Redfern Research

Consultation on the Proposed Domestic Policy and Implementation Framework on the Management of Low-Level Presence of Genetically Modified Crops in Imports

Report on Stakeholder and Public Consultations

FINAL

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1. Introduction

In 2012, the Government of Canada sought feedback from stakeholders regarding its *Proposed Domestic Policy on the Management of Low-Level Presence of Genetically Modified Crops in Imports and its Associated Implementation Framework*. This report summarizes the key themes emerging from the responses provided by stakeholders.

1.1. Consultation Background

The consultation builds upon an earlier consultation held in October and November 2011. At that time, the Government of Canada distributed a consultation document among a broad range of interested stakeholders to receive feedback on a suite of proposed policy approaches for the management of low-level presence (LLP) of genetically modified (GM) crops in Canada's agriculture imports. The consultation document was sent to more than 200 stakeholders across Canada including exporters, importers, growers, associations, biotechnology developers, provinces, non-government organizations, etc. Comments received from these consultations informed the development of the *Proposed Domestic Policy on the Management of Low-Level Presence of Genetically Modified Crops in Imports and its Associated Implementation Framework*, a document which outlines how the federal government would assess and respond to the presence of low levels of genetically-modified crops in imported grains for food and feed use.

Between November 6, 2012, and January 19, 2013, the Government of Canada sought feedback from stakeholders and the general public on this proposed policy to manage LLP, which is defined as the unintended presence, at low levels, of unauthorized GM crops in imported grain, food or feed; where the GM crop is authorized for food use in one or more countries but is not authorized in Canada. As explained in the proposed policy:

> "Once a GM crop is authorized for commercial use in a country, trace amounts of that crop may become mixed with other varieties of the same crop or other crops in that country. This can happen during the cultivation, harvest, transportation, and storage of the GM crop. Even when best management practices are strictly followed, it is often difficult to prevent this from occurring. As a result, a GM crop may be unintentionally present at low levels in the grain, food, seed, or feed products that are exported from that country. When this GM crop is not approved in the importing country, this is what is called low-level presence (LLP)." [1]

The essence of the proposed approach, depicted in Figure 1, is that a common Action Level would be set for LLP, below which no action would be taken, and that Threshold Levels would be set "for individual crop types and will be higher than the Action Level". The Threshold Level would be set to reflect achievable levels for unintentional presence based on

[1] Government of Canada Proposed Domestic Policy on the Management of Low-Level Presence of Genetically Modified Crops in Imports and its Associated Implementation Framework, Section 2.1

best management grain handling practices for each crop type while respecting the realities of the grain handling and transportation systems in place around the world. For Threshold Levels to apply, a risk assessment[2] for each GM crop must be conducted proactively to determine if the LLP of the GM crop at concentrations up to the Threshold Level is likely to pose a risk when it is used in, or as, food and/or feed. If the threshold concentration has been exceeded, a risk assessment for the specific situation will be conducted to determine the appropriate enforcement actions to return the situation to compliance with regulatory requirements. When there is reason to believe that the GM crop poses a risk, the LLP policy will not apply.

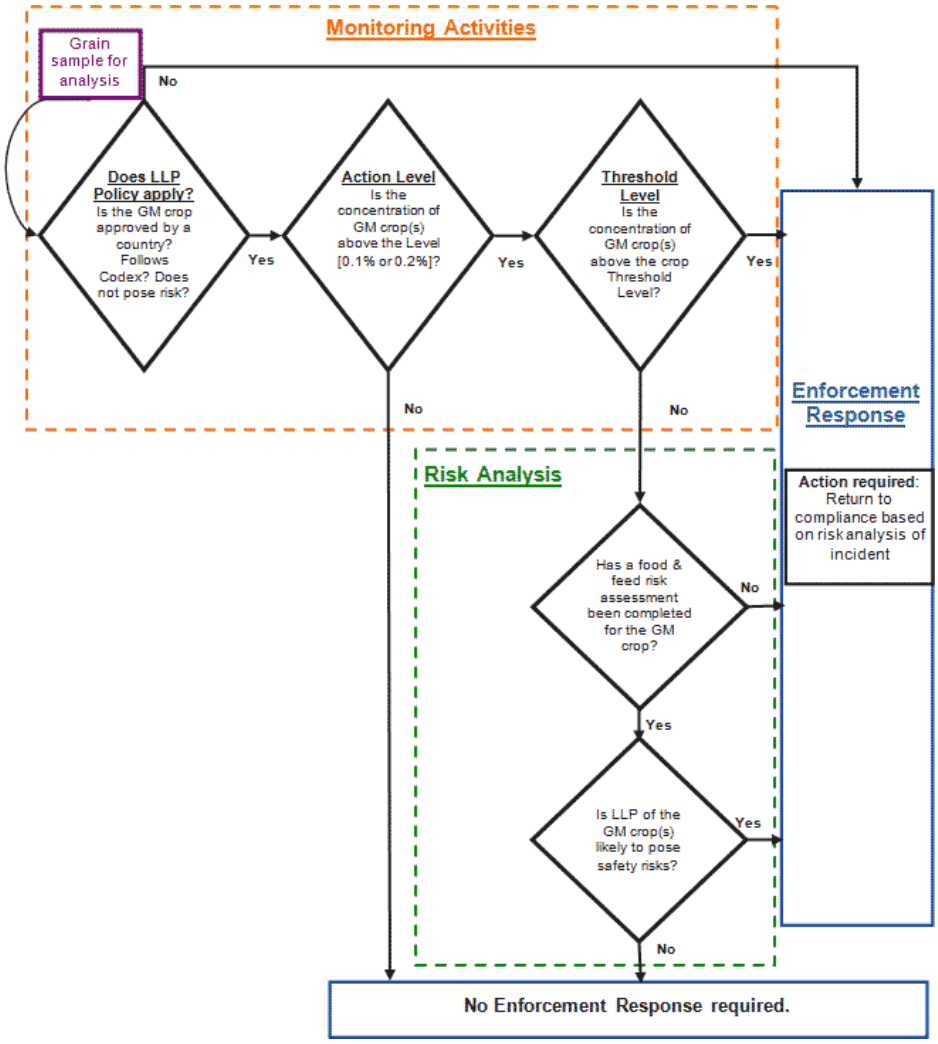
Critically, this approach would only apply to the presence of GM products which have been approved for food use in at least one country in accordance with the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003) as agreed by *Codex Alimentarius*[3]. Canada must have also determined that the food safety assessment process in the country that approved the GM crop is consistent with the Codex Guideline.

[2] A key difference between "safety assessments" and "risk assessments" is determined by the situations where these processes are used. Safety assessments are aimed at considering products for full regulatory authorization and commercialization, while risk assessments aim to determine the level of risk a non-compliant situation may pose in specific instances when unauthorized products are found in the Canadian environment or marketplace.

[3] The Codex Alimentarius Commission, established by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) in 1963 develops harmonized international food standards, guidelines and codes of practice to protect the health of the consumers and ensure fair trade practices in the food trade.

Figure 1: Elements for the Management of LLP in Grain

A flowchart illustrating the implementation of the framework to manage LLP in grain. The flowchart consists of a series of decision points to determine if an enforcement response is required.



1.2. Consultation Approach

The Canadian public and stakeholders were invited to respond to the proposed policy using an online form hosted on Agriculture and Agri-Food Canada's website.

The objective of this consultation was to gather feedback on the proposed Policy and Framework. The input received during this process will be used to inform the development of the final Policy and Framework that will be presented to the Government for its consideration.[4]

The consultation was open from November 6, 2012 to January 19, 2013. By the close of the consultation, a total of 144 responses had been received from a variety of stakeholder groups.

Table 1: Submissions

Stakeholder group	Submissions
Agriculture companies /associations	15
Biotech sector	2
Consumer groups	2
Environmental groups	2
Food processing industry	3
Grain sector	11
Organic sector	11
Provincial government officials	2
Seed industry	3
Other stakeholders, incl. research sector and universities	3
General public	90
Total	**144**

In addition to these 144 complete responses, a further 243 incomplete responses were received, many of which contained only a few words and did not respond to the proposed policy. For the purpose of this stakeholder consultation process, the Government of Canada focused on comments directly and specifically related to LLP. Off-subject comments and incomplete responses that did not respond to the proposed policy were not included in this report.

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 or to any particular stakeholder group.

[4] Consultation on the Proposed Domestic Policy and Implementation Framework on the Management of Low-Level Presence of Genetically Modified Crops in Imports, http://www.agr.gc.ca/eng/about-us/public-opinion-and-consultations/consultation-on-the-proposed-domestic-policy-and-implementation-framework-on-the-management-of-low-level-presence-of-genetically-modified-crops-in-imports/?id=1347469689149

2. Stakeholder Feedback

The following section of this report summarizes the input received from organizations including companies, industry associations, public interest groups, environmental groups, food processing industry, and provincial governments.

2.1. Summary of Institutional Stakeholder Positions

The responses received from organizations reflect a significant dichotomy of opinion among stakeholders. Generally speaking, food processors, grain producers, biotechnology companies, and their industry associations favour the proposed approach to LLP in principle, while sometimes questioning the basis of the proposed Action Level and expressing concern about the feasibility of implementing the new policy. The primary benefit they perceive is predictability in trade. In contrast, the organic sector, their industry associations and some public interest groups are opposed to the underlying principles of the proposed LLP policy, preferring that *any* presence of any unapproved GM crops in imported food be prohibited. Some perceive Canada's proposed LLP policy as an "open door" for the importation of unapproved GM crops with potentially significant negative consequences for the organic sector, exports to GM-intolerant markets and the health of the population.

2.2. Transparency and Predictability

The organic sector, environmental groups and consumer groups often indicated that the proposed LLP policy is not sufficiently transparent with regard to grain or to other imported food products. Many in this group expressed the view that the policy contains inherent assumptions about the safety of GM crops and the reliability of foreign safety assessments, which they noted have not been adequately demonstrated.

The grain, seed and biotechnology sectors generally indicated that the policy *is* transparent in most respects. Many in these groups, however, noted that the proposed approach to LLP does not contain enough information on how the proposed policy would be implemented. They had questions about:

- sampling methods, including how often shipments would be tested for LLP and the way that samples would be drawn.
- how the proposed LLP policy would apply to stacked events[5];

[5] Some GM crops contain more than one GM event and may include, for example, two or more genetic traits "stacked". Some stakeholders seek clarity about how this presence of multiple events within a single variety of grain would be assessed under the Action Level and Threshold Level.

- how the proposed thresholds would apply to multiple events within a single shipment; and
- which options would be available to importers to bring non-compliant shipments into compliance.

Some participants in all stakeholder groups indicated that the Threshold Level should be set based solely and transparently on science without any non-scientific influences. The grain, seed and biotechnology sectors noted that public and political opinions should not influence the decision-making process. In contrast, the organic sector, environmental and consumer groups noted that the process to set Threshold Levels should not be influenced by commercial interests.

Additional questions about how levels would be measured, how often, by whom, and what enforcement actions could be taken were also raised by grain stakeholders and some environmental and organic stakeholders. Some stakeholders in the environment and organic sectors specifically questioned what actions would be used to manage potential risks.

Although the proposed LLP policy explicitly excludes seeds, many participants from the organic sector expressed concern in their responses about the intermingling of GM crops with certified non-GM crops in the environment. They noted that such intermingling could lead to significant economic losses for their sector.

The organic sector indicated support for the implementation of a systematic approach to LLP which would routinely test imports and identify the presence of unapproved GM crops. They questioned whether information on LLP situations will be shared with the public so that the organic and non-GM food industries may take preventative action, if needed, to protect the integrity of their supply chains. Generally, this sector requested more detail on what information will be tracked and how LLP events will be communicated.

2.3. Scope

The proposed LLP Policy applies to all imported grain, food and feed products which contain LLP where the GM crop has been approved for use as food in at least one country; and Canada has recognized that the safety assessment conducted by that country is consistent with Codex Food Safety Assessment Guidelines. It does not apply to seeds for propagation in the environment, GM fruits and vegetables, adventitious presence[6], animals, microorganisms, other GM crops modified to produce plant-made pharmaceutical or industrial products unless

[6] Adventitious presence is defined in the proposed LLP policy as the unintended presence of research or "pre-commercial" or otherwise unauthorized material which has not been assessed for food or feed use and unconfined environmental release in any country.

approved for food and feed use; or GM crops for which there is reason to believe that LLP may pose a risk to the safety of human food, animal feed or the environment.[7]

There is widespread agreement, even among some of those who disagree with the proposed LLP policy, that the scope of the policy is appropriate. Those who consider the scope is not appropriate generally believe that any consideration of an "acceptable" LLP is misguided and prefer absolute prohibition of unapproved GM crops in imported products.

Even though many agree that the scope is appropriate, there is confusion among respondents about how LLP policies would be applied to food and feed products other than grain. There is uncertainty regarding which products would be subject to the proposed LLP policy, how these products would be identified and tested, and what Action and Threshold Levels might apply in the context of a product containing multiple ingredients.

2.4. The Action Level

Grain exporters and biotechnology industry groups are strongly supportive of an LLP policy for Canadian food imports. They indicated that this policy is an improvement over "zero tolerance" because LLP is an inevitability given the nature of international grain handling, storage and shipping. Generally, respondents in this group indicated that setting an "acceptable" amount of LLP provides certainty and predictability for importers who may not be able to obtain products which are completely free of residues of GM products not approved in Canada (but approved elsewhere). This group supported that if this proposed approach was adopted by Canada's major trading partners, it would create a more secure market environment for Canadian grain exporters.

Some grain exporters, biotechnology and seed companies noted that if a GM product has been certified as safe for food use by a competent foreign authority, it should not be of concern when present in small proportions in import shipments. Thus, they indicated that the Action Level is largely unnecessary or could be set much higher than 0.1% or 0.2%. However, most respondents in this group were supportive of the predictability which the Action Level offers importers.

Those in the organic industry, environment groups and consumer groups who oppose the Action Level concept generally expressed three opinions. First, that no level of GM product should be considered acceptable in a non-GM import, regardless of whether the GM product is approved or not. They noted "zero tolerance" to be the stated goal, even if this goal cannot be fully achieved. They cited the example of food industry compliance with allergen elimination as an example that the presence of unwanted materials can be

[7] *Government of Canada Proposed Domestic Policy on the Management of Low-Level Presence of Genetically Modified Crops in Imports and its Associated Implementation Framework*, Section 5.2

avoided with an appropriate incentive. Second, they expressed concerns about the impact of setting an Action Level higher than zero on Canada's credibility as a source of GM-free exports, including organic products. This is coupled with concern about domestic consumer confidence in organic and non-GM products. Third, that the Action Level absolves both the regulators and the importers from investigating and reporting the presence of GMs below the Action Level, thereby missing the opportunity to understand and mitigate problems in the supply chain. Several stakeholders pointed out that they perceive as a lack of incentive in the LLP policy to encourage importers to prevent the presence of GM products in non-GM products.

The majority of stakeholders do not support the idea of setting the Action Level at 0.1%.

Many in the organic sector do not support the idea of the Action Level, and therefore cannot endorse any level as acceptable. However, within that context, one stakeholder in the organic sector noted that 0.1% is an achievable level which would meet the overall objectives of the proposed LLP policy.

For many in the grain, seed and biotechnology sectors the 0.1% level is seen as too low. While the organic sector objected to the Action Level of 0.1% on principle, the grain, seed and biotechnology sectors objected on practical grounds. They indicated that testing is not presently precise enough to support an Action Level of 0.1%, meaning that detection and enforcement would be inconsistent. They supported setting the Action Level at 0.2%, noting that this percentage is in line with the current Canadian Food Inspection Agency Guidelines for testing and detection tools.

Most grain stakeholders who accepted the Action Level in principle prefer that the Action Level be set at 0.2% rather than 0.1%. Some would prefer that the Action Level be set even higher, noting that there is no safety threat given that the GM product has obtained prior approval by a recognized foreign authority in accordance with Codex Guidelines.

2.5. The Threshold Level

Stakeholders who do not support the Action Level concept for the reasons noted earlier also do not support the Threshold Level concept for the same reasons: they indicated that any level of GMs in non-GM foods should be prohibited in order to protect the integrity of the food chain, the organic export sector, and human health. This view is concentrated in the organic sector, consumer groups, and public interest groups.

In the grain, seed and biotechnology sectors, the Threshold Level is generally supported primarily because it introduces greater flexibility into the LLP system by taking the unique characteristics of particular crops into account, including the specific circumstances of harvesting, storage and shipment.

Some provincial government and industry stakeholders noted that the Threshold Level concept would introduce unnecessary cost and complexity; they expressed preference for

a single base level for all crops. In their view, a proliferation of different Threshold Levels for different products would create confusion for all stakeholders and for Canada's trading partners. They prefer that a single Threshold Level be set for all products or at most a small number of Threshold Levels, each applying to different classes of products. They indicated this single Threshold Level would be simpler for government and industry to implement.

2.5.1. LLP Risk Analysis for Threshold Level

There is some uncertainty among the grain, seeds and biotechnology sector respondents regarding the risk analysis process to be implemented under the Threshold Level, and how it would differ from a full safety assessment, leading to the view that the risk analyses conducted under the LLP policy might somehow be equivalent to a safety assessment, or lead to full market approval via a "backdoor". (As noted earlier, safety assessments are aimed at considering products for full regulatory authorization and commercialization, while risk assessments address specific instances when unauthorized products are found in the Canadian environment or marketplace.)

Overall, greater clarity is requested by industry stakeholders regarding the risk analysis process laid out in Annex 3 of the Codex Guideline which may not, in the view of some, always be necessary when the product and/or country are already familiar and trusted.

There is also concern in the grain and food processing sector, as well as one provincial government, about the time and cost required to conduct risk assessments and the potential consequent financial impact on importers whose shipments are found to have LLP. One stakeholder specifically suggests that the government should publish service standards for the risk assessment process.

2.5.2. Setting Threshold Levels

Stakeholders identified a number of factors which should be taken into account when setting the Threshold Levels. They also identified some areas where greater clarity is needed. The following direct quotations are representative, with the frequency of mention provided in brackets.

- *Threshold Levels should not be applied to "stacking" (2)*
- *Threshold Levels should not be cumulative for multiple LLP events in a single shipment.(2)*
- *[Threshold Levels should consider] the safety and health risk (3)*
- *Rotational considerations between crops (2)*
- *[Threshold Levels should consider] the secondary impact of pollination and pollinators.(1)*

- *[Threshold Levels should consider] whether these crops have GM presence in Canada already and it should be considered what the negative side effects of cross contamination would be (2)*
- *Further discussion is needed to take into consideration inter-species crop co-mingling/LLP (1)*
- *Biology and the challenge of containment should be the only consideration (1)*
- *[Threshold Levels should consider] potential economic loss to exporters, especially in the organic sector (7)*
- *Compliance costs and cost effectiveness (1)*
- *[Threshold Levels should consider] the economic impact it may have on international markets and sales (1)*
- *[Threshold Levels should consider] technical feasibility (2)*
- *[Threshold Levels should consider] market dynamics, end-uses, grain handling and transportation challenges and history with biotechnology. Additional factors could be previous experience with biotechnology, agronomic practices, and customer acceptance (1)*
- *The method of detection - accuracy, repeatability, reproducibility, sampling errors (1)*
- *The way the final product is consumed and the concentration of the LLP crop found in the final product. (1)*

2.5.3. The Expert Advisory Committee

All stakeholders within the industry expressing an opinion indicated that the Expert Advisory Committees should provide independent, unbiased advice about the Threshold Levels which are appropriate to each product. All stakeholders noted that these committees should be science-based. Furthermore, they indicated that members should be well-informed in the areas (such as product handling, product storage and public health) which are at the heart of the Expert Advisory Committee mandate.

Stakeholders outside industry expressing an opinion indicated that Expert Advisory Committee members should represent the public interest and be comprised of academics, members of the public and subject matter experts. Environmental and consumer groups noted specifically that industry should be excluded from the Expert Advisory Committees, especially industries whom they consider to be closely aligned with GM products.

In contrast, the grain industry, seed industry and biotechnology companies see the Expert Advisory Committees as expert panels made up primarily of subject matter experts from various sectors of the industries directly affected by the Threshold Levels.

Representatives of the organic, honey and feed industries specifically mention that they should be represented on the Expert Advisory Committees.

2.6. Market Impact

While the majority of stakeholders who provided input indicated that the importation of LLP of unauthorized GM crops would have an economic impact on Canadian exports, there is no consensus on the type of impact. The organic sector, public interest and environmental groups noted that the proposed LLP policy may undermine Canada's ability to export to jurisdictions which have a less tolerant approach to GM products in general. A small proportion of grain, seed and biotechnology stakeholders also noted that LLP on Canadian exports could have trade impacts if Canada's trading partners are not in general accord with the approach Canada takes on LLP. They do not support the federal government moving ahead with any LLP policy until some reassurance has been obtained from major trading partners regarding the likely reception this policy would receive and the impact it may have on Canada's exports.

The grain, seed and biotechnology sectors noted that an international approach to LLP will have significant benefits for Canada as a food exporter. They expect to see a common solution to the uncertainty created by the LLP issue.

The organic sector noted that the intolerance of GM crops in certain markets, while it might create barriers for grain exporters, actually creates export opportunities for Canada's organic farmers. While conventional food exporters indicated that LLP will reduce trade barriers for their products, the organics exporters noted that the proposed LLP policy will create trade barriers to their products.

2.7. Canada as First Adopter

Stakeholders are split on whether Canada should be the first to implement an LLP policy like the one discussed here. Generally speaking, the grain, seed and biotechnology sectors favour Canada taking a first step in order to show leadership and inspire other countries to harmonize their LLP policies with Canada's rather than adopting more stringent LLP policies which may be detrimental to Canadian exporters. The opportunity to provide global leadership and influence on countries in Canada's export market is a key motivator for the support these stakeholders express for the proposed LLP policy. A significant number of stakeholders in the grain, seed and biotechnology sectors advocate continued Canadian advocacy for an international approach to LLP, including alternatives to "zero tolerance", and promoting the use of Codex Guidelines.

Those stakeholders who support the LLP policy indicated that timing must be handled carefully. Canada may lead, they say, but it should not get too far ahead of its major trading partners; it should not implement an LLP policy without a reasonable expectation that others will follow suit.

3. General Public Feedback

Ninety individual members of the general public responded to the online consultation form regarding the proposed LLP policy. With a few exceptions, the responses did not address the details of the proposed policy in depth but instead made more general statements about LLP as it relates to wider questions regarding GM crops.

Generally speaking, these respondents did not distinguish between GM crops which have been approved for use in Canada, those which have been approved elsewhere but not in Canada, and those which have not been approved in any jurisdiction.

Responses were consistent and confined to a few key themes, listed below:

- The proposed LLP policy, including the Action and Threshold Level concepts, is almost unanimously rejected by general public respondents. Of the 90 responses, fewer than 5 were supportive of the LLP proposal.
- Most respondents with an opinion (35 of 44) indicated that Canada should *not* be the first to implement an LLP policy, primarily because they oppose the intent of the policy itself. The nine who supported Canada taking the first steps generally supported a modified policy which would restrict GM crop imports and require retail labelling.
- A small proportion of respondents also stated that:
    - The Expert Advisory Committee members should be independent (10) and include consumers (5) and organic farmers (4).
    - LLP would damage Canadian food exports in general (7), or organic exports in particular (5).

4. Appendix A: Consultation Document

Background

1. Governments as well as public and private institutions around the world are actively seeking ways to increase agricultural productivity. In support of these efforts, it is expected that the number and variety of genetically modified (GM) products commercialized will continue to increase.

2. Once a GM crop is authorized for commercial use in a country, trace amounts of that crop may become mixed with other varieties of the same crop or other crops in that country. This can happen during the cultivation, harvest, transportation, and storage of the GM crop. Even when best management practices are strictly followed, it is often difficult to prevent this from occurring. As a result, a GM crop may be unintentionally present at low levels in the grain, food, seed, or feed products that are exported from that country. When this GM crop is not approved in the importing country, this is what is called low-level presence (LLP).

3. As a result of the lack of synchronization in the approvals of new GM crops by countries and the expected increase in the commercialization of GM crops around the world, the likelihood of LLP entering Canada is expected to increase. Canada will continue to actively work with other countries on addressing the issue of asynchronous approvals with a view of minimizing unnecessary trade disruptions.

4. Under the current Canadian regulatory framework, the presence of an unauthorized GM crop constitutes non-compliance. Therefore, when an unauthorized GM crop is detected, the Canadian Food Inspection Agency (CFIA) and Health Canada (HC) evaluate the risk associated with the non-compliance and then determine which risk management and compliance actions are required to mitigate the risk. The goal is to maintain food, feed and environmental safety, while using the most appropriate level of intervention to return the situation to compliance. Commensurate with the risks posed by an LLP situation, a return to compliance can be achieved by:
    1. the authorization of the non-compliant product for food, feed and environmental release in Canada; or,
    2. the removal of the non-compliant product from Canada.

5. Enforcement actions may include: requiring corrective actions to be taken by the regulated parties, issuing product recalls, or taking legal actions. In LLP situations, even if a risk assessment shows that the product is unlikely to pose a risk to the health and safety, there is an obligation to return the situation to compliance.

6. The enforcement actions taken when an unauthorized GM crop is detected may disrupt trade and increase costs to industry and to governments, on both the import and export side. Under the current legislation, such disruptions and costs could occur despite the fact that the unauthorized GM crop, present at low levels, is unlikely to pose a risk to human or animal health or to the environment.

7. While the Government of Canada continues to encourage developers of new GM crops to seek full authorization in Canada, the Government recognizes that internationally

synchronized approvals of GM crops may not always be feasible. Therefore, the Government of Canada has developed the Proposed Domestic Policy on the Management of Low-Level Presence of Genetically Modified Crops in Imports and its Associated Implementation Framework to Manage Low-Level Presence in Grain.

8. The proposed Policy and Framework set out the Government of Canada's proposed direction for managing occurrences of LLP. It clarifies the risk management approaches that will be taken to address LLP occurrences and stipulates the conditions under which enforcement action will or will not be taken on imported food and feed products.

Proposed Domestic Policy for the Management of Low-Level Presence of Genetically Modified Crops in Imports

1. **Policy Statement**
   - 1.1 Upon detection of unauthorized GM crops in grain, food or feed products imported into Canada, it is the policy of the Government of Canada (GoC) to take action commensurate with the risk posed by the LLP, without unduly disrupting trade.
2. **Definitions**
   - 2.1 For the purpose of this Policy:
     - **Genetically modified (GM)** refers to plants that have been modified using recombinant deoxyribonucleic acid (DNA) technology.
     - **GM crop** refers to a plant with one or more specific or novel traits that have been introduced via recombinant DNA technology.
     - **Low-level presence (LLP)** is the unintended presence, at low levels, of unauthorized GM crops in imported grain, food or feed; where the GM crop is authorized for food use in one or more countries but is not authorized in Canada.
   - Additional definitions pursuant to this Policy are found in the glossary in Appendix 1.
3. **Objectives**
   - 3.1 The objectives of the Policy are to:
     - minimize disruptions to trade while protecting the health and safety of humans, animals and the environment;
     - facilitate an effective and efficient risk-based approach to managing LLP; and,
     - provide transparency and predictability for importers and exporters.
4. **Guiding principles**
   - 4.1 In managing situations of LLP, the GoC will follow these principles:
     1. The safety of human food, animal feed and the environment in Canada is paramount.
     2. Risk management decisions and actions to address LLP occurrences are science-based and risk-based.
     3. Risk management approaches for LLP are designed to mitigate potential risks and be resource efficient for both government and industry.
     4. Encourage compliance with Canada's domestic regulatory system including the requirements for full authorization of GM products.
     5. Risk management decisions and actions minimize unnecessary trade disruptions to the extent possible.

6. Risk assessments for LLP are conducted in a manner that is consistent with international guidance on managing LLP.

5. **Scope**
   - 5.1 The LLP Policy applies to all imported grain, food and feed products which contain LLP where:
     - the GM crop has been approved for use as food in at least one country; and,
     - Canada has recognized that the safety assessment conducted by that country is consistent with Codex Food Safety Assessment Guidelines.

     Recognizing that most components of a food safety assessment also apply to feed, a foreign feed assessment is not required for an unauthorized GM crop to be considered LLP.

   - 5.2 The Policy does **not** apply to:
     0. seed intended for propagation in the environment;
     1. GM fruits and vegetables;
     2. adventitious presence which is defined, for the purpose of this Policy, as the unintended release of research or "pre-commercial" GM crops, which have not been authorized for use in **any** country;
     3. genetically modified animals and microorganisms;
     4. other GM crops modified to produce plant-made pharmaceutical or industrial products unless approved for food and feed use; and,
     5. GM crops for which there is reason to believe that LLP may pose a risk to the safety of human food, animal feed or the environment.
   - 5.3 The Policy does not supersede any varietal purity, organic or other such agricultural standards.

6. **Risk Management for Grain**
   - 6.1 A stepwise risk-based approach is taken to manage LLP in grain which consists of two levels:
     0. A low, uniform **Action Level** will be set for LLP in grain of all crop types. When LLP is detected at concentrations below the Action Level, no enforcement action would be triggered. This risk management element will address potential trace amounts of LLP resulting from dust or other sources. Since the food safety assessment that the GM crop has passed is consistent with the *Codex Guideline for the Conduct of a Food Safety Assessment of Foods Derived from Recombinant-DNA Plants*, below the Action Level, LLP is unlikely to pose a risk. The GoC will publicly consult on the specific numerical value that should apply to the Action Level. An Action Level of 0.1% or 0.2% is proposed.

     1. Crop-specific **Threshold Levels** will be set for individual crop types and will be higher than the Action Level. The Threshold Levels will be set to reflect achievable levels for unintentional presence based on best management grain handling practices for each crop type while respecting the realities of the grain handling and transportation systems in place around the world. These Threshold Levels will only be applicable for an individual GM crop after a Canadian LLP risk assessment has determined that the presence of the GM crop at the proposed level is unlikely to pose a risk to food, feed or environmental safety.

- 6.2 When levels exceed the Action or Threshold Levels[8], a risk assessment for the specific situation will be conducted to determine the appropriate enforcement actions to return the situation to compliance with regulatory requirements. When there is reason to believe that a specific LLP occurrence may pose a risk, enforcement action will be taken to return the situation to compliance with regulatory requirements.

7. **Risk Management for Processed Products**
   - 7.1 For processed grain and other further refined processed food or processed feed products containing grain, the Action Level and Threshold Levels set for grain will apply indirectly. This is because the concentration of LLP in imported processed grain products will change from the level in the original grain, depending of the processing procedures used to transform the grain. In this context, if an unauthorized GM crop is detected in a processed grain product intended for food or feed use, a risk assessment will be conducted for the specific incident to determine the most appropriate response. The grain Action and Threshold Levels for LLP will be taken into consideration, as will any applicable risk assessments conducted for LLP of that GM crop in grain, prior to taking enforcement action on the imported processed grain product.
8. **Authorities**
   - 8.1 All foods sold in Canada are subject to the *Food and Drugs Act* and its associated Regulations. Novel foods, including those derived from GM crops, are specifically subject to Division 28 of part B of the *Food and Drug Regulations*.

   - 8.2 Livestock feeds manufactured in, sold in or imported into Canada are regulated under the *Feeds Act* and its associated Regulations. Novel feeds or feed ingredients, including those derived from GM crops must undergo a pre-market safety assessment and be approved before they can be manufactured in, sold in or imported into Canada as a feed ingredient.

   - 8.3 Under the *Canada Grain Act*, the Canadian Grain Commission has authority over 21 grains designated as grain in the *Canada Grain Regulations* and imported into Canada.
9. **Roles and Responsibilities**
   - 9.1 Regulated parties are responsible for:
     0. ensuring that products imported into Canada comply with relevant requirements;
     1. providing the GoC with information related to GM crops that have been approved by at least one country and that have a chance to be imported at low levels into Canada; and,
     2. providing the required information to the CFIA and HC for the completion of the LLP risk assessments.
   - 9.2 Agriculture and Agri-Food Canada (AAFC) is responsible for reviewing and maintaining this Policy.

   - 9.3 The Canadian Food Inspection Agency (CFIA) and Health Canada are responsible for implementing this Policy.

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[8] The principles of measurement uncertainty will be applied to the raw test result when they are interpreted to determine if the result is greater than the Action or Threshold Level as applicable

10. **Review**
    - 10.1 AAFC will review this Policy, including an evaluation of its success in achieving its objectives. The first review will take place two (2) years after the entry into force of the Policy. Subsequent reviews will take place every five (5) years, or earlier as appropriate.
11. **References**
    - 11.1 Current Canadian approach to managing cases of unauthorized presence of plants (and their products) derived through biotechnology in food, livestock feed, and the environment

    - 11.2 Guideline For The Conduct Of Food Safety Assessment Of Foods Produced Using Recombinant-DNA Plants (opens an external link, in PDF format) (ALINORM 03/34 Appendix III)
12. **Implementation Framework**
    - 12.1 The Policy will be supported by an Implementation Framework that outlines the approach to implementation and may be amended from time to time.
13. **Inquiries**
    - 13.1 AAFC is the contact point for this Policy. Any inquiry should be directed to: LLP-PFC@agr.gc.ca.

Proposed Implementation Framework to Manage Low-Level Presence in Grain

1. **Introduction**
    - 1.1 As a first step in implementing the Proposed Domestic Policy for the Management of Low-Level Presence of Genetically Modified Crops in Imports, this proposed low-level presence (LLP) Implementation Framework sets out how Health Canada (HC) and the Canadian Food Inspection Agency (CFIA) implement the LLP Policy for grain. The LLP Implementation Framework sets out how Canada manages LLP that does not pose a risk to human or animal health or the environment. It also applies to the management of LLP in downstream processed grain products, although its application in those circumstances is more indirect. Further, this framework sets out monitoring activities and clarifies when enforcement action will or will not be taken.

    - 1.2 This framework describes how the LLP Policy objectives of transparency, predictability, and efficient and effective risk management are achieved for imported grain. It is consistent with the CFIA's Compliance and Enforcement Operational Policy which requires compliance management to be guided by: fairness, impartiality, transparency and the principles of risk management.
2. **Framework Overview**
    - 2.1 The LLP Implementation Framework consists of two stepwise risk management elements that form the basis for a risk-based approach to managing LLP in grain imported into Canada for food or feed. Further, the framework includes risk-based monitoring activities to verify that imported grain meets Canadian requirements related to LLP and enforcement responses to achieve compliance. As well, information is provided to improve awareness of the LLP Policy and encourage compliance with regulatory requirements, in particular those related to the authorization of GM crops.

    - 2.2 The two risk management elements are the Action Level and the Threshold Level.

1. The **Action Level** is the level of LLP above which action is taken to assess whether the Threshold Level applies, or enforcement response is required. When LLP is below the Action Level, no enforcement action will be taken.

2. The **Threshold Level** is the maximum level of LLP for which no enforcement action will be taken, provided that a Canadian risk assessment of the GM crop has been completed and has determined that the LLP, when present at concentrations up to the Threshold level, is unlikely to pose a risk to human or animal health or the environment.

- 2.3 The LLP Framework does **not** apply:
  1. when LLP is detected at concentrations over the Action Level and the Threshold Level does not apply; or
  2. when the GM crop(s) is present at a level greater than the applicable Threshold Level; or
  3. in any case where LLP of a GM crop may pose a risk to humans, animals or the environment. In these situations, a risk analysis of the specific situation will be conducted to determine the most appropriate response to return the situation to regulatory compliance.
- In these situations, a risk analysis of the specific situation will be conducted to determine the most appropriate response to return the situation to regulatory compliance.

- 2.4 Appendix 2 illustrates how the Implementation Framework elements will be used to manage LLP in grain.

3. **Application of the LLP Implementation Framework**
   - 3.1 This LLP Implementation Framework applies to imported whole grain intended to contain only one species of grain, such as: cereals, oilseeds, pulses, buckwheat, corn, and rice intended to be used in or as food or feed.

   - 3.2 The Implementation Framework (including the Action and Threshold Levels) also applies to processed grain and other refined and further processed food or processed feed products derived from grain, but indirectly. This is because the concentration of LLP in imported processed grain will change from the level in the original grain, depending on the processing procedures that the grain has undergone. If an unauthorized GM crop is detected in a processed grain product intended for food or feed use, a risk assessment will be conducted for the specific incident to determine the most appropriate response. The grain Action and Threshold Levels for LLP will be taken into consideration, as will any applicable risk assessments conducted for LLP of that GM crop in grain, prior to taking enforcement action on the imported processed grain product.

Assessing whether the LLP Policy applies

- 3.3 Consistent with the LLP Policy, for the presence of an unauthorized GM crop to be considered eligible for the LLP Framework to apply, the following two overarching criteria must be met:
  1. the GM crop must be approved in at least one country in accordance with the *Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* (CAC/GL 45-2003), hereafter referred to as the **Codex Guideline**; and

2. Canada must have determined that the food safety assessment process in the country that approved the GM crop is consistent with the Codex Guideline.

- 3.4 To determine if a GM crop is approved in at least one country, Health Canada and the CFIA will refer to information about GM crop approvals that has been provided by importers, as well as national and international databases that house this information, such as the databases of the Food and Agriculture Organization (FAO), the Organisation for Economic Co-operation and Development (OECD) and the Biosafety Clearing House.

- 3.5 Health Canada and the CFIA will communicate with individual countries to assess whether their food safety assessment process is consistent with the Codex Guideline and therefore provides confidence that LLP of GM crops approved by the country is unlikely to pose a risk to food or feed safety. A list of countries verified as having regulatory frameworks that are consistent with the Codex Guideline will be published on-line and maintained by the CFIA and Health Canada. Countries will be reassessed, as required, to verify continued consistency with the Codex Guideline.

- 3.6 When it is determined that the unauthorized GM crop does not meet all of the above assessment criteria **or** when there are reasonable grounds to believe that a GM crop may pose a risk to the safety of food, feed or the environment, the LLP Framework does **not** apply. In such situations, a case-by-case risk analysis of the specific situation will be conducted to determine the most appropriate enforcement response.

4. **Action Level**
   - 4.1 The Action Level sets a concentration of LLP in grain above which an action is taken to manage potential risks by determining whether the Threshold Level applies, or an enforcement response is required. The Action Level is a common, low level that applies to grain of all crops and takes into consideration potential trace amounts (e.g. dust) of LLP.

   - 4.2 The Action Level will be set at 0.1% or 0.2%[9] total concentration of LLP in imported grain for use in or as food or feed.

   - 4.3 Enforcement action will **not** be taken when:
     1. the GM crop has been verified by Health Canada and the CFIA to meet all of the criteria set out in Section 3.3 thus providing confidence that the LLP is unlikely to pose a risk to food, feed, or the environment; and

     2. the total concentration of LLP is less than or equal to the Action Level 0.1% or 0.2% thereby minimizing the potential exposure to humans, animals, and the environment.
   - 4.4 The concentration of LLP is determined as the percentage by weight of the sample tested[10].

[9] The Action Level value of 0.1% or 0.2% will be selected in view of the feedback received from the consultation

- 4.5 When the total concentration of LLP is greater than the Action Level 0.1% or 0.2%, the CFIA will verify whether the Threshold Level applies. If the Threshold Level does not apply, the CFIA will assess the situation and determine the appropriate enforcement response.

5. **Threshold Level**
   - 5.1 The Threshold Level sets the maximum concentration of LLP that is considered to be a low-level presence resulting from unavoidable factors. The Threshold Level takes into account the biology of the crop and the realities of modern agricultural production and commodity trade, recognizing that small amounts of unintentional and unavoidable commingling can occur during crop production, transportation, bulk handling, conditioning, and storage.

   - 5.2 The Threshold Level is the maximum total concentration of LLP for which no enforcement action will be taken provided that:
     1. the GM crop(s) has been verified by Health Canada and the CFIA to meet all of the criteria set in Section 3.3; and
     2. a risk assessment, as defined in the Glossary, of the GM crop(s) has been completed by Health Canada and the CFIA and has shown that the LLP is unlikely to pose a risk to the safety of humans, animals or the environment at the Threshold Level.
   - 5.3 The concentration of LLP is determined as the percentage by weight of the sample tested[311]

   - 5.4 Importers, developers, or other interested parties should proactively submit data for risk assessments for GM crop(s) so that the Threshold Level will apply when LLP is detected in imported grain.

Setting a Threshold Level

- 5.5 Expert Advisory Committee(s) will be formed to make recommendations to Health Canada and the CFIA on the values for Threshold Levels in grain.

- 5.6 The LLP thresholds will be set by crop type (e.g. corn, soybean, flax, canola, etc.) and will take into consideration unavoidable factors which lead to unintentional presence of crops such as crop biology (e.g. out-crossing and pollination) and grain handling practices. Where appropriate, the threshold may take into consideration internationally accepted standards that are based on similar factors, such as the grain grading or seed varietal purity standards.

- 5.7 The Expert Advisory Committee(s) will be made up of a diverse representation of stakeholders, including representation from food or feed

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[10] The principles of measurement uncertainty will be applied to the raw test result when they are interpreted to determine if the result is greater than the Action or Threshold Level as applicable.

[11] Where a credible international expert body (e.g. a joint WHO & FAO expert committee) has completed a risk characterization of the GM crop, Health Canada and the CFIA will use this risk characterization to inform the risk assessment and management decisions and, therefore, the data package identified in section 5.10 may not be required.

producers and processors, retailers, crop developers, academia, and importers and exporters. Government officials will oversee the operation of the committee, and provide technical and regulatory information, but will not participate in formulating the committee's recommendation. The GoC will define the terms of reference for the Expert Advisory Committee(s).

- 5.8 Health Canada and the CFIA will set Threshold Levels for grain of each crop type, taking into consideration the recommendations from the Expert Advisory Committee(s). Once set, the Threshold Level for grain of each crop type will be published on-line.

Threshold Risk Assessments

- 5.9 In order for the Threshold Level to apply, Health Canada and the CFIA must have completed a risk assessment of the GM crop and determined that the GM crop is unlikely to pose a safety risk when present at concentrations up to the crop Threshold Level.

- 5.10 For a risk assessment to be completed, the following must be submitted to the CFIA: a complete data package in English or French, an appropriate detection method for the GM crop, and reference material for the GM crop, as per the data requirements outlined in Annex 3 of the Codex Guideline: *Food Safety Assessment in Situations of Low-Level Presence of Recombinant-DNA Plant Material in Food* [12], and the anticipated fee, if a fee has been set [Footnote 5].

  The CFIA will forward the complete data package to Health Canada; Health Canada will conduct a food risk assessment.

- 5.11 Health Canada will conduct a risk assessment of the GM crop, in accordance with Annex 3 of the Codex Guideline: *Food Safety Assessment in Situations of Low-Level Presence of Recombinant-DNA Plant Material in Food*, to determine if LLP of the GM crop in food at concentrations up to the Threshold Level is likely to pose a risk when it is used in or as **food**.

- 5.12 In cases where the submitted data package is not sufficient to assess the risks posed by LLP of the GM crop in food products as per Annex 3 of the Codex Guideline, additional information may be required.

- 5.13 The CFIA will conduct a risk assessment of the GM crop to determine if LLP of the GM crop at concentrations up to the Threshold Level is likely to pose a risk when it is used in or as **feed**.

- 5.14 In cases where the submitted data package is not sufficient to assess the risks posed by LLP of the GM crop in **feed** products (e.g. when the components of the plant used in feed are different from those used in food), additional information may be requested by the CFIA. The data request may include

[12] It is expected that a fee to conduct a risk assessment of the GM crop will be set in accordance with and following the process set out in the CFIA's Cost Recovery Policy & Framework

information outlined in the CFIA's *Guidelines for the Assessment of Novel Feeds*[13].

6. **Monitoring Activities**
    - 6.1 The CFIA will monitor to assess whether the imported grain meets Canadian requirements related to LLP in accordance with its *Compliance and Enforcement Operational Policy*. The CFIA takes a risk-based approach to compliance management. Given that the GM crops that result in LLP have been approved and deemed to be safe in another country that follows the same Codex Guideline as Canada, LLP is considered to pose low risk. As such, monitoring of imported grain will be conducted at a low frequency.

    - 6.2 The CFIA will monitor imported grain to verify compliance with regulatory requirements. Monitoring activities may be carried out at the border when the imported product is entering Canada, or post-border, when the imported product arrives at its destination. In addition, the CFIA will utilize its complaints and investigations processes to respond to complaints regarding compliance with LLP related requirements.

    - 6.3 Imported grain used for food or feed will be monitored based on several factors including the importer's compliance history and foresight analysis to identify GM crops that have been approved in other countries and therefore may be present in imported grain.
7. **Enforcement Response**
    - 7.1 The CFIA provides information to consumers and regulated parties to improve awareness about and encourage compliance with regulatory and policy requirements. Regulated parties have an obligation to understand the requirements of the LLP Policy and Framework and the regulatory requirements that apply to the commodity they are importing.

    - 7.2 When it has been determined that imported grain does not meet Canadian requirements, the CFIA will determine whether enforcement action is required. In order to determine if enforcement action is required, the principles of measurement uncertainty will be applied to the raw test results when they are interpreted. When enforcement action is required, the CFIA will select the appropriate response for the incident based on the gravity of the situation and considering factors such as the potential or actual harm and the compliance history of the regulated party.

    - 7.3 Enforcement action will **not** be taken when:
        1. the LLP does not exceed the Action Level 0.1% or 0.2; or
        2. when applicable, the LLP does not exceed the Threshold Level; and
        3. the LLP does not compromise the safety of food, feed, or the environment.
    - 7.4 Enforcement action will be taken when:
        1. the LLP exceeds the Action Level 0.1% or 0.2% or, when applicable, the Threshold Level; or

[13] RG-1 Regulatory Guidance: Feed Registration Procedures and Labelling Standards, Chapter 2 - Data Requirements for Single Ingredient Approval and Feed Registration.

2. regardless of the level of LLP, there is reason to believe that the unauthorized crop could compromise the safety of food, feed, or the environment.

- 7.5 Upon analysis of a sample, the following responses will be implemented to improve awareness about and encourage compliance with requirements related to LLP:
    1. Where LLP is detected in imported grain and the circumstances are consistent with the risk management approach outlined in the LLP Policy, a letter with the detection results will be issued to the importer. The letter will summarize the results of the analysis and provide information about the LLP Policy and Framework, as well as information about the approval process for GM products in Canada.
    2. Where an unauthorized GM crop is detected in imported grain and the circumstances are **not** consistent with the risk management approach outlined in the LLP Policy, a letter will be issued to the importer that will:
        1. summarize the issue;
        2. outline the measures that must be taken by the importer to comply with regulatory requirements;
        3. provide information about the LLP Policy and Framework; and
        4. provide information about the approval process for GM crops in Canada.

Glossary

For the purposes of the proposed Policy and Framework the following terms are defined as follows:

Adventitious Presence: Adventitious presence is defined as the unintended presence of research or "pre-commercial" or otherwise unauthorized material which has not been assessed for food or feed use and unconfined environmental release in any country.

Codex Alimentarius: The Codex Alimentarius Commission, established by the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) in 1963 develops harmonized international food standards, guidelines and codes of practice to protect the health of the consumers and ensure fair trade practices in the food trade.

Codex Alimentarius Commission: The Commission promotes coordination of all food standards work undertaken by international governmental and non-governmental organizations.

Codex Guidelines: The Codex Guidelines refers to the "Codex Guideline for the Food Safety Assessment of Foods derived from Recombinant-DNA plants". The Guideline describes the recommended approach to making safety assessments of foods derived from recombinant-DNA plants where a conventional counterpart exists, and identifies the data and information that are generally applicable to making such assessments. This guideline does not address animal feed (or animals fed with the feed) and does not address environmental risks.

Codex Guidelines - Annex 3 on LLP: The Annex describes the approach to the food safety assessment in situations of low-level presence of recombinant-DNA plant material or in advance of or preparation for such potential circumstances. This Annex also describes data

and information sharing mechanisms to facilitate utilization of the Annex and to determine whether it should apply.

Food: Food includes any article manufactured, sold or represented for use as food or drink for human beings, and any ingredient that may be mixed with food for any purpose whatever.

Feed: Feeds are any substance or mixture of substances manufactured, sold or represented for use for consumption by livestock. Only approved ingredients may be used as livestock feed. The list of approved ingredients can be found in Schedules IV and V of the *Feeds Regulations*. Included in the definition of feed are "novel feeds".

Grain: Grain is seed of cereal, oilseed, pulse or other field crops that is used in whole or in part for human food or livestock feed, either produced in Canada or imported into Canada.

Novel Feed: According to Canada's *Feeds Act* and Regulations, a novel livestock feed is composed of or derived from micro-organisms, plants or animal sources that

1. are not approved as livestock feed in Canada (not listed in Schedule IV or V of the *Feeds Regulations*) and/or
2. contain a novel trait. A novel trait is an intentional genetic change that results in a feed that is not deemed equivalent in terms of use and safety to a similar feed set out in Schedules IV or V of the *Feeds Regulations*.

Novel Food: According to Canada's *Food and Drugs Act* and Regulations, novel food means:

1. a substance, including a microorganism, that does not have a history of safe use as a food;
2. a food that has been manufactured, prepared, preserved or packaged by a process that
    1. has not been previously applied to that food, and
    2. causes the food to undergo a major change; and
3. a food that is derived from a plant, animal or microorganism that has been genetically modified such that
    1. the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism,
    2. the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or
    3. one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism.

Plant with a Novel Trait: A plant with a novel trait is a plant that contains a trait which is both new to the Canadian environment and has the potential to affect the specific use and safety of the plant with respect to the environment and human health. These traits can be introduced using biotechnology, mutagenesis, or conventional breeding techniques.

Processed Products: Processed products mean products intended for food or feed, which have been physically or chemically transformed from a raw agricultural commodity or agri-based ingredients. This definition does not include agricultural products which have simply been harvested, cleaned, sorted, graded and packaged.

Risk Assessment: Risk assessment is a process that involves determining the likelihood that a specific adverse effect may cause to the environment, livestock or human health following exposure to a particular agent. Risk assessment includes four tasks: hazard identification, hazard characterization, exposure assessment, and risk characterization (a summary and integration of the previous tasks). A risk assessment for a LLP occurrence, on the other hand, aims to identify potential hazards and potential routes of exposure and rely on information available at the time, focusing on data pertaining to allergenicity and toxicity of the product, amongst other factors, with the end goal of providing an opinion regarding the likelihood of an adverse effect on health or the environment.

Risk Management: Risk management is a term used to collectively describe the activities and considerations involved in addressing, and communicating information about risks to the environment, livestock and human health. Risk management includes a number of inter-related activities: identifying and analyzing options for addressing the risk, developing and implementing a strategy for managing the risk, monitoring and evaluating the effectiveness of the strategy, and communicating information both about the risk and about the decision-making process.

Safety Assessment: In contrast to a risk assessment, a safety assessment is meant to establish the safety of a product, or the relative safety of a product in comparison to another similar product which is deemed "safe", with the end goal of determining if a product should be allowed or not for commercial release. In the food and feed context, it is often performed using a comparative approach. In a safety assessment, specific 'points to consider' are taken into account in the assessment of hazard and exposure depending on the type of commodity being assessed. The outcome of a safety assessment influences the decision to authorize the product. An authorization indicates that the novel product, including one derived through biotechnology, is as safe and nutritious as its conventional counterpart and therefore can be similarly released and handled.

Stakeholder: A stakeholder is an individual, group, or organization who may be affected by or otherwise interested in a decision or policy.

5. Appendix B: LLP Frequently Asked Questions

1. What is low-level presence (LLP)?

LLP is the unintended presence, at low levels, of unauthorized GM crops in imported food or feed where the GM crop is authorized in one or more countries but not in Canada.

2. What conditions must be met for a GM content of an imported shipment to be considered low-level presence in the proposed LLP Policy and Framework?

Two conditions must be met for a GM content of an imported shipment to be considered LLP under this proposed Policy and Framework: (a) the GM crop must be approved for food in at least one country and (b) Canada must recognize that the foreign safety assessment is consistent with the Codex Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Plants (ALINORM 03/34 Appendix III).

3. How does LLP originate?

LLP situations can occur when there is a time gap in the authorization of GM crops between the importing and exporting countries, or when developers fail to seek authorizations in importing countries. Sources of LLP can vary, including lingering traces of discontinued varieties present in export streams, or unintentional mixing into export streams of crops intended for domestic use.

4. Is LLP avoidable?

In many countries, including Canada, grain is handled in bulk with grain storage, treatment facilities and conveyances such as trucks, railcars and ships being used for different loads at different times. This provides many opportunities for crops to commingle during transportation, conditioning and storage.

Although most GM crops entering Canada have been fully authorized prior to commercial use, the risk of LLP exists for imported products. An increasing number of GM crops are being developed around the world for domestic use only. In certain circumstances, it may be too expensive to pursue authorizations in other countries and developers may choose authorization of their GM products for that country only. If these authorizations were not sought in Canada, this will likely result in the occurrence of LLP in imported products into Canada.

5. What is the potential for LLP to enter Canada through imports?

Currently, the potential for LLP to enter Canada through imports is low. The vast majority of GM crops that are likely to be found in international trade have already undergone safety assessments by Health Canada and the Canadian Food Inspection Agency, and

have been authorized for use in Canada. However, the likelihood of LLP in Canadian imports is expected to increase as other countries develop more and more GM crops intended for domestic use

A 2009 report from the European Commission Joint Research Council 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 are not intended for exports, so there may be little incentive to pursue authorizations in other countries. However, these products could commingle with exports destined for Canada and therefore, the likelihood for LLP to enter the country is expected to increase in the future.

6. What is the difference between adventitious presence and LLP?

For the purpose of this Policy and Framework, adventitious presence is defined as the unintended presence of research or "pre-commercial", or otherwise unauthorized material which has not been assessed for food or feed use and unconfined environmental release in any country. Therefore, and contrary to the situation with LLP, a product found to contain any level of adventitious presence would be subject to immediate actions by the Canadian Food Inspection Agency, including border controls.

7. Why was a review of the current LLP Policy necessary?

With the increasing number of GM products being developed globally for commercial production, appropriate approaches are required to manage the increased likelihood of LLP situations. As such, Canada needs to put in place a transparent and predictable LLP Policy and Framework that keeps food, feed and the environment safe while not unnecessarily impeding innovation and trade.

Many countries enforce a zero-tolerance policy for unapproved GM crops, including those that have been deemed to be safe through a comprehensive safety assessment in another country. Therefore, if trace amounts of such an unapproved GM crop are found in import shipments, in a country where that GM crop is not approved, these imports may be rejected. This creates unpredictability and could have negative economic impacts on global trade, including incremental costs associated with the use of segregation systems that can extend into downstream industries. In recent years, some trade disruptions related to LLP have cost grain traders and local economies millions of dollars, in spite of the absence of concerns about the safety of GM crops for food, feed or the environment.

8. What impact will the proposed LLP Policy and Framework have on food, feed and environmental safety?

None. Protecting food, feed and environmental safety is a high priority for the Government of Canada. The proposed Policy and Framework will maintain our high standards for food, feed and environmental safety.

9. What is Canada's current approach to manage LLP?

The presence of an unapproved GM product, including LLP, constitutes non-compliance with current Canadian legislation. This triggers a risk assessment and risk management response to bring the situation back into compliance. The Canadian Food Inspection Agency (CFIA) has the flexibility to select the appropriate response based on the gravity of the non-compliance, considering factors such as the potential or actual harm, the compliance history of the regulated party and the intent.

Please visit the CFIA website for more information on the CFIA's Policy on Managing Cases of Non-compliance of Unauthorized Plant Products Derived through Biotechnology.

10. How did the Government of Canada arrive at the proposed LLP Policy and Framework?

In 2009, Canadian government officials established a working group to examine how Canada manages the occurrence of LLP and to explore whether alternative approaches should be considered. For any approach to be considered, it would need to continue to protect the health and safety of Canadians, animal health and the environment, while helping to provide greater trade predictability.

The working group is co-chaired by Agriculture and Agri-Food Canada and the Canadian Food Inspection Agency. Members include representatives from the Canadian Grain Commission, Foreign Affairs and International Trade Canada, Environment Canada, and Health Canada.

To understand the broad nature of this issue and to help to ensure that the proposed Policy and Framework meet the needs of all stakeholders, the government sought input and views in the fall of 2011 on various proposed approaches to manage LLP in imports. The feedback was used to inform the current proposal.

11. What considerations are being used to evaluate the current and proposed LLP Policy and Framework?

The following considerations are being used in the review of the proposed LLP Policy and Framework: (a) the safety of food, feed and the environment; (b) the scientific basis of the approach; (c) the promotion of and incentive for compliance with Canada's regulatory system for GM products; (d) minimization of unnecessary trade disruptions; (e) potential impact of imported LLP on exports from Canada; (f) administrative efficiency, transparency and predictability; (g) the facilitation of agricultural innovation; and (h) consistency with international guidance on LLP, as appropriate, such as the Codex Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Plants, and advice of the working groups of the Food and Agriculture Organization of the United Nations (FAO) and the Organisation for Economic Co-operation and Development (OECD).

The review focuses only on the treatment of LLP in imports and it does not pertain to the adventitious presence of a GM crop. In addition to this, the review does not include seed intended for sowing or address issues regarding other products derived through biotechnology such as GM crops developed solely for industrial purposes, GM fruits and vegetables, or GM animals or microorganisms.

12. What is the difference between safety assessment and risk assessment?

A key difference between "safety assessments" and "risk assessments" is determined by the situations where these processes are used. Safety assessments are aimed at considering products for full regulatory authorization and commercialization, while risk assessments address specific instances when unauthorized products are found in the Canadian environment or marketplace.

The outcome of a safety assessment influences a decision to authorize the product. An authorization typically indicates that the novel product, including those derived through biotechnology, is as safe and nutritious as its conventional counterpart and therefore can be similarly released and handled.

A risk assessment does not result in the authorization of a product. It aims to determine the level of risk a non-compliant situation may pose. In addition, its outcomes are considered when determining what risk management options are appropriate.

Because the questions asked in risk and safety assessments are different, the types of information required may be different. For example, a food safety assessment considers the potential for a novel food to replace traditional counterparts and, therefore, requires nutritional data for a novel food to be authorized. A risk assessment would not typically consider nutritional content if the presence of an unauthorized product in the marketplace is deemed to be at a low level. However, it may use available nutritional content data to characterize the product.

13. Why is the Codex Guideline referenced as the basis for the proposed Policy and Framework?

Standards developed by the Codex Alimentarius Commision are based on the best available science assisted by independent international risk assessment bodies or ad-hoc consultations organized by FAO and WHO. While recommended for voluntary application by member countries (such as Canada), Codex standards serve in many cases as a basis for national legislation and regulations.

In 2003, the Commission adopted the Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Plants (ALINORM 03/34 Appendix III). This guidance provides a robust, science-based and internationally recognized approach to assess the safety of GM foods. Canada, as well as many other countries, has based their own guidance for GM foods on the Codex Guideline.

As such, for the intent of this proposed Policy and Framework, Canada will only consider GM crops from countries which apply the Codex Guideline on a consistent basis in order to be assured that the products covered by this Policy and Framework have been assessed adequately and determined to be safe for use as human food. It should be noted that this Guideline does not address animal or environmental considerations.

14. Why is seed excluded from the scope of the proposed LLP Policy and Framework?

During the fall of 2011, the Government consulted a targeted group of stakeholders on a suite of three (3) proposed approaches for the management of LLP in imports. Complexities regarding the management of LLP in seed were identified in the consultation and resulted in a decision to have the proposed LLP Policy and Framework apply only to food and feed, with a review of LLP approaches for seed done separately.

LLP in seed is a challenge to the seed trade. There is international agreement on the need to work collaboratively to address this issue in order to determine how a risk assessment would be conducted for LLP in seed for propagation. The Government of Canada is committed to actively work with stakeholders and other countries to find a workable solution to manage LLP in seed.

If LLP of a GM crop is detected in seed, the current approach will continue to apply.

15. What considerations were used to arrive at the proposed Action Level values of 0.1% or 0.2%?

The considerations for selecting these Action Level concentration values include: minimizing to the extent possible the safety risks posed by LLP in grain; current detection technologies and internationally accepted methodologies to detect GM material in crops; and the practical challenges of quantifying the level of a GM crop present in monitoring samples.

Given that the GM crop has been approved for human consumption in another country that follows the same Codex safety assessment Guidelines as Canada, neither the 0.1% nor the 0.2% LLP exposure level is considered likely to pose a risk. In addition, the detection of 0.1% GM material in grain aligns with the capabilities of detection technologies, and is consistent with published, international GM detection methodologies. However, it is also recognized by the scientific community that detection of a GM crop is technically challenging even under ideal laboratory testing conditions. Therefore, a slightly higher level of 0.2% is proposed as an option to take into consideration the practical ability to detect and quantify LLP concentration in monitoring samples.

Enforcement action would be taken only if a sample test result exceeded the Action Level. In order to determine this, measurement uncertainty would be taken into account when interpreting the raw test result.

16. Why are the Threshold Levels set on a crop-specific basis in the proposed Policy and Framework?

The Threshold Level component of the LLP Policy and Framework addresses unavoidable, trace commingling that can occur during agricultural production and commodity trade. Given that small amounts of unintentional and unavoidable commingling can occur during crop transportation, bulk handling, conditioning, and storage, even when best management handling practices are followed, a risk management measure that recognizes LLP at up to this level would minimize trade disruptions. To determine an appropriate value for the Threshold Level, factors that contribute to commingling such as the biology of the crop (e.g. out-crossing), crop production, and grain handling will need to be considered.

Since these factors will vary for different crop types, it is proposed that a value for the Threshold Level would be set for each specific crop type. The crop specific Threshold Level values will be recommended by an Expert Advisory Committee(s). While the Threshold Level values will be set for individual crop types, Canadian risk assessments for GM crops must be completed for the Threshold Level value to apply. In other words, a GM crop would be allowed to be present in imported grain at up to the crop Threshold Level only after a Canadian risk assessment has been completed for the GM crop and determined that it does not pose a risk. When combined with risk assessments, the crop-specific Threshold Levels will provide a stable, predictable LLP level for importers, while protecting the safety of humans, animals and the environment in Canada.

17. What impact will the proposed LLP Policy and Framework have on the current authorization process for GM crops in Canada?

The proposed LLP Policy and Framework will not change the Canadian authorization 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 LLP because the products will have been assessed and decisions regarding authorization will have been made.

18. Will the proposed LLP Policy and Framework affect the rules for certification of organic products in Canada?

The proposed LLP Policy and Framework is not intended to supersede organic practices or to alter the requirements for organic certification. The Canadian Organic Products Regulations and Standards, which came into force on June 1, 2009, prohibit the use of GM ingredients in organic products, regardless of whether those GM ingredients are authorized.

Canadian organic farmers and food producers use a range of management practices to avoid the use of prohibited ingredients, including those which are genetically modified. 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.

19. What policies do our key trading partners have in place to deal with LLP?

Canada's trading partners have differing levels of acceptance of products of agricultural biotechnology and, as a result, react differently to the occurrence of LLP. Some markets have strict zero tolerance policies, others employ tolerance thresholds with varying conditions and still others have no established policy or are in the process of developing one.

20. How is Canada engaging the international community in resolving the issue of LLP?

Canada continues to advocate for further international guidance on the management of LLP and encourages countries to develop domestic LLP policies that are aligned with other countries' policies and regulations. Canada is also leading the international process on LLP where a group of countries with interest in the issue are working together to develop international approaches designed to facilitate the global management of LLP.