# **Redfern Research**

## Policy Approaches for Managing Low-Level Presence of Genetically Modified Crops Imported into Canada

**Report on Stakeholder Consultations** 

This report entitled "Policy Approaches for Managing Low Level Presence of Genetically Modified Crops Imported into Canada - Report on Stakeholder Consultation" was produced by Redfern Research. The content of the report does not necessarily reflect the opinions of the Government of Canada.

### **Table of Contents**

1 IN1	RODUCTION	4
2 CO	NSULTATION BACKGROUND	4
3 AN	ALYTICAL APPROACH	5
3.1.	PROFILE OF PARTICIPANTS AND SUBMISSIONS	6
4 SU	7	
5 INS	STITUTIONAL FEEDBACK	8
5.1.	CURRENT REGULATORY APPROACHES TO LLP	8
5.2.	IDEAL CHARACTERISTICS OF AN LLP POLICY	8
5.3.	MOVING AWAY FROM THE CURRENT POLICY	10
5.4.	REACTION TO "ACTION LEVEL" PROPOSAL (APPROACH #1)	11
5.5.	REACTION TO TEMPORARY THRESHOLD (APPROACH #2)	13
5.6.	REACTION TO INDEFINITE THRESHOLD (APPROACH #3)	13
5.7.	COMBINED APPROACHES	14
5.8.	TREATMENT OF LLP IN SEED IMPORTS	15
5.9.	INTERNATIONAL COOPERATION AND MUTUAL RECOGNITION	16
5.9	0.1. Early adoption of LLP policies	17
6 INI	DIVIDUAL FEEDBACK	19
7 AP	PENDIX A: CONSULTATION DOCUMENT	20

7. .... APPENDIX A: CONSULTATION DOCUMENT

### List of Tables

TABLE A. STAKEHOLDER GROUP	6
TABLE B. IDEAL LLP POLICY CHARACTERISTICS BY STAKEHOLDER TYPE	9
TABLE C. STAKEHOLDER REACTION: REPLACING CURRENT POLICY WITH NEW LLP POLICIES FOR IMPORTS	10
TABLE D. STAKEHOLDER REACTION: REPLACING CURRENT POLICY WITH NEW LLP POLICIES MAY HU	JRT
OR ENDANGER CANADIAN AGRICULTURE EXPORT SECTOR.	11
TABLE E. STAKEHOLDER REACTION: SETTING "ACTION LEVEL" OF 0.1% FOR LLP IN IMPORTS.	11
TABLE F. STAKEHOLDER REACTION: SETTING TEMPORARY THRESHOLD FOR GM CROPS AWAITING	
EVALUATION	13
TABLE G. STAKEHOLDER REACTION: SETTING INDEFINITE THRESHOLD FOR GM CROPS NOT AWAITI	NG
EVALUATION	14
TABLE H. STAKEHOLDER REACTION: COMBINING APPROACHES 1, 2 AND 3.	14
TABLE I. STAKEHOLDER REACTION: INCLUSION OF SEEDS UNDER PROPOSED LLP	16
TABLE J. STAKEHOLDER POSITIONS ON INCREASED INTERNATIONAL HARMONIZATION ON LLP	16
TABLE K. STAKEHOLDER POSITIONS: UNILATERAL CANADIAN LLP POLICY CHANGE	17

### 1. Introduction

The following report summarizes key themes emerging from the responses provided to the Government of Canada in response to a consultation initiative regarding the Low Level Presence (LLP) of Genetically Modified (GM) crops imported into Canada.

### 2. Consultation Background

On September 7 2011, the Government of Canada distributed a consultation document among a broad range of interested stakeholders regarding the low level presence of genetically modified organisms in imported food. That document, accompanied by an executive summary, glossary and Frequently Asked Questions, sought the written input of stakeholders regarding a number of specific options. Stakeholders were invited to respond by November 25<sup>th</sup>, 2011. The consultation document is provided as Appendix A.

The consultation document was sent to more than 200 Canadian stakeholders across Canada including exporters, importers, growers, associations, developers, provinces, NGOs, etc. In addition, the consultation initiative also included six regional face-to-face consultations (undertaken in Ottawa, Halifax, Montreal, Toronto, Winnipeg, and Saskatoon) as well as presentations to established consultative mechanisms such as Agriculture Canada's Round Tables, Health Canada's Food Advisory Committee and the Canadian Food Inspection Agency's Consumer Round Table, among others.

The criteria for analysis of the policy, as described in the consultation documents, were:

- 1. the safety of food, feed and the environment;
- 2. the scientific basis of the approach;
- 3. the promotion of and incentive for compliance with Canada's regulatory system for genetically modified products;
- 4. minimization of unnecessary trade disruptions;
- 5. potential impacts of imported low-level presence on exports from Canada;
- 6. administrative efficiency, transparency and predictability;
- 7. the facilitation of agricultural innovation; and
- consistency with international guidance on low-level presence incidents, as appropriate, such as the Codex Alimentarius Commission guidelines, and advice of the working groups of the Organisation for Economic Cooperation and Development (OECD) and the Food and Agriculture Organization of the United Nations (FAO).

Overall, participants welcomed the opportunity to comment and were pleased that Canada is reviewing this policy in an active, proactive manner. However, some stakeholders expressed strong concerns on specific aspects such as how seed should be included, lack of balance in the Government of Canada's policy priorities related to GM crops, cost and potential impacts to the organic sector, lack of international consensus and potential risk of targeting Canadian exports for increased testing and certifications.

### 3. Analytical Approach

Fifty-four substantive, unique submissions were received from institutional stakeholders in response to the consultation document. In addition, a large number of e-mail letters were received from individuals. These two forms of input are reported separately in this document.

For the purpose of this stakeholder consultation process, the Government of Canada focused on comments directly and specifically related to low-level presence. Off-subject comments were not included in this report.

The objective of the analytical approach used for this report is to provide an accurate, comprehensive summary of the input provided to the Government of Canada regarding LLP. To that end, simplified Content Analysis was used to capture key information from each submission which, translated into numerical terms, formed a database. That database has been used to describe and quantify the input.

It is important to note that the analysis conducted in this report *applies only to the input received*. While the consultation process was intended to provide Canadians with an opportunity to respond, there is no scientific or statistical basis upon which to generalize the consultation results contained in this report to the wider Canadian population. Percentages used in this report refer only to the body of input received during the consultation and do not purport to describe the views of the wider public overall or within specific populations.

Each item was read and seven pieces of information were captured related to the specific questions posed in the consultation document. These were:

- Name of author
- Organization represented (if applicable)
- Stakeholder type (Grains industry, organic industry, individual, etc.)
- Overall position on the current approach
- Specific positions on three proposed approaches to LLP.
- Position on the application of LLP proposals to seeds
- Support for Canadian implementation of LLP policies in advance of trading partners.

In addition, markers were used to record instances of 11 themes which were explicitly supported or opposed by at least four stakeholder submissions each:

• Any LLP policy and/or thresholds must be science-based.

- Action thresholds for LLP should be crop-specific or product-specific.
- More clarity and/or research is needed regarding which foreign regulatory regimes would be considered equivalent to Canada's and why.
- Any LLP policy must protect the organic farming sector.
- A compensation plan should exist for enterprises damaged by LLP.
- Any LLP policy will hurt or endanger Canadian agricultural exports.
- LLP policies must be transparent.
- LLP policies must be flexible.
- LLP policies must be predictable.
- LLP policies must be consistent, insofar as all agricultural products should be treated in the same regulatory manner. If thresholds are used, for example, they should be used for all products in the same way.
- International harmonization / mutual recognition should be pursued.

The themes above were raised or mentioned by stakeholders in their submissions.

Although each submission was from a unique source, there was considerable overlap in the language used and the ideas expressed. A number of stakeholders evidently coordinated their responses and shared parts of their submissions with each other. Joint submissions were treated as a single submission for the purposes of calculating numerical measures, except in the case of one joint submission that clearly fell into two sectors (grains and seeds), in which case it was counted in both categories.

A profile of the participants is provided in the following section.

#### 3.1. **Profile of Participants and Submissions**

The 54 stakeholders who provided written submissions may be broken down into nine general types, depicted in Table A.

Table A. Stakeholder Group	Submissions
Agric. Association	7
Biotech	5
Consumer Groups	2
Environmental Groups	4
Food Industry / Processors	5
Grain, oilseed, feed	13
Seeds	3
Organic Sector	10
Provinces	5
Total	54

To ensure a range of views, Agriculture and Agri-food Canada specifically sought input from various sectors and regions. Submissions generally ranged between one and five pages, with few submissions exceeding this length.

### 4. Summary of Stakeholder Positions

Although there is nuance in the positions expressed by stakeholders on the LLP proposals described in the consultation document, there is a clear delineation of two dominant and competing views of how this issue should be managed.

From the perspective of most agricultural associations, agricultural companies, grain companies, feed companies and biotechnology firms in the non-organic sector, the current approach to managing LLP in Canada represents a potential barrier to trade. Where a GM event has been found to be safe by a competent authority in another country, these stakeholders believe that its inadvertent presence in imported crops should be tolerated to some degree and should not trigger regulatory enforcement action.

A significant proportion of organic and food industry sector stakeholders, along with environmental groups, reject the suggestion that LLP should be officially tolerated in imported crops. They raise concerns about the impact of an allowable 'action level' on the domestic organic sector and overall trade with countries that maintain a 'zero tolerance' approach. They stress that any LLP in organic foods is not acceptable and that preventative measures and testing impose increasing financial burdens on the organic sector.

Between these two opposing views, a small number of stakeholders take a middle ground including some provincial governments and farmer organizations. They are generally willing to entertain the idea of LLP contingent on the specifics of the regulatory proposal.

Seed sector respondents tend to support the overall thrust of the proposed approaches to LLP but note that seeds will require special attention and that a single standard (0.1% or otherwise) is unlikely to be appropriate for all seeds.

Despite this difference in views, however, there is common agreement on several points. There is widespread agreement, for example, that international cooperation is important in the establishment of an LLP policy in order to avoid any country suffering trade problems due to being an early adopter. There is also agreement that there must be a strong scientific basis for any new LLP policies.

Individual Canadians who offered input generally rejected any LLP policy that would tolerate the presence of measurable amounts of unauthorized GM crops in imports. They furthermore oppose any reliance on the findings of foreign regulators in this context.

### 5. Institutional Feedback

### 5.1. Current Regulatory Approaches to LLP

Stakeholders express relatively few concerns about the regulation of Low Level Presence as it is *currently* conducted in Canada. They note that this aspect of the Canadian regulatory system has not created any significant barriers to imports or trade.

The concerns which exist about Canada's approach to LLP stem mainly from three issues, which are of concern primarily to agriculture industry stakeholders outside the organic sector:

First, there is the expectation that the incidence of LLP is destined to increase significantly in coming years as a result of increasing numbers of GM events and their interaction with non-GM products. This expected increase in GM crops is believed to warrant a reconsideration of the current policy toward LLP and the potential disruption to trade and expenditure of regulatory resources this policy may ultimately cause.

Second, there is recognition that improvements in measurement technologies to detect GM presence are *de facto* reducing the tolerance of LLP's, as smaller and smaller percentages are detectable which may render a given product non-compliant.

Finally, there is concern that 'zero tolerance' policies in major trading partners will present increasingly difficult barriers to Canadian agriculture exports in light of the other trends noted above. Some examples are raised.

Many stakeholders do not share these concerns, however, most notably the organic food and agriculture sector. In contrast, their views of GMOs in general lead them to seek *increasing* rigour in the current policy regarding LLP. They often view GMOs as undesirable products and, more specifically, as a risk to the economic health of Canada's organic sector. These stakeholders are more inclined to say the current regulatory approach should be maintained or made more rigorous through more stringent testing and monitoring.

### 5.2. Ideal characteristics of an LLP policy

There is some consensus among biotech, grain companies and the non-organic agriculture sector regarding the characteristics they believe any successful LLP policy should have. These are shown in Table B. These are: Predictability, Science-based, Flexibility, Transparency and Proactivity. The current LLP approach is often judged by these stakeholders based on whether it meets these four criteria.

In seeking a *predictable* LLP system, stakeholders are primarily stressing the importance to producers, importers and exporters of crops of knowing what is expected by regulators, how compliance will be assessed, and what measures will be taken in the event of non-compliance.

Table B. Ideal LLP policy characteristics by stakeholder type									
Sector	Total submissions	Predictable	Science- based	Flexible	Protection of organic sector	Define "Equivalence"	Transparent	Proactive	Compensation mechanism*
Agric. Assoc.	7	1	1	2		1			1
Biotech	5	4	2	2		2		3	
Consumer Groups	2	1				1		1	
Environmental Groups	4						1		
Food Ind. / Processors	5	2			1				
Grain, oilseed, feed	13	3	2	2	1	1	3	2	
Seeds	3	1		1					
Organic Sector	10		1		3		1		3
Provinces	5	2	3	1	2	1	1		1
Note: Each subm *or fund for econ				nore tha	in one cha	racteristic.			

In calling for an approach which is *science-based*, stakeholders are asking the government to make decisions about LLP based on the best available science rather than transient trade-related concerns or public opinion.

*Flexibility* is sought because stakeholders want a regulatory approach which can adapt to differing situations and practical realities in a complex and multi-faceted international market for agricultural products.

A *proactive* policy, advocated by a number of stakeholders in the non-organic agriculture and grain sectors, involves identifying in advance which GM crops are likely to be encountered as LLP in agricultural commodities shipped to Canada, so that initial evaluation of those products may be done in advance of an LLP incident. This would reduce the regulatory reaction time and thereby facilitate the return to compliance and the resumption of trade.

As noted earlier, the organic sector and environmental groups tend to be more or less satisfied with the current policy approach, indicating preference to reinforce the system rather than change it. For some in this group (7 submissions), the ideal LLP policy would explicitly prioritize the *protection of the organic sector*, given the potential trade harm caused by LLP. Five submissions explicitly suggest the

creation of a *compensation mechanism* for organic producers who suffer economic losses due to increased LLP in coming years. (Anticipated economic losses in the organic sector were not quantified.)

The idea of relying on competent foreign assessments for LLP in implementing the "action level" approach is controversial with some stakeholders and a source of interest for many. This leads them to seek information on how the Government of Canada will assess and determine the equivalency of foreign evaluation systems with that of Canada. As noted in Table B, six submissions specifically state that greater clarity is needed on this issue in order to assess the proposed approaches.

#### 5.3. Moving Away from the Current Policy

As Table C shows, 28 of 54 submissions explicitly supported the overall idea of replacing the current policies for LLP in imports with different types of LLP "threshold" policies for GM crops below which no regulatory action would be taken or required. In contrast, 17 stakeholders opposed this idea. Support is concentrated among agriculture associations, seed companies, biotech developers, and grain companies. Opposition is heard primarily from environmental groups and the organic sector. (See Table C.)

Table C. Stakeholder reaction: Replacing current policy with new LLP policies for imports						
Stakeholder Type	Support	Mixed	Oppose	N.O/ N.M*	Total	
Agric. Association	5		1	1	7	
Biotech	4			1	5	
Consumer Groups	1		1		2	
Environmental Groups			4		4	
Food Industry / Processors	3	1	1		5	
Grain, oilseed, feed	10	1	2		13	
Seeds	3				3	
Organic Sector		1	8	1	10	
Provinces	2	2		1	5	
Total	28	5	17	4	54	
*No opinion / Not mentioned						

A key reason why some stakeholders oppose any movement away from the current approach as official policy is their concern that this will undermine the market access enjoyed by Canadian exports, especially organic products sold into the United States and European Union. As Table D shows, this concern is widespread (13 submissions) and many others see some potential risk mixed with some potential benefit (11 submissions).

policies may hurt or endanger Canadian agriculture export sector.						
Stakeholder Type	Agree	Mixed	Disagree	N.O/ N.M*	Total	
Agric. Association	1	3		3	7	
Biotech				5	5	
Consumer Groups				2	2	
Environmental Groups	2			2	4	
Food Industry / Processors	1	2		2	5	
Grain, oilseed, feed	4	4		5	13	
Seeds			1	2	3	
Organic Sector	3			7	10	
Provinces	2	2		1	5	
Total	13	11	1	29	54	
*No opinion / Not mentioned						

Table D. Stakeholder reaction: Replacing current policy with new LLP policies may hurt or endanger Canadian agriculture export sector.

### 5.4. Reaction to "Action Level" Proposal (Approach #1)

# <u>Approach #1</u>: Apply an action level for low-level presence for products imported into Canada

Stakeholder reaction to the setting of an action level for managing LLP of GM crops imported into Canada reflects their overall view on modifying the current policy, with the biotech and non-organic agriculture industry supporting the idea while a significant proportion of the organic sector and environmental groups are opposed. However, there are more mixed responses to this idea from industry as some of these stakeholders take the view that action levels should be crop-specific or that the proposed action level of 0.1% is too low. These are shown in Table E.

Table E. Stakeholder reaction: Setting "action level" of 0.1% for LLP in imports.						
Stakeholder Type	Support	Mixed	Oppose	N.O/ N.M*	Total	
Agric. Association	3	2	1	1	7	
Biotech	3	1		1	5	
Consumer Groups			2		2	
Environmental Groups			4		4	
Food Industry /	1	3	1		5	
Processors						
Grain, oilseed, feed	10	1	2		13	
Seeds	3				3	
Organic Sector		1	8	1	10	
Provinces	2	2		1	5	
Total	22	10	18	4	54	
*No opinion / Not mentioned						

The seed sector supports an action level for most products, but expresses doubts about its application to seeds. As one seed stakeholder noted:

An "action level" concept may be workable for most grains and oilseeds destined to further processing into food and feed. However, we do not believe that would be the case for seed for planting that is destined for the intentional release into the environment.

Among those who explicitly support the 'action level' concept (22 submissions out of 54), one-half (10 submissions) suggest that an 'action level' threshold of 0.1% would be too *low*. This stems primarily from four factors:

- First, given that the GM crop in question has already been judged safe by a competent authority in a foreign country, they argue there is no need to set the LLP "action limit" so low.
- Second, they argue that for some crops coming from some regions, LLP will routinely and inevitably exceed the 0.1% threshold.
- Third, they note that measurement of LLP is not sufficiently accurate to confirm a presence conclusively above or below 0.1% and that the threshold should be higher to accommodate the reliability of current testing. As several stakeholders noted, the EU has stated that the level of uncertainty in testing will be in the order of 0.1% and therefore the effective level of detection for a level of 0.1% will become 0.2%, twice the action level suggested by AAFC.
- Finally, they note that other type of thresholds already exist, both internationally and domestically, which are used to measure incidental presences of crops not intended in a shipment (CGC grain standards, for example), and that these are often higher than 0.1%.

Most stakeholders who believe a higher threshold would be more reasonable do not suggest a specific percentage, saying instead that research would be required to fix the figure. Nonetheless, some others provide alternative "action levels" ranging from 0.2% to 5.0%.

Furthermore, four stakeholders (one each from biotech, consumer groups, provincial governments, and seeds) explicitly state that the "action level" should be set individually for different crops.

It should be noted that *opposition* to an action level of 0.1% is not based on the percentage itself. Opposition among organic producers and environmental groups is based on the proposal to exempt *any* measurable LLP of GM crops from regulatory action, regardless of the amount. For these groups, such exemption is unacceptable.

#### 5.5. Reaction to Temporary Threshold (Approach #2)

## <u>Approach #2</u>: Apply an interim threshold for low-level presence for products where a data package has been submitted to Canadian authorities

As shown in Table F, stakeholders who support a general "action level" of 0.1% also tend to support the option of setting a temporary threshold for any LLP of a GM crop which is currently awaiting market authorization in Canada. They agree that a somewhat higher threshold may be acceptable if a data package has already been submitted for evaluation. This option encompasses the flexibility that many feel should be built into the system as noted earlier. This support rests on the assumption that the product does not pose any significant risk to humans, animals or the environment.

Table F. Stakeholder reaction: Setting temporary threshold for GM crops awaiting evaluation						
Stakeholder Type	Support	Mixed	Oppose	N.O/ N.M*	Total	
Agric. Association	5		1	1	7	
Biotech	4			1	5	
Consumer Groups		1	1		2	
Environmental Groups			4		4	
Food Industry / Processors	2	1	1	1	5	
Grain, oilseed, feed	8	3	2		13	
Seeds	3				3	
Organic Sector			9	1	10	
Provinces		1	3	1	5	
Total	22	6	21	5	54	
*No opinion / Not mentioned						

Overall, however, stakeholders are more likely to express doubts about this approach than about the 'action level' concept in Approach #1. These doubts tend to center on uncertainty about why the submission of a data package would merit a different treatment by Canadian regulators before market authorization has been awarded.

#### 5.6. Reaction to Indefinite Threshold (Approach #3)

## <u>Approach #3</u>: Apply appropriate case-by-case thresholds for low-level presence in products imported into Canada

For a number of stakeholders in the non-organic agriculture sector, grains, seeds and biotech, this approach would form part of a suite of flexible responses available to regulators trying to manage LLP situations in the future. This is shown in Table G. They support this regulatory option as a complement to the "action level" used in Approach #1, appropriate when a risk assessment concludes that the LLP -

....

. . .

substance poses no threat but trade realities suggest that domestic market authorization is unlikely to be sought. (A product developed for strictly domestic use elsewhere, for example.)

Table G. Stakeholder reaction: Setting indefinite threshold for GM crops not awaiting evaluation						
Stakeholder Type	Support	Mixed	Oppose	N.O/ N.M*	Total	
Agric. Association	4	1	1	1	7	
Biotech	4			1	5	
Consumer Groups		1	1		2	
Environmental Groups			4		4	
Food Industry / Processors		3	1	1	5	
Grain, oilseed, feed	8	3	2		13	
Seeds	3				3	
Organic Sector			9	1	10	
Provinces	1	2	1	1	5	
Total	20	10	19	5	54	
*No opinion / Not mentioned						

To other stakeholders, however, this option appears to permit the continued presence in food imports of a product which has not been approved by Canadian regulators and are unlikely ever be approved. They view this as unacceptable and at odds with the principles they believe underlie market authorization in Canada. As seen in the foregoing table, this rejection of Approach # 3 is most common among the organic sector and environmental groups.

#### 5.7. Combined Approaches

# <u>Question</u>: These approaches are not mutually exclusive and the approaches could be combined in various ways. What additional impacts the combined approaches may have on your sector?

Support for combining the three approaches to LLP discussed earlier mirrors support for the measures themselves, shown in Table H. The non-organic agriculture, biotech, seeds and grain sectors tend to support combining these approaches which they see as complementary. In contrast, organic producers and environmental groups tend to oppose such a combination because they oppose each of the components. In sum, the three approaches are considered as complimentary and they are usually supported (or opposed) as a group.

Table H. Stakeholder reaction: Combining approaches 1, 2 and 3.						
Stakeholder Type	Support	Mixed	Oppose	N.O/ N.M*	Total	
Agric. Association	4		1	2	7	
Biotech	3			2	5	

Consumer Groups			1	1	2
Environmental Groups			4		4
Food Industry / Processors	2	1	1	1	5
Grain, oilseed, feed	7	1	2	3	13
Seeds	3				3
Organic Sector			9	1	10
Provinces	1	2		2	5
Total	20	4	18	12	54
*No opinion / Not mentioned					

The seed sector supports a combined approach, but cautions that a standardized action level of 0.1% is unlikely to be useful for seeds specifically.

#### 5.8. Treatment of LLP in Seed Imports

<u>Question</u>: These approaches could be limited to grain, food and feed, however, they could also be applied to seed, as long as no environmental safety concerns are identified. Please comment on whether you support applying your preferred approach to seed.

As seen in Table I, many stakeholders (34 of 54) declined to comment specifically on the inclusion of seeds in the proposed LLP approaches. In some cases, this appeared to stem from unfamiliarity with this sector. In others, stakeholders had already stated their strong opposition to the proposed approaches, rendering any specific comments on seeds somewhat moot.

Nonetheless, a number of stakeholders in the non-organic agriculture and grains sector (6) felt LLP in seed shipments could be treated more or less the same way as food and animal feed.

The seed sector supports an LLP policy for seeds, but cautions that a standardized action level of 0.1% (or any single standard) is unlikely to be appropriate for seeds specifically:

We see no strong rationale for not applying these combined approaches to seed – again with the provision for recognition of differences between crop kinds. We do consider it unlikely that one "action level" can be established and applied across all crop kinds for seed that is destined for intentional release into the environment. Therefore, case by case assessments through approach 2 or 3 would apply to seed for planting.

Another seed sector stakeholder suggested:

The proposed approaches could be applied to the issue of LLP in imported seed for planting as long as environmental safety concerns are not identified. However, separate considerations may be required for seed, particularly when setting an action level. Others (8), notably environmental groups, stressed the danger to the environment and the entire farm export sector they feel is posed by LLP in seeds. This is because they believe seeds could multiply to a point where the presence of such GM crops would not be considered at a low-level, which could subsequently deny entry of some Canadian crops into some current markets. Two stakeholders mentioned that the risk posed by LLP in seeds would depend on whether those seeds might reasonably be expected to survive in a Canadian climate, suggesting a case by case approach.

Table I. Stakeholder reaction: Inclusion of seeds under proposed LLP						
Stakeholder Type	Support	Mixed	Oppose	N.O/ N.M*	Total	
Agric. Association			1	6	7	
Biotech	1	3		1	5	
Consumer Groups			1	1	2	
Environmental Groups			4		4	
Food Industry / Processors				5	5	
Grain, oilseed, feed	2	2	1	8	13	
Seeds	2			1	3	
Organic Sector			1	9	10	
Provinces	1	1		3	5	
Total	6	6	8	34	54	
*No opinion / Not mentioned						

#### 5.9. International Cooperation and Mutual Recognition

A key goal of the proposed LLP approaches is to actively engage markets bilaterally and multilaterally to encourage alignment of approval processes for GM products. Many stakeholders explicitly applaud the Government of Canada for showing leadership in this area.

Table J. Stakeholder positions on increased international harmonization on LLP								
Stakeholder Type	Support	Mixed	Oppose	N.O/ N.M*	Total			
Agric. Association	2	1		4	7			
Biotech	3			2	5			
Consumer Groups	1			1	2			
Environmental Groups	1		3		4			
Food Industry / Processors	2			3	5			
Grain, oilseed, feed	8			5	13			
Seeds	2			1	3			
Organic Sector	1		2	7	10			
Provinces				5	5			
Total	20	1	5	28	54			
*No opinion / Not mentioned								

There is widespread agreement that it would be beneficial for trade if Canada's major markets (US, EU, China etc.) could come to a bilateral or multilateral agreement about how LLP will be managed. (See Table J.) This would provide predictability and consistency for commodities which are traded internationally. Indeed, 20 stakeholder submissions specifically identify this as a goal which Canada should pursue, while five disagreed. Those who disagree with the concept of international harmonization are generally motivated by a concern that the international community will harmonize to the *least stringent* LLP standard, not the most stringent, meaning that Canadian standards may be required to loosen. They also associate this type of international cooperation with the adoption, by Canadian regulators, of decisions made by regulators in other countries. This raises the specter that Canada may lose independence with regard to LLP in particular and the regulatory system in general.

#### 5.9.1. Early adoption of LLP policies

Given the stated goal of encouraging Canada's trading partners to rethink policies regarding LLP, stakeholders are sometimes uncertain whether Canada should enact such an approach before its major trading partners. (See Table K.)

Generally speaking, non-organic sector stakeholders encourage the government to "lead" internationally on the LLP issue while also protecting Canadian exports from trade disruptions due to differing LLP standards. In other words, Canada should move the international LLP agenda forward but avoid any official regulatory or policy change without international cooperation. Poor timing, they suggest, could undermine the objective of the LLP policy change and expose Canadian exports to risk if different standards apply to imports in Canada than in our major trading partners in the EU and US.

Table K. Stakeholder positions: Unilateral Canadian LLP policy change							
Stakeholder Type	Support	Mixed	Oppose	N.O/ N.M*	Total		
Agric. Association	3		1	3	7		
Biotech		2		3	5		
Consumer Groups				2	2		
Environmental Groups			1	3	4		
Food Industry / Processors				5	5		
Grain, oilseed, feed	1	2	4	6	13		
Seeds	1			2	3		
Organic Sector			3	7	10		
Provinces	1	1	1	2	5		
Total	6	5	10	33	54		

#### \*No opinion / Not mentioned

There is widespread enthusiasm for aggressive Canadian action in promoting LLP policies among our trading partners and appreciation for the fact that enacting our own policies demonstrates a commitment to the new approach. Nonetheless, there is also reluctance to see Canada move too quickly, possibly squandering the opportunity to coax similar reforms from our trading partners. One seed stakeholder appeared to speak for many participants in suggesting:

If the policy is the combined approach and continues to include the current approach, Canada can develop and communicate the proposed policy but maintain the status quo (i.e. current approach) until other countries, particularly key trading partners, establish similar policies.

### 6. Individual Feedback

As noted earlier, many individuals responded to the consultation document. A total of 2,696 communications were received from individuals. These documents generally include a considerable amount of common language and are focused on a few specific themes.

The majority of the feedback from individuals related to issues that are outside the scope of this consultation. They often expressed general opinions about GMOs in the food supply.

Those responses which do address the issue of LLP focus on several key points:

- No measurable amount of GM product which is not authorized in Canada should be permitted in food imports.
- Even the low level presence of *authorized* GMO's in food imports should not be tolerated, given the desire of many consumers to avoid these products.
- The decisions of foreign regulators should not be relied upon to determine whether Low Level Presence of a specific product not authorized in Canada is safe for Canadians.

### 7. Appendix A: Consultation Document

Government of Canada

Working Group on Low Level Presence

### **Consultation Document**

Policy approaches for managing the low-level presence of genetically modified crops imported into Canada.

#### **Table of Contents**

#### Part 1: Introduction

What is the purpose of this paper?

Why is the Government of Canada considering alternative approaches to managing lowlevel presence?

What are the Government of Canada's objectives in developing a policy for low-level presence?

What is the potential for low-level presence to enter Canada through imports? What impact will the proposed approaches have on food and feed safety?

What impact will these proposed approaches have on the current authorization process for genetically modified crops in Canada?

Will the approaches proposed in this paper change the rules for certifying organic products in Canada?

How is Canada engaging the international community in resolving the issue of low-level presence?

# Part 2: Proposed approaches for managing low-level presence in Canada

APPROACH 1: Apply an action level for low-level presence for products imported into Canada

APPROACH 2: Apply an interim threshold for low-level presence for products where a data package has been submitted to Canadian authorities

APPROACH 3: Apply appropriate case-by-case thresholds for low-level presence in products imported into Canada

#### Part 3: How to provide your feedback

#### Disclaimer

The information you provide on this document is collected by Agriculture and Agri-Food Canada (AAFC) in accordance with the Communications Policy of the Government of Canada for the purpose of seeking stakeholder comments on three (3) proposed policy approaches to manage low-level presence (LLP). Participation is voluntary and any personal information collected will be protected under the provisions of the Privacy Act and described in the Personal Information Bank PSU 914 entitled "Public Communications". Should you require information please contact the ATIP Coordinator at 613-773-1386.

Also note that the Government of Canada will not make individual submissions public, but does maintain the right to report publicly on the aggregate results.

For the purpose of this stakeholder consultation process, the Government of Canada will only take into account comments directly and specifically related to low-level presence. Any off-subject comments will not be considered.

Written comments will not be considered if they are: submitted after the deadline; and/or contain irrelevant or offensive statements or material.

#### **Part 1: Introduction**

#### What is the purpose of this paper?

The purpose of this paper is to provide information and seek stakeholder comments on proposed policy approaches. These policy approaches could be used in Canada to manage unintended, low levels of unauthorized genetically modified (GM) crops<sup>1</sup> found in imported grain, seed, food and feed products.

To gather stakeholder comments, the federal government will undertake consultations during the fall of 2011. The information gathered will help inform the Government of Canada's decision on a path forward.

This paper uses the term **"low level presence."** This term means the unintended presence, at low levels, of a GM crop that is already authorized for commercial use or sale in one or more countries but is not yet authorized in an importing country.

Once a GM crop is authorized for use in a country, trace amounts of that crop may become mixed with other varieties or crops in that country. This can happen during cultivation, harvest, transportation, storage or processing. Even when best management practices are strictly followed, it is difficult to completely prevent this from occurring. As a result, a GM crop may be present at low levels in the grain, seed, food and feed products that are exported from that country. This is called low-level presence.

This can happen in grain, seed, food and feed products that are imported into Canada. Likewise, Canadian exports can be a source of low-level presence in other countries.

The path forward on low-level presence will take into consideration the following:

- the safety of food, feed and the environment
- the scientific basis of the approach
- the promotion of and incentive for compliance with Canada's regulatory system for GM products
- minimization of unnecessary trade disruptions
- potential impacts of imported low-level presence on exports from Canada

<sup>&</sup>lt;sup>1</sup> For the purposes of this document, "genetically modified" (GM) refers to new plants that have been modified using recombinant DNA technology. A "GM crop" refers to a crop plant with a specific trait or traits that have been introduced via recombinant DNA technology.

- administrative efficiency, transparency and predictability
- the facilitation of agricultural innovation
- consistency with international guidance on low-level presence incidents, as appropriate, such as the Codex Alimentarius Commission guidelines, and advice of the working groups of the Organisation for Economic Co-operation and Development (OECD) and the Food and Agriculture Organization of the United Nations (FAO).

This paper focuses only on genetically modified crops for food, feed and/or seed that have been approved in one or more countries, but have not been approved in Canada (making them "unauthorized" in Canada).

- It does not pertain to the adventitious presence of a GM crop. Adventitious
  presence is defined as the unintended release of research or "pre-commercial" GM
  material, which has not been authorized for use in *any* country.
- In addition to this, the paper does not address issues regarding other products derived through biotechnology such as GM crops developed solely for industrial purposes, GM animals or microorganisms.

#### Why is the Government of Canada considering alternative approaches to managing lowlevel presence?

The Government of Canada is proactively looking at ways to enhance an effective regulatory system that protects human and animal health and the environment, while not unnecessarily impeding innovation and trade.

Under the current regulatory approach, any presence of an unauthorized GM product in the Canadian marketplace is considered "regulatory non-compliance". This means that the product is considered to be not compliant with the regulations. Therefore, grain/seed shipments that contain even trace amounts of a GM product unauthorized in Canada would be considered non-compliant and this triggers a risk assessment of the low-level presence situation.

The intent of the risk assessment is to examine the risk to the food and feed supply and the environment. The risk management process uses this risk assessment, along with other factors, to determine the most appropriate level of intervention required to make the situation compliant with the regulations. This would require developers either to have their GM product approved in Canada or to put measures in place to remove the product from the marketplace and the environment. In these situations, even if a risk assessment shows that the product is not likely to pose a risk to health and safety, the developer is required to be compliant.

As governments and industry around the world continue to search for ways to increase agricultural productivity, it is expected that the number of GM products will continue to increase. As a result, the number of low-level presence incidents is also expected to increase. Two factors contribute to this.

- Public and private developers have little incentive to pursue authorizations in other countries because many of these new GM products are only intended for domestic use in their own country and it is expensive to seek approvals elsewhere.
- There are many opportunities for crops to comingle during crop production, transportation, conditioning and storage. Due to the very nature of modern agriculture, there will always be the possibility of low-level presence in exports and imports.

For countries around the world, this could, without appropriate planning, lead to more disruptions in trade, along with an increased demand for monitoring, testing and risk analysis, even with materials that have been assessed as safe for food, feed and/or the environment. The need to address this issue has been recognized internationally.

- Some countries are currently in the process of developing low-level presence policies (the Philippines). While some countries (Japan, the European Union) have implemented limited low-level presence policies, more needs to be done.
- For this reason, multilateral discussions on low-level presence have occurred in international forums such as the OECD and the Codex Alimentarius Commission; in the latter case a CODEX Annex to the Plant Guidelines was developed and adopted to provide guidance on performing a food risk assessment when occurrences of low-level presence arise.

Canada is developing this policy to manage domestic occurrences of low-level presence. However, Canada's policy could also provide a model for aligning guidance and regulations internationally. Such alignment would provide greater assurances for Canadian exporters who face the risk of trade disruptions related to low-level presence.

# What are the Government of Canada's objectives in developing a policy for low-level presence?

The Government of Canada's objective in developing a policy for low-level presence is to keep food, feed and the environment safe, while providing, transparency and predictability for importers and minimizing disruptions to trade.

With the increasing number of GM products being developed globally for commercial production, low-level presence is unavoidable. Therefore, it is timely for Canada to review current policies and assess alternate approaches for managing low-level presence.

If approval processes between Canada and our key trading partners were synchronized, there would be no instances of low-level presence. However, given the regulatory complexity of this issue, instances of low-level presence can be expected to increase over the medium term. These proposed approaches to managing low-level presence represent immediate steps that the Government of Canada can take in the short term.

In 2009, Canadian government officials established a working group to examine how Canada manages incidences of low-level presence and to explore whether alternative approaches should be considered that would continue to protect the health and safety of Canadians, while offering benefits for the Canadian agricultural sector. The working group is chaired by Agriculture and Agri-Food Canada (AAFC). Members include representatives from the Canadian Food Inspection Agency (CFIA), Canadian Grain Commission (CGC), Foreign Affairs and International Trade Canada (DFAIT), Environment Canada and Health Canada.

#### What is the potential for low-level presence to enter Canada through imports?

Currently, the potential for low-level presence in a shipment to enter Canada through imports is low. GM crops that are likely to be found in international trade have already undergone safety assessments by Health Canada and the CFIA, and have been authorized for use in Canada.

However, many countries are actively engaging in researching and developing new GM crops. A 2009 report from the European Commission Joint Research Council<sup>2</sup> predicts that by 2015, the number of GM crops in commercial production globally will increase from about 30 to over 100.

Many of these products are intended for domestic use in countries other than Canada and may not be exported, so there may be little incentive to pursue authorizations in other countries, resulting in isolated foreign approvals. In addition, foreign approvals may be time-limited. These products could comingle with exports destined for Canada, potentially resulting in more low-level presence situations. Therefore, the potential for low-level presence to enter Canada is expected to increase in the future.

#### What impact will the proposed approaches have on food and feed safety?

Food safety is a high priority for the Government of Canada. The proposed approaches will fully maintain our high level of food safety and will continue to protect Canada's plant and animal resources.

<sup>&</sup>lt;sup>2</sup> <u>http://ipts.jrc.ec.europa.eu/publications/pub.cfm?id=2420</u>

Under the proposed threshold approaches, when a low-level presence incident has been identified by regulatory authorities, risk assessments with respect to the low-level presence are conducted to determine any potential risk for food, feed and the environment. These risk assessments form the basis for determining the most appropriate enforcement response. One of the approaches proposes an action level. This differs in that a Canadian risk assessment would not be triggered, if the low-level presence incident involves trace levels of a GM material that has been fully authorized by a regulatory system deemed equivalent to the Canadian system.

The Government of Canada has many different types of measures available to deal with non-compliance of unauthorized plant products. These could range from developing agreements on corrective action plans with the regulated parties; to issuing mandatory product recalls; to taking legal actions against the offending parties; and other measures.

## What impact will these proposed approaches, which will be dealt with below, have on the current authorization process for genetically modified products in Canada?

These proposed approaches will not change the Canadian approval process for GM products. Regulatory submissions will continue to be assessed under the current authorization process for GM products.

Developers of GM products will continue to be encouraged to submit a regulatory package to all major markets, including Canada, even when the product is not intended for full commercial release in those markets. This will reduce the occurrence of low-level presence because the products will have been assessed and decision regarding authorization would be determined.

# Will the approaches proposed in this paper change the rules for certification of organic products in Canada?

None of the low-level presence approaches proposed in this document are intended to supersede organic practices or to alter the requirements for organic certification. The *Canadian Organic Products Regulations, 1999* (SOR/2006-338), which came into force on June 1, 2009, prohibit the use of GM ingredients in organic products, authorized or not.

Canadian organic farmers and food producers use a range of management practices to avoid the use of all prohibited ingredients, including those which are GM. Importers of organic products produced in Canada can continue to be confident that these management practices will continue to prevent the use of prohibited ingredients in these products.

# How is Canada engaging the international community in resolving the issue of low-level presence?

Canada is engaging the international community on many fronts. Canada's primary intent is to actively engage markets bilaterally and multilaterally to encourage alignment of approval

processes for GM products. When GM products receive simultaneous approvals in all import markets, trade risks posed by situations of low-level presence can be avoided.

This is not currently the case right now because, even if the major developers submit new GM products to different markets at the same time, there is a great variance in the time it takes for a product to be approved in different countries' regulatory frameworks. In addition, developers may choose not to seek approvals in markets they do not think they will soon be exporting to. Other countries have also recognized the problem and some are moving forward with policy reviews or have begun to implement limited low-level presence policies.

Canada will continue to advocate for additional international guidance for the regulation of GM products, as this can play a role in aligning countries' policies and regulations. If aligned policies for low-level presence are adopted internationally, this may help to address situations that arise when products receive approvals at different times in various countries.

The Government of Canada thinks there is more that can be achieved in this area if markets are willing to work together. Efforts may include international standards development, and work with bilateral and regional partners on aligning safety assessment criteria or using mutual recognition agreements. Canada intends to engage key international partners and will encourage them to similarly adopt appropriate low-level presence policies.

# PART 2: Proposed approaches for managing low-level presence in Canada

In this section, we outline the current Canadian approach to managing low-level presence and propose three additional approaches for consideration. It is important to note that the current approach would remain in place for any situations that did not meet the criteria set out in approaches 1-3, and that these approaches are not mutually exclusive. All or several approaches could be combined in various ways. We are interested in perspectives and suggestions on all aspects of the proposed approaches from all stakeholders.

# <u>CURRENT APPROACH</u>: For low level presence of unauthorized products derived through biotechnology

This section describes the current approach used to manage low-level presence, where the identification of a low-level presence incident leads to a risk assessment. This risk assessment is used to:

- decide the most appropriate level of enforcement required to manage identified risks to food, feed and the environment, and
- return the situation to one which is compliant.

# *In this approach, some flexibility does exist with respect to the risk management measures that can be applied.*

When a new GM crop is submitted to the CFIA and Health Canada for authorization in Canada, it enters into a queue for products awaiting review. Regulators review applications in the order they are received. The length of time to review a product in Canada depends on many factors, but it can take up to 24 months until a regulatory decision is announced.

Before products can be marketed, the CFIA and Health Canada conduct rigorous safety assessments to verify that GM plants and any derived products/by-products are as safe and effective for their intended use as their conventional counterparts. These full safety assessments of products are in-depth scientific reviews that take into account a range of considerations, such as potential indirect or long-term impacts on human and animal health, sustainable agriculture<sup>3</sup> and the environment.

Under the current regulatory framework, any presence of an unauthorized GM product (low-level presence or other) in the Canadian environment or marketplace constitutes what

<sup>&</sup>lt;sup>3</sup> For example, through developing herbicide resistant weeds.

is called regulatory non-compliance. When an unauthorized product may be found in the Canadian marketplace or the environment, a risk assessment process is initiated and importers of grain, seed, food and feed would be required to demonstrate that their shipments are free from unapproved GM crop, prior to import. Health Canada does caseby-case risk assessments to determine human health and safety risk, while the CFIA determines environment and feed safety risk.

In a low-level presence situation, these assessments aim to identify any potential hazards and potential routes of exposure, focusing on the potential allergenicity and toxicity of the product, among other factors. The goal of the risk analysis process is to verify food, feed and environmental safety, and to determine the most appropriate level of intervention that will result in the situation being in compliance.

Risk management decisions are based on the risk assessment and on other factors such as

- legislative and regulatory requirements,
- policy,
- international obligations,
- economic impacts, and
- priorities in resource allocation.

The CFIA also has the flexibility to select the appropriate response, considering factors such as

- the potential or actual harm,
- the compliance history of the regulated party (for example, previous instances of non-compliance and severity of non-compliance), and
- the intent (for example, evidence that the regulated party knowingly contravened the legislative requirements).

Specific responses can be directed at the product and/or the regulated party. The CFIA has a range of tools available to deal with non-compliance of unauthorized plant products. Examples include:

- agreeing on corrective action plans with the regulated parties,
- issuing mandatory product recalls, and
- taking legal actions against the offending parties.

Risk management also includes follow-up activities confirming that the situation is returning to compliance. In addition, it includes the review and evaluation of the corrective actions to reduce the likelihood of reoccurrence.

Under current policies, a return to compliance can be achieved by

• obtaining regulatory approval of the non-compliant product for use in food, feed

and environmental release in Canada; or

• implementing measures to remove the non-compliant product from Canada (depending on the level of risk, removal of the non-compliant product can be done over time).

The current case-by-case approach to managing low-level presence in Canada is flexible in responding to non-compliant situations where a "return to compliance" is desired by all parties involved and is achievable over time. However, given the expected increase in asynchronous approvals, and incidents of low-level presence, a policy review may lead to a policy approach that can provide greater predictability, transparency, and timely decision-making without compromising health and safety.

# <u>APPROACH 1</u>: Apply an action level for low-level presence for products imported into Canada

This approach proposes setting an "action level" for low-level presence for food, feed and grain entering into Canada. Understanding that science based systems should provide consistent results, an action level sets a small margin, at 0.1 percent, that addresses several factors, such as:

- the limits of accuracy of testing methodologies, and
- the reproducibility of sampling methodologies.

This margin would only cover unintended and unavoidable trace levels of unauthorized GM.

In this approach, a risk assessment would not be done, and the government would not take enforcement measures, if the level of product detected is below 0.1 percent (the action level). However, Canadian regulators would do a comparison with the regulatory system for GM products in the exporting country, to determine if it is equivalent to Canada's. This assessment would permit regulators to have confidence in the safety assessment conducted in the exporting country, to verify that the low-level presence of the GM product would not compromise the safety of food, feed and the environment in Canada.

Canada could establish a policy where the action level for low-level presence of food, feed and grain entering Canada is set, for example, at 0.1 percent. In the majority of low-level presence situations, the presence is due to trace amounts of that crop becoming mixed with other varieties or crops along the production pathways for agricultural products. The low-level presence is unintentional. An action level at 0.1 percent provides an exemption for low-level presence that is due to unavoidable trace levels of unauthorized GM.

In this approach, the government would not do a risk assessment for GM products that are below the 0.1 action level. However, Canadian regulators would do a comparison to determine if the regulatory system for GM products in the exporting country is equivalent

to Canada. This assessment would permit regulators to have confidence in the safety assessment conducted in the exporting country, to verify that the low-level presence of the GM product would not compromise the safety of food, feed and the environment in Canada. Below the 0.1 action level, the low-level presence would be allowed to enter the country and no enforcement action would be taken.

However, if the low-level presence is above 0.1 percent, a risk assessment would be done and enforcement measures might be put into place. This could include implementing measures to reduce levels to below 0.1 percent.

This level is also associated with testing limitations of large grain shipments. It is very difficult to get reliable, reproducible results confirming the presence of low-level presence at levels below 0.1 percent.

This policy would be applied only if

- the product is approved by another country where the food safety assessment is equivalent to the assessment used in Canada, and
- the assessment is based on Codex Plant Guidelines and other internationally agreed upon procedures and guidance documents.

This action level is not intended to supersede any existing quality or purity standards that may apply to specific commodities, such as organic products.

Regarding low-level presence in seed, a case-by-case review would be needed. In cases, where there are unique environmental considerations in Canada, the 0.1 action level could be limited to grain, food and feed. However, if no Canadian environmental concerns were identified, the action level may be applied to seed.

# <u>APPROACH 2</u>: Apply an interim threshold for low-level presence for products where a data package has been submitted to Canadian authorities

In this approach, an interim threshold would be set for the GM product in question, provided that regulatory submissions for full approvals have already been made to the Canadian regulatory authorities and that other conditions are met.

This approach would allow low-level presence on a temporary basis and would provide assurances to Canadian regulators that the low-level presence situation will be brought into compliance in time. No enforcement action would be taken on shipments with levels below the threshold. The threshold would be in effect until the GM product is fully approved in Canada. It is important to note that this approach would only be pursued for those GM products where it can be determined that they are unlikely to pose a risk to human and animal health and the environment. If a risk assessment identified a potential risk associated with the product, it would be treated as in the current approach (Approach 1).

In this approach, Canada could establish an interim threshold for specific products of lowlevel presence. Whether an interim threshold (up to a set maximum) could be applied would be determined on a case-by-case basis, based on specifics of the low-level presence situation.

In the context of a low-level presence situation, Canada could allow importers of grain, seed, food and feed to bring trace amounts of low-level presence into the country at a specified interim threshold, provided that the following conditions are met:

- The GM product has already been assessed and authorized for use in a country that has similar assessment processes to those used in Canada.<sup>4</sup>
- The GM product is in the assessment queue in Canada. This means a complete data package, including a detection method, is available to Canadian regulators. In some cases, where the data package does not meet the current submission requirements, regulators could consider alternative approaches that will result in returning the situation back to compliance; however a detection method would be required.
- Canadian regulators have evaluated the relevant parts of the data package and are able to confirm that the entry of low-level presence into Canada is unlikely to pose a food, feed or environmental risk.
- The GM product will not be intentionally imported into Canada until explicitly authorized by the CFIA or Health Canada.

When these conditions are met, Canada would allow the low-level presence in question to enter the country below a specified set threshold, on a temporary basis, until the GM product has received authorization in Canada. This threshold would be set at a reasonably low level that is achievable based on factors such as

- level of prevalence<sup>5</sup>,
- the biology of the crop, and
- segregation and handling practices of the specific commodity.

<sup>&</sup>lt;sup>4</sup> Approval of the product would be in accordance with Codex Plant Guidelines and other applicable domestic regulations (for example, feed, environment)

<sup>&</sup>lt;sup>5</sup> The term level of prevalence is meant to describe the level of unapproved product which can perpetuate in the commercial stream and still be considered low level.

Importers of grain, seed, food and feed would not be required to demonstrate that their shipments are *free* from low-level presence of that GM crop, but rather that their shipments are within the interim threshold before being imported. If future shipments containing the low-level presence in question are identified above the set level, enforcement measures may be taken. These could include implementing measures to reduce levels to meet that threshold level. As such, there would be a requirement for monitoring to verify that future shipments are below the interim threshold.

This product would not be eligible for an interim threshold if

- the data package submitted is not sufficient,
- a potential risk associated with the product is identified, or
- conditions are not met for Approach 2.

In such a situation, Canada would implement the current approach to return the situation back to compliance.

This approach provides incentive for developers of new GM crops to continue to apply for regulatory authorization of their products in Canada. It ensures that scientific data is available to Canadian regulators to directly assess whether there are any risks associated with an interim threshold for low-level presence of a product, pending a regulatory decision in Canada. In addition, products that may enter Canada as low-level presence must continue to wait their turn in the assessment queue.

It is important to note that, in this approach, low-level presence will not become a means to expedite a regulatory decision in Canada.

# <u>APPROACH 3</u>: Apply appropriate case-by-case thresholds for low-level presence in products imported into Canada

This approach would allow low-level presence to enter the country below a certain minimal threshold value, in an indefinite period of time (rather than on a temporary basis like in Approach 2).

In this case, Canadian regulators would collect all relevant available safety information about the product, to conduct a risk assessment.

If the risk assessment determines that the low-level presence of the GM product is unlikely to pose a health or safety risk, then a case-by-case threshold will be implemented to manage the low-level presence situation. In the future, more and more GM crops may be developed that are intended for domestic use in another country, and are not intended for cultivation in Canada or for intentional export to Canada. In some cases, these products may be developed by public research institutions for purposes such as combating climate change or for increasing food security (for example, by using drought-tolerant traits). The incentive for these products to be submitted to Canadian regulatory authorities may be small.

In this approach, Canadian regulators would collect all available relevant safety information (including publicly available information) regarding the product in order to conduct a risk assessment, since access to a data package may be difficult. Sufficient data would be required in order to conduct a risk assessment. If the risk assessment determines the product is unlikely to pose a health or safety risk then a case-by-case threshold will be implemented to manage the low-level presence situation. Regarding the low-level presence in seed, it is necessary to have appropriate data reflective of the Canadian environment to conduct an environmental risk assessment. If this data is not available it would not be possible to apply this approach to seed.

Canada would allow the low-level presence to enter the country at or below the specified threshold, indefinitely. However, if future shipments containing the low-level presence are identified above the threshold, the government would take enforcement actions, which could include implementing measures to reduce levels to below the threshold level.

Establishing a case-by-case threshold would be based on the realities of commercial trade. The level of prevalence could be one of the factors used in establishing a threshold for entry of low-level presence into the country. However, a risk assessment would need to determine that the low-level presence of product(s) does not pose a risk and other specific conditions would need to be met. This threshold would be set at a reasonably low level that is achievable and could be based on factors such as

- the level of prevalence
- the biology of the crop, and
- segregation and handling practices of the specific commodity.

These thresholds would remain in place indefinitely, ending only if the product developer was to apply for and receive regulatory authorizations in Canada or the product was removed from the market. Enforcing the thresholds would require monitoring, sampling and testing.

#### PART 3: How to provide your feedback

#### A: Information about you

## Question 1: Are the views expressed your own, that of a corporation, association or other?

- your own
- a corporation
- an association
- other, please specify

## Question 2: What is your primary business or professional focus? Please select all that apply.

- agricultural producer
- seed companies
- crop marketer or handler
- miller
- crusher
- grain exporter
- processed food/beverage exporter
- grain/food transportation
- food/beverage manufacturer
- feed manufacturer
- ingredient manufacturer
- retailer/grocer
- restaurant/food service
- farm organization
- industry association
- consumer association
- organic sector
- academia
- federal government
- provincial government
- municipal government
- general public

Other, please specify (for example: Corporation X): \_\_\_\_\_

## Question 3: Where do you live? If representing a corporation or association, where are your Canadian headquarters?

- British Columbia
- Alberta
- Saskatchewan
- Manitoba

- Ontario
- Quebec
- New Brunswick
- Nova Scotia
- Prince Edward Island
- Newfoundland and Labrador
- Northwest Territories
- Nunavut
- Yukon

#### Question 4: If applicable, where do you do business? (Check all that apply)

- British Columbia
- Alberta
- Saskatchewan
- Manitoba
- Ontario
- Quebec
- New Brunswick
- Nova Scotia
- Prince Edward Island
- Newfoundland and Labrador
- Northwest Territories
- Nunavut
- Yukon
- United States of America
- Europe
- Asia
- Latin America
- Australia
- Africa
- Other, please specify

#### **Question 5: Identification of respondents**

Organization or association (if applicable) and contact information:

Would it be acceptable for us to contact you/your organization to follow-up on the responses provided, if required? Yes/No

\*\*\*

#### **B:** Questions for discussion

#### General

1. Please comment on the domestic approaches for managing low level presence of genetically modified crops.

If you think there are additional considerations associated with implementation that the Government of Canada should take into account, please describe them here. For example, please consider the impacts of each option on a particular sector, resource implications, impact on the supply chain, risks to exports and information on trends and drivers that may influence Government of Canada policy.

- a) Current approach for any presence of unauthorized products derived through biotechnology.
- b) Approach 1: Apply an "action level" for low-level presence for products imported into Canada
- c) Approach 2: Apply an interim threshold for low-level presence for products where a data package has been submitted to Canadian authorities
- d) Approach 3: Apply appropriate case-by-case thresholds for low-level presence in products imported into Canada
- e) Combined approaches: These approaches are not mutually exclusive and the approaches could be combined in various ways. What additional impacts the combined approaches may have on your sector?
- 2. If none of the proposed approaches meet the requirements or objectives you view as critical to Canada's low-level presence policy, what changes do you or your sector would propose?
- 3. These approaches could be limited to grain, food and feed, however, they could also be applied to seed, as long as no environmental safety concerns are identified. Please comment on whether you support applying your preferred approach to seed?
- 4. Please comment on whether you support Canada establishing a policy that would provide allowances for import of low-level presence, before our key trading

partners establish similar measures? In your response, consider impacts on your sector or area of interest and the potential impact on Canadian exports (either grain or processed food exports).

\*\*\*

#### Thank you

The Government of Canada appreciates your input into developing alternative policy approaches for managing low-level presence.