechnology is congruent with the existing, vertical regulatory jurisdictions. Regulating according to existing regulations assumes 'essential equivalence' whereby the risk of a GM product will be compared to the prevailing risks of the traditional product. The key result of regulating products is that existing vertical regulatory jurisdictions may be employed, building on the expertise, capacity and trust in existing vertical agencies, thereby avoiding the inevitable delays and difficulty associated with establishing new regulations that cut horizontally across divergent, often competing, departments and agencies. Regulating the technology potentially provides a more integrated approach than using divergent product regulations in different vertical agencies because given that the fundamental features of biotechnology remain virtually the same regardless of the application. Further, the mandates of traditional vertical regulatory agencies in most cases were developed prior to the biotechnological revolution and were not designed to address the risks associated with this new technology. A new, horizontal regulatory approach focused on the technology could possibly provide a more appropriate level of oversight, regardless of the product application. However, new horizontal regulations face the inevitable political challenges of appeasing all actors, which at times leads to over-regulation and anti-competitive restrictions on the market (Cantley, 1998).

Third, the extent of regulation ultimately depends on society's risk tolerance. Most countries base their regulations on the precautionary principle, which has two somewhat different interpretations. Some countries—but especially the US where product liability laws provide a credible check on risky product launches—accept that regulators may be only *reasonably certain* that no adverse affects will occur. This approach explicitly accepts that some level of risk is inevitable, yet tolerable, and supports research, development and commercialization efforts since that will further the knowledge base and lead to greater understanding of the risks. Other countries, especially the EU, direct their regulators to be *certain* that no adverse affects will occur. This approach explicitly pursues zero risk. Anticipating the worst, regulators heavily scrutinize research and development and do not permit commercialization until it can be proven to be free of risk. The interpretation of the precautionary principle employed in regulatory development can lead to significantly different regulations.

Fourth, the development and operation of regulations are influenced by the actors who participate in decision-making. In a traditional, independent regulatory jurisdiction such as agriculture, there is a clear set of involved actors. GMPs have tended to increase the number of interested actors because of the broad range of consumer concerns. The greater the number of actors, the greater will be the number of competing interests and, by implication, the more complex will be regulatory decision-making. Again, appeasing such a wide range of interests tends toward over-regulation which can adversely impact the development and commercialization of agricultural biotechnology.

Together, the consumer concerns about the credence GMPs, the regulatory tradition of the state and the four fundamental principles of biotechnology regulation characterize government regulatory intervention. The North American and EU regulatory approaches are examined next.

The North American Regulatory Approach

The North American regulatory approach for biotechnology is employed in Canada, the US, Mexico and Australia. The regulatory tradition is one of a laissez-faire market model, with pro-competitive interventions to assist supply-side research, development and commercialization. This approach employs product-based regulations within the existing vertical regulatory jurisdictions, where supplemental regulations have been developed to deal with novel organisms and products. The regulatory decision-making employs the *reasonably certain* interpretation of the precautionary principle and there are only a limited number of actors that directly influence regulatory decision-making.

The Canadian regulatory system adjusted rapidly to the biotechnology challenge. Before biotechnology was used in the agri-food system, the health and safety regulatory system supported and assisted the agri-food sector to develop and tended to take its lead from the industry. The regulatory base has been expanded to incorporate more intensive examination of new biotechnology-based products (Table 3). Revisions to the Seeds Act in 1985 allowed new crop varieties that were equivalent with the existing varieties to be registered; previously new varieties had to be better than reference varieties. Shortly thereafter rules were enacted to allow for "confined" releases of new varieties to assist with breeding and regulatory compliance. By 1988, the federal government had developed a coordinated system of regulations in the environment, agricultural and health departments, including Novel Foods Guidelines to review biotechnology-based products involving trangenes. The first test of the system came with the herbicide tolerant canola varieties produced by Monsanto and Agrevo. By 1989, after more than six years of research in the labs and greenhouses, both Monsanto and Agrevo had identified specific genes and expressed them into superior breeding lines that were candidates for commercialization. They successfully applied for approval for confined field trials and began the field work in earnest. By 1992 each of the companies had identified the cultivars they would seek regulatory approval to commercialize. Over the 1989-94 period, the two companies each conducted more 400 confined field trials, first to select their commercial lines and then to provide the scientific evidence to satisfy the regulatory system. Over the 1992-95 period, the companies provided data and information to Health Canada to meet the Novel Foods Guidelines, to Agriculture Canada for animal feed approval and variety registration and to Environment Canada for environmental approval. Approvals from each agency to proceed came within six months for each variety. Since then, the regulatory system has been streamlined, with the Canadian Food Inspection Agency assuming responsibility in 1997 for all the regulatory functions except the Novel Foods Guidelines, which continue to be managed by Health Canada. Canada now, it appears, is the only country with a fully integrated regulatory system.

TABLE 2 The Canadian Biotechnology Regulatory System		
Agency	Product	Act
CFIA, Science & Technology Services	Agri-food products (meat, dairy, eggs, fruits, vegetables, honey, maple products)	Meat Inspection Act Canada Agricultural Products Act
CFIA, Feeds Section, Plant Products Division	Livestock feeds, additives (e.g. novel feeds)	Feeds Act
CFIA, Fertilizer Section, Plant Products Division	Fertilizers, supplements (e.g. biofertilisers)	Fertilizers Act
CFIA, Plant Biotech Office, Plant Products Division	Plants (including plants with novel traits and with genetically engineered micro-organisms)	Seeds Act (field trials) Plant Protection Act
Health Canada, Food Directorate, Food Inspection Directorate	Genetically Engineered (Novel) Foods	Novel Food Guidelines, Food and Drugs Act: regulates GE foods in same manner as if produced conventionally; reviewed for safety prior to reaching the food system; no labeling required
Source, http://www.cfia-acia.agr.ca/english/		

In Canada, the regulatory approach has resulted in the approval of more than 3,800 field trials, 29 plants with novel traits for feed, 34 trials for veterinary biologics, and 3 novel foods by 1997. It has been able to achieve this flow of regulatory decisions partly by assuming 'substantial equivalency' (e.g. canola oil from a herbicide tolerant plant is essentially equivalent to the oil from a conventional cultivar) and partly by limiting 'standing' in the regulatory decision-making process to the proponent and the regulators. Citizens, consumers, environmental groups, and provinces, while allowed relatively free access to applications and specific decision documents, do not have any say on individual product approvals in the science-based system. So far, in Canada, that has not created any backlash by either the major lobby groups or the general public. While respondents to surveys indicate some concern with biotechnology (Optima Consultants, 1994), there has been little general public debate.

The US regulatory system (Table 3), which has led much of the rest of the world in developing the regulatory base for biotechnology products, is based on the 1976 National Institutes of Health (NIH) decisions that the degree of regulatory oversight should vary based on the degree of containment and the scientifically-determined hypothetical risk; as such, the NIH judged that there was no significant risk inherent in the use of biotechnology which required technology-based regulations (Chen and McDermott, 1997). US regulations are therefore based on a sectoral or vertical approach, such that biotechnology is dealt with when it is employed in the production or processing

methods of products according to traditional sectoral jurisdictions. Currently three US agencies share responsibility for biotechnology-based agri-food product regulation. The Animal and Plant Health Inspection Service (APHIS) of the USDA is responsible for environmental assessments of plant risk, issuing permits for field testing, and for regulating the importation and interstate movement of genetically modified plants. To speed review, APHIS regulations provide for a petition process, where the proponent can request their product be granted a non-regulated status. The petitioning company submits the necessary evidence to show that the genetically modified plant does not pose a plant pest risk, APHIS reviews the evidence and, if approved, the plant product (and its entire offspring) no longer requires APHIS review for movement or release in the US.

The US Environmental Protection Agency (EPA) is responsible for the environmental release of both bio-engineered pesticides and bio-engineered plants with pesticidal characteristics, such as Bt varieties. EPA's environmental assessments consider adverse impacts upon humans, non-target organisms and biodiveristy. The Food and Drug Administration (FDA) of the Department of Health and Human Services has traditional responsibility over ensuring the safety of food and feed use of plants. FDA consultation is not mandatory but is recommended prior to the market release of genetically modified food and feed. Foods and feed derived from new plant varieties only comes under direct FDA jurisdiction if they are determined to be food additives (i.e. if they are significantly different in structure, function, or amount than substances currently found in food). Many of the food crops currently being developed using biotechnology do not contain substances that are significantly different from those already in the diet and thus do not require FDA's pre-market approval. Genetically engineered foods judged to be additives must meet the same safety standards for all other food additives. Although there are no national requirements for varietal registration of new crops, genetically engineered plants must conform with standards set by state and federal marketing statutes, such as seed certification laws. A number of state and local governments also enact their own laws to address environmental concerns. Several states have legislation regulating field trials, requiring either notification of the release of GMO varieties (Hawaii, Illinois, Wisconsin) or requiring formal permits for trials (Minnesota and North Carolina). Nevertheless, once a product has been approved for unconfined release by APHIS and EPA, states lose power to regulate biotechnology elements of the crops (Chen and McDermott, 1997).

The US regulatory system provides industry with predictable, timely decisions. APHIS acknowledged between 1988 and 1998, more than 3,930 notifications of movements of genetically engineered materials and issued 886 permits for release. Only about 4% of the requests were denied. Between 1992 and 1999, APHIS received 65 petitions for deregulation: 49 were approved (the average time for the decision was about four months, with the range between 1 and 10 months), 11 were withdrawn/voided and the rest are pending. EPA reviewed 34 proposals for biopesticides in the 1987-96 period while the FDA reviewed and approved 43 food products between 1994 and 1998 (www.aphis.usda.gov/biotech/OECD/usregs.htm). From the consumer perspective, relying on the National Institutes for Health (NIH) rules and the FDA processes provides confidence in the system, as they view both institutions as credible information sources

on biotechnology (Hoban, 1998). If the US had developed a new set of rules or created a new regulatory agency, that confidence would have been lost and had to be rebuilt.

TABLE 3 US Biotechnology Regulatory System		
Agency	Products Regulated	Authority
U.S. Department of Agriculture (APHIS)	plant pests, plants, veterinary biologics	Federal Plant Pest Act - 7 USC 7B
Environmental Protection Agency	microbial/plant pesticides, new uses of existing pesticides, novel micro-organisms	Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)-7 USC 136 Federal Food, Drug, and Cosmetic Act (FFDCA)-21 USC 9 Toxic Substances Control Act (TSCA) - 15 USC 53
Food and Drug Administration	food (except meat, poultry, and egg products), feed, food additives, veterinary drugs	Federal Food, Drug, and Cosmetic Act (FFDCA)-21 USC 9 Statement of Policy: Foods Derived from New Plant Varieties

Given the significant linkages between Canadian and US agriculture, and especially the extensive cross-border research efforts by private firms such as Monsanto and Agrevo, the lead regulatory agencies (APHIS of the USDA and CFIA in Canada) have worked to streamline the approvals of products in the two countries. In the past the two agencies have undertaken simultaneous reviews of transgenic plants prior to their commercialization and have shared data and observations informally. In 1998, USDA, CFIA and Health Canada regulatory officials met to compare and harmonize, where possible, the molecular genetic characterization requirements of the regulatory review process for transgenic plants. Ultimately, the two agencies believe this may lead to mutual acceptance of assessments in the future. The Canadian–US coordination of agricultural biotechnology regulations is congruent with the agriculture agreement under the NAFTA which calls for long-term regulatory coordination. In the interim, the exchange of information is believed to expedite the review process. This level of coordination between the two countries is made possible by the similarity in regulatory approach, which ensures that there are few insurmountable regulatory barriers to trade.

The EU Regulatory Approach

The current EU regulatory approach is built on the tradition of political control over regulatory decision-making in order to preserve democratic accountability. As a result, the influence of public interest and 'social dimensions' of biotechnology are significantly more important than ensuring market efficiency and effectiveness. In general, the EU approach is a technology-based approach, employing new, horizontal

regulations. The EU regulatory approach employs the certain interpretation of the precautionary principle so that regulatory decision-making must be certain of no adverse affects. This interpretation very much reflects the influence of DG-XI (the environment directorate) in the development of Council Directives 90/219 and 90/220, as this use of the precautionary principle has its roots in environmental regulations (Tait and Levidow, 1992). Finally, due to the influence of the public interest and 'social dimensions' (European Commission, 1983), many actors engage in the regulatory decision-making process.

Another important aspect of EU regulations is that they represent minimum requirements, rather than a harmonized approach for all member states. This has come about because DG-XI insisted that the horizontal biotechnology directives be primarily about community environmental safety, not about enhancing the internal market. Given the general EU policy of subsidiarity, member states can and do unilaterally impose regulations more stringent than the EU regulations in order to protect health and safety.

Prior to the 'European Unionization' of biotechnology regulation, there were divergent views among member states on the need for and means of regulating biotechnology. At one extreme, the French government allowed the industry to manage biotechnology in France with little regulatory intervention; in contrast, Denmark established an extensive regulatory system (Cantley, 1995). Even at the EU level there was, and remains, a great deal of disagreement on an appropriate regulatory framework among the relevant directorates. However, despite the internal European conflicts associated with regulation building, this paper is concerned with the regulatory outcome, and therefore, examines the EU regulatory approach (Table 4).

The regulatory system for food safety in Europe is somewhat beleaguered, with recent negative coverage of genetically modified products in the UK and other northern countries and with the BSE-tainted meat scare in the UK, which together have brought all food regulators in the EU into disrepute. Consumers have become increasingly aware of the presence of biotechnology-based food products and, due to the credence nature are uneasy about them in the food chain. In part, the EU and its member states are being challenged to develop their regulatory system to handle highly politicized issues associated with a significant loss of trust and faith in public regulation. The result has so far been more stringent and less responsive regulation, without any noticeable increase in confidence in either the food safety or regulatory systems.

Since 1990, deliberate release of GMOs into the environment for both research or commercialization has been regulated by the horizontal Council Directive 90/220/EEC. The entry point for seeking EU approval is through the competent regulatory body of a member state or *rapporteur* chosen by the company making the submission. Operationally, the European system has been likened to a "gigantic maze" (Hedley, 1997). If the product is recommended for approval by the rapporteur, the Commission forwards the dossier to all other member states. If there are no objections within 60 days, the Commission informs the originating Member State to proceed with written consent to place the product on the market. However, if another member state objects, the

TABLE 4 The EU Regulatory System			
Agency	Authority	Application	Status
Horizontal legislation			
DG-III & DG-XI	Council Directive 90/219/EEC of 23 April 1990	Contained Use of Genetically Modified Micro-Organisms: covers contained use of genetically-modified micro-organisms (GMMs), both for research and commercial purposes.	Implemented
DG-XI	Council Directive 90/220/EEC of 23 April 1990 and Directive 94/15/EC	Deliberate Release of Genetically Modified Organisms into the Environment: covers experimental and marketing-related aspects of genetically modified organisms (GMOs), which covers any R&D release of organisms into the environment and contains a specific environmental risk assessment for the placing of any product containing or consisting of such organisms onto the market.	Implemented
DG-III	Reg 258/97/EC, 15 May 1997	Regulation on Novel Foods regulates the placing on the market of foods and food ingredients for human consumption containing, consisting of, or derived from GMOs. However, Novel Foods Directive still granted 'essential equivalence'.	Implemented
DG-XI	Annex III of the 90/220 as amended 18 June 1997	Sets labeling and information notification requirements for all GMO approvals for put-ting products on the market in the EU. This annex supersedes the Novel Foods directive by eliminating the essential equivalence and requiring labeling for all GMOs.	Implemented
DG-XI	Revisions to Directive 90/219/EEC, November 1997	Proposed that authorizations to place GMOs on the market, issued under 90/220, be valid for a period of seven years only; if the authorization is not renewed after the seven-year period, the product must be withdrawn from the market.	Pending, adopted by the Council of Ministers
Product legislation			
DG-VI	Directive 93/114/EEC, amending Directive 70/524/EEC	Feeding stuffs. This amendment introduced new categories of additives, including, among others, additives containing or consisting of GMOs into the existing legislation: the amendment will enter into effect as of 1 October 1994.	Implemented
DG-VI	Decision 94/730/EEC	Establishing simplified procedures for the release of genetically modified crop plants (first simplified procedure).	Implemented
DG-VI	Directive 98/95/CE, 14 December 1998	Establishes terms and conditions for the registration of GMO varieties in official catalogues; specifies that GMO varieties must be indicated in catalogues.	Pending

Commission will convene and chair an Article 21 committee of member states to resolve the issue. Once a decision is made, it is binding on all member states. When biotechnology products or processed foods incorporating genetically modified ingredients enter the market, they are also required to be labeled as containing GMOs.

Although the system has timelines and a formal process, it has not been working as planned in Directive 90/220/EEC. The time lines are often ignored by both the member states and the European Commission and in some cases decisions under 90/220/EEC are not being adhered to by member states. The tortuous regulatory road traveled by canola illustrates the problem. In 1996, Agrevo made a submission to the government of France for approval to release a Liberty-Link canola. The French government subsequently recommended an approval to the European Commission. The Commission undertook its consultative process and, albeit with delays, ultimately informed the French government that it could provide written approval for the variety. In the interim, the French government changed and the new Ministers, who were less supportive of biotechnology, overruled the approval of the competent authority. The French government has yet to implement the Commission decision, a delay of about two years.

The European Commission is currently considering revision or modification to Directive 90/220/EEC, where many of the proposed revisions would further the divergence between the EU and the North American regulatory approaches. Potential revisions include a limited-term for market approvals for genetically modified products, where, upon expiration, market approval would have to be renewed. The current proposal is that the limit could be seven years and that during that period there would be mandatory market monitoring of all approved products. As well, market approval would be subject to consultation with a Scientific Committee and final approval decisions by the Commission could be overturned by the Council of Ministers by only a simple majority vote. These proposed changes reflect the politicization of the biotechnology issue and the desire to more fully regulate the 'social dimensions' of biotechnology.

The EU regulatory system has not met the development and commercialization needs of producers. Some products have faced a near impenetrable regulatory barrier to commercialization. Some 18 genetically modified products had been provisionally approved for use as of April 1999, but the four most recent applications were rejected. In addition, Denmark, Britain and France have called a partial halt to GMO approvals in their countries while Austria, Luxembourg and France have all imposed unilateral bans on certain new crops (Western Producer, 1999).

Conclusions and Discussion

This paper has shown that both consumer acceptance is influenced by the nature of GMPs and credence concerns are poorly handled by the unregulated marketplace. The market fails to provide consumers with the relevant information necessary to assuage

their concerns, maintain rationality, sovereignty and choice. This adversely impacts consumer acceptance.

In the highly politicized arena of GM food products, domestic governments are under increasing pressure to address the concerns through regulations and legislation. There is a growing circularity to regulatory decision-making where consumers will not accept products without government approval, yet governments, ever sensitive to public interest, will not approve products unless consumers accept them. The type of government regulatory approach employed to address consumer concerns significantly impacts the market access of GMPs and the development and commercialization of agricultural biotechnology. Two competing regulatory approaches have evolved; the supply-push North American approach and the demand-pull EU approach (Table 5).

TABLE 5 Competing Regulatory Approaches for Agricultural Biotechnology

	North American Approach	EU Approach
Orientation	Supply push	Demand pull
Tradition	Independent/market failure	Accountability/public interest
Features of regulatory system		
Trigger	Novel product attributes	Use of biotechnology processes
Regulatory base	Vertical through existing regulations and agencies	Horizontal through new regulations and agencies
Precautionary principle	Reasonably certain	certain
Access to system	Closed to interest groups	open to interest groups

The supply-push North American regulatory approach, with an almost corporatist structure of review, has proven to be the most conducive to the development and commercialization of agricultural biotechnology. This approach, however, may not be able to sufficiently address the credence concerns if North American consumers become fearful of GMPs. Further, GM crop approvals under the North American regulatory approach are incongruent with the EU system because they neglect the 'social dimensions' of biotechnology, which represent an important part of EU regulatory compliance.

The demand-pull EU regulatory approach tends to create a regulatory environment that is politically sensitive to domestic consumer preferences, but at the cost of impeded development and commercialization. In the EU, specially developed, technology-based, horizontal regulations that seek certainty of outcome and involve multiple agents and actors have been detrimental to commercialization because they lack the specificity and certainty obtained from evolutionary, vertical, sectoral, product-directed regulations. The horizontal European regulatory level has also tended to create a regulatory floor rather than a regulatory ceiling. From the minimum essential require-

ments, member states set more stringent regulations, often not coordinated with other member states. The result is a fragmented European market with different rules in different national jurisdictions. From a commercial perspective, this market fragmentation impedes the search for economies of scale, increases commercial uncertainty and creates structural barriers to market access.

Ultimately, the two competing regulatory approaches result in structural market access barriers not easily negotiated away through trade diplomacy, as evidenced by recent market access difficulties for North American products in the EU. In order to minimize the potential commercial threat of domestic regulations and maximize market access, producers may need to abandon the assumption that regulatory approval equals consumer acceptance. For instance, even though regulatory approval has been gained for GM products in the EU, many retailers, reacting to consumer attitudes, have rejected these products. Instead, producers may need to directly target consumer acceptance and the credence nature of GM products in export markets in order to address the structural market access barriers which adversely impact the long-term development and commercialization of agricultural biotechnology. Producers may need to be encouraged or forced to take a more proactive role in addressing consumer concerns and increasing consumer acceptance. Given that consumer acceptance is a function of consumer understanding of the risks and perception of primary beneficiary, producers may be advised to provide more transparent information to enhance consumer understanding of both the risks and the benefits. For instance, although many of the monetary benefits of the current crop of genetically-modified plants are captured in the supply chain, there still are some positive results for consumers, such as the reduced use of herbicide and pesticide treatments. In the longer-run, consumers would likely welcome the potential for fully renewable and biodegradable bio-engineered commodities to replace non-renewable and non-biodegradable chemical and petroleum-based processes. Similarly, as genetically engineered products with end-use traits become more readily available, there will be a more concrete base for communication between consumers and producers. Focusing both research and marketing on attributes consumers value could circumvent the commercially-adverse circularity of inwardly-focused and politically-sensitive government regulatory intervention.

Endnotes

[1]Grant E. Isaac is Ph.D. Candidate, London School of Economics and Peter W. B. Phillips is NSERC/SSHRC Chair Professor, University of Saskatchewan. This paper is based on Ph.D. research by Grant E. Isaac with extensions from research on the Canadian canola (rapeseed) industry by Professor Phillips. Contacts: G.E.Isaac@lse.ac.uk and phillips@duke.usask.ca

[2]It should be noted that a consumer might still be rational and sovereign even without actually acquiring perfect information. This is because it is access to information and choice that is crucial. A consumer may choose not to be fully informed because, for instance, the costs of being fully informed are too dear or the time required is not justified

by the perceived risk of consumption, or the consumer trusts that the partial information received is accurate and a fair reflection of the underlying benefits and risks of consumption. In this case, the consumer is said to be boundedly rational (Williamson, 1995). The consumer is still sovereign and rational because it is the consumer's choice to have partial information. It is often rational for the consumer to sacrifice information as long as the consumer retains the choice.

[3]One school of thought is that marketing problems in the agri-food sector may disappear when the new biotechnology "products" with differentiated characteristics begin to appear, because they have the potential to create visible value that consumers are willing to pay for. GM agri-food products, in contrast to commodities, have the potential to be branded, which increases the incentive for private firms to manage them more actively, including marketing campaigns aimed at filling the information gap and promoting consumer choice in the market.

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