



**Making LLP The Highest Priority  
CSTA Policy and Potential Strategy  
March, 2010**

**The Issue for the Trade of Seed**

In November, 2000, Bill Leask wrote a well known paper called "The Trouble with Thresholds". In that paper he predicted that the unintended presence of trace levels of foreign materials and genetic off-types, including genetically modified material was going to become a very serious issue in the future.

Now, 10 years later, there is tremendous potential waiting in the seed technology pipeline.

The promise of new varieties that will not only continue to increase yield and productivity, but will deliver health benefits, improve food quality and help to reduce agriculture environmental footprint, means that there will be an increasing presence of genetically modified traits in production all around the world.

Trade of seed has been increasing steadily over the years. The value of seed exports from Canada regularly reaches over \$400 million to over 60 countries.

Given the scale of production, transportation and trade, even when multiple precautions are taken, it is generally agreed that it is impossible to ensure zero presence of GM traits in any shipment of seed. And, the predictions made in the "Trouble with Thresholds" paper are coming true. For example:

- Shipments of seed have been rejected when very low levels of GM material (ranging from whole seeds to broken seeds and dust) have been found.
- CSTA members regularly asked to sign documents to accompany shipments, guaranteeing a zero presence of GM
- Many international customers are requiring seed samples of almost all crop kinds so that the customer can test for the presence of GM material before a shipment is made.

As an early adopter of new technology, and a significant exporter, Canada is particularly vulnerable to the uncertainty around low level presence of GM material and as such, should play a leading role in the effort to address the issue.

## What is Required?

The most effective way to deal with the possibility of LLP in shipments of seed is to gain approvals of new traits in important destination markets, and CSTA's members are vigilant in their efforts to do so.

However, in order to minimize trade disruptions, a common international LLP policy must become a high priority for the Government of Canada.

The international LLP policy should:

1. Apply when a trait or event that is approved in one or more countries, but not in the country of import, is found.
2. Be flexible and international in scope, and should recognize safety assessments conducted by other countries, based on sound, internationally recognized science.
3. Be formally agreed at the international level and should commit signatories to following it.
4. Be based on risk. Risk management procedures, while the decision of the importing, should be related to the level of risk posed by the LLP.

## RISK ASSESSMENT

Begins with the acknowledgement that:

- Risk assessments are intended to determine the risk to consumers, livestock and the environment of unauthorized material.
- The process of risk assessment must be rigorous but flexible enough to adapt to the particulars of each case.
- In assessing risk, countries should recognize the risk assessments that have already been done, leading to approval by other countries.

### *Risk Assessment Process*

CSTA supports the processing for assessing risk that is currently used by Canada when unauthorized material is found. The risk assessment process is described below.

1. **Risk** is defined and assessed based on sound, internationally recognized science using two criteria: **Hazard and Exposure**.
  - a) **The hazard component considers the following:**
    - i. Does any characteristic of the product have the potential to cause harm to human health due to consumption? Scientific data that should be considered:
      - Data regarding any novel proteins expressed and the level of expression in tissue
      - Potential toxicity
      - Potential allergenicity
    - ii. Does any characteristic of the product have the potential to cause harm to the health of livestock due to consumption? The same scientific data should be considered.

- iii. Does any characteristic of the product have the potential to cause harm to the environment? Scientific data that should be considered:
    - potential to become a weed of agriculture or be invasive of natural habitats;
    - potential for gene-flow to wild relatives whose hybrid offspring may become more weedy or more invasive;
    - potential to become a plant pest;
    - potential impact on non-target species, including humans;
    - potential impact on biodiversity;
- b) The exposure component considers the following**
- i. Is there a potential exposure route for food, feed or the environment?
  - ii. What is the likelihood of each exposure pathway?
  - iii. How much of the product will enter the food or feed market, or the environment?

In conducting the risk assessment, the importing country should give recognition to the safety assessment process that led to approval of the material in other countries. In addition, other information could be considered:

- Product information from the developer
- Data generated by regulatory authorities
- Published scientific literature from internationally recognized sources

**Risk = hazard X exposure**, so if there is no route or a limited route for exposure the risk level would be reduced. Similarly if no hazard is identified regardless of the level of exposure, the risk would be reduced.

### **RISK MANAGEMENT**

The steps taken to manage the risk, once it is defined, would be the decision of the assessing country, but should reflect the risk determined.

CSTA believes that the following would serve the international seed trade well.

#### ***A Possible Risk Management Strategy for Seed***

Once it has been determined, through the internationally recognized risk assessment process, that the unapproved trait or event poses little or no risk to humans, livestock or the environment, it is no longer a health and safety issue in the importing country.

However, the LLP may be a quality issue, and in some countries could be a “need to know” or labeling issue. **Neither of these should be confused or communicated as issues of health and safety.**

For quality and labeling purposes, the international seed industry has operated for many years under an international trading scheme: *"The OECD Scheme for the Movement of Seed in International Trade."* 57 countries around the world participate in the OECD Seed Schemes, which include detailed requirements for acceptance criteria for varieties, categories of seed for certification, and standards for seed production and labeling. Canada's seed regulations and certification systems conform to the OECD Seed Schemes.

CSTA has been proposing that when an LLP issue is found to not be a health and safety issue, the requirements of the Seed Schemes could serve as the main component of a risk management process for quality and labeling purposes.

Imports containing LLP of an unapproved event would be “in compliance” with quality and labeling requirements if the level of the LLP is falls within (or is equivalent to) the standards for “off-types”, or “other crop kinds” and “inert material” found in the tables governing pedigreed seed. In other words, the “LLP thresholds” that would apply when the event or trait is found to not pose a risk to health and safety, would be equivalent to the existing quality and regulatory standards as specified for production pedigreed seed of conventional, non-GE seed under the Seeds Act and Regulations.

It is important to note that the event must still be submitted to the full approval process of the importing country before quantities could be imported at levels higher than LLP.