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OPEN-ENDED EXPERT MEETING ON
CAPACITY BUILDING FOR THE
CARTAGENA PROTOCOL ON BIOSAFETY
Havana, 11-13 July 2001
Item 3 of the provisional agenda*

REPORT OF THE EXECUTIVE SECRETARY SUMMARIZING INFORMATION RECEIVED IN RESPONSE TO THE QUESTIONNAIRE ON CAPACITY-BUILDING

Capacity-building needs: submission by India

Note by the Executive Secretary

At the request of the delegation of India, the Executive Secretary is circulating herewith, for the information of participants in the Open-ended Expert Meeting on Capacity-building for the Cartagena Protocol on Biosafety, a document entitled "Capacity building needs", published by the Indian Ministry of Science and Technology. The document is being circulated in the form and in the language in which it was received by the Secretariat.

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CAPACITY BUILDING NEEDS

A. The three top priority areas requiring capacity building / strengthening in India to prepare for the entry into force of the Protocol

(i) Institution Building : Multidisciplinary strategic planning capacity

1. Risk assessment of an LMO includes a safety assessment, which is designed to identify whether a hazard or safety concern is present, and if present, to gather information on its nature and severity. Such a risk assessment approach would include a consideration, on scientific basis of multi disciplinary data and information on various related and identified factors. This would require capacity to plan, analyse and take decisions on the basis of data generated on a case by case basis. Risks from LMOs include deeper understanding of the behavior of transgenic microorganisms, plants and animals. In all LMOs, the three factors namely the transgenic nucleotide sequences including the host compatible promotors, the target transgenes and the hosts need to be analyzed and understood through scientific methods. Core competence include abilities to construct and identify sequences, analyze sequence base pairs and optimize conditions for the best expression of the genes in the hosts. Multidiciplinary expertise is required to develop competence starting from molecular biology to skills in handling of sophisticated instruments. Besides, knowledge in microbiology, plant sciences as well as animal sciences are also required. The relationships between the symbiotic or antagonistic activities among different forms of life are to be understood in greater detail. With respect to food safety, there is a need to build infrastructure to:

(a) Assess the impact of LMOs on human health due to changes in key nutrients or nutrients intake levels.

(b) Detect the LMOs in the food chain.

(c) Establish network for inspection, right from the stage of import/development/marketing that is a monitoring and enforcement capacity

(d) Establish proper traceability.

(e) Establish inspection system, including appropriate segragation.

(f) Establish laboratory set up including appropriate equipment/chemicals and

(g) Have adequate trained manpower.

2. Besides, expertise is also required for building competence in quantitatively estimating the transgenic traits expressed by LMOs, and their implications on the environment and on food security issues. Though India has several institutes specializing in some of these disciplines, the need for capacitating them with more sophisticated instruments and methodologies for quantitative analysis of different analytes cannot be over emphasised. More over, right relationships among the related institutes are also to be developed in order to enable them to broaden their horizon of activities.

3. The first steps in the capacity building needs of institutes are to have proficiency in the isolation of genes, preparation of constructs alongwith development of the right cloning strategies. Transformation and isolation of fit transformants are other related areas of expertise building. After the selection of the fit transformants, the backcrossing and breeding strategy are to be adopted. The techniques in molecular biology require capacities to discover genes by the production of cDNA libraries, genomic libraries, bio-informatics (for easing sequence studies and authentication) along with capabilities to sequence natural polymeric DNA pieces. Further, there is a need for amplifying and understanding gene functioning

wherein the transformed prokaryotic hosts are to be constructed and isolated. In addition, there is a need for molecular and bio-chemical assay of the genes and gene products. For studying the expression in plants, initially constitutive promoters are to be procured, which include ubiquitin promoters, CMV-35S promoters etc. Strategies are also to be developed for over-expression. Thereafter, target specific utilization of genes by use of tissue specific promoters and terminators are to be made. In order to isolate the target constructs, proper marker genes are also to be incorporated into the constructs. Once a transformation is completed to some satisfaction, the right kinds of transformants with better agronomic benefits and traits are to be selected that concomitantly have minimum risks to the environment and to human health.

4. In order to carry out different experiments in molecular biology efficiently in areas of LMO plants in India there are presently close to 25 institutes that carry out at least some components of the above work. These institutes include Indian Agricultural Research Institute; National Bureau of Plant Genetic Resources; South Campus Delhi University; International Center for Genetic Engineering and Biotechnology; Jawaharlal Nehru University; National Center for Plant Genetic Resources; National Botanical Research Institute; Central Institute of Medicianl and Aromatic Plants; Central Institute of Cotton Research; Bhaba Atomic Research Center; Bose Institute; Calcutta University; Madurai Kamraj University; Tamil Nadu Agricultural University; Hyderabad University; Osmania University; Directorate of Rice Research, Indian Institute of Science; University of Agricultural Sciences; Indian Institute of Technology - Kharagpur; National Chemical Laboratory; Indian Institute of Horticulture Research; GB Pant University for Agriculture; Punjab Agriculture University; Hissar Agriculture University; Central Potato Research Institute; and the Central Tobacco Research Institute. These institutes are in the process of building up their infrastructure and need to step up efforts in key areas such as transformation of plants into transgenic cultivars of agronomic value. One of the main constraints is that although many of these institutes are equipped with instruments and equipment, they do not have adequate number of trained people to carry out such a developmental work. Trained manpower in this context means a minimum number of people that have complete capabilities from gene isolation to preparation of the desirable constructs, abilities to transform the hosts efficiently, competence in transforming the transformed materials into plants, and abilities to assess at each stage the extent of transgenic traits. These call for considerable training in multidisciplinary facts of molecular biology. Unless, therefore, the critical mass is in place, it would be difficult to make inventions by developing countries on a stand alone basis. Even it would be difficult to appreciate the complexities of the products and technologies.

5. In India, there are several companies in the private sector which are working on transgenic crops. There is a need to strengthen infrastructure and train the personnel in advanced techniques.

(ii) General risk assessment capacities

6. Besides capacity in molecular biology, India yet does not have adequate expertise in assessing the environmental risk from GM plants both on a short term basis as well as on a long term basis. Here also, there is a need to increase the capacity by creating infrastructure, protocols and trained manpower in different agricultural universities in the public domain as have been stated as under.

7. Environmental risk assessment capacities include study of extent of pollen flow, implications of out crossing/ cross fertilisation, the aggressiveness characteristics of LMOs, susceptibility to diseases and pests, stability of the transgenic genome, germination rates, resistance to abiotic stresses etc. Food safety evaluation includes capabilities of determination of composition and assessment of the quality of LMOs, compositional analysis and near equivalent studies of major ingredients to assess substantial equivalence, impact on human health due to changes in key nutrients, in nutrients intake levels as well as due to unintended effects from random insertion of DNA sequences or formation of new or changed patterns of metabolites, or the impact of food processing on such products. toxicity and allergenicity implications of LMOs handling procedures for allergenic substances etc. It also involves capacity to assess an LMO in

terms of a component as well as a whole food an approach distinct from risk assessment for conventional foods. For environmental risk assessment and evaluation of food safety, a series of protocols are to be developed, including post marketing monitoring from the point of view of food safety, to address specific safety issues.

(iii) Involvement of stakeholders e.g. non-governmental organisations, local communities, private sector : process for community, NGO consultation prior to decisions

8. For the acceptance of LMOs, the scientific assessment cannot be the ultimate basis of decision making, how so ever precise the scientific study may be. Scientific evaluation can not guarantee cent percent safety, although this statement does not in any way belittle the great assurance the scientific experiments provide for. The gray areas, are there in the range of less than 0.001% or even further lower, but up to these precision science can find some definitive answers. Consequently, while the major concerns would be adequately addressed on the basis of scientific experiments, there would be gray areas where the present knowledge in science would not provide a definite answer. For example, the effects of cross-pollination by transgenic pollen to its near relatives cannot be accurately predicted. The question of transfer of marker genes including antibiotic resistant genes from LMO plants to microorganisms and further to higher life forms along with the effect of such transfer can not be quantitatively resolved. In such cases, having assessed the probabilities of risks through scientific experiments and taking cognizance of the limitations of such studies, the societies would have to decide on accepting or rejecting LMOs. Such decisions would have to be taken on the basis of other non-scientific considerations such as cost benefit analysis, the relevance of LMOs to societal needs in relation to addressing the problems of hunger or meeting the nutritional requirements etc. In such instances the public including NGOs would have to play an important role in making a choice. Therefore, process for community consultation as well as NGO consultation prior to decisions will go a long way in the implementation of the Protocol.

B. The three top areas in which India has expertise and Protocol

(i) Institutional Building: Development/strengthen legal and regulatory structures

9. India has already a comprehensive legal and regulatory structure to deal with LMOs. This structure oversees the development of LMOs from research stage to contained use followed by large scale commercial use. All LMO plants require evaluation in the open environment. Guidelines have been developed for such field evaluation. Food safety issues are also addressed in the guidelines. There are detailed procedures for involving the state Government authorities as well as the Scientists from state and central government institutions. The regulations adequately bring closer the scientific personnel, the government officials as well as the legal system while considering the evaluation of LMOs for introduction in the environment.

(ii) Risk assessment: Understanding of relevant biotechnology process and applications

10. India has a well developed scientific man power who are trained in various aspects of molecular biology, immunology, microbiology, virology, plant pathology, agronomic evaluation etc. There are several R&D institutions and infra structure for the conduct of research in this area. India has also established its agricultural universities and institutional network. In addition, there are some eminent institutions undertaking food safety assessment, particularly in the areas of allergenicity, toxicity and nutrition related issues. This infrastructure has contributed to the development of stable, disease free cultivars that have contributed to increased food production. In many of these Institutes, people can be trained in specific areas.

(iii) Human resources strengthening and development: All aspects of regime development, evaluation and maintenance for risk assessment and risk management

11. Over the years India has developed expertise in scientific, managerial and legal skills to handle LMOs. A large number of locally developed scientific protocols have been utilised to assess risks of LMOs. There is a need to involve a large group of scientists and managers to coordinate risk assessment programmes. Here also experience has been gained by India through the conduct of several field experiments through out the country. Many training programmes have been organised to expose the people to nitty-gritty of risk assessment and risk management. Indian experts have also been consulted by several countries in order to frame their domestic regulations. In this area also in specific aspects, India can provide training to scientists of developing countries.

C. On the basis of the potential approaches and options for achieving the required capacity to implement the protocol suggested in paras 19-34 of the ICCP document, which ones do you consider to be useful in responding to the needs of your country identified in the previous question

12. Out of the potential approaches listed at paras 19-34 in the ICCP document on capacity building, India considers the approach suggested at paras 21 and 22 as elaborated under "Comprehensive national capacity" would be useful for responding to the needs identified above. India has a growing biotechnology sector. Products in the health care area, agriculture, industry and environmental management have made good progress in research stage. A number of products are expected to be commercialized soon. In such a scenario India needs to comprehensively strengthen its core competence in risk assessment and risk management practices.

D. What other suggestions do you wish to make on capacity building for implementing the Biosafety Protocol

13. In India there is a need for the Government to identify Institutes and Centres of Excellence and to take assistance from such Institutes in the conduct of experiments for addressing various issues of environmental safety and human food safety. There is a need to upgrade these institutions for generating data and to provide appropriate technical inputs to decision making and risk management. Environment safety questions need to be addressed in a transparent manner in order that credibility and confidence is generated. Publicly funded institutions can be supported and the efforts of private companies encouraged.
