**Draft outline for the content of training material on the detection and identification of living modified organisms**

**1. Overview of the Cartagena Protocol on Biosafety**

* What is Biosafety?
* What are living modified organisms (LMOs)?
* History, Objective and scope of the Protocol
	+ LMOs for intentional introduction into the environment - Advance Informed Agreement (AIA)
	+ LMOs for direct use as food, feed, or for processing
* Competent National Authorities
* Biosafety-clearing House
* Detection and identification of LMOs
	+ Links to detection methods

**2. Detection and Identification of LMOs**

* Why the need to detect LMOs?
* National and international regulatory contexts
* Relevance of detection and identification of LMOs in the implementation of the Cartagena Protocol
* Other international agreements (SPS agreement, etc)
* Implications to the international trade

**3. Brief introduction to genetic modification of living organisms**

* DNA, RNA and protein synthesis
* Commonly used techniques and transformation methods
* The pipeline for developing LM crops: selection, breeding, seed production and commercializationMost common LMOs currently being traded, and prospects for the near future

**4. Sampling and challenges to detect trace amounts of LMOs**

[Goal: to understand the critical role of sampling in a testing program, and the uncertainties that are inherent in obtaining a sample, especially when attempting to detect trace concentrations of LMOs.]

* Principle of sampling
* Uncertainty introduced by sampling and illustration of how two samples from the same seed or grain lot are unlikely to be identical (hands on demonstration)
* Sampling of seed and plants (including control of cross contamination between samples)
* Handling and Sampling of large (commodity) shipments
* Difficulties in identifying and quantifying trace amount of GMOs
* Practical exercise in sampling

**5. Techniques for detection and identification**

[Goal: To strengthen participants’ understanding of the technologies, methodologies and platforms appropriate to the work being conducted in LMO detection and identification as they relate to DNA and/or protein based analysis. (Assumption: Participants have a working knowledge of the fundamental scientific basis of molecular biology.)]

* 1. *Choice of methods*
* Experimental design and selection of methods based on the purpose of the analysis and nature of the goods under investigation
* Sample handling and preparation
* Applicability of matrices

*5.2 Protein-based methods*

* Overview of different methods, including their advantages and disadvantages
	+ Lateral Flow Strip: Theory; Sample preparation; practical exercise; analysis of results
	+ ELISA: Theory; Sample preparation; analysis of results
* Limitations of protein-based methods (e.g. cross-reacting antibodies, lack of specific antibodies, sensitivity, availability of commercial kits, etc)

*5.3 DNA-based methods*

* DNA extraction/isolation and handling procedures (analysis of DNA samples quality)
	+ Qualitative PCR methods (end-point PCR and gel electrophoresis; real-time PCR)
	+ Quantitative PCR methods (real-time PCR for relative and absolute quantification)
* PCR-based screening strategies (matrix approach)
* Interpretation of results (LOD, LOQ, statistics, etc)
* Limitations of DNA-based methods (e.g. lack of DNA sequence information, lack of reference material, etc).

*5.4 Other novel technologies/strategies for LMO Detection*

* Novel approaches for simultaneous detection of multiple LMOs
* Sequencing strategies, LAMP, etc.
* Detection of RNA species

**6. Introduction to the quality assurance/quality control standards**

[Goal: To ensure participants are aware of best practices for QA/QC as they apply to LMO detection and identification and have an understanding of certification/ accreditation procedures so that they can design appropriate laboratory workspaces and documentation procedures.]

* Lab set-up requirements and lab environment
* Equipment calibration and maintenance
* Minimal standard criteria and requirements for experimental quality assurance ((e.g. negative, positive controls, reference materials, replicates, etc.)
* Method Validation
* Proficiency tests
* Non-conformances and Corrective Actions
* Access to information and certified reference materials
* Documentation requirements
* Laboratory documentation policy (paper and/or electronic)
* Overview of relevant accreditations and International standards
	+ ISO Standards(e.g. ISO17025)
	+ Codex Standards and guidelines (Methods and LLP)
	+ Role of Standards Developing Agencies
	+ ISTA guidelines

**7. Reporting**

Goal: To provide instruction to participants on reporting analytical results or issuing written notifications according to the laboratory's policy, and in compliance with national and international regulations and practices

* Laboratory policy on sample file content
* Report writing, sections and contents
* Technical and Administrative Review
* Report issuance according to laboratory policy
* Compliance with national and international standards on reporting
* Confidentiality/disclosure of information