PROJECT CODE

BRE1209

TITLE

Economic and Regulatory Research Pertaining to Pulse Crops and

European Regulator and Consumer Perceptions of Novel Breeding Techniques

INVESTIGATORS

Stuart J. Smyth and Jillian McDonald,
Department of Bioresource Policy, Business and Economics,
University of Saskatchewan

FUNDER(S)

Saskatchewan Pulse Growers

TYPE OF STUDY

GENETIC IMPROVEMENT - REGULATORY

OBJECTIVES

To review the regulatory status of genetically modified organisms, particularly in countries which import significant amounts of Canadian pulses.

WHY STUDY NEEDED

As scientific innovations in plant breeding techniques continue to advance, the importance of global regulatory systems and their acceptance of these new breeding techniques will become a dominant factor in the variety approval process for new crop varieties. Domestic regulatory systems that are science-based are expected to be able to render variety approval decisions on crop varieties developed using new breeding techniques with no pauses for additional risk assessments. Those regulatory systems that have incorporated socio-economic considerations and rely on the precautionary principle, such as the European Union system, will face an increasingly difficult situation when it comes to the regulation of crop varieties developed using these new technologies.

Innovation in the technology of plant breeding will continue to advance. Applying these new technologies to the development of some varieties will make economic sense, while in other instances it will not. Careful consideration needs to be given to the variety approval process and existing biosafety regulatory frameworks. Commercialization of varieties developed through newer breeding techniques may require the implementation of an identity preservation system to ensure that co-mingling is minimized in serving markets that express a desire to avoid products developed by these new technologies.

STUDY DESIGN

This analysis reviews the approach to genetically modified (GM) plants and other plants with novel traits in North America, Europe, and such key marketing areas for pulses as Turkey, China, India, Bangladesh, and African countries, and identifies the roadblocks for acceptance and commercialization of such plants. It then assesses newer plant breeding methodologies such as targeted mutagenesis approaches in terms of their probable acceptability to different regulatory bodies and markets.

FINDINGS

This report provides a review of the two dominant models for regulation of biotechnology, and provides perspective on some of the regulations surrounding GM plants in the main exporting markets for Saskatchewan pulses and pulse products.

For the most part, the Americas have moved towards the 'scientific evidence-informed' or what is referred to as the 'science-based' assessment of risks. The Australasian nations have followed the lead of North America and begun to commercialize GM crop technologies. Nations of Europe have pursued an alternate regulatory framework for the assessment of risks, one that incorporates scientific evidence into regulatory decisions regarding the approval of biotechnology, but also other socio-economic considerations. This is a more precautious approach towards the future, potential risks associated with biotechnology. What has resulted is a trans-Atlantic gap in how the leading industrial nations deal with GM crops. Ultimately, a solution to this gap needs to be found, but for the short term, no easy remedy appears.

The two dominant models for regulating biotechnology, the North American and the European, have influenced other nations in developing regulations for GM or other novel plant traits. Some developing countries will align themselves with science-based regulatory jurisdictions, while others may be dependent on trading relationships with countries with strict no GM policies and be fearful of losing their export markets. Some nations have hybrid models with elements from both the North American and the EU models.

For the purposes of pulse marketing, the stance of the importing nation must be known. For peas, the three largest importers are India, China, and Bangladesh; for lentils, Turkey and India are the largest markets, with several other nations each taking up 4-7% of Canadian lentil exports.

Canada: Canadian regulators established regulations which focus on the end product, not the process used to create the product, developing the category of plants with novel traits (PNTs). Plants that are classified as PNTs are plants that do not have a history of production and safe consumption in Canada. They may have been introduced from elsewhere, or genetically modified using genetic engineering, mutagenesis, or any other breeding method. Plants developed using non-recombinant methods have triggered regulatory review for expressing novel traits;

examples are a low-phytate barley developed by conventional breeding, and a Clearfield canola developed from a somaclonal variant. All commercialized GM plants to date have been considered to contain novel traits and, therefore, have been assessed for safety. Some plants with recombinant DNA, however, would not trigger this scrutiny if the same gene modification had been assessed previously.

The regulation of products created via biotechnology is the responsibility of the CFIA and Health Canada. All novel trait products must receive approval for unconfined release from the CFIA prior to their submission for variety registration consideration to the respective commodity variety recommendation committee. Data from confined field trials is compiled and submitted to the CFIA for a safety assessment. The confined field trials data is thoroughly reviewed by the CFIA and Health Canada officials using scientific approaches. Officials from all departments work together on a new variety application. Officials do not conduct or redo the scientific experiments and research information that is submitted by the applicant (usually a private company or public university); rather, they analyze the data submitted. Frequently, regulators will ask the applicant to provide them with additional information. After review, if unconfined release status is granted, then the applicant can submit the new variety to the respective variety recommending committee for variety approval consideration.

Health Canada assesses the safety of all GM and other novel foods proposed for sale in Canada. Companies are required to submit detailed scientific data for review and approval by Health Canada, before such foods can be sold.

The first approvals of PNT's in Canada occurred in 1995. As of 2013, there have been 95 decision documents released by the CFIA.

Europe: The EU's approach to risk assessment of genetically modified organisms (GMOs) covers all aspects of the production process. The scientific risk of harm that a specific GMO poses to humans, animals, and the environment is but one of the aspects that is regulated. As well, the risk of harm that GMOs can pose to socioeconomic aspects of the food system and their potential for future harms is considered. This has caused trade disputes with international trading partners such as the US and Canada that do not include these aspects of the production process in their risk assessments of GMOs.

Following the European Union's moratorium on the importing of GM crops between 1999 and 2003, the EU established the European Food Safety Authority (EFSA) to undertake the risk assessment on all new crop varieties submitted for regulatory approval, to be followed by a European Commission vote on approving the varieties for commercial release. These risk assessments were to be done using science-based risk assessment procedures, and appear to be carried out in a timely manner. However, the votes on variety approval at the political level are often not taking place, some of the variety submissions have waited for a vote to be held for over eight years. For those that do, the strong "environmental" movement in Europe has

contributed to oppose approval.

This politicized system contributes to delay in the approval of the registration of new crop varieties developed by biotechnology. The EU is not moving expeditiously to make a decision on how to treat varieties developed via new breeding techniques, adding to the uncertainty that exists regarding the EU's regulatory approval process.

Large costs are incurred in delayed research development. In 2012 BASF decided to relocate all of its plant biotechnology research from Europe to North and South America. In part, this decision is based on the fact that it took the EU thirteen years to render approval for a BASF variety of GM potato. In 2013, Monsanto announced it would no longer invest in biotech varieties and R&D in Europe. The regulatory uncertainty in the EU regarding the approval process for GM crops has contributed to the reduction in crop innovation research in Europe.

Turkey: While Turkey is not an official member of the EU, the approval of biotech crops in the EU greatly influences how GM events are regulated. The Biosafety Law covers all aspects of GM events within Turkey. Under this law, the cultivation of GM crops is banned within Turkey and any imports into the country must be from approved GM events. While some events have been approved for feed use, the approval process does not appear to be consistent or transparent. Combined with the facts that it has close trading ties to Europe and has applied for membership in the EU, Turkey does not look to be a favourable market for GM crop exports.

China: China's regulatory framework for the biotech industry follows those in North America and Europe, borrowing elements from both. All GMOs undergo risk assessment in China, and not all GMOs are viewed as equally risky. Like the EU, there is zero tolerance for unapproved GMOs. China has not yet approved a GM crop intended for food that was produced outside of the country. Trading partners such as the US claim that there is a lack of transparency regarding regulations and application procedures for new products, and that China's 'zero tolerance' policy for unlicensed GMOs in imports constrains trade.

India: The regulatory framework for biotechnology in India employs some elements of the Canada/US product-based risk assessment framework. At the same time, however, it draws upon elements of the EU process-based risk assessment framework in its legislation. This contributes to a degree of inefficiency in how decisions are made. India has generally been cautious in its approval of GM crops. It has also included the goal of not causing economic harm to farmers through their commercialization. India evaluates applications for commercialization of GMOs on a case-by-case basis.

Criticisms of India's regulatory system for biotechnology come from both industry and nongovernmental organizations. Regulators are viewed as too closely affiliated with government officials to make approval decisions independent of ministerial influence. While GM Bt cotton (resistant to many insect pests) has been legally grown since 2003, as of 2013 there is still a *de facto* moratorium on new commercial approval of

GM crops within India.

Bangladesh: Bangladesh has been slow to implement a consistent regulatory process for biotechnology. Initial Biosafety Guidelines have been approved in principle, but have still not been regulated into law (as of 2013). Despite this, the Biosafety Guidelines had been clearly developed, with a procedure for application and approval of GM crops available to applicants. Although there is still ambiguity in GM regulations within the country, Bangladesh authorities have not stopped the entry of any imported consignment into the country due to its bioengineered status. Generally, Bangladesh has been considered a very favourable market for the introduction and acceptance of GM crops. Individual government levels had a pro-biotechnology attitude and GM crops did not have much opposition from civil society groups.

With the commercialization of the first GM crop to be grown in Bangladesh of a pest resistant brinjal (eggplant) in 2013, the country becomes the first in the region to grow a GM food crop.

The absence of a national biotech policy and concurrent regulatory system is the major biotechnology-related barrier that could hurt agricultural exports to Bangladesh. Bangladesh also lacks effective legislation to protect the intellectual property rights in plant varieties.

African Continent: African countries are beginning to build regulatory frameworks for biotechnology, but the regulatory development across the continent is uneven. Regional-level organizations designed to help establish country-level regulatory frameworks have been successful to varying degrees. Many of the regulatory frameworks that exist in Africa are based on the Precautionary Principle found in the EU model. Regulatory costs remain prohibitively high in Africa, as there is inadequate development of expertise in intellectual property management. There are seventeen African countries that have National Biosafety Frameworks or laws enacted regarding biotechnology, five with interim NFBs, twenty with (NBFs) ‘in progress’ and ten that do not have regulations pertaining to biotechnology (as of 2013).

Some countries, like South Africa, have embraced biotechnology, while the refusal of food aid containing GMOs during the food crisis of 2002 demonstrated the suspicion held by some African governments about their safety. However, there are several GM crops currently under commercial production in Africa: cotton, maize, and soybean in South Africa; cotton in Burkina Faso; and maize in Egypt.

Food safety issues are of primary concern to many African countries. Another issue is the relationship between patents of GM products and how they impact food security in a continent that has some of the poorest countries in the world. As well, the impact of patents on GM products on food security, in a continent that has some of the poorest countries in the world, is of concern. The non-GMO markets developing in the EU for agricultural products from Africa have also been influential in the hesitation towards the acceptance of GM technology in countries that depend on

this European market.

Issues related to Other Methods: Additional approaches to changing genes or gene expression patterns are mutagenesis, which usually triggers no regulatory response, and cis-genesis, which uses only the plant's own genes, although they may, for example, be transformed back into the plant in a reversed orientation, which may or may not be considered GM. In some species, plants are often grafted, and a graft onto a transgenic rootstock may possibly be considered as GM in some way, although the harvested material (such as fruit) would carry no transgenic DNA.

New Methods: New plant breeding techniques for gene modification, involving targeted mutagenesis, have been developed in the last several years. These include oligonucleotide directed mutagenesis, zinc finger nuclease technique, meganuclease technique, and transcriptional activator like effector – nuclease technique. At present (2016) a simpler method using an enzyme which is guided by a RNA molecule matching the target DNA (CRISPR/Cas9 and comparable methods) is being introduced and has the potential to replace these methods. In all cases, the desired outcome is one where a precise, minimal change is made in the plant genome, without adding any extraneous stretches of DNA or acting elsewhere in the genome. The change may be as little as one single nucleotide.

Currently (2013) these techniques are being evaluated under the GM regulatory framework of the EU, and elsewhere. One of the proposed regulatory outcomes is that they should be considered under the same regulatory framework as conventional mutagenesis, as they produce events that are indistinguishable at the molecular level from events produced with conventional mutagenesis. However, political considerations may lead to their being considered as GMOs.

Pulse Crops: To date (2013), there are no transgenic pulses approaching market, although PNT lines derived from other methods could be (e.g. low-phytate pea developed through mutation). However, the example of soybean, where much greater resources have been available for crop research, shows the potential of transgenic legumes in agriculture. Together with recent advances in tissue culture and transformation techniques for pulses, the newer approaches to altering gene sequences may have application to pulse crops in the fairly near future. Whether such developments become a realistic possibility depends not only on technical advances, but on the evolution of regulations in the key markets for these crops.

SIGNIFICANCE OF STUDY

Increased crop genomics research inevitably results in new products and processes which raise questions about whether the regulation of these new products and processes will be used as a barrier to trade. The study surveys the situation with emphasis on areas which import Canadian pulses in large amounts.

PUBLICATIONS, PRESENTATIONS, EDUCATIONAL MATERIALS PRODUCED

NONE SHOWN.

VALUE TO PRODUCERS

This study provides information on the continuing marketing challenges presented by the wide variety of approaches to the regulation of genetically modified organisms, particularly with reference to the new (targeted mutagenesis) technologies for plant improvement. While applicable to crop species generally, the information will be relevant in going forward with either transformation approaches or newer approaches to pulse improvement. [Although at this point there are no GM pulses approaching release, the information will be relevant in going forward with either transformation approaches or newer approaches to pulse improvement.]