
Regulatory and Economic Aspects of Accessing International Markets

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COMMODITY CROPS: VISION VS. REALITY

In 1995, AgrEvo Canada's Liberty Link canola (variety Innovator) became the first crop derived from biotechnology to be registered in Canada. Having undergone seed production in the previous year, Innovator canola was grown on close to 40,000 acres in Canada in 1995 under a contract-to-crush closed loop delivery system. This system ensured that our first biotechnology-derived canola variety was directed only to approved destinations. Now in the third year of commercial production, with clearances in Canada, the United States, and Japan, Innovator canola is no longer being handled under special systems and will be entering the Canadian export stream at the 1997 harvest, with the agreement of the Canola Council of Canada. This paper discusses the regulatory and economic challenges encountered in moving this crop out of the research world and into the international export stream.

Canola is Canada's Cinderella crop. It is a crop Canada created, a market demand Canada developed, and an export trade sector Canada dominates. It is also a difficult crop to grow and keep weed-free. Fortunately, it is a crop that responds well to many modern genetic techniques and is one of the first major crops to be improved through the use of biotechnology. That is essentially why AgrEvo chose canola as its first target crop for improvement through biotechnology. Another factor that made canola suitable for a leading role in biotechnology is its processing characteristics. Any foreign protein that might have been present in plant parts is destroyed in the process of making canola oil. For the first food crops of biotechnology, this means that there is no risk to

the public of exposure to foreign protein. Innovator canola is the first in a stream of products that respond to the Canadian farmer's need for enhanced possibilities for production of canola. Additional glufosinate-tolerant *Brassica napus* and *Brassica rapa* canola varieties have been developed (Independence, Phoenix, HCN14, Expo), and hybrids (PGS 3850, PGS 3880, InVigor 2063, InVigor 2153, InVigor 2173 and InVigor 2163) are at various stages of seed multiplication or production.

Canola is also a commodity crop that is mixed and handled in a co-mingled export stream that serves to guarantee the quality of the grain received by the end-use customer. Canadian canola reaches over 50 export destinations as seed, meal, and oil. These two features — responsiveness to biotechnology techniques and being a commodity crop — have made canola one of the first products of agricultural biotechnology to experience the regulatory and economic challenges of entering international markets. This paper reviews these challenges and recommends ways to address the future needs of the complicated world of export trade.

BACKGROUND

It is mid-1997; crop products of biotechnology have been with us for almost ten years, and our international regulatory system is still for the most part in its infancy. Canada, the United States, and Japan have fully functional, predictable regulatory systems in place. These countries are actively working to keep their systems timely and rigorous as the number of products increases exponentially.

Another group of countries is actively working to provide a regulatory framework for the same products. Mexico is moving forward as part of the North American Free Trade Agreement (NAFTA), while struggling to address its own unique issues (including being a centre of genetic diversity for corn). Within the European Union (EU), the United Kingdom's (UK) system has been the most predictable to date. As a result, the UK is the European country of preference for many importers. France has also been a highly favoured sponsor country. With the contradictory and confusing developments of this past spring, it remains to be seen if this status will be maintained. The EU system has moved significantly forward this year with the institution of the Novel Food regulation and significantly backward with the virtual collapse of the EU 90/220 environmental review process. In Australia, only a decorative carnation has been granted unrestricted approval for production and commercialization. Several food products have been reviewed but cannot be officially approved until new guidelines are in place. China is commercializing crops derived from biotechnology at a tremendous pace. To Westerners, the regulatory process being used is unclear. Meanwhile, the rest of the world has no process at all.

For a commodity crop outward bound to the rest of the world, this patchwork of regulations, nonregulations, and emerging regulations is a labyrinth of epic proportions.

REGULATORY REQUIREMENTS

At least in theory, the core scientific data package required to address food safety, feed safety, and environmental risk should be the same everywhere. Numerous international forums have been held to discuss the concerns and to propose robust scientific approaches to addressing the issues. There is also a high level of awareness that while products of biotechnology need to be scientifically assessed to determine that they pose no unmanageable risks, these products hold great promise for feeding a hungry world and reducing environmental strain. A common theme is to avoid artificial trade barriers that would limit the use of these products.

The reality, however, is several steps away from the theory. Identifying responsible government officials and uncovering their local requirements (precise study requirements, formats of presentation, and acceptable statistical approaches) is a demanding exercise. Local requirements all too frequently result in additional studies with added costs and delays. Moreover, each country or region defines its decisions in a different scope. “Import,” “varieties,” “events,” “lines,” and “release” have different meanings in different jurisdictions. No wonder exporters have a hard time understanding exactly what is approved and what is not and what needs to be approved and what does not! Each local bureaucracy has its own unique formatting requirements. The United States will not accept Canadian submissions, although the reverse is true. Throughout it all, it becomes clear that there are those who are seeking to create facilitative systems and those who are seeking to create prohibitive systems to meet local economic strategies regarding imports versus local production.

Commenting on proposed guidelines through the World Trade Organization (WTO) is an industry necessity but a challenging one because the operational reality of guidelines is often totally unclear.

One must have considerable resources available to identify the people and the requirements, get the work done while specifications change, create a customized submission for each audience, and shepherd the package through the review process. Even if the review is strictly science-based and political influences do not influence the process (currently a rare event), considerable effort is needed. Because of the personnel and financial costs, only large corporations with extensive resources can hope to succeed. The customized country approach also means that simultaneous global submissions are an impossibility. Everyone wants it “their way” but no one wants to wait for the revisions to occur. Customized submissions mean sequential submissions, which, in turn, mean clearances in some countries before others. Needless to say, since the processing times are different everywhere, the time gap between clearances for various trading partners is large. The resultant patchwork of cleared “here” but not cleared “there” is tremendously complicating for trade. It is not surprising that the public is confused. What does it mean if one country says it’s OK, and one says it isn’t, and one hasn’t answered the question?

ECONOMIC ASPECTS

The regulatory process, whatever it is, has an economic impact. It determines what is possible, who the players will be, and often predestines the winners and the losers.

More and more countries are recognizing that agricultural biotechnology holds great promise. Those who saw only risks now see benefits, too. Germany, for instance, has completely reversed in its position on biotechnology, from being a major detractor to being a major proponent. That is not to say that risks are taken lightly, but rather that with proper scientific proof one can now move forward where previously no proof was considered adequate. This reflects a truly science-based approach. Industry is becoming more aware of regulatory complexity and its impact on trade. That is an important development because the industry lobby is always stronger than any individual corporate effect on trade issues of this magnitude. Most important, the introduced products are succeeding despite the uphill nature of the endeavor. Each sequential regulatory decision reinforces previous decisions.

The challenge that faces the industry is to find a controlled stepwise approach that balances the sequential pattern of regulatory clearances and the slow maturation of public awareness and acceptance with the need of the export trade to keep commodities moving freely. It is difficult to make allies and educate everyone who needs to be informed in an environment that changes daily and is highly charged with diverse political pressures. Nevertheless, in the case of food, the industry must be willing to discuss public acceptance professionally and responsibly in an honest and frank dialogue with consumers and their representatives. A product label is not the only way, or necessarily the best way, to convey information about food. The challenge is to find the right way to promote information sharing for each of a wide variety of products.

In addition to considering issues of public acceptance, the industry must also come to understand how local economic strategies are influencing developments in agricultural biotechnology and learn to react appropriately to this information. Not all antibiotechnology activities are based on public issues; many are economic strategies put forward by those who see an opportunity to win economic success by niche marketing against a glut of products of biotechnology. Only by recognizing these forces can industry focus its efforts where they will do the most good.

The Canola Council of Canada has undergone a tremendous education in agricultural biotechnology over the last several years. Its members devoted the time and effort to understand the near-term situation as well as the long-term trend. They have taken a strong position on when to go forward and at what pace. They are actively working to move the regulatory process forward internationally. This is what has to happen for industry to succeed. In some cases, this is an extension of previous activities, but in some cases it will represent a significant change in the nature of industry liaison activities. Again,

the already big and the already powerful will have a distinct advantage, whether they are individual corporations or industry associations. To the public, this may be problematical because multi-national corporations are often viewed with suspicion, while local small companies are favored. In the regulatory system that has evolved, few, if any, small companies will be able to survive without major support.

THE VISION

In international regulatory circles, progress is measured in “inches,” and the dedicated individuals who have struggled to get us where we are today deserve congratulations for the progress achieved. But we must do more. Today’s patchwork of politics and science is a potentially volatile environment for traders. In many ways, this is nothing new for traders, but it is avoidable. Each one of us needs to promote the resolution of the needless international complexity and confusion that exists. Many needs are simple, but the solutions will be challenging to implement.

Recommendation 1: Experts must determine which decisions can be transferred between jurisdictions with confidence. Food and feed safety assessments would seem the most likely. If canola oil has been determined to be safe for humans in North America to consume, it is difficult to imagine the value of repeating the evaluation of risk in country after country. Such acceptance would increase consumer confidence. Acceptance of safety reviews is not just an issue between North America and other regions. Mutual recognition of decisions between EU member states is as important as between the EU and North American countries.

Recommendation 2: Experts must distinguish between high-risk and low-risk parts of the decision process and devote appropriate resources to each. Importation for processing is likely to be a relatively low-risk decision process and should not receive the same intensive evaluation as high-risk decisions. Submissions to allow use for growing and importation for processing need to be separated and rationalized.

Recommendation 3: Regional alliances need to be developed to cover relevant ecological risk zones. This approach would guarantee proper scientific rigor in all global reviews and ensure an economical approach that minimizes the need for redoing reviews.

Recommendation 4: Global expertise needs to be developed to ensure that enough people are trained to handle the workload that lies ahead. This implies that nations with existing expertise should take on a role as trainer. It should not be taken, however, as an invitation to develop duplicative systems in country after country. Capabilities must be developed. Bureaucracies need to be managed and efficient ways of going about the global business must be found.

Recommendation 5: The focus must be on science. If there are concerns about operational implementation, the challenge should be to develop the management plans and the educational training programs to address the concerns. Politics under the guise of science must end.

Recommendation 6: The strategies of the players need to be recognized. Some in the antibiotechnology lobby have relevant comments worthy of our consideration. Some are only looking for a niche-marketing opportunity. Some of these players are individuals, some are groups, and some are nations. To put our always limited resources to the best use, we must recognize the differences and communicate with those who will benefit from the information we have to offer and who have points of view we need to hear.

CONCLUSION

Agricultural biotechnology holds great potential for feeding a hungry world and reducing the strain on the planet's environment. North America is leading in its development. Japan and Europe are not far behind. The products of agricultural biotechnology will circle the globe as exports and imports. Currently, international regulatory systems represent an uneven maze of pragmatism and politics that creates a nightmare for commodities grain traders and confusion for the public. Everyone engaged in agricultural biotechnology has a role to play in educating, communicating, and promoting a science-based global system that will facilitate rather than impede trade of agricultural biotechnology products.