

**CARTAGENA PROTOCOL ON BIOSAFETY:
Sampling and Detection Methods for LMOs**

A number of international organizations, such as the International Standards Organization (ISO), *Codex Alimentarius* Commission (Codex) and the Organisation of Economic Co-operation and Development (OECD), have well-established work plans focused on development and harmonization of systems and standards for living modified organisms (LMOs). These organizations incorporate applicable scientific expertise to determine the appropriate integrated systems, standards, and specifications to best enable global trade in LMOs. Therefore, and in order to create synergies and avoid duplication of efforts, the GIC¹ recommends that Parties to the Cartagena Protocol on Biosafety (Protocol) focus on information-sharing with these and other relevant international bodies rather than developing criteria for acceptability and harmonization of sampling and detection techniques under the Protocol.

A. Experience Gained with the Use of Sampling and Detection Methods of LMOs

- A number of different entities are involved in developing, assessing, and utilizing detection methods for products of modern biotechnology. As part of the assembly of dossiers for submission to regulatory agencies, biotechnology companies develop and validate detection methods and create reference materials. Biotechnology companies provide methods that are developed in accordance with existing national and international standards as published by the ISO, Codex and the OECD.
- Some governments choose to develop their own methods in addition to the method provided by the biotechnology company applicant. These various detection methods may be used to conduct safety and regulatory studies on newly-developed LMOs, ensure the genetic purity of LMOs and conventional seed varieties, and analyze food and feed matrices as required by governments that implement mandatory labeling laws. Due to the wide variety of uses, these analyses may be performed by seed companies, grain handlers, food/feed companies and/or government agencies to verify the presence or absence of LMOs, presence or identity of particular transgenic events, or to quantify a transgenic event.
- Most grain used for food, feed or processing is shipped by bulk handling systems. Bulk systems are characterized by high volumes needed to achieve low costs (economies of scale). To comply with the requirements of the country-of-import, commodity exporters, importers, and governmental authorities must work together to meet national needs, including any documentation requirements, in a manner that is consistent with global standards.
- This need to comply with any national documentation requirements necessitates the availability of easy-to-use, rapid, reliable, and cost-effective sampling and detection techniques for LMOs which are intended for direct use as food or feed, or for processing (LMO-FFPs).

¹ The Global Industry Coalition (GIC) for the Cartagena Protocol on Biosafety receives input and direction from trade associations representing thousands of companies from all over the world. Participants include associations representing and companies engaged in a variety of industrial sectors such as plant science, seeds, agricultural biotechnology, food production, animal agriculture, human and animal health care, and the environment.

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- For the past three years, four significant international organizations – the ISO, Codex, the Bureau International des Poids et Mesures and National Measurement Institutes, and the OECD - with decades of experience and success in establishing systems and standards, including reference standards and detection methods in the medical field, have become directly engaged in developing globally harmonized standards and systems for detecting LMOs in commerce. These organizations and the experts they convene are able to conduct a science-based assessment and to determine the appropriate integrated systems, standards, and specifications to best enable global trade in LMO-FFPs for the long term.
- Parties to the Protocol can benefit from the experience and expertise of these organizations in considering the Protocol's plan of work and Parties' capacity building needs as implementation of the Protocol progresses.

B. Elements of a Draft Decision

Due to the large number of LMOs that are in research and development, that are currently commercialized, and that will be commercialized in the future, and the associated needs of Parties with respect to sampling and detection methods, it is the view of the GIC that:

- The Parties should focus their efforts on information-sharing with relevant international bodies working on sampling and detection methods to ensure that information on sampling and detection methods for LMOs are available to the Parties via the Biosafety Clearing-House.
- Parties should take advantage of the work of these relevant international bodies related to sampling and detection techniques of LMOs to ensure awareness of existing work and to create synergies and avoid duplication of efforts, rather than expending resources on the development of criteria for acceptability and harmonization of sampling and detection techniques under the Protocol.

Background:

Paragraph 2(a) of Article 18 of the Protocol requires Parties to take measures to require documentation accompanying LMO-FFPs clearly identify that they “may contain” LMOs and are not intended for intentional introduction into the environment. It also requires the Parties to take a decision on the detailed requirements for this purpose, which occurred at the third meeting of the Parties to the Protocol in 2006. In their decision on this Article, Parties requested submissions on experience gained with the use of sampling and detection techniques, and on the need for and modalities of developing criteria for acceptability of, and harmonizing, sampling and detection techniques. Parties requested the Executive Secretary to compile this information received and prepare a synthesis report for the Parties to consider at their fourth meeting in Bonn, Germany from 12-16 May 2008.

The GIC's submission on sampling and detection techniques for LMOs pursuant to the Article 18.2(a) decision by the Parties can be found at www.croplife.org, biosafety protocol, documentation requirements.