

CORN AND BIOTECHNOLOGY – AN INTERNATIONAL PERSPECTIVE

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Abstract: Planting of corn derived from biotechnology has grown rapidly since commercialization in 1996. Early efforts to develop harmonized regulations for the approval, trade and labeling of biotechnology crops and foods derived from them had little practical effect on rationalizing international trade in these products. In the absence of internationally harmonized regulations, a myriad of complex and conflicting regulations have been adopted around the world, hampering the ability of technology companies to bring new products to market, farmers to confidently plant new crop varieties and food companies to market foods produced using genetically modified raw materials. Some promising developments in international fora are appearing, and the next several years may determine if the promise of biotechnology to provide new producer and consumer benefits will be realized in the short-term or will be a promise deferred.

Key words: Biotechnology, corn, regulation, harmonization

The adoption of biotechnology by U.S. and other farmers has been one of the most rapid examples of use of a new technology by agricultural producers. According to the International Service for the Acquisition of Agri-biotech Applications global planting of genetically modified crops in 2001 totaled around 130 million acres – close to the size of the entire U.S. corn and soybean crops. Within that total corn accounted for about 25 million acres. Here in the U.S. the Department of Agriculture recently predicted that U.S. corn farmers will plant 32 percent of their 2002 crop to biotech varieties, up from 26 percent last year.

Adoption of biotech crops in other countries has been impressive as well, if not up to the levels in the United States. South America has been a major

adopter of both biotech corn and soybeans, and China has been a pioneer in the planting of genetically modified cotton.

Well before these crops hit the market, regulators in a number of countries had begun designing systems to account for the entry of this new technology. Earlier speakers have described the U.S. coordinated regulatory framework established in 1986, and in Europe an EU-wide regulation to government biotechnology crops was introduced in 1990.

As national governments were beginning to grapple with the advent of this new technology, so were international organizations. As early as 1982 the Organization for Economic Development and Cooperation (OECD) began to convene international groups of technical experts to develop guidelines for safety assessment of recombinant DNA technology – not only in agriculture but also in the areas of medicine and industrial production as well. In the area of food, organizations such as the UN Food and Agriculture Organization recognized that the successful development of this technology would require regulatory and safety assessment tools and began examining these. And, on the environmental side, the Convention on Biological Diversity began examining systems to govern the movement of so-called “Living Modified Organisms” (LMOs) in international trade.

These efforts, and others, were designed to begin a process of regulatory harmonization of the products of biotechnology. But, before this process could come to fruition a number of events overtook the well-intentioned efforts of these groups.

In 1996 Ciba Seeds (now Syngenta) offered the first commercial Bt corn in the U.S. market and Monsanto began marketing Roundup Ready™ soybeans. Because of the relatively advanced regulatory structure in the U.S., planting approval of these crops was received many months before approval for import was received in Europe. As the harvest of 1996 progressed, it became clear that European import approval might not be granted before the harvest was underway. While approval for soybeans was received at the time of harvest, and corn within a few months of harvest, the prospect of imports of U.S. crops without E.U. approval provided fertile ground for anti-technology, anti-corporate and anti-globalization activist to ring loud alarm bells. The resulting accusations that the U.S. was trying to “shove biotechnology down Europe’s throat”, coupled with the revelation that British and E.U. regulators had failed to identify the human health risks of mad cow disease, created a major crises of confidence in the E.U. regulatory system. We still live with the result today, and one was a slowdown in the serious efforts to harmonize regulatory systems.

In early 1997 the Transatlantic Business Dialogue, a group of corporate executives from both sides of the Atlantic, recognized the growing discontinuity between U.S. and European approval paces as a potential barrier to trade between the two regions. Over a two-day meeting in Brussels, they convened the top regulators from both sides to compare notes on how biotechnology was regulated. There were two striking things about that meeting: the near-unanimity of the regulators over the technical data to be examined and the best way to assess biotechnology safety, and the total difference in how the advice of the technical regulators was received by their political masters. In the United States the advice of technical regulators was generally accepted as-is, while in Europe it was only the starting point for an intense political discussion that brought in numerous non-science based factors into the decision making process.

The resulting inability of the two regions with the most advanced biotech regulatory systems to agree on anything resembling harmonization, or even mutual recognition or equivalence, spelled the end for the time being of serious efforts to do so on a global scale.

What has emerged in the absence of a global movement toward harmonization is an increasingly fragmented system of global regulation of biotech crops and derived foods. Let's take a quick trip around the globe and

review what's happening – or in some cases not happening, in the major markets for U.S. agriculture.

Let's start with Europe. I liken the situation there to the proverbial vanishing point of parallel lines – out on the horizon your eye seems to see the lines coming together, but for every step forward you take, the lines continue to diverge.

In 1998 five E.U. countries declared that until fundamental updates were made to European Commission regulation of biotechnology, they would withhold their vote to approve any new applications brought to them by the regulatory authorities. First was a request to update the 1990 regulation on product approvals. This was completed early last year. Second was a request to formulate new regulations on traceability, labeling and animal feed approval. These were proposed last July. Next was a demand that the new approval regulations be fully implemented by E.U. member states. This will happen this October. Next will likely be a demand that the traceability, labeling and feed regulations be finalized - that won't happen until late 2003 at the earliest. Finally, there are some that oppose handling any new approval applications until environmental liability regulations come into force as late as 2005.

Product approvals are only part of the issue in Europe. The EU has been at the forefront of efforts to require foods made using biotechnology to be labeled, whether or not there is any detectable residue of the protein or DNA from crop modification in the final food. Food companies have made it clear that they will not market biotech-labeled foods in Europe in the current climate of public opinion. The derived-product labeling proposal now working its way through the European Parliament and Council is a direct threat to the multi-billion dollar market for U.S. soybeans and would also threaten markets for corn products such as crystalline fructose. Critics have noted that the proposals conveniently do not require labeling of foods like European cheese made using genetically modified enzymes.

No issue has been more important to the corn refining industry in Europe than continued market access for the \$400 million of corn gluten feed exported under a long-standing zero duty agreement with the E.U. The proposals would also dramatically change the landscape for CGF exports. In Europe CGF made from biotech corn is, for legal purposes, no different than CGF made using conventional corn since CGF is not a “genetically modified organism” under E.U. law. However, last summer’s proposals would require that a separate approval be granted for use of individual biotech varieties in manufacturing animal feed.

U.S. planting of crop varieties that do not have E.U. approval has been a commercial challenge for the corn refiners. European customers prefer that the industry only use corn varieties that have an-EU safety assessment. The joint efforts of programs like NCGA's Know Before You Grow, seed company marketing restrictions and grain contracting practices of corn refiners have been sufficient to provide confidence to our European customers that we are respecting their commercial desires. However, when the pending Novel Feed regulations are adopted it will become a legal requirement that corn refiners only use corn varieties with a Novel Feed approval if they want to export to Europe. Under these circumstances seed companies will come under intense pressure to withhold new varieties from the market unless they have European approval. They face this pressure with Japan and other major raw corn markets, but – unlike Europe – these markets generally have working regulatory approval systems.

Europe is of special interest to the corn refiners and to growers because of the large influence it exerts in international markets. However it has not been a major corn market since the 1980s.

Japan remains our number one corn market. Japan's policies on biotechnology reflect their pragmatic approach as a major importer, but a country with a long history of detailed regulation of food safety and imported

products. Japan operates a formal biotech approval system that while somewhat slower than the U.S. is predictable and timely. NCGA has insisted that before any new biotech traits come to market in the U.S. they gain Japanese approval, and by and large that has occurred. At this writing one new trait that is ready for U.S. introduction is still awaiting Japan approval. Japan has put a detection-based labeling system into effect, but exempts important refined products such as HFCS and dextrose, includes reasonable tolerances and only requires labels where there is substantial biotech content in a finished food. For Japan, as for many other countries, StarLink has been the major biotech issue of the past several years and grain exporters are required to follow a detailed testing protocol for shipments to Japan. The StarLink incident knocked nearly a million tons off our exports to Japan in 2001, but as StarLink disappears from the U.S. grain supply Japan is expected to resume its normal corn imports.

Other Asian countries, notably Taiwan and Korea, are major U.S. export markets but were not affected as much as Japan by the StarLink incident. In fact, increases in Taiwanese and Korean imports from 2000 to 2001 equaled the decrease in the Japanese market. The major concern for US industry in these countries has been Korea's inconsistent administration of its labeling regulation. While the regulation is similar to that in Japan, U.S. processed food exporters

have encountered difficulty in administration by customs and other regulatory agencies.

Since the passage of NAFTA Mexico has grown to be our second biggest corn market, accounting for over a half a billion dollars in sales last year. In Mexico the news on corn biotechnology has been dominated by concern that the genetic nature of native Mexican corn could be altered by crossing with biotech corn. Last year two scientists published an article in *Nature* claiming that transgenic DNA had found its way into traditional Mexican corn varieties. This news set off a wave of calls for control on U.S. corn exports. However, in April, the editors of *Nature* said, “*Nature* has concluded that the evidence available is not sufficient to justify the publication of the original paper.” Whether this admission will be sufficient to dampen the political calls for import restraints remains to be seen – and test the proposition that calls for restricting imports were based on scientific evidence or on protectionist sentiments.

South America is rapidly becoming our biggest competitor in the world market for both soybeans and corn. Outside of the U.S., Argentina has been the most positive country on biotechnology. Nearly a quarter of the world’s transgenic crops will be grown in Argentina, including nearly its entire soybean crop and most of its corn crop. It’s little wonder Argentina is the US’s staunchest ally in global debates over biotechnology.

Brazil continues to be an interesting dichotomy. While on paper production of transgenic crops is not permitted, up to 30 percent of the country's soy crop is being planted to herbicide-tolerant beans. For several years exporters relied on a certificate of origin from Brazil as de facto evidence that shipments were "GMO Free", but the bloom is coming off that rose as more people understand the true extent of biotech plantings in Brazil. Brazil's administration is pushing hard to end the legal ban and when that happens it will pose a very interesting situation for Europe. Legalization of biotech planting in Brazil will force Europe to recognize that strict segregation of bulk commodities can only come at an unacceptable cost, if it is possible at all, and that identity-preservation systems cannot be bought on the cheap.

Africa is the most interesting region to watch these days. African nations view biotechnology through a totally different filter than the rest of the world. More than any other region, Africa is curious about the agronomic benefits of biotechnology -- not as a matter of economic advantage but of basic food security. Generalizations about Africa are dangerous given its incredible climatic and biologic diversity. Depending on the locale, chronic drought, poor soils, crop pests, plant viruses and food spoilage are major problems for African food production, and crop varieties addressing these problems will be of special interest to Africa. However, as a continent heavily dependent on both aid and

trade with Europe, many African nations fear the consequences of advancing their agriculture with biotechnology.

At the outset I mentioned the failure of early efforts to achieve some sort of global harmonization of biotechnology regulations. In the past several years however, the fragmentation that has occurred around the world has sparked a new effort in this area.

For the food and agriculture industries two global groups are having the most impact – the Codex Alimentarius Commission and the Convention on Biological Diversity.

Codex is a food standards and safety group organized under the auspices of the UN's Food and Agriculture Organization and World Health Organization. Over 160 countries belong to Codex and it has produced recommended standards for hundreds of foods and commodities as well as recommendation for pesticide residues, food contaminants and food hygiene. National standards that mirror Codex standards are considered to be in compliance with the World Trade Organization's Agreement on Sanitary and Phytosanitary Measures.

Three years ago Codex organized an Ad Hoc Task Force on Biotechnology. Meeting under the auspices of the Japanese government, the

group is nearing completion on a recommended set of safety assessment procedures for food derived from biotechnology. While there have been occasional digressions into political debate, the work of the task force has generally stuck to the science of safety assessment. These guidelines should be adopted by the Codex Commission in the summer of 2003 and will provide a useful tool for countries that have yet to develop their own safety assessment system, and be a benchmark for judging the performance of those that already have such systems.

Codex is also addressing the labeling debate through its Committee on Food Labeling. Between this writing and the CUTC, the committee will have met to try and decide between two recommended labeling strategies – one pushed by Europe to make biotech labeling mandatory, and one backed by the U.S. to provide guidance for marketers who want to voluntarily label non-biotech products. Finally, in a number of committees, Codex continues to debate the application of precaution in risk management decisions about biotechnology. However these debates turn out, they will exert a strong force for countries coming closer together in the regulatory arena.

For companies shipping whole grains and oilseeds in international trade, the Biosafety Protocol of the Convention on Biological Diversity is an important forum. This protocol was originally designed to regulate the environmental

effects of movement of new genetic material around the world. In the course of its negotiation, it spilled over into recommending guidelines for so-called “FFP” – food, feed and processing – commodities. Working groups are now debating what kind of information needs to accompany shipments of genetically modified crops that are not intended for planting, but for direct use. The U.S. and most exporters back provisions that these shipments only need documentation that they may contain biotech products. That view is pitted against European countries that would like documentation of each distinct genetic event that is contained in a shipment. The International Grain Trade Coalition is also looking to this group to adopt an interim tolerance on the amount of biotech grain that might be found in a shipment designed to be non-biotech, and have suggested a 5% tolerance.

On the regional level there are also some new developments worth noting. In particular, the Asia-Pacific Economic Counsel, APEC, recently held its first meeting to explore potential common positions on biotechnology. While there are widely different positions on biotech regulation among APEC members, there is some possibility that an APEC group, coupled with the Latin American group, could become a strong counterweight to Europe in the international arena.

Finally, no discussion of the international regulatory arena would be complete without discussing the role of the World Trade Organization in biotechnology. As disputes in biotechnology have increasingly turned from philosophical debates to real trade disputes, there has been more discussion of how that agreement could be used to arbitrate and adjudicate these trade problems.

WTO members agreed a number of years ago that as financial barriers to trade came down there was a danger that countries would turn to technical barriers to protect their domestic interest. To address this, they adopted two important agreements; one covering technical barriers to trade (the “TBT” Agreement) and the other on sanitary and phytosanitary measures (the “SPS” Agreement).

The SPS agreement establishes guidelines for how countries should fairly install rules that regulate trade on the basis of human or plant health. The TBT agreement establishes rules on the application of technical standards. While they are not specific to biotechnology, the increasing array of import rules on products from biotechnology can be viewed against the standards of these agreements.

The SPS agreement requires that health protection standards be based on a scientific risk assessment demonstrating they actually protect health and don't arbitrarily exclude products from trading partners; that risk assessments be conducted in a timely manner; and that standards be transparent and understandable to those who have to comply with them. Many observers question whether Europe's proposed traceability regulation and its approval system for new biotech products pass muster under these tests. Likewise the new regulations adopted in China have been questioned under the standards.

The TBT agreement affirms the right of WTO members to set technical standards for "legitimate objectives" Consumer information can be one of those objectives. But a key element of the TBT agreement requires that standards be set at a level "no more trade restrictive than necessary" to meet those objectives. Mandatory biotech labeling rules may not pass this test if it can be demonstrated that consumer's right to know about biotechnology can be met just as well by setting rules that permit companies to market non-biotech products in a truthful and non-misleading way.

So far only one case involving biotechnology has been brought to the WTO – a ban on import of Thai tuna packed in soybean oil by several Middle Eastern countries. The case never proceeded to the formal WTO dispute settlement

process after it was determined that the countries applying the ban mistakenly presumed that the soy oil came from beans modified with porcine genes.

It has been widely reported that the US is mulling bringing a WTO case against Europe for its failure to complete work on many pending approval applications for biotech products, most notably Roundup-Ready corn. The US has filed comments with the WTO claiming that the pending traceability and labeling regulations in Europe would likely violate both the SPS and TBT agreements. Some have argued that bringing these disputes before the WTO would not change the internal situation in Europe, and runs the risk of hardening EU anti-biotech and anti-American attitudes. Others have suggested that while a WTO case may never change European regulations it will prevent their spread around the world. The government will be mulling the possibilities of bringing a case over the coming months and their decision will certainly influence the tone and location of the biotech debate.

Thank you very much, and I would be glad to answer any questions you may have.

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