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WORKSHOP OF THE NETWORK OF LABORATORIES FOR THE DETECTION AND IDENTIFICATION OF LIVING MODIFIED ORGANISMS
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SUMMARY OF THE ACTIVITIES UNDER THE ELECTRONIC NETWORK OF LABORATORIES FOR THE DETECTION AND IDENTIFICATION OF LIVING MODIFIED ORGANISMS (2014-2015)

INTRODUCTION

1. In its decision BS-V/9, the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP) established an electronic network of laboratories with a view to bringing together representatives of laboratories involved in the detection of living modified organisms (LMOs) for the sharing of information and experiences that could help facilitate the identification of LMOs. The COP-MOP requested the network to carry out online discussion fora and workshops to exchange information and experience on the implementation of relevant standards and methods involved in the detection and identification of LMOs.

2. Furthermore, in decision BS-V/16,[1] the COP-MOP adopted a Strategic Plan for Implementation of the Cartagena Protocol. Under its operational objectives 1.6, 1.8 and 2.3, the Strategic Plan sets out outcomes related to the detection and identification of LMOs.

3. In response to the above decisions, the Network of Laboratories for the Detection and Identification of Living Modified Organisms (hereinafter "the Network") developed a set of Technical Tools and Guidance,[2] through a series of online discussions and a face-to-face workshop, to assist Parties in fulfilling their relevant obligations under the Protocol and achieving the outcomes of the Strategic Plan that are relevant to the detection and identification of LMOs.

4. Further, in its decision BS-VII/10, the COP-MOP requested the Network to continue working with a view to achieving the operational objectives of the Strategic Plan for implementation of the Protocol that are relevant to the detection and identification of LMOs and implementation of Article 17 on Unintentional Transboundary Movements.

* UNEP/CBD/BSDIWS/2015/1/1.

[1] Available at http://bch.cbd.int/protocol/issues/cpb_stplan_txt.shtml.

[2] Available at http://bch.cbd.int/protocol/cpb_detection/toolsandguidance.shtml.

5. In that same decision, the Parties also requested the Executive Secretary to organize, in cooperation with relevant organizations and subject to the availability of funds, capacity-building activities such as online and face-to-face training workshops on sampling, detection and identification of LMOs.

6. In light of these requests, the Secretariat organized a series of online discussions[3] through the Network as a starting point for the implementation of the relevant elements of the decision.

II. SUMMARY OF ACTIVITIES OF THE NETWORK

A. Drafting an outline of training material for capacity-building workshops on sampling, detection and identification of LMOs

7. The Network resumed its activities with a view to making progress toward the implementation of decision BS-VII/10.

8. Two online discussions[4] focusing on the drafting of an outline of training material for capacity-building workshops on sampling, detection and identification of LMOs were held from 16 February to 27 April 2015 with the specific objectives of (a) providing input on elements to consider in the design of content for the capacity-building workshops on the detection and identification of living modified organisms; and (b) compiling didactic materials for capacity-building on sampling, detection and identification of living modified organisms.

9. To facilitate the first round of discussions, the Secretariat provided an outline of a training material including topics relevant to the detection and identification of LMOs for consideration as elements of the training material for use at the training workshops.

10. Participants were invited to review the background document containing the outline and to provide suggestions on how to improve the proposed content, as well as to share case studies and examples of practical exercises that could be carried out during the training.

11. An updated outline of the training material, integrating new elements based on participants' suggestions from among the key issues that were discussed, was prepared by the Secretariat and presented to the Network in their second round of discussion. Participants reflected positively on the updated version of the outline of the training material. The revised draft outline in attached hereto as annex I.

12. In elaborating on the target audience of the training material, as well as the capacity-building workshops, most participants supported focusing the workshops towards laboratory personnel. It was noted that while other stakeholders may benefit from such training, it would be most efficient to focus on one specific target audience such that a comprehensive and in-depth training that is thorough and efficiently delivered to engage participants with varying levels of expertise. Several participants also noted that it may be useful to include other relevant stakeholders, such as policymakers, in the training workshop to facilitate communication at the policy-science interface.

13. Furthermore, participants also suggested that there is a need for the development of other complementary workshops and training materials on sampling at the border or in the field. Participants

3 Available at http://bch.cbd.int/onlineconferences/portal_detection/discussions.shtml.

4 The discussions and their summaries are available through the BCH at http://bch.cbd.int/onlineconferences/portal_detection/discussions.shtml.

also noted that the training material on sampling is relevant to the detection and identification process since sampling directly affects the outcome of the laboratory analysis.

14. Other considerations that were noted by participants included the need to tailor the proposed capacity-building workshops to include regionally specific workshops. This can be achieved by inviting resource experts from regional laboratories with a strong background in the detection and identification of LMOs.

B. Drafting working definitions for "unintentional transboundary movement" and "illegal transboundary movement"

15. At their eleventh meeting, the Compliance Committee under the Cartagena Protocol on Biosafety[5] recognized that Parties have "different approaches in understanding and addressing illegal and unintentional transboundary movements". As a result, the Compliance Committee recommended that the COP-MOP provide guidance on what constitutes unintentional transboundary movements in contrast with illegal transboundary movements and what follow-up action is required in each circumstance.

16. In response to this recommendation, the COP-MOP invited Parties and other Governments to submit views on what constitutes unintentional transboundary movements in contrast with illegal transboundary movements and what type of information should be exchanged through the Biosafety Clearing-House, and requested the Executive Secretary to synthesize the information submitted for consideration by the Compliance Committee. The Secretariat issued a notification[6] requesting Parties and other Governments to submit views on the aforementioned topic.

17. The Secretariat also organized two online discussions focusing on clarifying what constitutes an "unintentional transboundary movement" and "illegal transboundary movement". The discussions were held from 26 January to 1 March 2015 with the objective of drafting working definitions for "unintentional transboundary movement" and "illegal transboundary movement" of LMOs for the consideration of the Compliance Committee at its thirteenth meeting and an analysis of the implications on detection and identification of LMOs.

18. The emerging understanding among participants over the course of the discussion was that the terms "illegal" and "unintentional" are two different concepts in the context of the Protocol.

19. With regard to providing conceptual clarity for the term "illegal transboundary movement" as defined in the Protocol (i.e. "transboundary movements of living modified organisms carried out in contravention of domestic measures of a Party to implement this Protocol"), the term relates to (a) an LMO that has not been authorized through the decision procedure of the importing country either because a notification was not submitted, is under evaluation or was withdrawn without a decision being taken; or (b) an LMO whose import for one or more intended uses has been prohibited in the importing country.

20. Additional and more general considerations regarding "illegal transboundary movements" were also made and referred to cross-border movements of LMOs that are carried out in contravention to requirements specified in the relevant national regulations with respect to, for example, labelling, packaging, and documentation accompanying an LMO shipment.

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[5] Report of the eleventh meeting of the Compliance Committee under the Cartagena Protocol on Biosafety https://www.cbd.int/doc/meetings/bs/bscc-11/official/bscc-11-04-en.pdf.

[6] Notification https://www.cbd.int/doc/notifications/2015/ntf-2015-002-bs-en.pdf.

21. The views posted during the discussions were more divergent with regard to the term "unintentional transboundary movement", drawing attention to various considerations that may need to be taken into account when drafting a working definition for the term.

22. Among the considerations that participants deliberated on was whether intent can be used as a criterion in determining if a cross-border movement is "unintentional". The outcome of the discussion is that, notwithstanding the use of the term "unintentional", intent is very subjective and difficult to prove.

23. Furthermore, the issue of whether or not the quantity of the LMO is a determining factor when attempting to define an "unintentional transboundary movement" was discussed. Some interventions noted that "unintentional transboundary movements" include cases where:

(a) Imported conventional agricultural commodities (e.g. seeds) contain a small quantity of LMOs, which is also referred to as "botanical impurity" caused by, for example, mixing of the commodity during handling;

(b) Non-LM products are accidentally/involuntarily mixed with LMOs, which are present in quantities that are below analytical limits of detection;

(c) An LM crop accidentally makes its way into the international food or feed supply chain through "low level presence" and/or "adventitious presence", as defined by other bodies.

24. On the other hand, some participants also noted that one can also have an "unintentional transboundary movement" of an LMO that is present in large amounts and, as such, quantity should not be a determining factor in defining the term "unintentional transboundary movement".

25. In an attempt to amalgamate the essence of the points raised during the discussions, the following proposals could be distilled for working definitions:

(a) "Illegal transboundary movements" include the cross-border movements of LMOs that have not been approved for particular use in the importing Party or that are carried out in contravention of any of the requirements specified in the relevant national legislations;

(b) "Unintentional transboundary movements" are cross-border movements resulting from a deliberate or accidental release, including dispersal or mixing, of an LMO in the country of origin that are not properly notified or documented to the receiving country. In the event the LMO in question, or a particular intended use of that LMO, is not authorized in the receiving country, the transboundary movement may also be considered illegal.

III. OTHER MATTERS

A. Development of additional technical tools and guidance as outlined in the operational objectives 1.6 and 1.8 of the Strategic Plan for Implementation of the Cartagena Protocol on Biosafety

26. During the Workshop of the Network of Laboratories for the Detection and Identification of Living Modified Organisms which was held at the European Commission's Joint Research Centre (JRC), Institute for Health and Consumer Protection in Ispra, Italy, from 25 to 27 November 2013, participants agreed on the need to compile technical tools and guidance that could assist Parties in the detection and identification of LMOs in the context of the Protocol.

27. During that workshop, participants prioritized four topics for the compilation of Technical Tools and Guidance[7] prior to the seventh meeting of the COP-MOP, as listed below:

(a) Overview of available detection methods, including validated methods;

(b) Overview of available databases for methods and sequence information, and available screening matrixes;

(c) Minimum performance criteria for sample handling, extraction, detection and identification methodology;

(d) Experience and case-studies on detection and identification.

28. Furthermore, participants agreed on a list of additional topics that could be developed into technical tools and guidance after the seventh meeting of the COP-MOP, as appropriate. The topics that were proposed are as follows:

(a) Topics pertaining to laboratory testing and analysis:

- Criteria for the selection of detection methods based on a Party's national needs (including decision trees or checklists of possible strategies at different levels of detection requirements, i.e., presence, identification or quantification);
- Minimum requirements for detection laboratories according to their attributions, level of responsibility, handling of samples (quality system and proficiency testing);
- Access and availability of reliable reference materials;
- Selecting laboratories and assessing their competences;
- Steps to be taken for screening and/or identification (including the screening of landraces);
- How to interpret the results from matrix screening.

(b) Topics pertaining to setting up supporting systems ("pre-detection"):

- Setting up sampling strategies;
- Setting up a monitoring system (how to monitor for unauthorized LMOs, how to establish a surveillance programme for unauthorized LMOs including landraces);
- Setting up an inspection system;
- How to implement national enforcement;
- Setting up a rapid alert system among laboratories within a region/network.

29. Participants of the upcoming workshop will be invited to consider the continuation of the development of technical tools and guidance, as outlined under the relevant operational objectives of the Strategic Plan for implementation of the Protocol during 2011-2020 that are relevant to the detection and identification of LMOs.

[7] Available at http://bch.cbd.int/protocol/cpb_detection/toolsandguidance.shtml.

Annex I

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 commercialization
- Most 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 programme, 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.)]

5.1 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

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