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CAPACITY-BUILDING FOR POST-RELEASE MONITORING OF LIVING MODIFIED ORGANISMS

I. INTRODUCTION

1. Article 16 on Risk Management of the Cartagena Protocol on Biosafety requires Parties to establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of the Protocol associated with the use, handling and transboundary movement of living modified organisms (LMOs).

2. Annex III on Risk Assessment states that where there is uncertainty regarding the level of risk, it may be addressed, *inter alia*, by implementing appropriate risk management strategies and/or monitoring the LMO in the receiving environment.

3. In addition to monitoring of LMOs in the context of risk assessment and risk management, monitoring of LMOs may be relevant for the detection of LMOs introduced into the environment through illegal transboundary movements or unintentional releases. The Conference of the Parties serving as the meeting of the Parties to the Protocol (COP-MOP) has identified the issue of illegal transboundary movements of LMOs as one of the key areas in which Parties require capacity-building. Thus in the Updated Action Plan for Building Capacities for the Effective Implementation of the Protocol adopted in decision BS-III/3 "measures to address unintentional and/or illegal transboundary movements of living modified organisms" are among the key elements requiring capacity-building support and action.

4. According to the second national reports, only 50% of the Parties to the Protocol have established a mechanism for monitoring potential effects of LMOs that are released into the environment (among these, 20% are in Africa, 12% in Asia-Pacific, 7% in GRULAC, 14% in CEE, and 19% in WEOG). Moreover, only 38% of the Parties have established a strategy for detecting illegal transboundary movements of LMOs into their territories (among these, 8% are in Africa, 12% in Asia-Pacific, 4% in GRULAC, 12% in CEE, and 17% in WEOG).

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5. This document contains information that may be relevant when considering the need for, and ways to foster, capacity-building for monitoring of LMOs, including how to assist countries in establishing a national strategy for monitoring for potential adverse effects resulting from the introduction of LMOs into the environment as well as for monitoring for LMOs introduced into the environment through illegal transboundary movements or unintentional releases. Section 2 of this document summarizes how some countries address monitoring in their biosafety policy and legislation. Section 3 provides examples of guidance on monitoring developed under the Protocol and by other international/regional organizations. Section 4 contains summaries of previous and ongoing capacity-building activities on monitoring of LMOs. Section 5 elaborates on strategies for strengthening national capacities relevant to monitoring.

II. PROVISIONS IN NATIONAL BIOSAFETY REGULATORY FRAMEWORKS RELEVANT TO MONITORING OF LIVING MODIFIED ORGANISMS

6. Monitoring of LMOs is explicitly mentioned in the national biosafety regulatory frameworks of a few countries.[1] Some examples of countries' policy and legal requirements with regard to monitoring of LMOs are described below.

7. In Australia, monitoring in risk management, though not a requirement, may be a condition for approval of an LMO release to enable the Competent National Authority, the Office of the Gene Technology Regulator (OGTR), to stay informed or collect post-release information on the LMO. A number of written notices are required under the under the licence to assist the OGTR in designing and implementing its risk-based monitoring programme for approved LMOs. If monitoring activities identify changes in the risks associated with the approved LMOs, may also change the conditions of the approval, or if necessary, suspend or cancel the approval.

8. In Brazil, the Biosafety Law provides that for LMOs that have already been released, monitoring shall be conducted under strict observance of the principles of precaution, transparency and scientific independence. In cases of environmental releases, either for experimental or commercial purposes, Brazil's framework also requires the applicant to develop and present case-specific post-release monitoring plans. Furthermore, the framework requires the integration of a genetic marker into an LMO that could be used to differentiate it from morphologically similar conspecifics. If monitoring reveals adverse effects caused by the LMO, the decision to approve the release of the LMO may be reversed. In November 2011 the Brazilian National Biosafety Committee (CTNBio) approved a new monitoring system for marketed LMOs. The new system provides for the possibility of building up an information network with the effective participation of many actors from the areas where the monitoring will be conducted.[2]

9. In Cambodia, the Law on Biosafety (Article 5) requires any legal or natural person responsible for any activity or operation involving LMOs to ensure that contained use, intentional introduction into the environment, direct use as food, feed or for processing, import, and export of LMOs is carried out in conformity with the law and all Sub-decrees implementing the law by, among other things: developing a risk management strategy; providing an emergency response plan for accidental release; and establishing mechanisms for internal monitoring of safety.

[1] It is noted that many national biosafety laws and regulations use the term "monitoring" in different contexts such as for detection (e.g. "monitoring the LMO content in seeds") or compliance (e.g. "monitoring, regulation, and control of the use").

[2] See: http://genpeace.blogspot.com/2011/12/brazils-new-post-release-monitoring.html.

10. In the European Union, Directive 2001/18/EC requires applicants to submit a post-market environmental monitoring (PMEM) plan as a part of the notification for marketing and release of an LMO into the environment. In addition, Part C (Placing on the Market as or in Products) states that when the competent national authority provides its consent in writing it may stipulate conditions that are to include monitoring and the public release of subsequent results to ensure transparency (art.20(4)). In 2004, a mapping of existing general environmental monitoring programmes for LMO monitoring purposes was initiated in different EU member countries at the request of the European Commission. The resulting report provided better insight into the applicability of the programmes for monitoring of LMOs. It also provided baseline data for monitoring as well as a tool for conducting general surveillance. The mapping revealed that many European countries have a variety of monitoring programmes in place aiming at observing short and long-term trends in the environment that may be relevant to monitoring LMOs.

11. In Indonesia, the Ministerial Decree on the Provisions on Biosafety of Genetically Engineered Agricultural Biotechnology Products, obliges the person holding the approval to submit a periodic report every six months or any time there is an "event of biosafety harm" (art.43). The oversight agency appears to be responsible for monitoring use (art.44(2)).

12. In Lithuania, a monitoring plan of genetically modified organisms and/or genetically modified products after placing on the market (post-commercial monitoring) is defined as an integral part in compiled notification. The specific aims of the monitoring plans are focused on (i) defining whether assumptions and findings during the conduction of risk assessment for human health and environment can be proven, and (ii) detecting unintended negative impacts for environment and human health, not evaluated during the environmental risk assessment.

13. The Mexican Standard NOM-056-FITO requires the issuance of a plant certificate for the release into the environment and/or import of LMOs. If the certificate is granted, the Secretariat of Agriculture, Livestock and Rural Development appoints officers to inspect and to monitor the transgenic product released. They are also to receive a periodical update.

14. In Namibia, the Biosafety Act, 2006 (Article 23, paragraph 3 (c)) provides that if any dealing proposed to be authorised by a permit involves the intentional release of a LMO or LMO product into the environment, the application for the permit must include, or be accompanied by, a statement containing: (c) proposed strategies and procedures to monitor any anticipated or potential effects of such release, or an explanation of the reasons if such monitoring is not required.

15. In the United Kingdom, every consent issued for importation, acquisition, keeping, releasing or marketing of LMOs comes with conditions, which include (i) keeping informed of any risks of environmental damage from the permitted activity, (ii) notifying the Secretary of State of any new information regarding the risks of environmental damage being so caused and the effects of any releases especially those when it appears the risks are more serious than apparent when the consent was first granted, and (iii) using best available techniques, not entailing excessive costs, to prevent environmental damage as a result of the activity (sect. 112 of the 1990 Environmental Protection Act as amended by regulation 9 under the GMO Deliberate Release Regulations of 1992).

16. In Tonga, the Biosafety Act – 19 of 2009 provides that the National Biosafety Advisory Committee shall, *inter alia*, monitor the development, use, handling and transboundary movement of LMOs within the Kingdom, and all matters related to the application of modern biotechnology, and coordinate responses to unintentional and unlawful transboundary movements (Clause 6, paragraph 2(f)). It also provides that the Secretary for Environment shall have the power to arrange for the monitoring and reporting of the effects to the environment arising from LMOs and the application of modern biotechnology within the Kingdom (Clause 9, paragraph 1 (f)).

III. GUIDANCE ON POST-RELEASE MONITORING OF LIVING MODIFIED ORGANISMS DEVELOPED UNDER THE PROTOCOL AND OTHER ORGANIZATIONS

Cartagena Protocol on Biosafety

17. An Open-ended Online Expert Forum and an Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management were established by the Parties at their fourth meeting and extended at their fifth meeting, to address the identified need for guidance on specific aspects of risk assessment and risk management. Following a priority setting process established by Parties to identify specific topics for the development of guidance, the AHTEG agreed to develop guidance on five specific topics including "Monitoring of Living Modified Organisms Released into the Environment".

18. The draft guidance[3] focuses on the development of a monitoring plan to address uncertainty regarding the level of risk of an LMO in the context of (i) the results and recommendations of the risk assessment, including adverse effects that were identified but not addressed in the risk assessment and (ii) unanticipated adverse effects that were not identified in the risk assessment. It includes, for example, considerations on "why", "when" and "how" to monitor, as well as how the results of the monitoring should be reported.

Food and Agriculture Organization of the United Nations

19. The FAO preliminary draft International Code of Conduct on Plant Biotechnology Post-approval[4] addresses both the development of a monitoring strategy as well as its implementation after the release of an LMO. It states, for example, that (i) governments and international organizations should monitor and assess socio-impacts of biotechnologies as a part of their technology assessment programmes (Article 8, paragraph 2), (ii) the technology assessment procedures should include monitoring and long-term assessment of environmental impact (art.8.2), and (iii) a proposer must ensure adequate and proportional monitoring of the actual effects that the organisms had on the environment as part of technology assessment procedures; suggestions are made as to what information should be recorded (Article 14, paragraph 3).

European Food Safety Authority

20. The European Food Safety Authority (EFSA) has developed the "Guidance on the Post-Market Environmental Monitoring (PMEM) of Genetically Modified Plants"[5] to clarify the objectives, tasks, tools and requirements for PMEM. Firstly, this document explains the scientific rationale for PMEM, including the concept of developing management and monitoring strategies based on the overall conclusions and assumptions of the Environmental Risk Assessment. Secondly, it provides examples and guidance to applicants on how to develop and implement their plans for Case-Specific Monitoring (CSM), taking into account the case-by-case character of CSM. In addition, it provides guidance to applicants on the strategy, methodology and reporting of General Surveillance (GS). Different tools and approaches to implement a plan for GS are considered. The EFSA GMO Panel proposes a holistic and integrative approach for monitoring LM plants in the EU that considers GS within a framework of general environmental protection monitoring. Finally, the EFSA GMO Panel makes proposals to risk managers for the future conduct of PMEM in the EU and suggests that access to PMEM data could be facilitated by setting-up standardised and centralised reporting centres.

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[3] Available at http://bch.cbd.int/onlineconferences/discussiongroups_ra.shtml.

[4] Available at http://www.fao.org/DOCREP/006/Y4839E/y4839e00.htm.

[5] Available at http://www.efsa.europa.eu/en/efsajournal/doc/2316.pdf.

Additional guidance relevant to monitoring

21. A number of other international bodies have produced guidance that refer to post-approval monitoring in a general way. These include:

(a) The Codex Proposed Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology which focuses on risk management measures including post-marketing monitoring (section 3, para. 19);

(b) The Pest Risk Analysis Guidelines of the Plant Protection Convention, which states that the effectiveness of phytosanitary measures should be monitored and risk management options should be reviewed if necessary (section 3, para. 3);

(c) The Convention on Biological Diversity, which identifies processes and categories of activities which have or are likely to have significant adverse impacts on biodiversity and monitor their effects (Article 7(c); and

(d) The UNIDO Voluntary Code of Conduct for the Release of Organisms into the Environment which states that researchers/proposers have the general responsibility to notify unexpected or adverse public health or environmental impacts to the appropriate national authorities (section II-C-3 (e)).

IV. EXAMPLES OF RECENT CAPACITY-BUILDING INITIATIVES ON POST-RELEASE MONITORING OF LIVING MODIFIED ORGANISMS

22. The capacity to undertake post-release monitoring of LMOs varies globally. Some developed countries have undertaken large-scale, long-term research and post-release monitoring programmes for LM crops that have provided an effective basis for decision making. A few of projects and initiatives have been also been implemented specifically to strengthen national capacities for LMO detection and post-release monitoring in some developing countries. Some examples are described below.

23. The Food and Agriculture Organization of the United Nations (FAO) has supported projects aimed to build or strengthen capacities on LMO detection and post-release monitoring in different countries including: the Dominican Republic, Kenya, Malaysia, Paraguay and the United Republic of Tanzania. FAO has also included a specific module on LMO detection and post-release monitoring, and hands-on training in its training programme.[6] It has also strengthened infrastructure and laboratory facilities for regulatory agencies to provide greater capacity for LMO detection and post-release monitoring.[7]

24. In 2008, South Africa and Norway initiated an Environmental Biosafety Cooperation Project (2008-2010) to help develop a post-release monitoring framework for LMOs focusing on post-release monitoring research of LM maize in terms of gene flow, impacts on target and non target insects as well as the microbial soil rhizosphere. Specifically the project sought to: develop and make available improved tools to conduct research, monitoring and assessments on environmental impacts of LMOs; improve biosafety management and research capacity and biosafety knowledge base; and strengthen the national infrastructure needed for risk assessment and monitoring of LMOs.[8] The project resulted in the

6 Available at http://www.fao.org/docrep/014/i1905e/i1905e03.pdf.

7 See: http://www.fao.org/docrep/012/i1033e/i1033e03.pdf.

8 See: http://www.sanbi.org/programmes/conservation/gmo-research-and-monitoring.

development of a framework for environmental monitoring of insect resistant maize.[9] Terms of reference for a centre of excellence (CoE) were compiled and submitted to relevant authorities for further consideration. It was recommended that the centre would, *inter alia*, offer/host training courses in biosafety; maintain a bibliographic database of references on biosafety; provide surveillance and applied research programmes on selected topics; provide independent scientific data to support the national regulatory framework and publish research findings in peer-reviewed journals. The project was preceded by a pilot project, implemented in 2007, to establish a baseline for measuring the impact of LMOs released into the environment. This included implementing a pilot project to assess the impact of LMOs (focused on LM cotton) in the environment and to establish a knowledge database and network to monitor the impact of LMOs in the environment.

25. A number of capacity-building workshops on post-release monitoring of LMOs have also been organised in different countries and regions. For example, in June 2010, a workshop on post-release and post-market monitoring of LMOs was organised in Zagreb, Croatia with support from the European Union. Participants were introduced to the legal and scientific basis and European guidelines, standards and recommendations for the methodology of the Post Market Environmental Monitoring Plan (PMEM) of LMOs. Emphasis was put on the design, procedure and evaluation of the PMEM as well as on the necessary information and systems that are important for collecting, clustering and analysis of data from the PMEM studies. The topics covered included: introduction to the "Ecological monitoring of GMOs", a conceptual framework for the design of post-market environmental monitoring of LM plants and; farm questionnaires as tool for post-market environmental monitoring of LM crops.[10]

26. The DDRN/BiosafeTrain/IOBC Global Working Group on GMOs workshop on “Environmental consequences of growing GM crops in the developing countries”, which was held at the University of Copenhagen on 29-30 November 2007 addressed the issue of post-release monitoring. The topics discussed included:

(a) “Monitoring for GM resistance in developing countries”;

(b) “Post-release monitoring regimes – is it possible to develop a blueprint?”; and

(c) “Gene flow and its consequences in non-temperate countries”.

Participants had exposure to the LM post-release monitoring system that was developed by the German Corps of Engineers. The participants agreed that monitoring is an important issue in developing countries and called for training courses and guidance in this field.[11]

27. A series of international workshops on post-market environmental monitoring (PMEM) of genetically modified plants have also been organized since 2006 under the auspices of the International Society for Biosafety Research to explore the challenges of PMEM linked to the worldwide cultivation of living modified crops.[12]

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9 See: http://www.sanbi.org/sites/default/files/documents/documents/sanbimaizereportlr.pdf.

10 See: http://ec.europa.eu/enlargement/taiex/dyn/taiex-events/library/detail_en.jsp?EventID=41585

11 See: http://www.ddrn.dk/filer/forum/File/GM_Workshop_Report_final.pdf

12 See: http://www.isbr.info/?q=node/741

V. STRATEGIES FOR STRENGTHENING NATIONAL CAPACITIES IN POST-RELEASE MONITORING OF LIVING MODIFIED ORGANISMS

28. Lack of national capacity, including lack of capacity in post-release monitoring of LMOs, is one of the obstacles hindering the effective implementation of the Cartagena Protocol on Biosafety. As countries move towards implementation of their national biosafety frameworks, there is a need to strengthen institutional and human capacity to conduct post-release monitoring of LMOs. Some government institutions (such as plant protection inspectorates and others) have experience in their traditional fields that may be relevant to monitoring of LMOs.

29. Many countries may benefit from the development of a national LMO strategy for (i) monitoring of adverse effects that were identified but not addressed in the risk assessment, (ii) monitoring of unanticipated adverse effects that were not identified in the risk assessment, (iii) detection of LMOs unintentionally introduced into the environment or that entered the country through illegal transboundary movements.

30. The following is a non-exhaustive list of examples of measures that could be taken to enhance national capacity for post-release monitoring of LMOs:

(a) Setting up a national policy and an operational system for monitoring LMOs;

(b) Adapting existing monitoring initiatives (e.g. for plant protection) to LMOs;

(c) Identification of information to be included in the application of an LMO for release into the environment, encompassing, for example, detection methods and methodological conditions for detection, including sensitivity and specificity of the methods, a proposed monitoring plan,

(d) Development of inspection materials or manuals to assist inspectors;

(e) Training of scientists and inspectors from the regulatory agencies to detect LMOs and monitor the environmental impacts of LMOs, including:

(i) Choosing sites and duration of the monitoring;

(ii) Parameters and indicators to be monitored;

(iii) Methods for data gathering and analyses; and

(iv) Requirements for reporting of monitoring results.

(f) Development of guidelines and common formats for reporting the results of monitoring (e.g. to a national database), indicating the conditions, methodology and duration of the monitoring process; and

(g) System and guidelines for subsequent verification/validation of monitoring results.

31. Participants at the eighth coordination meeting may wish to consider the information provided in this document in elaborating measures to assist Parties to develop their capacities for monitoring of LMOs, taking into account the ongoing work of the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management to develop guidance on “Monitoring of Living Modified Organisms Released into the Environment”.
