GRAIN TRADE AUSTRALIA

Grain Trade Australia Limited
PO Box R1829 Royal Exchange NSW 1225
Phone: +61 2 9235 2155 Fax: +61 2 9235 0194
Email: admin@graintrade.org.au Web: www.graintrade.org.au

30 August 2013

Ms Christie Downard
Assistant Director | Productivity & Food Security Unit
Department of Agriculture, Fisheries and Forestry
GPO Box 858
Canberra ACT 2601

Dear Ms Downard,

Re: Low-Level Presence (LLP) Risk Management Polices for Transboundary Movements of Grains and Grain Products for Food, Feed or Processing

Thank you for the recent opportunity to brief DAFF and the related agencies being Food Standards Australia New Zealand and the Office of the Gene Technology Regulator on the forthcoming Global LLP Initiative to be held in South Africa.

As discussed, the attached document details the position of the members of Grain Trade Australia in relation to the development of LLP Risk Management Polices for Transboundary Movements of Grains and Grain Products for Food, Feed or Processing.

GTA believes this document would be an excellent base for the development of policy for the Australian Government.

Although the Australian production of GM grain is relatively small, the global policies that are currently being developed will impact on future GM events and the ability to trade them when they are commercialised in Australia.

About Grain Trade Australia
Grain Trade Australia (GTA) is the focal point for the commercial grains industry within Australia. It facilitates trade and works to provide an efficient, equitable and open trading environment by providing leadership, advocacy and commercial services to the Australian grain value chain.

GTA members are responsible for over 95% of all grain storage and freight movements made each year in Australia. Over 95% of the grain contracts executed in Australia each year refer to GTA grain standards and/or trade rules.

GTA members are drawn from all sectors of the grain value chain from production to domestic end users and exporters. GTA members are involved in grain trading activities, grain storage, human and stock feed milling.

Thank you for consideration of this submission.

Geoff Honey

Chief Executive Officer

International Grain Trade Coalition Discussion Paper

Low-Level Presence (LLP) Risk Management Polices for Transboundary Movements of Grains and Grain Products for Food, Feed or Processing

Highlights of Discussion Paper

The International Grain Trade Coalition (IGTC) urges importing governments to adopt policies immediately to minimize trade disruptions resulting from Low Level Presence (LLP) of GM in imported agricultural products currently threatening importing and exporting countries alike and global food security in general.

Any policy to minimize trade disruptions resulting from LLP of GM in imported agricultural products has to:

- provide for human, animal and environmental safety in all circumstances as well as be practical and facilitate the trade;
- be scientifically based and internationally consistent by being in line with international food standards from organisations like the Codex Alimentarius;
- encourage importing and exporting governments to work together to improve harmonization of GM policies and synchronization of GM events approvals;
- minimize disruptions of the market by being in line with the reality of the international grain bulk handing and transportation systems as well as food and feed manufacturing processes;
- ensure the viability of the supply of raw materials at sustainable and affordable prices in the country of import and provide legal certainty for the food and feed business operators;
- require biotech developers, producers and subsequent holders to be fully responsible for the commercial activities under their respective remit. However, under no circumstances should the responsibility of the biotech developer in managing the GM event presence and related risk of market disruption be shifted to the producers and subsequent holders.

The importing governments can meet the above mentioned objectives for the management of the potential risk associated with LLP through several policy options:

- **Policies for the elimination of LLP**: the full synchronization of event approvals and the full recognition of other government(s) risk assessment systems eliminate the possibility of LLP by having all events approved in both exporting and importing countries simultaneously. These options are the most effective ways of reducing trade disruptions due to LLP. However, while there is an immediate need to address the risk to trade arising from LLP, full synchronization and recognition are difficult to achieve and implement by importing countries (see section 3);
- **Policies for the management of LLP**: If the risk cannot be eliminated in the short term by synchronization of event approvals and full recognition of risk assessments by other governments, governments have to adopt other options to immediately reduce and manage the risk created by LLP trade disruptions. Proactive domestic risk assessment/risk management policies and proactive international risk assessment processes for LLP are options which are easier and faster to implement by importing governments (see section 2).

1. Definitions

For the purpose of this initiative, the following definitions apply:

- **Low-Level Presence (LLP)**: "low levels of recombinant DNA plant materials that have passed a food safety assessment according to the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003) in one or more countries, but may on occasion be present in food in importing countries in which the food safety of the relevant recombinant-DNA plants has not been determined[1]"
- **LLP from asynchronous approval:** "may occur when the country of export has already approved a GM event for cultivation, while the country of import is in the process of authorizing it"
- **LLP from isolated foreign approval (often described as asymmetric approval):** "may occur when the country of export approves a GM event for commercial production and in the country of import no submission for the approval is sought by the developer of the event or in which an approval is not to be granted for reasons falling outside food safety".
- **LLP from discontinued event:** "may occur when the approval of the GM event expires and the technology developer does not submit an application for the continuation of the approval".
- **Adventitious Presence (AP) of research events (often described as "field escape")**: "AP refers to the unintentional presence of GMOs that have never been authorized in any country on the basis of the Codex international guidelines for food plant safety assessment".

2. Policies for the management of LLP

There are several effective policy options available to the importing country to manage LLP that employ proactive domestic risk assessment/risk management and proactive international risk assessment processes **Even when the country of import is attempting to synchronize its approval system these options should be undertaken to provide protection if synchronization fails and an event is commercialized in an exporting country before domestic approval**.

While each importing country has to put in place its own domestic LLP risk management policy, the LLP risk assessment portion can either be done domestically by each importing country or globally by an impartial and internationally recognised organization, such as the Food and Agriculture Organization of the United Nations (FAO). The domestic LLP Risk Assessment is a very time consuming, resource rich and expensive option. As a result this option may not be available to all countries. The option of an international LLP risk assessment process tries to overcome this problem by removing the need for each country to develop its own risk assessment capacity.

2.1 Scope of the policy

Any policy for the management of LLP shall:

- apply to all agricultural products for use in food, feed and further processing;

Although the LLP definition refers specifically to food safety, LLP policies must apply to both food and feed. Nearly all crops are produced for food, feed and for processing. History confirms that split approvals create a recipe for costly trade disruptions. Feed LLP risk assessments can be undertaken on a

[1] International Statement on Low Level Presence Policy singed by Australia, Argentina, Brazil, Canada, Chile, Costa Rica, Mexico, Paraguay, Philippines, Russia, United States, Uruguay and Vietnam in 2012,

case by case basis, recognizing that the event is present at very low levels. While separate risk assessments may be performed for food and feed, final LLP risk management policies adopted by governments must apply to both food and feed:

- cover LLP of GM events approved for commercial use on the basis of the Codex based food plant safety assessment in at least one exporting country and for which the LLP determination of no adverse effects to consumers' and animal health on the basis of the Codex based food LLP safety assessment has been recognized by the importing country;
- not cover AP of GM events that have never been approved in any country on the basis of the Codex based food plant safety assessment.

Without synchronous approvals or recognition of another country's plant risk assessment, the safety of human and animal health can best be achieved by limiting the scope of the policy to include only those events that have passed a Codex based risk assessment in one or more countries but have not been approved in the country of import. There is a significant difference in risk to human and animal health between an event that has never undergone a risk assessment and an event that has passed a Codex based scientific risk assessment and has been determined to be of minimal risk to human health at 100% exposure.

- consist of two elements, namely: LLP risk assessment and LLP risk management.

LLP risk assessments must be science based to ensure that the event is safe to human and animal health. Once safety is established, LLP risk management policies must be adopted by the governments. These measures must include commercial feasibility to minimize food and feed price increases in importing countries.

2.2 LLP domestic risk assessment phase

Some importing governments may wish to have their competent authority conduct a Codex based LLP risk assessment on the event at the low level established for the country. Only events that pass Codex LLP food safety assessments should be eligible to enter the country at the established low level, unless the importing government has decided to recognize the risk assessments of other countries up to the established low level.

Any domestic risk assessment phase shall:

- determine if the GM event is approved in at least one country in accordance with the food safety assessment of the Codex plant guideline, i.e. Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003). The importing country will refer to information on GM approvals as provided by exporting countries as well as national and international databases that house this information such as the FAO database[2];
- require technology providers to submit an LLP data package for the GM events eligible to be covered by the LLP policy as prescribed by the Codex guideline for food LLP safety assessment;
- conduct an LLP risk assessment on the GM event based on the Codex LLP safety Assessment Annex guidelines, i.e. Codex guideline for the conduct of food safety assessment in situations of

low-level presence of recombinant-dna plant material in food[2]; (Not required if importing government has decided to recognise the risk assessments of other countries up to the LLP threshold level established.)

- posts on the competent authority(s) web page(s) all GM events for which the LLP approval has been granted;

On 1st July 2008, Codex adopted Annex 3 of the "Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants CAC/GL 45-2003". The Annex provided guidelines to importing governments on how to perform LLP food safety assessments on products that had already been determined to be safe by one or more countries employing the Codex Plant Guideline but had not yet been authorized in the importing country. The Codex guideline outlines the information required by importing governments to perform the food LLP safety assessment. This includes information of the GM events approved in each country as well as information on safety assessment, detection method protocols and reference material.

The following actions should be undertaken by the FAO and exporting and importing governments to facilitate the implementation of the domestic risk assessment:

- **work with the FAO to operationalize FAO's web site "International Portal on Food Safety, Animal and Plant Health (IPFSAPH)" to become the central information source for events intended to be commercialized for food, feed or for processing.** The data base must contain:
  - risk assessment information for each event and if intellectual property rights are involved, the name and contact information where necessary information can be obtained;
  - list of GM events approved for food, feed and for processing and for LLP in each country .

2.3 LLP international risk assessment phase

The option of the international risk assessment removes the need for each country to develop its own risk assessment capacity. If this option is chosen, the performing of the risk assessment will be done by an impartial and internationally recognised organization, such as the FAO, instead of the single competent authorities of the importing country.

Exporting and importing Governments need to take the following actions toward the establishment of the international risk assessment phase:

- **Explore with FAO the possibility of creating an international process to confirm that events that have been assessed in one or more countries using a Codex Plant Guideline risk assessment process are of minimal risk to human and animal health at a low level:**
  - The international process could involve FAO, Codex Alimentarius and WHO;
  - The process would use the information already being sent to FAO by exporting and importing governments and/or technology developers as required by the Codex LLP Annex;
  - The process would be proactive with an objective of having LLP decisions taken within 6 months of the event's first approval.
- **Countries commercializing events should provide dedicated funding to FAO to insure that the international risk assessment process has sufficient resources to meet the demand.**

[2] www.codexalimentarius.net/input/download/.../CXG_045e.pdf

2.4 LLP risk management phase

Any risk management phase has to foresee the adoption and implementation of risk management measures from the importing government as well as from the industry. Only the implementation of effective measures from both the importing government and the industry will result in an effective LLP policy able to minimize trade disruptions resulting from LLP of GM in imported agricultural products.

Any risk management phase shall:

- **provide for different approaches as determined by the number of LLP sources required by following a process-based approval for LLP of GM events. While the priority should be given to the management of "asynchronous approval", LLP from the other sources should also be addressed by the policy**:
    - LLP from "asynchronous approval": the LLP approval should ultimately be replaced by a full approval by the competent authority in the country of import. The policy should provide for an interim LLP approval intended to bridge the time gap between the Codex LLP determination of no adverse impacts and the full approval of the GM event by the competent authority in the country of import;
    - LLP from "asymmetric approval": the policy approach should provide for an open-ended LLP approval to the GM event for which the biotech developer does not seek a full approval or in which an approval has not being granted due to non-scientific reasons. The policy should provide an-open ended LLP approval intended to bridge the time gap between the Codex LLP determination of no adverse impacts and the full disappearance of the GM event in the commercial channels;
    - LLP from "discontinued GM event": the LLP approval should last until the complete disappearance of the GM event in commercial channels. The policy should provide for an interim LLP approval intended to bridge the time gap between the expiring of the approval and its full disappearance in commercial channels.

LLP policies have to address potential LLP from each of the major causes creating LLP trade disruptions in order to minimize potential food and feed price increases in importing countries. The food safety of the event has been assured by limiting scope to those events that have passed a complete Codex based food safety assessment in one or more countries and the event has passed a Codex based LLP food safety risk assessment performed by the importing country's competent authority at the established low level. In the case of discontinued events, the event has also passed a food safety assessment in the country of import prior to expiry of the approval.

- **provide for automatic minimus level for all events commercialized by a country that employs Codex based risk assessment processes to apply to both food and feed**:
    - Di minimus level must be set to ensure consistency of results among different laboratories and to prevent cross contamination among commodities caused by LLP in dust particles. It must also take into account levels of uncertainty in both laboratories and bulk sampling;
    - Di minimus level is temporary and it must be used in conjunction with the LLP threshold level. It is removed as soon as the importing government has completed the Codex based LLP risk assessment to determine that the event is eligible for the LLP threshold.
    - no action would be taken on shipments at or below di minimus level by the control authorities of the country of import;

- Di Minimus levels are not necessary if the importing government decides to recognize the risk assessments of other countries up to the LLP threshold level established.

- **provide for a 5% LLP marketing threshold level for all GM events which have passed the Codex based LLP risk assessment. The LLP threshold has to be** :
  - internationally consistent, commercially practical and achievable;
  - temporary, i.e. applicable from the date the competent authority in the importing country recognizes that the LLP of the GM event does not have any adverse effects to consumers and animal health at the established threshold level and until the LLP situation ceases to exist.

- **ensure that control authorities recognise the low safety risk associated with GM events which have passed the Codex LLP risk assessment in the importing country. Only low frequency monitoring is required:**
  - If shipments are detected above the established LLP threshold, recognizing laboratory and bulk sampling levels of uncertainty, governments should contact the technology developer of the event to modify the LLP Stewardship Program, if necessary, to bring shipments back into compliance;
  - In taking actions to bring shipments into compliance governments must recognize the low risk associated with LLP and that LLP is a temporary measure while full risk assessments are being conducted.

With food safety concerns addressed, governments must ensure that LLP policies do not create unintentional increases in food and feed prices. LLP threshold levels established by the importing government will have significant impact on food and feed prices. Costs increase exponentially as thresholds decrease. International grain trade experience confirms that 5% threshold levels can be achieved with minimal cost impact within the global bulk handling and transportation system. Guillaume Gruere of the International Agricultural Trade Research Consortium in a paper presented in June 2009 on what LLP Policies would mean for APEC countries reported that "going from 0% to 5% would reduce total cost by over 70% in both the case of maize and soybeans."[3]

Environmental concerns should be of minimal consideration in establishing LLP threshold levels for products destined for food, feed or for processing. These products are not intended for introduction into the environment. Potential spills can be addressed through notification and clean-up to the satisfaction of competent authorities rather than reducing threshold levels and increasing food and feed prices to minimize environmental impact in case of a spill:

- **Be linked to the commitment of the public and private biotech developer to be fully responsible for the commercialization of the GM event. As such the biotech developer shall**:
  - accept full responsibility for the event during the event's life cycle, following the successful completion of the Codex based plant risk assessment in the country of export. This includes responsibility from the time the decision is taken to commercialize the event for seed to produce grain for food, feed or for processing in countries of origin to the time following discontinuation when final traces of the event fall below regulatory requirements in major markets;

[3] "Asynchronous Approvals of GM Products, Price Inflation, and the Codex Annex: What Low Level Presence Policy for APEC Countries?" by Guillaume P. Gruere of the International Agricultural Trade Research Consortium, June 2009

- seek LLP and full approvals for new events simultaneously in the importing countries, before there is a risk of the event appearing in international shipments. When events are discontinued, they have to ensure that the discontinued events continue to meet the regulatory requirements in place in major markets, while being placed in a specific LLP category;
- adopt Biotechnology Industry Organization's (BIO) 20012 Product Launch Stewardship Program of no commercialization of new modern biotechnology crop events until major market approvals are in place unless the product is in an LLP Stewardship Program employing channeling systems to be in compliance with the established LLP threshold in an importing country;

Most technology developers have adopted the BIO stewardship program to obtain approval in major markets before commercializing a new event. The Biotechnology Industry Association (BIO) recognized the adverse impact along the supply chain triggered by technology developers making a decision in countries of export to commercialize an event before approvals has been obtained in major markets. The BIO 2012 **Product Launch Stewardship Program** states "that individual companies, prior to commercialization of a new biotechnology-derived plant product in a Commodity Crop intended for food and feed, should meet applicable regulatory requirements in key countries identified in the trade assessment that have functioning regulatory systems and are likely to import commodities including the new biotechnology-derived plant products."

- develop and implement **LLP Stewardship Programs** employing delivery systems capable of being in compliance with established LLP threshold levels in importing countries. It should include:
  - contractual arrangements with producers and subsequent holders to be compliant with the risk management requirements necessary in the channeling system to operate within established LLP thresholds as well as a scheduled and strictly progressive introduction of new events into the market, accordingly with the LLP threshold;
  - a commitment to the LLP Stewardship Program involving delivery systems and the previously described control mechanisms to enable shipments to be in compliance with the importing country's established LLP threshold level.

Public and private technology developers have a significant role to play in managing LLP to minimize trade disruptions. In accepting this responsibility, public and private technology developers must consider to implement and adopt a LLP Stewardship Program to complement the Product Launch Stewardship Program. The development of LLP policies in importing countries triggers the need for public and private technology developers to take responsibility to develop and implement **LLP Stewardship Programs** to meet LLP threshold levels in importing countries. Technology developers must accept responsibility for LLP thresholds that would be attainable through LLP Stewardship Programs employing channeling systems. Technology developers must inform key stakeholders in major markets of plans to launch a product under an LLP stewardship plan. The adoption of LLP Stewardship Programs by technology developers would create benefits along the supply chain. Firstly producers and technology developers would benefit from early commercialization, rather than waiting to commercialize until approval is received in the last major market. LLP thresholds would be attainable through LLP Stewardship Programs using channeling systems and the related control and retention mechanisms. Importantly such an approach would enable normal commercial practices to be harnessed to manage LLP threshold levels. Developers would then enter into commercial contracts with producers and members of the grain industry to specify the requirements of each supply chain link necessary to be in compliance with the LLP Stewardship Program. This is critical not only for traders, but also further

processors who fear legitimately that competent authorities could do routine LLP checks while in their plants checking for food safety issues. If an event is detected above LLP thresholds, they would be out of compliance and yet would not have had anything to do with the LLP of the event in their inventory. Through an LLP Stewardship Program, the technology developer would have the responsibility to identify the problem and take whatever action may be necessary along the supply chain, to return to compliance through contract provisions within its LLP Stewardship Program.

- **ensure that the producers and subsequent holders of this technology are in compliance with the terms of technology developers' LLP Stewardship Programs in order to make sure shipments are in compliance with LLP thresholds in importing countries**.

3. Policies for the elimination of LLP

There are several policy options available to the importing country to eliminate the LLP risk: the full synchronization of event approvals and the full recognition of other government(s) risk assessment systems. While these options are the most effective ways of reducing trade disruptions due to LLP, they are not easily achieved as importing countries usually prefer to retain the sovereignty of their approval systems.

3.1 Fully Synchronized Approvals of Events

One of the most effective risk management tools available to governments to manage LLP is to synchronize approvals of new events. **If the approval process in importing countries is fully synchronized with the approval process employed in exporting countries, then no LLP trade disruptions will occur.**

The following actions are required to achieve synchronization of approvals:

- **exporting and importing governments must work together to improve synchronization potential by taking the following actions**:
  - work together to develop common approval data packages;
  - work together and exchange information during the risk assessment process;
  - recognize a portion of the risk assessment that they determine to be equivalent with their own analysis, such as animal health.
- **importing governments must examine their approval systems to ensure there are no unnecessary impediments that could create delays;**
- **technology developers must submit necessary approval data packages to major importers at the same time as data packages are submitted to exporters.**

3.2 Full Recognition of Risk Assessment Processes

Another effective policy option available to countries to avoid LLP trade disruptions is for governments to enter into bilateral or regional agreements with other governments to recognize equivalency in each country's Codex based risk assessment system. **This option would stop LLP from occurring as the events would be approved as soon as the first country approved the product.**

This alternative would be particularly attractive to developing countries that may not have the financial and human resources necessary to perform multiple risk assessments. The use of such policies to

manage GMO products could significantly reduce costs without reducing regulatory quality at a time when governments and industry are being pressured to reduce food costs.

The following actions are required to achieve recognition:

- **governments must examine thoroughly the Codex based risk assessment processes employed by the country(s) of interest to ensure that the risk assessment processes employed are equivalent to the risk assessment processes used in their own country;**
- **governments must post on the web page of their competent authority the names of the countries with recognition agreements in place.**

Recognition of equivalency of risk assessment processes can also be particularly attractive for countries that share common borders and / or handling and transportation facilities such as many African countries or have existing regional trade agreements such as Mercosur or NAFTA countries. In this specific case, an additional policy tool would be available, i.e. **LLP automatic threshold**:

- importing governments to recognize another government's risk assessment process up to a marketing LLP threshold to be established by the importing country;
- LLP threshold is temporary. It is removed as soon the full risk assessment has been completed by the country of import.

The IGTC has 22 members representing more than 8000 organizations involved in the international movement of grain operating in more than 80 countries.

The IGTC is an unincorporated coalition of national and international non-profit trade associations and councils whose purpose is to convene significant expertise and representation to provide advice to governments from a global perspective on the commercial requirements and economics of the world's food, feed and processing industries, including but not limited to implementation of the Cartagena Protocol on Biosafety.

The IGTC recognizes its existence is based on the goal of avoiding risks to global food security by minimizing disruptions in the international trade of grain, oilseeds, pulses and derived products.

To do so the IGTC endeavors to provide for the establishment of policies to provide for a regulatory environment supportive of such international trade.

For further information contact: Dennis Stephens, Secretary, International Grain Trade Coalition, Box 215, Oakbank, Manitoba, Canada, R0E 1J0; Phone: 1-204-955-2423; email: DennisStephens@mymts.net or dstephens@igtcglobal.com

16th July 2013