Developing a Policy for Low-Level Presence (LLP): A Canadian Case Study

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Agricultural biotechnology research and adoption is increasing. It is estimated that by 2015 there will be a three- to four-fold increase in the number of commercialized biotech products. Also increasing are the complications with international trade given the wide range of acceptance and regulatory capabilities currently in practice globally, specifically, the increasing low-level presence (LLP) of biotech products that have received full regulatory approval in one or more countries but not in the country of import.

Canada, recognizing the impact of LLP on international trade, is taking a leadership role. Using a government-industry collaborative model, the Canadian government is developing a domestic regulatory policy to manage LLP from imports and building international collaborations to raise awareness of the impacts of LLP on trade globally. This article details the collaborative government-industry process and the current status of the draft domestic LLP policy and international engagement.

Key words: agriculture biotechnology, Canada, international trade, low-level presence (LLP), stakeholder collaboration, genetically modified, policy.

Introduction

One of the current greatest challenges is how to feed our growing global population and to do so in a more sustainable manner. By 2030, the United Nations predicts there are likely to be 1.7 billion more mouths to feed (United Nations Secretariat, Department of Economic and Social Affairs [DESA], 2009). A population set to exceed 8 billion by 2030 brings with it the need to meet growing caloric demand.

Biotechnology or genetic modification (GM) is one tool available to increase agricultural production. Modern agriculture using plant biotechnology has doubled the production of world food calories since 1960. Farms can grow more on each hectare than ever before. In the 1980s, one hectare of arable land produced 1.8 tonnes of food annually on average. Today, one hectare produces 2.5 tonnes of food (United Nations Environment Programme [UNEP] Global Environment Outlook, 2007).

Farmers are also realizing economic gains from plant biotechnology. From 1996 to 2008, biotech crops have increased global farm incomes by $52 billion due to enhanced crop productivity and more efficient farming techniques. In 2008 alone, the direct global farm income benefit from biotech crops was $9.4 billion, and more than half of these income benefits have been realized by farmers in developing countries (Brookes & Barfoot, 2010).

This increased productivity has led to a rapid global adoption of the technology. According to the 2011 International Service for the Acquisition of Agri-biotech Applications (ISAAA) biotech crop report, the outlook for biotech crop adoption points to continued growth with current global biotech adoption at 16.7 million farmers in 29 countries, with 160 million hectares planted.

However, the adoption of biotech crops has not occurred uniformly across the globe and regulatory approaches are diverse. Since biotech crops were first commercialized in the mid-1990s, global approvals and acceptance have varied, ranging from rapid adoption in countries such as the United States, Canada, and Argentina, to low adoption and even GM moratoria in some European, Asian, and African countries.

Even in countries with well-established regulatory systems for biotech crops, approval timelines and duration of authorizations differ from country to country. These differences can lead to asynchronous authorizations among key trading countries, which can potentially affect international trade (Table 1).

International trade may be further impacted if a minute amount of a biotech crop already authorized and produced in one country is detected in an importing...
Table 1. Asynchrony of first approvals of GM crops (for any use) between the United States and the European Union, status in early 2009.

<table>
<thead>
<tr>
<th>GM crop</th>
<th>United States</th>
<th>EU</th>
<th>Delay (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roundup Ready soy (MON 40-3-2), Monsanto</td>
<td>1994</td>
<td>1996</td>
<td>2</td>
</tr>
<tr>
<td>Bollgard cotton (MON531), Monsanto</td>
<td>1995</td>
<td>1997</td>
<td>2</td>
</tr>
<tr>
<td>Roundup Ready cotton (MON1445), Monsanto</td>
<td>1995</td>
<td>1997</td>
<td>2</td>
</tr>
<tr>
<td>NaturGard KnockOut maize (Bt176), Syngenta</td>
<td>1995</td>
<td>1997*</td>
<td>2</td>
</tr>
<tr>
<td>LibertyLink maize (T25), Bayer</td>
<td>1995</td>
<td>1998</td>
<td>3</td>
</tr>
<tr>
<td>YieldGard CB maize (MON810), Monsanto</td>
<td>1996</td>
<td>1998</td>
<td>2</td>
</tr>
<tr>
<td>Agrisure CB maize (Bt111), Syngenta</td>
<td>1996</td>
<td>1998</td>
<td>2</td>
</tr>
<tr>
<td>Agrisure GT maize (GA21), Syngenta</td>
<td>1997</td>
<td>2005</td>
<td>8</td>
</tr>
<tr>
<td>LibertyLink canola (T45), Bayer</td>
<td>1998</td>
<td>1998</td>
<td>0</td>
</tr>
<tr>
<td>LibertyLink soy (A2704-12), Bayer</td>
<td>1998</td>
<td>2008</td>
<td>10</td>
</tr>
<tr>
<td>Roundup Ready canola (GT73), Monsanto</td>
<td>1999</td>
<td>1996</td>
<td>-3</td>
</tr>
<tr>
<td>InVigor canola (MS8xRF3), Bayer</td>
<td>1999</td>
<td>1999</td>
<td>0</td>
</tr>
<tr>
<td>LibertyLink rice (LLRICE62), Bayer</td>
<td>2000</td>
<td>Assessment</td>
<td>Current AA</td>
</tr>
<tr>
<td>SeedLink canola (MS1xRF1), Bayer</td>
<td>2002</td>
<td>1996*</td>
<td>-6</td>
</tr>
<tr>
<td>SeedLink canola (MS1xRF2), Bayer</td>
<td>2002</td>
<td>1997*</td>
<td>-5</td>
</tr>
<tr>
<td>TOPAS19/2 canola (HCN92), Bayer</td>
<td>2002</td>
<td>1998*</td>
<td>-4</td>
</tr>
<tr>
<td>Roundup Ready 2 maize (NK603), Monsanto</td>
<td>2000</td>
<td>2005</td>
<td>5</td>
</tr>
<tr>
<td>Herculex I maize (1507), Dow/Pioneer</td>
<td>2001</td>
<td>2006</td>
<td>5</td>
</tr>
<tr>
<td>Bollgard II cotton (MON15985), Monsanto</td>
<td>2002</td>
<td>2003</td>
<td>1</td>
</tr>
<tr>
<td>YieldGard RW maize (MON863), Monsanto</td>
<td>2002</td>
<td>2006</td>
<td>4</td>
</tr>
<tr>
<td>LibertyLink cotton (LLCotton25), Bayer</td>
<td>2003</td>
<td>2008</td>
<td>5</td>
</tr>
<tr>
<td>Widestrike cotton (210-23x24-236), Dow</td>
<td>2004</td>
<td>Assessment</td>
<td>Current AA</td>
</tr>
<tr>
<td>Herculex RW maize (59122), Dow/Pioneer</td>
<td>2005</td>
<td>2007</td>
<td>2</td>
</tr>
<tr>
<td>Roundup Ready sugar beet (H7-1), KWS/Monsanto</td>
<td>2005</td>
<td>2007</td>
<td>2</td>
</tr>
<tr>
<td>YieldGard VT maize (MON88017), Monsanto</td>
<td>2005</td>
<td>Assessment</td>
<td>Current AA</td>
</tr>
<tr>
<td>Roundup Ready Flex cotton (MON88913), Monsanto</td>
<td>2005</td>
<td>Assessment</td>
<td>Current AA</td>
</tr>
<tr>
<td>Mavera High Value maize (LY038) Renessen/Monsanto</td>
<td>2006</td>
<td>Assessment</td>
<td>Current AA</td>
</tr>
<tr>
<td>Roundup Ready 2 soy (MON 89788), Monsanto</td>
<td>2007</td>
<td>2008</td>
<td>1</td>
</tr>
<tr>
<td>Agrisure RW maize (MIR604), Syngenta</td>
<td>2007</td>
<td>Assessment</td>
<td>Current AA</td>
</tr>
<tr>
<td>Amylaze maize (3272), Syngenta</td>
<td>2007</td>
<td>Assessment</td>
<td>Current AA</td>
</tr>
<tr>
<td>YieldGard VT PRO maize (MON89034), Monsanto</td>
<td>2008</td>
<td>Assessment</td>
<td>Current AA</td>
</tr>
<tr>
<td>Optimum GAT maize (98140), Pioneer</td>
<td>2008</td>
<td>Assessment</td>
<td>Current AA</td>
</tr>
<tr>
<td>Optimum GAT soy (356043), Pioneer</td>
<td>2008</td>
<td>Assessment</td>
<td>Current AA</td>
</tr>
<tr>
<td>3 events in soy and cotton</td>
<td>Submitted</td>
<td>Submitted</td>
<td>(0)</td>
</tr>
<tr>
<td>1 event in potato (BASF’s amflora)</td>
<td>Not submitted</td>
<td>Submitted</td>
<td>Isoleted foreign approvals</td>
</tr>
<tr>
<td>7 events in maize, soy, cotton, and alfalfa</td>
<td>Submitted</td>
<td>Not submitted</td>
<td>Isolated foreign approvals</td>
</tr>
<tr>
<td>&gt;60 events in maize, soy, cotton, canola, potato, rice, and sugar beet</td>
<td>Approved</td>
<td>Not submitted</td>
<td>Isolated foreign approvals</td>
</tr>
</tbody>
</table>

Notes: Approvals in the EU that are marked with an asterisk (*) have already expired and no renewal has been sought by the developer.

Apart from asynchronous approval (AA) and isolated foreign approval of GM crops between the United States and the EU, there is also a rising number of GM crops from other countries (China, India) that contribute to this issue.

Differences in approval time can also be due to the timing of the submission of the respective dossiers by the developer. In the case of canola, which is of less importance in US agriculture, there are also cases where the event was approved in the EU first.

Source: Stein and Rodriguez-Cerezo (2010).
country that has not yet approved the product and does not have a regulatory process in place to deal with low-level presence (LLP).

Low-level presence does not have one universal definition, but for the purposes of this article, the definition is taken from a presentation by the Government of Canada entitled, “Low-Level Presence Policy Review and International Engagement” (Bergeron, 2012).

Low-level presence (LLP) refers to the unintended presence, at low levels, of a genetically modified (GM) event which has undergone a full science-based safety assessment and has been approved in accordance with the Codex Plant Guidelines for food (and domestic regulatory process for feed and environment) in at least one country but not in the country of import.

In Canada, the definition of adventitious presence (AP) of GM plants is different from LLP in two important aspects. First, the event in question has not received full regulatory approval by a regulatory authority in any jurisdiction; and second, the AP occurrence is a rare event, likely occurring by accidental release of seed from research or field trial activities.

An understanding of the differences between biotech crops for food, feed, and processing (FFP) and those used as seed for planting is important in the development of a LLP policy. While all biotech products are assessed for their safety to humans, animals, and the environment, seed is intended for planting and therefore risk assessments (RA) need to focus on the potential environmental impacts. Food, feed, and products for processing—while they could in some cases be whole and act biologically as seeds—are generally destined for consumption and are not intended to be planted. In this article, LLP is specific to grain and used in reference to food, feed, and process products (FFP), unless specifically referred to as LLP in seed.

While there is an enormous infrastructure dedicated to the bulk handling and movement of grain and seed from farms to consumers around the world, even the most sophisticated infrastructure cannot prevent different crops or crop varieties from potentially coming into contact with one another. As an example, in 2009, a shipment of soybeans from the United States was put into quarantine before it could enter Europe, where there is a zero-tolerance policy for traces of unapproved GM products (Wager & McHughen, 2010). Dust particles of a GM corn (MON88017), which received full safety approval by both Canadian and United States regulatory authorities and was given full commercial release for production and consumption in both countries, accidentally made it into the shipment of soybeans somewhere in the transportation process. These traces of fully approved corn dust caused the soybean shipment to be quarantined, triggering significant economic losses.

Several researchers have analyzed the potential economic impact of LLP on the agri-food sector, especially for its impact on the European agri-food industry where there is a zero tolerance policy (Brookes, 2008; Freitag, Minol, & Stein, 2011; Kalaitzandonakes, 2011; Landmark Europe, 2009). One study (Landmark Europe, 2009) estimates the potential cost of an LLP incident involving EU-unauthorized GM maize from the United States could cost between 5 and 46 million Euros, not including potential indirect costs such as supply shortages or plant shutdowns.

In the future, incidents of LLP are expected to increase as the pipeline for new GM crops increases, as seen in Table 2 (Stein & Rodriguez-Cerezo, 2010). Countries such as China and India are close to commer-

| Table 2. Events in commercial GM crops and in pipelines worldwide, by crop. |
|------------------|------------------|------------------|------------------|------------------|------------------|
| **Crop**         | **Commercial in 2008** | **Commercial pipeline** | **Regulatory pipeline** | **Advanced development** | **Total by 2015*** |
| Soybeans         | 1                | 2                | 4                | 10               | 17              |
| Maize            | 9                | 3                | 5                | 7                | 24              |
| Rapeseed         | 4                | 0                | 1                | 5                | 10              |
| Cotton           | 12               | 1                | 5                | 9                | 27              |
| Rice             | 0                | 1                | 4                | 10               | 15              |
| Potatoes         | 0                | 0                | 3                | 5                | 8               |
| Other crops      | 7                | 0                | 2                | 11               | 23              |
| All crops        | 33               | 7                | 24               | 61               | 124             |

Notes: * The total number of GM crops by 2015 represents an upper limit, given that by then some of the current GM crops may have been phased out commercially or legally. However, traces of the events could still be found in commercial samples—and therefore represent a problem of LLP if they are not authorized. Source: Stein and Rodriguez-Cerezo (2010)
cializing new domestically developed GM crops that, although intended for domestic use, could end up inadvertently in shipments destined for international trade and enter other countries, including Canada, as LLP.

Canada, recognizing the challenge of effectively managing the international trade of biotechnology-derived products and minimizing the trade impacts caused by the low-level presence of GM products which have been approved in one or more countries but not in the country of import, has been working on a domestic LLP policy and is leading international engagement on this important issue.

**Canadian Political Engagement**

In 2009, a GM flax variety, Triffid, was found in shipments bound for European ports. Following a red alert, trade of all Canadian flax with the European Union was halted. Triffid flax represents a prime example of LLP in that the variety, while never commercially grown and then de-registered in 2001, had received a full food, feed, and environmental approval in both Canada and the United States. But with Europe’s zero threshold for unauthorized GM events, all flax shipments were stopped.

The impact on Canadian flax producers was significant, estimated at approximately $30 million (Ryan & Smyth, 2012). This situation, while causing substantial economic harm, had a positive effect by raising the political awareness of the importance of LLP and its impact on international trade. Canada’s Minister of Agriculture, the Honorable Gerry Ritz, acknowledged the importance of the flax trade to Canadian producers, understood the concept of LLP, and recognized how a regulatory policy to deal with LLP could assist the trade of GM products internationally.

The Canadian Government, after discussions with importing countries, also realized that its own LLP system was inadequate to manage shipments entering Canada that may contain traces of GM crops that have not had a full approval in Canada. Driven by senior political support, Canada started working on a domestic LLP policy (described later in this article).

The Canadian Government further supported international engagement of this issue at the 36th Cairns Group (CG) Ministerial meeting in Saskatoon, Saskatchewan on September 9, 2011. The following quote by Minister Ritz is taken from an Agriculture and Agri-Food Canada news release (AAFC, 2011) and highlights this commitment:

“Minister Ritz underlined the importance to adapt trade regulations to the growing, innovative agriculture sector. Canada strongly supports innovation in agriculture, which will help farmers continue to produce high quality and quantity of food stuffs and help achieve our global food security objectives. During the conference, Minister Ritz pledged to continue to lead discussions with the international community on the effective management of unintended low-level presence of genetically modified materials in agricultural imports.”

**Canadian Industry Engagement**

Starting in 2007, prior to the Triffid flax issue, the industry recognized that LLP was going to be a key issue with respect to the international trade of products of plant biotechnology. The Canadian agricultural value chain came together—under the Canada Grains Council and supported financially by AAFC through the Advancing Canadian Agriculture and Agri-Food (ACAAF) program—to produce a report on “Creating an Environment for the Successful Commercialization of Canadian Crop Innovation” (Canada Grains Council, 2008). This report, which highlights 26 recommendations to increase agricultural innovation aimed at both industry and governments, was endorsed by more than 50 Canadian organizations including researchers and crop developers, primary producers, grain handlers and marketers, as well as end-use processors. The recommendations in the report encompass innovation from “mind to plate” and LLP was identified as a key limiting factor.

As a result of the collaborative approach to the development of the report and to facilitate the implementation of the report’s recommendations, the Grains Innovation Roundtable (GIRT; AAFC, n.d.) was formed in 2009 with the assistance of AAFC. The strength of this roundtable process was the cross-sectoral involvement of the industry sitting alongside senior officials from the Canadian government regulatory departments. Together, participants delved deeper into the issues identified and strategized on methods to create solutions that would be acceptable to both government and the industry.

The 26 recommendations identified in the original report were divided and covered by five working groups, each with a set of co-chairs and interested participants. The five groups included
• Crop Regulation Working Group
• Communications Working Group
• Primary and Further Processing Working Group
• Crop Research Funding Working Group, and
• Trade Policy Working Group.

The Trade Policy Working Group (TPWG), co-chaired by Janice Tranberg (author of this article) and Senator JoAnne Buth, previously the President of the Canola Council of Canada while participating on this committee, were tasked with responding to recommenda-
tions involving the removal of trade barriers associ-
ated with the approval and commercial production of
innovative crops and products in Canada and importing
countries, including LLP.

The TPWG consisted of approximately 20 members
representing a range of sectors and organizations experi-
ced with regulatory and political challenges affecting
international trade of innovative crops and products, as
well as regulatory experts from the Canadian Food
Inspection Agency (CFIA), AAFC, Health Canada, and
the Market Access Secretariat (MAS).

The TPWG started by undertaking a comprehensive
review of the current regulatory system—the Acts and
Regulations which govern GM crops—in order to fully
understand its benefits and limitations, and if and where
regulatory changes might be required. As part of this
analysis, a LLP scenarios subgroup was formed to test
several specific examples and their implications on cur-
rent regulations and guidelines. Part of the strength of
this process was the involvement of Canadian regula-
tors—not to provide direction per se, but to help the
group understand the impact of its suggestions on cur-
rent acts and guidelines and determine whether existing
acts would need to be changed or whether suggestions
could be put into place by regulatory changes. Follow-
ing this extensive review, the TPWG proposed a frame-
work for a LLP policy in Canada.

**Canadian Regulatory Agency Engagement**

In response to the Government of Canada’s commitment
to develop a domestic LLP policy, an Interdepartmental
Assistant Deputy Ministers (ADMs) Committee on
Trade in GMOs was initiated in 2010. Comprised of
ADMs from AAFC, Health Canada, Department of For-
egn Affairs and International Trade (DFAIT), the Cana-
dian Grain Commission, and Environment Canada, this
high-level committee was mandated to address market
access issues involving GM crops while ensuring the
continued protection of human and animal health and
the environment in Canada.

The committee’s work plan consisted of several
complementary activities, including the development of
an issues paper analyzing domestic and international
LLP management approaches, an assessment process
identifying priority sectors and countries involved, an
international engagement strategy for advocating trade-
friendly approaches for managing LLP, and the develop-
ment of a domestic LLP policy.

To facilitate appropriate information exchange
between the TPWG and the Interdepartmental ADM
Committee, representatives from the multi-department
secretariat supporting the ADM Committee participated
in the TPWG.

The value of the government-industry roundtable
approach is that it provided a forum for the open
exchange of ideas working towards a mutual goal. It
helped to increase communication and understanding
from all perspectives, reduced the chances of misunder-
standing through a ‘ping-pong’ approach, and increased
time and efficiency.

Recognizing the value of this roundtable, and con-
tinuing to build on the work in this area, AAFC orga-
nized a permanent (and renamed) Grains Roundtable
(GRT) with an inaugural meeting occurring March 17-
18, 2011 in Winnipeg, Manitoba. At this meeting, the
TPWG was changed to the Market Access Working
Group (MAWG) to expand its focus, and a biotech sub-
working group chaired by Janice Tranberg was formed
to focus on biotech-specific issues, including LLP.

**Industry Recommendations**

Under the initial GIRT, the TPWG produced a report
that defined the agreed upon scope, objectives, princi-
pies, and approach for a LLP policy for Canada. On
September 16, 2010, several members of the GIRT
Steering Committee and TPWG co-chairs were invited
to the the Interdepartmental ADM Committee to present
the Proposed Framework for Canada’s Future LLP Pol-
cy, as summarized in Table 3.

The key objective of the proposed approach included
increasing predictability for grains and seed exporters/
importers, minimizing trade disputes, and reducing
“emergency-like” responses. The new approach is
intended to increase public confidence in the system and
minimize potential negative impacts on trade.

In making recommendations to the government, the
TPWG felt it was important to stress that a ‘one-size-
fits-all’ approach would not work. Instead, a tool-kit
approach was envisioned, which would be flexible enough to fit current and new innovative technologies and crops in the ag-biotech industry.

**Canadian Domestic LLP Policy Development**

The Government of Canada is proactively looking to enhance its regulatory system to manage LLP while protecting human and animal health and the environment, and minimizing the impact on innovation and trade.

Through the Interdepartmental ADM Committee, a series of options for the creation of a domestic LLP policy for Canada was drafted and sent out for initial consultation in September 2011. Approximately 180 invitations were sent to stakeholders, including developers, grower groups, grain handlers, and organic and food industries, asking for their input. Stakeholders were able to provide their feedback in two ways: written and in-person consultations. The in-person consultations occurred in six locations across Canada (Ottawa, Toronto, Montreal, Halifax, Winnipeg, and Saskatoon).

The draft consultation laid out three potential approaches which were not mutually exclusive and could be used in combination. The three draft approaches are graphically outlined in Figure 1.

1. First is an action level (0.1%) for LLP for products imported into Canada that have been fully approved in a country where Canadian regulators have confidence in the safety assessment process using the CODEX guidelines. Below this level, regulatory enforcement would not be taken.

2. Second is an interim LLP threshold for products with a data package currently in the Canadian regulatory system, but not yet fully approved. The threshold would be based on factors including biology of the crop, segregation, and handling procedures. The threshold would remain in effect until a full assessment has been completed.

3. Third is a case-by-case, indefinite LLP threshold for products brought into Canada at trace amounts (but not intended for import) that are not intended to seek Canadian approval. In other words, products developed for domestic use only by a country and not intended for import into Canada but found as LLP. The threshold would be based on factors including

| Scope | • Grains for direct use in food, feed, or processing  
<table>
<thead>
<tr>
<th></th>
<th>• LLP only (events approved in at least one country); not AP (events that have not been approved for commercial use in any country)</th>
</tr>
</thead>
</table>
| Objectives | • Increase predictability for grain and seed exporters and importers  
|       | • Minimize trade disruption  
|       | • Inspire the adoption of trade-friendly LLP policies in other importing countries  
|       | • Reduce “emergency-like” responses  
|       | • Ensure food, feed, and environmental safety  
|       | • Increase public confidence in Canadian system |
| Principles | Canada’s future LLP management approach should:  
|       | • Replace “zero tolerance” policies with reasonable, risk-based thresholds  
|       | • Be science-based  
|       | • Be consistent with international trade rules and obligations and aligned with applicable international standards  
|       | • Consider and minimize potential for unwanted impacts on export markets  
|       | • Be flexible—provide the tools to respond to a variety of circumstances  
|       | • Be proactive, where possible  
|       | • Be operationally practicable for industry and government |
| Approach | A tool-kit approach is envisioned, in which Canada could employ strategies specific to the particular LLP situation.  
|       | • Promote increased synchronization of approvals among countries  
|       | • Consider and, to the extent possible, recognize the conclusions of risk assessments completed in other countries when formulating a risk management decision and/or establishing administrative tolerances  
|       | • **Proactively** initiate research or risk assessments to enable development of a risk management policy **before** the event appears in international shipments  
|       | • Risk management procedures should reflect the level of risk as determined by CODEX-based LLP risk assessments and complimentary feed and environment assessments  
|       | • When a risk management decision is made, it should be communicated publically along with any identified threshold and/or testing requirements |

*Table adapted from the GIRT TPWG final report*
biology of the crop, segregation, and handling procedures, for example.

As a result of the consultations, the Government heard from stakeholders with more than 60 detailed written submissions. By and large, the main issue raised was concern over the proposed action level. On one side, does the action level increase the risk of cross contamination, while on the other hand is the level too low for bulk grain handling and segregation procedures?

Taking the information gathered from the consultations, the Government of Canada’s Interdepartmental working group was tasked with looking at the domestic LLP policy directions and implementation considerations to refine the policy. Work continues with the industry through the GRT MAWG Biotech sub-working group on specific issues, including refining a potential action level and identifying a measurement of uncertainty associated with this level; this measurement is based on science and assures consistent results.

Regarding the two threshold-related proposals, the Canadian Government recognizes that the establishment of a risk management decision (RM) and threshold is separate from the risk assessment (RA) process and takes into account separate factors. Officials are considering the establishment of an expert committee to make recommendations on the thresholds, using information from the risk assessment which will be conducted within the Canadian government regulatory system. The government is also considering a threshold approach based on crop type as opposed to GM event-by-event, realizing that event-specific thresholds would create significant cost implications if different thresholds were introduced for different events that could be within the same commodity.

A second draft of Canada’s domestic policy for LLP, modified using information captured in the first consultation, was made available for consultation from November 6, 2012, to January 19, 2013, after this article was written and submitted for publication.

**International Engagement**

Increasing global hectares of biotech crops highlights the increasing potential for LLP incidents in Canada and abroad. The Canadian Government, recognizing this as a global issue, clearly sees the need to raise awareness internationally.

Championing this issue, Canada held the first international workshop on LLP in Vancouver, Canada on March 21-23, 2012, hosting senior government representatives from 15 countries.1 The meeting was in response to Minister Ritz’s commitment at the Cairns Group Ministerial Meeting in September 2011 that Canada would facilitate discussions with the international community on the effective management of LLP in agricultural imports.

To open the workshop, industry and government representatives from the 15 countries came together to discuss the challenges of LLP, starting with the perspective of the seed and trait developer, to the farmer growing the crops, to segregation by the grain handlers and

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1. Argentina, Australia, Brazil, Canada, Chile, Costa Rica, Indonesia, Mexico, New Zealand, Paraguay, Philippines, Russia, United States, Uruguay, and Vietnam.

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complications of multi-jurisdictional transportation, and finally the importers’ and end-use processors’ ability to secure stable supply chains. While certain aspects differed between geographies and the stage within the value chain, two consistent messages became clear.

2. With LLP defined as products that have received full safety approval in one or more countries and are found at trace levels, LLP should not impede trade.

Following the joint industry-government day, separate government-to-government and industry-to-industry meetings occurred. Within the industry meeting, representatives shared the status of their individual countries activities in regards to LLP and engaged in concepts to work collaboratively, building on the experiences around the table and tailoring it to their individual country’s challenges.

At the government-only meetings, senior representatives from the 15 countries explored opportunities to work collaboratively on the issue of LLP, with the understanding that finding global solutions to facilitate the management of LLP will reduce the likelihood of trade disruptions and increase transparency and predictability of trade. Participants reviewed and provided their intent to an International Statement on LLP and collaborated on a work plan to move this issue forward. The six main elements of the work plan include

1. Establishment of a mechanism to ensure continued information exchange on countries’ experiences in managing LLP domestically;
2. Development of an International Engagement Strategy on LLP;
3. Identification and development of an approach, or a set of approaches, to manage LLP globally;
4. Exploring practical ways to reduce asynchronicity in submissions, reviews, and approvals;
5. Engagement of interested stakeholders; and
6. Identification of future meetings to culminate in the endorsement of the approach or set of approaches by Ministers.

Canada agreed to champion the development of a model(s) for an internationally recognized independent expert body to undertake LLP risk assessments of current and new plant biotech products. The concept would be to provide countries, including those with limited regulatory expertise in this area, with a consistent science-based risk analysis on which to base risk-management decisions. One proposed concept involves an expert group modelled after the Joint FAO/WHO Expert Committee on Food Additives (JECFA) using the Codex Alimentarius Plant Guidelines, Annex 3, to provide consistent, transparent and predictable advice.

At the conclusion of the Vancouver meeting, the goal of building awareness and connections among participating countries was met, laying the foundation for future collaboration. Argentina will host a follow-up meeting, which is set to take place in Buenos Aires in September 2012.

Conclusion

The number of GM crops developed, cultivated, and traded is expected to increase globally over the next few years, as reported by the Joint Research Council of the European Commission (Stein & Rodriguez-Cerezo, 2010). Due to the fact that many of these new GM crops are anticipated to be developed for domestic use only and global regulatory submissions and approvals may not occur, an increase in LLP incidents is anticipated.

A proactive approach by Canada to establish a domestic LLP policy could minimize trade disruptions resulting from imports coming into Canada inadvertently containing LLP, which would be beneficial to all sectors of the seed and grain industry. Potentially being the first country to fully develop and employ a LLP policy would also provide an example for other countries to follow on the management of LLP globally.

Establishing a domestic LLP policy prior to or in concert with Canada’s key trading partners will enable Canada to encourage trading partners to establish LLP policies that reflect consistent, science-based factors and which would assist in mitigating future incidences of LLP.

As a result of the leadership Canada has shown, both through the development of a draft domestic policy for LLP and through its work to encourage international engagement, this issue is recognized globally. Work continues in Canada and abroad with the goal to minimize or prevent future trade disruptions associated with the unintentional LLP of GM crops in trade.

References

Tranberg — Developing a Policy for Low Level Presence (LLP): A Canadian Case Study


