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

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Canada

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Background

i. 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.

ii. 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).

iii. 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.

iv. 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:

    a. the authorization of the non-compliant product for food, feed and environmental release in Canada; or,
    b. the removal of the non-compliant product from Canada.

v. 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.

vi. 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.

vii. 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.

viii. 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 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. Objective(s)

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:

1. seed intended for propagation in the environment;
2. GM fruits and vegetables;
3. 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;
4. genetically modified animals and microorganisms;
5. other GM crops modified to produce plant-made pharmaceutical or industrial products unless approved for food and feed use; and,
6. 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:

1. 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.

2. 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[1], 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:

[1]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

1. ensuring that products imported into Canada comply with relevant requirements;
2. 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,
3. 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.

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:
http://www.inspection.gc.ca/plants/plants-with-novel-traits/applicants/non-compliance/fact-sheet/eng/1338518900639/1338519150701

11.2 Guideline For The Conduct Of Food Safety Assessment Of Foods Produced Using Recombinant-DNA Plants (ALINORM 03/34 Appendix III):
http://www.codexalimentarius.org/download/standards/10021/CXG_045e.pdf

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*[2] 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.

a. 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.

b. 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

[2] Compliance and Enforcement Operational Policy - http://www.inspection.gc.ca/english/agen/transp/comp/pole.shtml

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:

a. when LLP is detected at concentrations over the Action Level and the Threshold Level does not apply; or
b. when the GM crop(s) is present at a level greater than the applicable Threshold Level; or
c. 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.

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:

a. 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

b. 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%][3] total concentration of LLP in imported grain for use in or as food or feed.

4.3 Enforcement action will not be taken when:

a. 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

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

b. 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.[4]

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:

a. 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
b. 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.[3]

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.

[4] 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.

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 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*[5], and the anticipated fee, if a fee has been set[6].

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

[5] 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.

[6] 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 - www.inspection.gc.ca/english/agen/manges/polrec/polrece.shtml

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 information outlined in the CFIA's *Guidelines for the Assessment of Novel Feeds*[7].

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] RG-1 Regulatory Guidance: Feed Registration Procedures and Labelling Standards, Chapter 2 - Data Requirements for Single Ingredient Approval and Feed Registration - http://www.inspection.gc.ca/english/anima/feebet/regdir/sect2_6e.shtml

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:

a. the LLP does not exceed the Action Level [0.1% or 0.2]; or
b. when applicable, the LLP does not exceed the Threshold Level; and
c. the LLP does not compromise the safety of food, feed, or the environment.

7.4 Enforcement action will be taken when:

a. The LLP exceeds the Action Level [0.1% or 0.2%] or, when applicable, the Threshold Level; or
b. 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:

a. 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.

b. 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:
   i. summarize the issue;

ii. outline the measures that must be taken by the importer to comply with regulatory requirements;
iii. provide information about the LLP Policy and Framework; and
iv. provide information about the approval process for GM crops in Canada.

Appendix 1: 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 (a) are not approved as livestock feed in Canada (not listed in Schedule IV or V of the *Feeds Regulations*) and/or (b) 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: (a) a substance, including a microorganism, that does not have a history of safe use as a food; (b) a food that has been manufactured, prepared, preserved or packaged by a process that (i) has not been previously applied to that food, and (ii) causes the food to undergo a major change; and (c) a food that is derived from a plant, animal or microorganism that has been genetically modified such that (i) the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism, (ii) the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or (iii) 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.

Appendix 2: Elements for the Management of LLP in Grain