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LOW LEVEL/ADVENTITIOUS PRESENCE OF MATERIAL DERIVED FROM BIOTECHNOLOGY

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Low Level/Adventitious Presence refers to the unintended, incidental occurrence of trace levels of plant material or protein from crops developed through modern biotechnology in seed, grain, livestock feed or food as the result of natural, mechanical or human means. Without a policy and trace level safety assessment process, the standard or threshold for biotechnology-derived products has become zero or zero detection. This lack of policy and assessment process has negatively impacted seed, grain and food trade.

CSTA is committed to working with international industry and governmental organizations to address the issue of Low Level/Adventitious Presence to facilitate the international trade of seed.

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 for seed 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.
5. Be comprised of two components – risk assessment and risk management.

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

RISK MANAGEMENT

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

A 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.

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 strict, internationally recognized purity standards that have facilitated the international trade of seed all around the world. Where an LLP is found to not be a health and safety issue, the requirements of these existing purity standards should serve as the main component of a risk management process for quality and labeling purposes.

The existing purity standards come in two forms:

1. Varietal Purity. Varietal purity levels vary by crop kind (based on biology of the species) and are set within the OECD Seed Schemes or the Association of Official Seed Certification Agencies (AOSCA). Although the purity levels do vary, they are generally in the area of 99.5 per cent. Determining whether purity levels have been achieved is based on process verification and visual or phenotypic measures. This standard identifies an allowable percentage of "off-types" of the same crop kind as the seed being produced, i.e. one GM canola plant in a non-GM canola seed field/plot. If the purity meets the standard for the species, i.e. 99.5% or higher of the labeled variety, then testing to identify individual impurities, including suspected LLP impurities, is not necessary because any amounts found would be in compliance.

2. Mechanical Purity. Mechanical, or Analytical, purity pertains to weed seeds, inert matter, and seeds from other crops that may be present in a seed lot, i.e. one LLP corn kernel in a non-GM soybean seed lot. Sampling and testing for mechanical purity is done using International Seed Testing Association (ISTA) or the Association of Official Seed Analysts (AOSA) procedures and the results are reported on a Certificate of Analysis which is a condition of import of seed. The Mechanical standards are defined by existing domestic Seed Regulations of the importing country.

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.

This proposal does not suggest the implementation of any new event-specific testing or other changes to existing processes for establishing the purity of seed, In essence, this proposal represents "business as usual" for the trade of seed.