

SHARING THE OUTCOMES OF THE COP-MOP - 8 MEETING

**December 4-17, 2016
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**Shri Gyanesh Bharti
Joint Secretary,
Ministry of Environment, Forest and Climate Change
Government of India**

COP-MOP 8 MEETING AGENDA

- COP-MOP 8 meeting agenda is based on Mid-term Evaluation of the Strategic Plan (2011-2020) and Third Assessment and Review of the Protocol
- The key issues deliberated by the Working Group 1 of the COP-MOP 8 meeting included:
 - **Report of the Compliance Committee**
 - **Review of Framework and Action Plan for capacity building**
 - **Operation and activities of the Biosafety Clearing-House (Article 20)**
 - **Risk assessment and risk management (Articles 15 and 16)**
 - **Unintentional transboundary movements and emergency measures (Article 17)**
 - **Transit and contained use of LMOs (Article 6)**
 - **Socio-economic considerations (Article 26)**

CAPACITY BUILDING (ARTICLE 22)

- Capacity building has been recognized as the critical element
- Several measures taken such as setting up of online groups, liaison groups, organizing regional and sub-regional workshops etc.
- **Framework and Action Plan for Capacity Building** for effective implementation of the CPB adopted in 2012 in COP-MOP6
- A **Short Term Action Plan (2017-2020)** has been discussed in the Subsidiary body to enhance and support capacity building for the implementation of the Convention and its Protocols

CAPACITY BUILDING (ARTICLE 22)

Issues considered at COP-MOP8

- To continue the “Framework and Action Plan for Capacity Building (2012-2020)” for effective implementation of CPB
- To enhance efforts towards capacity building
- The Short-Term Action Plan for the period of 2017-2020 with capacity-building activities prioritized to focus on **development of national biosafety legislation, risk assessment, detection and identification of LMOs and public awareness, education and participation**
- To integrate biosafety in their National Biodiversity Strategies and Action Plan

The four thrust areas of UNEP/GEF supported Phase II Capacity Building Project on Biosafety are in line with priority areas identified under the capacity building activities. India’s contribution to biosafety capacity building needs was highlighted

CAPACITY BUILDING (ARTICLE 22)

Decision adopted:

- To continue to work in order to achieve the expected outcomes of the Framework and Action Plan within the remaining time until the end of the Framework and Action Plan.
- To facilitate support for implementing the capacity building activities prioritized in the Short Term Action Plan for the period 2017-2020.
- GEF to continue its support for further implementing the Framework and Action Plan for Capacity-Building

CAPACITY BUILDING (ARTICLE 22)

Suggested activities for the intersessional period:

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- Participate in the online forums and webinars
- Initiate capacity building activities towards integrating the biosafety issues into the NBSAPs and national development plans, sectorial policies , SDGs etc
- Use of the E-learning module and toolkit developed by the CBD Secretariat (NBSAPs Forum)

BIOSAFETY CLEARING HOUSE (ARTICLE 20)

- Article 20 establishes the Biosafety Clearing-House (BCH) as a mechanism to facilitate the exchange of information on Living Modified Organisms (LMOs) and assist the Parties to better comply with their obligations under the Protocol
- BCH facilitates exchange of scientific, technical, environmental and legal information on and experience with LMOs

BIOSAFETY CLEARING HOUSE

Issues considered at COP-MOP8

- Updation of records on the BCH to be continued specifically information related to :
 - national biosafety frameworks, legislation, regulations and guidelines,
 - summaries of risk assessments
 - final decisions regarding LMOs and LMOs intended for direct use as food or feed, or for processing
 - national focal points and national points of contact
 - information on bilateral, regional or multilateral agreements or arrangements into which they have entered and which have relevance for biosafety
- Contributions to the Voluntary Trust Fund for the Roster of Experts by Parties
- Strengthening collaboration between the biosafety databases of the Food and Agriculture (FAO) of the UN & Organisation for Economic Co-operation and Development (OECD)
- India supported the improvement plan for the operations and activities of the BCH test the new platform before its face-to-face meeting in 2018.

BIOSAFETY CLEARING HOUSE

Decision adopted:

- Continue registration of information
- Make improvements in the central portal of the BCH
- Strengthen the collaborations with other biosafety databases and platforms including those of FAO and OECD
- Organize regional online discussions and use other means for information exchange etc
- Create additional tools for facilitating statistical analysis of information contained in the BCH

BIOSAFETY CLEARING HOUSE

Suggested activities for the intersessional period:

- To participate in BCH workshops organized by CBD Secretariat
- To organize workshops on BCH trainings in India
- To prepare and distribute booklets on accessing BCH as the key information source.

RISK ASSESSMENT AND RISK MANAGEMENT (ARTICLE 15 & 16)

- **Article 15** on Risk Assessment establishes the basic requirements for risk assessment under the Protocol and refers to Annex III for further guidance.
- **Article 16** on Risk Management deals with the management of risks of those organisms that fall within the scope of the Protocol. The protocol requires each Party to manage and control any risks that may be identified by a risk assessment.
- **Annex III** sets forth the objectives of the risk assessment, what the risk assessment will be used for, general principles that the risk assessment must follow, the methodology of the risk assessment and particular points to consider when assessing the potential risks of LMO.

RISK ASSESSMENT AND RISK MANAGEMENT

Issues considered at COP-MOP8

- Consider endorsement of the revised version of the Guidance document *viz.*, “Guidance on Risk Assessment of Living Modified Organisms and Monitoring in the Context of Risk Assessment”
- Sharing of experience submitted by Parties in using the Guidance through their national reports in order to monitor and ensure applicability of the Guidance in relation to scientific progress
- Enhance efforts towards capacity-building activities in risk assessment of LMOs using the Guidance document

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RISK ASSESSMENT AND RISK MANAGEMENT

Issues considered at COP-MOP8

- Requirement of funds from GEF for a global capacity-building project on risk assessment and risk management with an emphasis on the use of the Guidance.
- Action plan for development of further guidance based on outline provided by AHTEG on specific topics of risk assessment *viz.*, “Risk assessment of LM fish” and “Risk Assessment of LMOs developed through synthetic biology”, in coordination with relevant processes under the CBD.
- The need for extension of the Open-ended Online Expert Forum and the AHTEG to develop guidance on specific topics and also for taking into account additional topics

RISK ASSESSMENT AND RISK MANAGEMENT

India's submission at the COP-MOP 8:

India supportive of :

- The essentially of developing guidance on risk assessment with appropriate uniformity in terms of terminology whereas scope should be linked to national experience.
- The capacity building activities through sharing of experiences as well training workshops
- The work of AHTEG and the online forum, but it was suggested that preparation and validation of guidance documents may be entrusted to scientific bodies experienced in the area such as OECD, International Life Science Institute etc

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RISK ASSESSMENT AND RISK MANAGEMENT

India's submission at the COP-MOP 8:

Regarding the endorsement of the Guidance document:

- India has gained experience in **developing its national Guidelines on Environmental Risk Assessment of GE plants, 2016** through the Problem Formulation approach which is emphasized globally for environmental risk assessment
 - Overall revised guidance document viz., “Guidance on Risk Assessment of LMOs and Monitoring in the Context of Risk Assessment”, is difficult to read and interpret specifically for novice risk assessors.
 - Not a practical working document to conduct risk assessment and risk assessments conducted on the basis of this guidance document would lack scientific vigor.
- Contd/-
- *It was proposed that India may not accept the guidance document*

RISK ASSESSMENT AND RISK MANAGEMENT

India's submission at the COP-MOP 8:

Regarding developing further guidance on additional topics:

- Developing further guidance on specific topics such as LMOs developed through synthetic biology is too premature since research and development in this area is in the nascent stage and there are no experiences even in the most scientifically advanced countries for their risk assessment
- Developing new guidance on additional topics could be left to the regulatory authorities on the basis of national need

RISK ASSESSMENT AND RISK MANAGEMENT

Decision adopted:

- After detailed deliberations and in view of differences in views of Parties, the guidance document was accepted as “Voluntary Guidance on Risk Assessment of LMOs and Monitoring in the Context of Risk Assessment”.
- To use the voluntary guidance document alongside other guidance documents and national approaches for conducting risk assessment and share their experiences through BCH
- Extended the Open Ended Online Forum for development of further guidance on specific topics
- Bureau of the COP-MOP to appoint a lead moderator for the online discussions and be responsible for reporting to the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA)

RISK ASSESSMENT AND RISK MANAGEMENT

Suggested activities for the intersessional period:

- To organize training workshops on environmental risk assessment (ERA) using the recently adopted Guidance documents on ERA of GE plants
- To develop an e-learning module on the Guidance documents for ERA of GE plants
- To establish an expert working group to address issues on risk assessment and risk management of LMOs developed from new and emerging

UNINTENTIONAL TRANSBOUNDARY MOVEMENTS AND EMERGENCY MEASURES

Unintentional transboundary movements and emergency measures :

[ARTICLE 17]

Party is required to take appropriate measures to notify affected or potentially affected States, BCH and relevant international organizations, information on unintentional transboundary movement of LMOs that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health in such States.

To notifications should include:

- Available relevant information on the estimated quantities and relevant characteristics and/ or traits of the LMOs.
- Information on circumstances & estimated date of release and on use of the LMOs in the originating Party.
- Any available information about the possible adverse effects on the conservation and sustainable use of biological diversity including risks to human health, as well as available information about possible risk management measures.

UNINTENTIONAL TRANSBOUNDARY MOVEMENTS AND EMERGENCY MEASURES [ARTICLE 17]

Issues considered at COP-MOP8

- Adoption of the operational definitions on “illegal transboundary movements” and “unintentional transboundary movements”
- Draft “Training manual on the detection and identification of LMOs”.
- Information to be submitted in BCH on mechanisms for emergency measures in case of unintentional transboundary movements and capacity needs in the detection and identification of LMOs
- Establishment of mechanisms to support the workflow for sampling, detection and identification by, for example, providing border control officials and laboratories with the appropriate mandates to sample, detect and identify LMOs, ensuring that laboratories remain functional and that they receive high-

UNINTENTIONAL TRANSBOUNDARY MOVEMENTS AND EMERGENCY MEASURES [ARTICLE 17]

Issues considered at COP-MOP8

- Establishment of regional and sub- regional LMO detection networks for promoting technical cooperation in detection of LMOs
- Capacity-building workshops on sampling, detection and identification of LMOs using the training manual
- Improvement of the user interface of the “Technical Tools and Guidance for the Detection and Identification of LMOs” with a view for creating a searchable and indexed database and regularly updating its content, as needed

UNINTENTIONAL TRANSBOUNDARY MOVEMENTS AND EMERGENCY MEASURES [ARTICLE 17]

India's submission at the COP-MOP 8:

- India suggested for definition on unintentional transboundary movements *“Unintentional transboundary movement” is an inadvertent occurrence resulting in release of a living modified organism under its jurisdiction that leads to or may lead to adverse effect on the conservation and sustainable use of biological diversity including risks to human health.*

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UNINTENTIONAL TRANSBOUNDARY MOVEMENTS AND EMERGENCY MEASURES [ARTICLE 17]

India's submission at the COP-MOP 8:

- Agreement on definition on illegal transboundary movement as recommended by the Compliance committee
- Mechanisms have been established for addressing emergency measures in case of unintentional transboundary movements of LMOs.
- India has strengthened detection labs under Phase II Capacity Building Project
- India supports activities such as preparation of Technical manual on detection, guidance for border control officials etc

UNINTENTIONAL TRANSBOUNDARY MOVEMENTS AND EMERGENCY MEASURES [ARTICLE 17]

Decision adopted:

- The definition adopted as:

“Illegal transboundary movement” is a transboundary movement of LMOs carried out in contravention of the domestic measures to implement the Protocol that have been adopted by the Party concerned.

“Unintentional transboundary movement” is a transboundary movement of a LMO that has inadvertently crossed the national borders of a Party where the LMO was released, and the requirements of

UNINTENTIONAL TRANSBOUNDARY MOVEMENTS AND EMERGENCY MEASURES [ARTICLE 17]

Decision adopted:

- Creating a searchable and indexed database for detection and identification of LMOs.
- To create in BCH a system for the easy identification of capacity-building training opportunities related to detection and identification of LMOs.
- To continue cooperation with relevant organizations at regional and sub-regional level for capacity-building activities
- Online training and face-to-face workshops in the fields of sampling, detection and identification of LMOs
- GEF to provide financial support for hosting of training workshops on detection and identification of LMOs

UNINTENTIONAL TRANSBOUNDARY MOVEMENTS AND EMERGENCY MEASURES [ARTICLE 17]

Suggested activities for the intersessional period:

- To review the draft “Training Manual on Detection and Identification of LMOs” and identify the gaps
- Establish mechanism/systems for supporting the workflow for sampling, detection and identification of LMOs, with focus for the enforcement officials and custom officials.
- To support and participate in regional level

TRANSIT AND CONTAINED USE

Transit

- While the Parties have a right to regulate the transit of LMOs, the provisions of this protocol with respect to advanced informed agreement procedure do not apply to LMOs in transit.

Contained Use

- Contained use defined in Article 3b
- As in case of transit, the provisions of the CPB with respect to the advance informed agreement procedure do not apply to the transboundary movement of LMOs destined for contained use, though Parties have a right to subject all LMOs to risk assessment prior to decisions on import and to set standards for contained use within its jurisdiction.
- Article 18, paragraph 2 (b), sets out the requirements for documentation accompanying LMOs destined for contained use, such that the documentation, inter alia, clearly identifies them as LMOs and specifies any requirements for the safe handling, storage, transport and use.

TRANSIT AND CONTAINED USE

Issues considered at COP-MOP8

- Practical guidance about the type of information to be submitted in the BCH when a final decision is taken regarding the import of LMOs destined for contained use.
- Improvement in the BCH to allow easy retrieval of information relating to transit and contained use
- Monitoring and assessment for gaps in existing tools and practical guidance regarding contained use, based on, among other things, the information submitted in the BCH when a final decision is taken regarding the import of LMOs destined for contained use.

TRANSIT AND CONTAINED USE

India's submission at the COP-MOP 8:

- Need for clarity on the type of information that is required to be submitted to the BCH on final decisions regarding the import of an LMO destined for contained use
- International guidance is also available on type of contained levels of containment, documentation requirement etc.
- Most of the decisions on contained use are related to R&D and difficult to be posted on BCH as researchers wish to protect their intellectual property rights (IPR) and business interests
- India has well established system for regulating LMOs in contained use.

TRANSIT AND CONTAINED USE

Decision adopted:

- The Compliance Committee to assess the information submitted in the BCH and report to the COP-MOP9 with a view to identifying areas where activities might be needed to support Parties in their efforts to develop national measures.
- To continue improving in the BCH the means to allow easy retrieval of information relating to transit and contained use.

TRANSIT AND CONTAINED USE

Suggested activities for the intersessional period:

- To compile and upload information about available guidance on contained use of LMOs on BCH.

SOCIO-ECONOMIC CONSIDERATIONS

- In Article 26, the Protocol has provided that Parties may take Socio-Economic Considerations (SEC) into account in making decisions on imports of LMOs or under its domestic measures
- Any decision on the inclusion of SEC however must be considered with that country's other international obligations
- The Protocol encourages Parties to cooperate on research and information exchange on any socio economic impacts of LMOs, especially on indigenous and local communities
- The AHTEG has prepared a report developing conceptual clarity on SEC arising from the impact of LMOs on the conservation and sustainable use of biological diversity and developing an outline for the guidance.
- An online portal on SEC has been set up in addition to Online regional conferences and discussions.

SOCIO-ECONOMIC CONSIDERATIONS

Issues considered at COP-MOP8

- Report of the AHTEG on SEC, particularly Annexure on “Revised Framework for Conceptual Clarity”.
- Extension of the work of AHTEG on SEC

India’s submission at the COP-MOP 8:

- Due to complexity of issues involved and lack of agreement during the deliberations while developing the Framework for Conceptual Clarity, more work needs to be done in this area
- Countries need to take an expansive view of SECs in line with their domestic regulations
- It is premature to initiate the preparation of guidelines on the basis of the revised Framework for Conceptual Clarity.

SOCIO-ECONOMIC CONSIDERATIONS

Decision adopted :

- Takes note of the “Revised Framework for Conceptual Clarity”
- Extended the mandate of the AHTEG, replacing any experts, as needed, including indigenous peoples and local communities as observers and in accordance with the consolidated modus operandi of the SBSTTA of the CBD, to allow it to meet face-to-face, subject to the availability of funds, to work on the guidelines envisaged under the outcomes for operational objective 1.7 of the Strategic Plan for the CPB
- The AHTEG to submit a report for consideration by the COP-MOP9

PUBLIC AWARENESS, EDUCATION AND PARTICIPATION (ARTICLE 23)

- Article 23, paragraph 1 (a), of the Protocol requires Parties to “Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health”.
- In doing so, the Parties are required to “cooperate, as appropriate, with other States and international bodies.”

PUBLIC AWARENESS, EDUCATION AND PARTICIPATION (ARTICLE 23)

Issues considered:

- Extension of the Programme of Work until 2020
- Sharing of experience/lessons learnt in implementing Programme of Work
- Adopt the priority areas/activities for the Programme of Work to achieve a streamlined strategic focus and foster further commitment to advance the implementation of the Programme of Work.
- Promote the integration of the Programme of Work into NBSAPSs
- Cooperation to be enhanced with other initiatives, such as the Aarhus Convention, gender initiatives and other international, regional and national initiatives
- GEF to provide eligible Parties with dedicated financial resources to facilitate effective implementation of the Programme of Work

PUBLIC AWARENESS, EDUCATION AND PARTICIPATION (ARTICLE 23)

India's position/submission:

- Supported the extension of Program of Work up to 2020 along with the prioritized areas
- Biosafety outreach material prepared and translated in regional languages under the Phase II Capacity Building Project on Biosafety for public awareness.
- Risk Analysis Framework, 2016 prepared under the Phase II Capacity Building Project streamlines process for public participation in decision making as per the Article 23 of the CPB

PUBLIC AWARENESS, EDUCATION AND PARTICIPATION (ARTICLE 23)

Decision adopted :

- Program of Work extended till 2020 with revised priority areas and activities
- Linking national websites and national biosafety clearing-houses to the CBD website
- Enhance cooperation with relevant organizations, as well as gender initiatives and other international, regional and national initiatives
- Continue to enhance capacity for
 - public awareness, education and participation, including access to information regarding the safe transfer, handling and use of LMOs
 - integrate training, public awareness, education and participation into national initiatives for communication, education and public awareness,

PUBLIC AWARENESS, EDUCATION AND PARTICIPATION (ARTICLE 23)

Suggested activities for the intersessional period:

- Develop tools and methods for public education on biosafety, including developing training of standardized biosafety curricula at primary, secondary and/or tertiary levels and promoting new learning methods/technologies
- Consultation with Stakeholders involved in public education (e.g. Ministries, academic institutions, school boards, teachers, scientists/researchers)
- Develop various communication tools such as biosafety messages, films, E-learning modules etc for organizing training workshops for public awareness
- Ensure participation of women, indigenous peoples and local communities. and custom officials to access biosafety related information
- Train and assign scientists and media to communicate biosafety issues

PUBLIC AWARENESS, EDUCATION AND PARTICIPATION (ARTICLE 23)

Suggested activities for the intersessional period:

- Promote exchange of programmes for scientist and public servants on a national and regional level
- Regularly promoting up-to-date access to information of websites and traditional tools to a wider-audience
- Use effective mechanisms and procedures for public participation (e.g. early participation in the decision-making process regarding LMOs, recording inputs, designating/training staff, collaborate with organizations and incorporate key public inputs into decisions)

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Thank you