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

1. **Overview of the CPB**

* History, Objective and scope of the Protocol
* Uses of LMOs
  + 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
  + Relation to articles of the Protocol
  + Links to detection methods

1. **Drivers for detecting LMOs**

* National and international regulatory contexts
* Other international agreements (SPS agreement, etc)
* Application and impact of detection methods in trade

1. **Overview of LMO developments**

Goal: To understand how LMOs are developed, grown and traded.

* (assumed knowledge?) Commonly used transformation methods
* Selection of an event and breeding and producing the seed that is grown by farmers
* Testing along the LMO product life cycle (introduction, use and discontinuation)
* Most common LMOs currently being traded, and prospects for the near future

1. **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 and where ‘zero tolerance’ is unmanageable due to sampling considerations
* Practical exercise in sampling

1. **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
* Overview of different methods, including their advantages and disadvantages

*4.1 Protein-based methods*

* Lateral Flow Strip: Sample preparation, analysis of results (practical exercise)
* ELISA: Protein extraction, reaction
* Analysis of results

*4.2 DNA-based methods*

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

*4.3 Choice of methods*

* Developing a sampling and testing plan which is fit for purpose.
* Choice of methods and sources of methods, and freedom to practice

1. **International standards**

Goal: To understand the role that standards can and do play in harmonizing processes and methods especially in relation to transboundary movements.

* ISO Standards
* Codex Standards and guidelines (Methods and LLP)
* Role of Standards Developing Agencies

1. **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
* Method validation
* Proficiency Tests
* Overview of relevant accreditations and ISO standards (e.g. ISO17025) and ISTA guidelines
* Documentation requirements
* Non-conformances and Corrective Actions
* Equipment calibration and maintenance
* Laboratory documentation policy (paper and/or electronic)

1. **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

1. **References**

* Sampling of grain and seed to estimate the adventitious presence of biotechnology-derived seeds in a lot. Freese et. al.. Ceareal Foods World V60, No.1, 2015 (<http://www.aaccnet.org/publications/Documents/CFW-60-1-0009-EP.pdf>)
* Sampling for the Detection of Biotech Grains (http://www.gipsa.usda.gov/fgis/biotech/sample2.htm)
* Immunoassay as an Analytical Tool in Agricultural Biotechnology. GROTHAUS ET AL.: JOURNAL OF AOAC INTERNATIONAL VOL. 89, NO. 4, 2006 (http://www.aeicbiotech.org/WhitePapers/AEICproteinpaper\_2006.pdf)
* Polymerase Chain Reaction Technology as Analytical Tool in Agricultural Biotechnology. LIPP ET AL.: JOURNAL OF AOAC INTERNATIONAL VOL. 88, NO. 1, 2005 (http://www.aeicbiotech.org/WhitePapers/polychnrctn.pdf)

Standards and Guidelines

* ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories (http://www.iso.org/iso/catalogue\_detail.htm?csnumber=39883)
* ISO TC 34/SC 16 and their Standards for Molecular Biomarker Analysis (<http://www.iso.org/iso/standards_development/technical_committees/other_bodies/iso_technical_committee.htm?commid=560239>)   
  <http://www.iso.org/iso/home/store/catalogue_tc/catalogue_tc_browse.htm?commid=560239>)
* Codex CAC/CL 74-2010: guidelines on Performance and Validation of Methods (<http://www.codexalimentarius.net/download/standards/11667/CXG_074e.pdf>)
* EURL Definition of minimum performance requirements for analytical methods of GMO testing (<http://gmo-crl.jrc.ec.europa.eu/doc/Min_Perf_Requirements_Analytical_methods.pdf>)
* ISO 542:1990 - Oilseeds – Sampling (<http://www.iso.org/iso/catalogue_detail.htm?csnumber=4619>)
* GIPSA Grain Inspection Handbook - Book I Grain Sampling (<http://www.gipsa.usda.gov/Publications/fgis/handbooks/gihbk1_insphb.html>)
* GIPSA Mechanical Sampling Systems Handbook (<http://www.gipsa.usda.gov/publications/fgis/handbooks/mech_insphb.html>)