REGULATORY CONFLICTS AND TRADE

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INTRODUCTION

Genetically modified (GM) food is not a new regulatory issue, but to effectively provide both safe and affordable products to consumers, the effects of GM regulations on the seed production industry must be addressed. This Article will analyze the issue of regulatory conflicts and trade from a non-technical perspective. Specifically, the Article will examine the regulatory complexities surrounding GM food and the significance these regulations have for seed-producing companies. In addition, the Article will consider the need for consumer confidence in GM products, which cannot necessarily be created by additional regulation.

The seed production industry is increasingly subject to multinational regulation. If we wish to allow public companies to remain in the market, this regulation must be clear and based on scientific risk analysis. Since consumers often act on perceptions of risk rather than scientific risk possibilities, however, companies must provide consumers with a choice of GM and non-GM labeled foods. Labeling, however, will be cost-prohibitive to both consumers and companies if the industry is required to obey a threshold level less than one percent.

I
FOUR LEVELS OF REGULATION

The total commercial seed market world-wide is estimated to be around thirty billion dollars per year.[1] Industry leaders typically record gross revenues of approximately one billion dollars per year and often have operations located throughout the world. Until quite recently, the seed business was relatively lightly regulated. Under today's more stringent regulatory cli-

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[1] *See* International Seed Trade Federation and International Association of Plant Breeders, *World Seed Statistics* (last modified Feb. 2, 2000) <http://www.worldseed.org/stat.htm/>.

mate, however, seed producing companies must comply with regulations at several different regulatory levels.

It is not unusual for a seed variety to pass through as many as four different countries, each with its own form of regulation. For example, a corn variety may be developed in the United States and Chile, produced in Argentina, grown in France, and sold in Egypt. For each of these steps, and for each country where the seed producer either operates or affects the food chain, the seed producer must successfully navigate the regulatory pathway.

The first level of regulation occurs in the research and development phase of seed production. Wherever seed producing companies operate, regulations govern biotech work in contained environments such as laboratories or greenhouses. In addition, there are regulations which affect the research once it moves from the laboratory to the field. Although these types of regulations may appear straightforward, problems arise even in countries such as the United States, which have a formulaic approval and rejection system.

An enormous timing problem arises in the first stage of seed production. Developing a variety from a new combination of genes takes between ten and fifteen years. Breeders—professionals who receive the GM crops from molecular biologists and produce commercial varieties from the modified crops—can cut this period in half, however, by growing one generation in the northern hemisphere and the next generation in the southern hemisphere to take advantage of the variation in seasons. This method has become routine for breeding crops, whether or not they are genetically engineered.

Logistically, the timing of these operations is critical. For example, corn has a growing season of up to 140 days. Between the harvest in one hemisphere and the sowing season in the other hemisphere, breeders have approximately six weeks to decide which material to grow, determine where and under what conditions, and deliver the seeds to the field stations. Moreover, a large breeding program may need to transport 100,000 individual lots of seed from the northern hemisphere to the southern hemisphere during those six weeks. This presents a daunting logistical problem, but seed companies are well-organized to face the chal-

lenge. Complications arise, however, when companies must obtain approval for the movement of each individual seed lot.[2]

The seed production phase presents companies with a second level of regulation. Most seed companies, when they have identified the varieties that will eventually be sold, produce that seed in quantities suitable for the farmer in a second group of countries, which only partially overlaps with the first group. So the companies need permission for those up-scaling operations.

The third level of regulatory requirements governs the sale of seeds to farmers. In addition to the countries where seed development and production occurs, a third group of countries and their regulations become involved at this level. Seed companies typically are responsible for obtaining the necessary permits for farmers to grow seeds commercially. In most countries, the regulation of the sale of GM seeds is the most difficult and unstable of all GM regulatory processes. For example, in the European Union (E.U.), it now takes more than three years to obtain the permits, and in 1999, the whole process ground to a halt.[3]

The final phase in which seed companies face regulation is the commercialization of the product. The commodity trade ships the crop harvested by the farmer to a fourth group of countries, which may require approval for GM food.

II
Running the Regulatory Maze

Clearing the regulatory pathway at each stage is an expensive process. Moreover, it is destabilizing, since a company's finances may be adversely affected by the risk of potential roadblocks. Consequently, investors question the reliability of investing in seed companies.

Although private companies have integrated these expenses into their business planning, it is not clear how public institutions will find the resources necessary to guide their products through the regulatory maze. Many GM crops are developed in the pub-

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[2] *See* Draft Cartagena Protocol on Biosafety, Jan. 28, 2000 (last modified Apr. 7, 2000) <http://www.biodiv.org/biosafe/BIOSAFETY-PROTOCOL.htm>, adopted at the Extraordinary Meeting of the Conference of the Parties to the Convention on Biological Diversity, Montreal, 28 January 2000.

[3] The June 1999 Report of the Council of Ministers of the Environment is widely quoted by the media in Europe. *See, e.g.*, *Environment Council: Ministers Agree GMO Compromise*, Eur. Env't, June 29, 1999, *available in* WESTLAW, 1999 WL 9716033.

lic sector. Much of the tropical crop breeding is conducted by public institutions such as the Consultative Group of International Agricultural Research Centers (CGIAR). The exploding complexity and costs of the regulatory framework are making it increasingly difficult for such organizations to bring new GM crops to the farmer. As a result, seed production may become the exclusive province of large, multinational companies.

Of course, the potentially negative repercussions for public institutions cannot be addressed by simply eliminating the regulatory process. It is important, though, that the process be organized so its complexity does not become a major entry barrier, thus inhibiting innovation. Regulations should be clear, stable, and based upon international consensus regarding the scientific basis for risk assessment.

The biotech industry has recently been accused of trying to block the international negotiations of the Biosafety Protocol within the Biodiversity Convention. This allegation is untrue and defies logic. In reality, the industry has a vital interest in regulatory harmony throughout the world. Seed companies will benefit from a system with mutual acceptance of safety evaluations and scientifically-based risk assessments.

III
Building Consumer Trust

A significant aspect of the discussion on biosafety concerns unfounded fear rather than an awareness of the actual risks involved. Several excellent research centers, such as the Harvard Center for Risk Analysis,[4] study risk, risk perception, and risk analysis. A common theme in their findings is the significance of perception in the creation of fear and uncertainty over innovation.[5] The evidence overwhelmingly demonstrates that perception of risk is more important in decision-making at the individual and collective levels than actual risk. Fear, however,

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[4] *See Harvard Center for Risk Analysis* (visited Apr. 13, 2000) <http://www.hsph.harvard.edu/organizations/hcra/hcra.html>.

[5] *See* J.K. Hammit, Risk Perceptions and Food Choice: An Exploratory Analysis of Organic-Versus-Conventional-Produce Buyers 367-74 (1990); S.E. Spedden, Intuitive Toxicology: Comments on the Effects of Complexity and Uncertainty on Expert Assignments and Lay Perception of Risk 524-32 (1992); S.E. Spedden, Judgments and Perceptions of Human Risk from Chemical Carcinogens (1992) (unpublished Ph.D. dissertation, Harvard University School of Public Health) (on file with author).

can only be addressed and mitigated by trust. The biotech industry and the molecular biology scientific community have for fifteen years deluded themselves by thinking that fear can be reduced through facts. The conclusion that facts do not mitigate fear does not sit comfortably with scientists who have been taught that science is the embodiment of the triumph of rational thought as a way to observe and understand the world around us. Fear can only be effectively removed, however, by building credibility of the biotech industry's safety assurances.

The Biosafety Protocol discussion has recently become dominated by trade issues. Resolution of the trade issues, however, will not necessarily solve the problem of public mistrust. If the United States and Europe resolve the trade issues over GM crops, the biotech industry will still need to address the lack of public confidence in the food the industry produces. For example, over the last ten years, the biotech industry has had to adapt to enormous changes in consumer priorities. As consumers become more informed, they raise ethical questions about production methods. These issues matter to the consumer, and therefore matter to the industry. The industry cannot rely on the law and regulations to address these issues because individual consumers, not governments, pay for the products. Consequently, even with a better system in place, the industry will continue to need consumers' trust and confidence.

The answer to this trust problem is to provide consumers with the choice between GM and non-GM food products. Although labeling alone is not sufficient to provide the consumer with a fully informed choice, it is an essential part of that process. In the E.U., labeling has become somewhat of a panacea, which is as unsatisfactory as wholesale rejection of labeling as a confidence-building tool. Consequently, the public discussion on labeling in the E.U. has still not triggered the efforts to provide quality public information, as in the United States and in Canada.

Choice through labeling also comes at a cost. In the current commodity production system, the farmer's harvest contributes to a combined river of products that travels across the world. In order to divide that river into two streams—GM and non-GM products—costs will increase and be passed on to the consumer. The average consumer is perfectly capable of recognizing the costs involved, and by fostering public discussion which weighs

the choice against the increased cost, the industry may build consumer trust.

Another important issue surrounding labeling and related to its cost is identity preservation. The cost of preserving the identity of crops depends on the purity threshold. For example, identity preservation at a five percent level will cost much less than at a one percent level. Current E.U. legislation mandates that every product in which GM genes can be found through state-of-the-art technology must be labeled.[6] The cost of complying with such a regulation becomes excessive because in state-of-the-art laboratories GM genes can be recognized in a mixture at a rate of one in 100,000. No living material can be kept "pure" at those standards. The European Community Commission recently passed a regulation setting a threshold of one percent.[7] This one percent threshold represents a major step forward, although even this level of identity preservation will impose heavy costs on the production of food—costs that will ultimately be paid by the consumer.

Conclusion

In conclusion, for perception of risk to align with scientific facts, consumers need to be provided with a clear choice between two types of products, and the industry must develop a workable system for supplying those products. Once a reasonable purity threshold is in place, mutually approved methods of control, appeal, and certification must follow. Only when these mechanisms are in place can the biotech industry claim to have provided the consumer with a choice within the bounds of technology, science, and business. And only then can the industry build the public confidence that is necessary for advancing discussion about the benefits of genetic modification.

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[6] *See* Commission Regulation 258/97 of 27 January 1997 Concerning Novel Foods and Novel Food Ingredients, art. 8, 1997 O.J. (L 043) 1.

[7] *See* Commission Regulation 49/2000 Amending Council Regulation 1139/98 Concerning the Compulsory Indication on the Labeling of Certain Foodstuffs Produced from Genetically Modified Organisms of Particulars Other Than Those Provided for in Directive 79/112/EEC, 2000 O.J. (L 6) 13. The Regulation entered into force on April 10, 2000.