**Draft outline for the content of regional and sub-regional training workshops on the detection and identification of LMOs.**

**1. Introduction**

**Overview of the CPB**

* History
* What is Biosafety?
* What are living modified organisms?
* 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
* Detection and identification as it relates to various articles of the Protocol
* Biosafety-clearing House and links to detection methods

**2. Why the need detect LMOs?**

* Working within a national regulatory context
* Other international agreements (SPS agreement, etc)

**3. Brief introduction to biotechnology**

* DNA, RNA and protein synthesis
* Commonly used transformation methods
* Most common LMOs currently being traded

**4. 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.)

* Experimental design and selection of methods in practice according to the purpose of the analysis
* Sample handling and preparation

*4.1 Protein-based methods*

* Overview of different methods, including their advantages and disadvantages
* Lateral Flow Strip: Sample preparation, analysis of results (practical exercise)
* ELISA: Protein extraction, reaction
* Analysis of results

*4.2 DNA-based methods*

* End-point PCR and gel electrophoresis
* Real-time PCR
* Quantification
* Analysis of results (use of matrices, statistics, etc)

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

Goal: Participants are to be aware of best practices for QA/QC as they apply to LMO detection and identification and have an understanding of certification/ accreditation procedures. Participants can design appropriate workspace with laboratory provided and documentation procedures.

* Lab set-up requirements and lab environment
* Handling of samples and Nucleic acid extraction
* Qualitative nucleic acid based methods
* Quantitative nucleic acid based methods
* Documentation requirements
* Non-conformances and Corrective Actions
* Proficiency Tests
* Equipment calibration and maintenance
* Protocol Validation studies
* Laboratory documentation policy (paper and/or electronic)
* Overview of relevant accreditations and ISO standards

**6. Reporting**

Goal: To provide instruction to participants on reporting analytical results or issuing written notifications according to the laboratory's policy.

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