Market Access Issues for Transgenic Plants in Canada and Abroad

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Summary

In this paper the factors affecting the commercialization of ag-biotech products in Canada destined for international markets. Public acceptance issues, lack of internationally harmonized regulatory systems and data requirements, politicized regulatory systems, intellectual property rights, unclear and inconsistent labeling laws, and the current uncertainty cultivated by the United Nations Convention on Biological Diversity (CBD) Biosafety Protocol, all contribute to market access barriers for Genetically Modified Organisms (GMOs) are discussed.

Key words:
Canada, GMO, trade, legislation.

Economic returns, in recent years, for producers in Canada have been compared to those for producers during the Great Depression. Inconsistent national policies and protectionism in the world has increased global competition and created an unfair trading environment. Innovation in agricultural practices are key to competing in today's global environment. The „first generation" of ag-biotech products provided producers with tools to compete globally by reducing input cost and/or increasing yields.

There are many factors affecting the commercialization of ag-biotech products in Canada destined for international markets. Public acceptance issues, lack of internationally harmonized regulatory systems and data requirements, politicized reg-

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ulatory systems, intellectual property rights, unclear and inconsistent labeling laws, and the current uncertainty cultivated by the United Nations Convention on Biological Diversity (CBD) Biosafety Protocol, all contribute to market access barriers for Genetically Modified Organisms (GMOs). As well, International market access for Genetically Modified Organisms (GMOs) is limited due to the lack of internationally harmonized regulatory systems, and data requirements. Despite this the world has witnessed a number of innovative ag-biotech products enter the commercialization stage.

It is difficult to assess the Canadian approach to regulating biotech products without considering how other countries regulate GMOs. I will focus this paper on Canada's approach to regulating transgenic plants, relative to the USA, Japan and the European Union, and the effect these regulations have on commodity markets in Canada. However, it is important to remember that all of the issues that effect market access for GMOs are interconnected, and interdependent.

1. Regulating transgenic plants in Canada

Most developed countries have adopted the OECD developed concepts of *familiarity* and *substantial equivalence* to assess the potential environmental and health risks associated with transgenic plants. The potential risks are determined by comparing the biology between a transgenic plant and a reference plant, usually its traditional counterpart (if it has one). It is important to note that all assessments for GMOs are done on a case by case basis.

Biotechnology products are regulated under Legislative Acts of Parliament in Canada. Rather than create new legislation for biotech products, Canada created guidelines to existing Acts. In Canada there are four acts that cover regulation of transgenic plants; The Food and Drugs Act is administered by Health Canada (HC), The Seeds Act and The Feeds Act are both administered by the Canadian Food Inspection Agency (CFIA), and the Canadian Environmental Protection Act is overseen by Environment Canada (EC).

The Canadian Food Inspection Agency (CFIA) is responsible for assessing the environmental and feed safety data for plants with novel traits (PNTs). These data are collected from field trial plots. Regulators determine if there is a potential negative impact on the environment by assessing, among others, whether there is increased weediness or out-crossing, compared to the plants traditional counterpart. If the plant is determined to be substantially equivalent to its traditional counterpart it can receive conditional or unconditional release permission. The CFIA is also responsible for regulating feed. The nutritional components of a transgenic plant are assessed to determine feed safety. The process for regulatory approval is transparent, and there is an open dialogue between the regulator and the proponent. The CFIA is also responsible for variety registration.

Food safety in Canada is assessed by Health Canada's Health Protection Branch. Responsible for the Food and Drugs Act. Regulators assess whether there have been substantive changes in the plant. They address concerns with regard to allergens and nutritional quality differences.

The Environmental Protection Act (CEPA) can be considered as a safety net legislation intended to regulate biotech products that are not covered by other Acts.

The trigger for regulation in Canada is when a plant has incorporated a *novel trait*. The means by which the plant incorporated this novel trait is irrelevant with respect to being subject to regulation. However, the information required by the regulatory can differ depending on the ability to collect data for addressing a particular concern.

2. Regulating transgenic plants in The United States

Plants produced by recombinant DNA technology are subject to regulation in the United States. The United States Department of Agriculture (USDA) is responsible for environmental risk assessments for transgenic plants. The process is transparent and there is an open consultation between the regulator and the proponent.

The United States Food and Drug Agency (FDA) is responsible for assessing food and feed biosafety for transgenic plants. The process is transparent and there is an open consultation between the regulator and the proponent.

3. Regulating transgenic plants in Japan

Like Canada and The United States, Japan has a multi-ministerial approach to regulating GMOs. Even though the process used to create the GMO is the trigger for regulatory requirements, the biosafety of the end product and intended use of the end product are the basis for the risk assessment.

The Ministry of Agriculture Forestry and Fisheries (MAFF) performs environmental biosafety assessments and feed additive health assessments for ag-biotech products intended for commercialization. Field trial data **obtained in Japan** is required for the environmental biosafety assessment even if the product is not intended for cultivation in Japan. The Society for Techno-Innovation of Agriculture, Forestry and Fisheries (STAFF) coordinates the required field trials with the petitioner and a national agricultural institution. The Innovative Technology Division of MAFF can provide „Guidelines for Application of rDNA Organisms in Agriculture, Forestry, Fisheries, the Food Industry and Other Related Industries" and „Guidelines for Safety Assessments of Application of rDNA Organisms in Feed Additives". A Food approval from the Ministry of Health and Welfare is usually a prerequisite for Feed approval. The Ministry of Health and Welfare regulates GMOs in Food with „Guidelines for Food and Food Additives Produced by the rDNA Techniques".

Under the Japanese regulatory system only a company that has a registered address in Japan can be a Petitioner. This can create significant challenges for smaller Canadian companies, who must find a partner in Japan that will act on their behalf with the submission. The regulatory submissions must be written in Japanese, and correspondence between MAFF and the petitioner should be in Japanese. Applicants should be aware that there are deadlines for submitting petitions at various stages of the risk assessment process. These requirements can cause significant barriers to small ag-biotech companies, or public institutions wishing to commercialize their products. The cost the required field trial, as well as the cost of translating documents is substantial.

4. Regulating transgenic plants in Europe

Unlike, Canada, the U.S.A and Japan, the European Union developed new legislation for regulating GMOs rather than writing guidelines to existing legislation. The appropriate regulation for approval of transgenic plants for environmental approval and marketing in the European Union is EU90/220. A new food directive has recently been adopted. The system has proven to be quite politically sensitive. The trigger for regulation of a plant variety, like Japan, is the process used to create the variety (modern biotechnology-recombinant DNA technology).

An application (data submission) is submitted to a member state that will act as a sponsor country. The sponsor member state has their scientific committee evaluate the data, conduct inquires and assess the safety. If the member state's scientific committee determines that the transgenic plant is acceptably safe, they recommend acceptance to the EU Commission. The application is then referred to the scientific committee of the EU, a committee with representation from all the EU member countries, who will re-evaluate and either call for more examination or approve. If the application is approved a letter is sent to all the member states, which have sixty days to respond. If a qualified majority of the member states approve then the product is approved. The sponsor country then officially approves the product. In practice there is tremendous opportunities to stall the application at the political level. This has been the cause for extremely long processing times, more than three years in some cases.

5. Commodity trade of GMOs

In Canada, if a transgenic plant is determined to be „substantially equivalent" to it's traditional counterpart, and imparts no additional environmental or health risks, it can obtain environmental release approval. The first transgenic varieties, that received unconditional release approval, had agronomic traits incorporated (herbicide

tolerance), and were therefore destined for the general grain handling system. There is no down stream value added to the seed, and thus they did not warrant the cost of Identity Preserving (IP) or segregating from the „substantially equivalent" non-GMO seeds. Once a transgenic crop obtains variety registration approval (a peer review evaluation process) it can enter into the mainstream commodity system. Market regulatory approvals are not part of the evaluation process for a novel plant, therefore it is possible for an approved variety in Canada with out approvals in a particular market entering the grain handling system and jeopardizing the entire shipment to that market. Developments in the EU, regarding the granting of regulatory approvals for transgenic crops, have caused great concern among the shippers and exporters of grain in Canada and other trading countries.

It is important that strategies are developed in order to address the concerns of stakeholders, such as shippers and exporters of ag-biotech products, to prevent major damage to the ag-biotech community.

6. Labeling of GMOs

With genetically modified (GM) foods finding there way into the market place, every country is dealing with the question of how to best provide meaningful, factual information to the public for these products. Labeling products as the means for providing this information has received tremendous attention, and controversy. Views among different countries are generally split between mandatory labeling required under all circumstances, such as in the EU, and labeling requirements only when the GM food has a potential health or safety concern (i.e. increased allergen potential, nutritional composition changes compared to conventional food), such as in Canada.

In Europe there has been a tremendous push, from many stakeholders, for mandatory labeling of GM foods. There are two directives in the EU that address GMO labeling. Regulation 258/97 – The Novel Foods and Food Ingredients Regulation; and Directive 79/112 – Compulsory Labeling of Certain GM Foodstuffs. The former regulation applies to all GM foods placed on the market after June 16th, 1997 in the U.K. (not retrospective). The Agriculture Council of Europe adopted the latter regulation on May 25th, 1998. It relates specifically to GM soya and GM maize placed on the market prior to the Novel Foods Regulation. Article 8.1 of Regulation 258/97 sets the provision for labeling. Labels must indicate the characteristics or properties modified and the method by which these were obtained. Labels must inform the final consumer of the presence in the novel foods or ingredients of material which is not present in an existing equivalent foodstuff and which may have implications for the health of certain sections of the population, or give rise to ethical concerns. Labels must inform the final consumer of the presence of a genetically modified organism. Directive 79/112/EEC makes it compulsory on all European food manufac-

turers to label products containing GM soya and GM maize. It sets a precedent for future labeling of all GM foods.

The council agreed to a regulation on labeling of all ingredients based on the detection of DNA or protein that relate to the genetic modification of a food. The following GM soya derivatives require labeling: Whole beans; Full-fat flour; Defatted flour; Tofu; Protein Concentrate; Protein Isolate; Soya Milk and Textured soya. Refined soya oil would not require labeling. It has not been determined yet whether soya sauce or hydrolyzed proteins would require labeling. The following GM maize derivatives would require labeling: whole grains, flour and maize protein. Corn oil, starch, maltodextrins, glucose syrup and dextrose would not require labeling. One of the major draw backs for detection methodology is that as the number of GMO products grows the number of detection tests, such as Polymerase Chain Reactions (PCR) reactions and Western blots, that will have to be done will be astronomical. It is interesting to note that only those derivatives in which methodology exists for detecting DNA or protein currently have the requirement for labeling. As detection technology becomes increasingly more sensitive, GM derivatives, such as corn oil, may one day require labeling in the EU. Because of this there has been pressure in Europe for the council to adopt threshold levels of GM food in non-GM food.

International bodies such as the *Codex Alimentarius* Commission, joint FAO/WHO Food Standards Program, have a food labeling committee charged with considering food labeling issues, including GM foods. Unfortunately progress has been slow towards achieving a consensus for labeling. Based on the current position of the EU compared to other countries, such as Canada, Australia and the United States, it seems unlikely that the Codex committee will be in agreement in the near future. So until the time in which there is consensus, many countries will continue to address the difficult task of ensuring that the consumer has the right to chose, while at the same time offering factual, meaningful information so the consumer can make an informed choice. All stakeholders believe that providing information to the consumer is necessary, however, the debate mounts when addressing how that information is to be provided. A label serving solely as an alert to the presence of GMOs hardly seems appropriate.

7. Conclusion

There has been a perception (hope) within industry that a regulatory approval victory for one GMO will pave the road for future GMOs. Unfortunately, if anything, the road appears to be getting bumpier. As the industry matures and more GMOs are making their way to market, governments are giving careful consideration to adding socio-economic and ethical concerns to the list of requirements for granting regulatory approval. In this case, the public must support ag-biotech in order to gain regulatory approval.

There has been a tendency within industry to tackle the symptoms of these regulatory decisions rather than their cause. The short-term success achieved by lobbying governments doesn't solve the problem. This success can actually damage the industry further by frustrating the public, who for the most part have been inundated with misinformation from special interest groups. We must remember that governments are under tremendous pressure and public scrutiny due to the recent emergence of public safety issues, such as Bovine *Spongiform Encephalopathy* (BSE), AIDS and Hepatitis C.

The perception within industry is that the rules surrounding approvals for GMOs are constantly changing. However, it is public outcry that feeds the political decisions we see emanating from regulatory agencies around the world. Would trade barriers exist if there were public demand for ag-biotech products? The ag-biotech stakeholders must focus on a long-term sustainable ag-biotech industry. Fortunately, many governments in the world recognize the benefits of ag-biotechnology, as evidenced by an increase in public funding for biotech research and development.

Governments and Industry have long recognized the importance of the public accepting modern biotechnology, but both have been slow to act. There has to be a commitment among all stakeholders in the ag-biotech industry to inform and address the concerns of the public. The best way to achieve market access for GMOs is by obtaining regulatory approvals with the full support of the public. There is a lot of talking about harmonizing international regulatory systems, perhaps as well much more energy and resources should be put into harmonizing international public acceptance.