Capacity Building on Biosafety : Training Needs Assessment

Project Coordinating and Monitoring Unit (PCMU)
Ministry of Environment & Forests
New Delhi

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सत्यमेव जयते

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GOVERNMENT OF INDIA
MINISTRY OF ENVIRONMENT & FORESTS

Foreword

Biotechnology has great promises for medicine, agriculture and industry. Even though the use of biotechnology products and processes in diverse application areas are playing an important role in sustainable development, such widespread applications have at the same time, raised new challenges for end users. This has brought about a new area of global concern amongst the scientific community for environmental protection and conservation, and the need for a policy of sustainable development in harmony with the environment. Keeping the socio-economic structure and the scientific developments in the field of biotechnology in view, a necessity for addressing the biosafety issues has been felt and as a consequence the Cartagena Protocol on Biosafety was adopted in January 2000 as a supplement to the Convention on Biological Diversity. This protocol addresses the issues of safe transfer, handling and use of Living Modified Organisms (LMOs) that may have an adverse effect on biodiversity, taking into account risks to human health and focusing specifically on transboundary movements. India has ratified the "Cartagena Protocol on Biosafety" in January 2003. As per Article 22 of the Protocol, each country that is Party to the Protocol has to develop and/or strengthen the human resources and institutional capacities in biosafety for the purpose of the effective implementation of the protocol.

The first step in the evolution of a national biosafety system requires framing up of a national policy consistent with policy objectives related to food, agriculture, the environment, and sustainable development. It is, therefore, felt necessary for an assessment of the existing scientific and

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technical capacity and strengthening capacity that would support this process. Capacity building, therefore, in this context, assumes great significances to strengthen and/or develop both human resources and the institutional and infrastructural capacities. This would ensure that, in the wake of the emerging biotechnology revolution, countries, in particular developing countries are able to cope with new advances and applications of biotechnology and to achieve safety in biotechnology.

Ministry of Environment and Forests is currently implementing a GEF-World Bank Capacity Building Project on Biosafety, which will enhance India's national capacity to implement the Cartagena Protocol on Biosafety. This project addresses the capacity building needs of the country for implementing the national biosafety framework related to the transboundary movement on LMOs in the context of the Cartagena Protocol and coordination of the implementation of the Biosafety Clearing House (BCH). As part of the capacity building project, this Training Needs Assessment Survey has been undertaken to identify priority areas for training of various agricultural biotechnology stakeholders in both public and private sectors in regards to genetically engineered crops and its derived products. The survey was conducted through a process of consultation with experts and other stakeholders which suggest that a combination of national and international events, series of workshops for various stakeholders, laboratory/ technical training, studies, circulation of publications and documents etc. are required to create awareness as well as to provide training on key issues. The survey was carried out by M/s Biotech Consortium India Ltd. (BCIL). The survey was coordinated by Dr. Vibha Ahuja, Deputy General Manager, BCIL & Dr. Manoranjan Hota, Project Coordinator & Additional Director, Ministry of Environment & Forests.

I am sure that this document will be useful for structuring and implementing the capacity building exercises.

Desh Deepak Verma
Project Director & Joint Secretary

Contents

1. INTRODUCTION

In the recent past, there has been a rapid increase in research and development activities involving genetically modified organisms (GMOs)/living modified organisms (LMOs). At the same time, there has also been considerable apprehension and concerns about ensuring safety in use of GMOs, particularly with respect to their handling, containment and the impact on human health and environment. To address these concerns, the Ministry of Environment and Forests (MoEF) and the Department of Biotechnology (DBT), the two apex regulatory bodies, have formulated regulations and brought out guidelines on biosafety. India has also ratified the Cartagena Protocol on Biosafety, which has specific focus on transboundary movements of LMOs so as to ensure adequate level of protection in their safe transfer, handling and use.

There has been significant progress in building institutional capacities and regulatory framework in India through the cumulative efforts and initiatives of many organizations to keep pace with the advances in development and use of GMOs/LMOs. However, there is an urgent need to take stock of the situation and identify major components of capacity building requirements in terms of strengthening scientific institutions, development of human resources, research and technology, legislation, regulations, policies and programs for biosafety to have a consolidated action plan in place to meet the obligations of the Cartagena Protocol and effective implementation of the national regulatory framework.

Ministry of Environment and Forests (MoEF) has initiated a GEF-World Bank capacity building project on biosafety, to enhance India's national capacity to implement the Cartagena Protocol on Biosafety. The specific objectives of the project include strengthening the institutional and legal framework, to improve capacity and coordination

in decision making across Ministries, improve capacity for risk evaluation and management etc. Training being one of the key elements for achieving the above, MoEF carried out a Training Needs Assessment Survey with the assistance of Biotech Consortium India Limited (BCIL) to assess the requirements in these areas through a process of consultation with various stakeholders prior to initiating countrywide training programmes.

2. OBJECTIVE

The objective of the survey was to identify the training needs of agricultural biotechnology stakeholders in the public and private sectors as regards genetically engineered crops including plants used for biopharmaceuticals products, livestock and the products derived from these (including foods).

3. METHODOLOGY

The survey was a combination of field studies through questionnaires and personal discussions supplemented by extensive desk research. A detailed questionnaire was prepared covering the following areas for identifying the training needs as well as other capacity building requirements:

- identification and development of LMOs/GMOs;
- risk assessment (impact on human health and environment) and management;
- regulatory capacity building;
- human resource development and training;
- public awareness, education and participation;
- information exchange and data management;

- scientific and institutional collaborations;
- technology transfer;
- socio-economic considerations; sustainable use and conservation of biodiversity

A scale of 1-5 was given for priority ranking in the above areas. Out of the detailed questionnaire, short questionnaires were also drafted for state level officials, quarantine officials, social experts etc. The questionnaire was prepared in such a way so as to get inputs for assessment of training needs as well as designing the training programmes. Personal interviews were held with selected stakeholders by visits and telephonic conversation.

About 150 responses were received from various stakeholders viz. Central Government, State Government, research organizations, industry, regulatory bodies, civil organizations, social experts, agriculture service providers and others. A computerized programme was prepared for analyzing the results of the survey, which was used to generate different query based reports. Priority ranking of the areas for capacity building has been done for total number of responses as well as for individual stakeholders. The written responses to questionnaires as well as personal discussions with the respondents were used for each area for assessment of the training needs.

Extensive desk research included collection of information on country's obligations to the Cartagena Protocol, existing regulatory systems of approval as well as trade of LMOs/GMOs and overview of existing initiatives for capacity building etc. The status of implementation of Cartagena Protocol in India and the requirements for each Article have been studied. An overview of the existing training programmes has been prepared which includes the stakeholders targeted, course content and the recommendations that emerged out of such training programmes. Over 5000 participants have attended the events organized

by MoEF, DBT and BCIL in the last few years. The feedback received from the participants in these programmes through surveys conducted from time to time (for IBSCs, state level officers, agriculture service providers, farmers etc.) as well as presentations made by eminent experts have also been taken into account for assessment of training needs.

The field survey findings have been combined with the above to workout the requirements of various stakeholders by drawing a training needs matrix, based on which the training modules have been proposed. A stakeholder consultation was organized to discuss the field survey findings with experts from government, industry, institutions, etc. The participants endorsed the field survey findings and gave suggestions. The inputs received have been suitably incorporated in the report. The report was also presented to Steering Committee of the GEF-World Bank project which approved the report.

4. REGULATORY FRAMEWORK

Regulatory framework in India for GMOs/LMOs including rules notified in 1989 under Environment (Protection) Act, (EPA)1986 guidelines issued in 1990 and 1998 and sections of Seed Policy, 2002 was studied. Food control system under Prevention of Food Adulteration Act, (1954) has been studied with respect to applicability to food derived from GM crops. Provisions related to GM food under Food Safety Standards Bill, 2005 prepared by Ministry of Food Processing Industries have also been detailed. Report of the task force on application of agricultural biotechnology set up by Ministry of Agriculture under chairmanship of Prof. M. S. Swaminathan was also consulted. An overview of sections related to GM crops in the Draft National Environment Policy, 2004 and Draft Biotechnology Strategy, 2005 has also been included.

5. CARTAGENA PROTOCOL ON BIOSAFETY

Cartagena Protocol on Biosafety is an attempt to produce a globally harmonized regime for biosafety under the Convention of Biological Diversity (CBD). The objective of the Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of LMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account the risks to human health, and specifically focusing on transboundary movements. The Protocol entered into force on September 11, 2003. As on date 131 countries largely comprising of developing countries, have ratified the Protocol. India ratified the Protocol in January 2003.

The Protocol features two separate sets of procedures, one for LMOs that are to be intentionally introduced into the environment and one for those that are to be used directly as food or feed or for processing. Various elements of the protocol that merit attention are Advance Informed Agreement (AIA) procedure, simplified system for agricultural commodities, risk assessment, risk management and emergency procedures, export documentation, Biosafety Clearing House (BCH), capacity-building, public awareness and participation and issue of non parties. Present status of compliance and capacity building needs for various provisions of the Cartagena Protocol have been studied.

6. ONGOING TRAINING PROGRAMMES

A review of the existing training programmes for various stakeholders indicated that there has been ongoing efforts in implementing training through organizing national and international events, websites, publications etc. Most of these programmes have been under the aegis of apex regulatory bodies i.e. MoEF and DBT. About 50 events have been organized by MoEF, DBT and BCIL in the last few

years with active participation of government officials, scientists, industry representatives, NGOs, farmers etc. in these events. The feedback received from the participants in these programmes through surveys conducted from time to time (for IBSCs, State level officers, agriculture service providers, farmers etc.) as well as presentations made by eminent experts have also been taken into account while drawing the recommendations. Other institutions who have conducted trainings include: National Bureau of Plant Genetic Resources (NBPGR), G.B. Pant University of Agriculture and Technology and Central Food Technological Research Institute (CFTRI). Organizations such as The Energy Resources Institute (TERI) and Research and Information System for Developing Countries (RIS) have organized stakeholders' consultations on some issues related to GMOs/LMOs.

The approval conditions for commercialization of Bt cotton in India accorded to MAHYCO in 2002 included undertaking awareness and education programme, *interalia* through development and distribution of educational material on *Bt* cotton to farmers, dealers and other related stakeholders. In view of the above, M/s. MAHYCO conducted awareness programmes for dealers, company executives, field assistants as well as agriculture department officials in the various districts of Bt cotton growing states. In addition, farmer education programmes were organized in two phases i.e. pre-sowing and post-sowing through farmer meetings, mailers, audio cassettes and pamphlets in local languages. The training programmes covered information on various aspects related to cultivation of Bt cotton. Similar programmes have been taken up by other industries who are marketing Bt cotton hybrids.

In addition, representatives of private sector have been regularly participating in various training programmes and also have sponsored various events.

MoEF and DBT have prepared the following websites for

information dissemination and awareness creation:

- Capacity building on biosafety -(http://www.envfor.nic.in/divisions/csurv/biosafety/default.htm)
- Biosafety Clearing House (www.indbch.nic.in)
- Indian GMO Research Information System (IGMORIS)
- Biosafety regulation website (to be launched shortly)

Several publications such as background documents or proceedings of various events have been widely circulated in the country. Industries such as Monsanto and Syngenta are also circulating newsletters covering information about GMOs. MoEF is also publishing a quarterly biosafety newsletter for wider dissemination of information for all the stakeholders. DBT and BCIL have released a handbook for IBSC members.

7. FINDINGS OF THE SURVEY

Risk assessment and management has emerged as the top most priority for imparting training for human resource development. Other major priority areas listed are public awareness, education and participation followed by scientific, technical and institutional strengthening and collaborations.

Majority of the respondents indicated that risk assessment capabilities in India are limited among molecular biologists engaged in development of GMOs. Those currently involved in the risk assessment are mainly agricultural scientists and the members of the regulatory bodies i.e. IBSC, RCGM and GEAC. For studying the impact on human health and environment, scientific data need to be generated by experts from several disciplines, thereby clearly indicating the need to provide training to a multiplicity of stakeholders. Foreign collaboration and

training have been recommended not only for the areas for the development of scientific methods and protocols for risk assessment, but also to enhance competence to review/audit risk assessment and national biosafety research programmes. It has been suggested that there should be a dedicated technical cell within the two apex regulatory bodies i.e. DBT and MoEF equipped with requisite Information Technology tools to have rapid access to reference material/databases on risk assessment for effective review within the stipulated time.

Under risk management, maximum emphasis has been given to detection, management and prevention of unintentional transfer of LMOs. The committees and institutions involved in the compliance and monitoring also need to be extensively trained particularly at the functional level.

A multi pronged approach is required for human resource development in the country through focused training programmes for specific categories of stakeholders, participation in national and international events, circulation of various publications as well as long term training programmes.

The status of regulatory capacity has been rated as medium in the legal framework and low in compliance mechanisms. Regulatory capacity building has been divided into three areas i.e. legislative, administrative and technical and scientific framework. Regular training of both regulators and compliance officers by noted national and international experts, at least once a year has been suggested. Development of handbooks and manuals for specific target segments viz. health inspectors, agriculture officials, pollution control board officials, border control and quarantine officials has also been suggested.

Risk communication, public awareness and education skills and strategies (documents viz. newsletters, bulletins, articles in the

newspaper etc.), and organizing of biosafety awareness activities have been indicated as priority areas. Suggestions for achieving these objectives include training of risk communicators particularly among members of regulatory bodies and institutions involved, seminars, radio and television talk shows including reputed scientists, local case by case synthesis of information and dissemination, regular meetings with media to give authentic information etc.

Guidelines for safe handling, packaging and transport of LMOs need to be developed along with methods and systems for their identification. Systems for inspection and segregation of LMOs have been listed as the priority areas. The target segment for providing training include organizations involved in trade and border control. Suggestions have also been made for training of social and economic experts for undertaking analysis of awareness levels in different strata of the society.

8. STAKEHOLDERS

Stakeholders to be involved in the capacity building activities have been identified as given below:

(i) **Decision/Policy makers:** Senior government officials from the concerned Ministries and Departments and the advisory bodies, which are involved in decision making as well as drafting of national policy need to be informed about the basics of biotechnology/ GMOs, national regulatory framework and international commitments. Regular interaction/collaboration between different departments helps in handling various issues within legislative and multilateral framework, thereby avoiding of duplication of efforts.

(ii) **Regulators:** Members of various regulatory as well as administrative committees have to be updated with advances in technology and regulatory aspects at both national and global level. These officers

include technical advisors, administration and subject experts, application reviewers/assessors. Their responsibilities include review of applications/assessment, providing feedback for decisions, inputs for policymaking, formulation/updation of various guidelines etc.

(iii) **Scientists/technical experts:** These include scientists and technical experts from both public and private sector, who are involved in the research and development of GMOs and biosafety studies.

(iv) **Enforcement officials:** Members of State Biotechnology Coordination Committees (SBCCs) and District Level Coordination Committees (DLCCs), officials from State Departments of agriculture, health,environment, health and food inspectors, officials involved in border control such as customs, plant quarantine and other port officers need to regularly updated about the development in the regulation front as well as introduction of new products for planning implementing mechanisms.

(v) **Legal experts:** Selected group of lawyers particularly those who are specializing in environmental law need to be informed about biotechnology and biosafety aspects of GMOs so that they can help in international negotiations as well as harmonization of relevant laws/policies at both regional and national level.

(vi) **Economists:** Socio economic considerations being an integral component of decision making, economists particularly agriculture economists need to be involved for evaluation of GM crops with respect to economic benefits at various sections of the society.

(vii) **Data/ information managers:** Training of information managers is extremely important for compilation of up-to date information and data management as per the requirements of specific stakeholders.

(viii) **Researchers and technicians:** Scientific staff at the level of researchers and technicians need to be trained by short/long term programmes to meet widespread laboratory requirements of field testing as well as identification of LMOs both for domestic use and transboundary movement.

(ix) **Graduate and undergraduate students:** Students of various biotechnology courses need to be informed about biosafety aspects as well as applicable regulations of GMOs/LMOs in addition to the basic concepts.

(x) **Interest groups:** Various interest groups such as consumer organizations, farmers, industry associations etc. need to be adequately informed about specific risks and actions taken to alleviate them. Both formal and informal dialogues by regulators/ scientists and industry with these groups help in increasing mutual trust and credibility and reducing controversies.

(xi) **Mass media and outreach/extension workers:** Media is the primary source of information for general public and their education is important in promoting informed discussions on merits and concerns associated with GMOs. Outreach/extension workers such as agricultural extension departments in the state agricultural universities need to be educated about the latest developments and biosafety issues so as to enable them to communicate effectively based on the facts.

(xii) **General public and political leadership:** Uninformed public is more receptive to inaccurate and biased messages than those who have some knowledge about GMOs. Therefore, it is very important to provide clear and accurate information translated into everyday language to general public.

9. TRAINING NEEDS MATRIX

A matrix has been prepared to identify the training needs by marking the competency, knowledge and skill required for major target groups. This matrix will help in drawing the recommendations for training of various stakeholders as well as in devising the course content for these training modules.

10. PROPOSED TRAINING MODULES

Training programmes need to use various approaches to support capacity building for handling various activities involving biosafety issues related to genetically modified organisms including import, export, manufacture, use etc. Whereas seminars and consultations will help in highlighting the need for appropriate policies for Government in this regard, educational conferences involving national and international experts can be organized to raise awareness of various stakeholders about potential benefits as well as environmental and food safety concerns associated with biotechnology. Technical training for conducting biosafety reviews is extremely important for building capacity in the critical area of implementation of rules and regulations of biosafety.

In addition to these training programmes for scientists, regulators and industries, massive campaign is required for promoting public awareness about the applications of genetic engineering in agriculture, its potential benefits as well as risks and constraints. A multi pronged strategy need to be used to target various stakeholders through both print and electronic media.

Training need requirements, preferred communication media and duration of the training programmes by various target segments have been taken into account to draw the following recommendations to strengthen the capacity for handling issues related to national regulatory

TRAINING NEEDS	MAJOR TARGET GROUPS												
(KEY COMPETENCES-KNOWLEDGE AND SKILLS REQUIRED)	Decision/ polity-makers	Government regulators	Scientists/technical, advisors & experts	Enforcement officials	Customs officials	Lawyers	Economicsts	Data/information managers	Researchers & technicians	Graduate & undergraduate students	Interest groups (Consumer groups, farmers, NGOs) Associations	Mass medial/ extension workers	General public, politicians
General biosafety/ biotech knowledge	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Molecular biology skills									✓	✓			
Biosafety research/ field trial techniques (e.g. buffer zone, isolation distance, etc.)		✓	✓						✓	✓			
Risk assessment & management	✓	✓	✓	✓			✓	✓	✓	✓			
Audit of risk assessment reports and risk management plans			✓	✓					✓				
Safety requirements and procedures for international and unintentional LMO releases	✓	✓	✓	✓					✓				
Tools for monitoring the handling, transport, packaging and use of LMOs	✓	✓	✓	✓	✓				✓				
Compliance requirements under the CPB	✓	✓	✓	✓		✓		✓	✓	✓	✓	✓	✓
Harmonization of biosafety related sectoral laws/policies including international agreements	✓		✓	✓		✓				✓	✓	✓	✓

TRAINING NEEDS	MAJOR TARGET GROUPS												
(KEY COMPETENCES-KNOWLEDGE AND SKILLS REQUIRED)	Decision/ polity-makers	Government regulators	Scientists/technical, advisors & experts	Enforcement officials	Customs officials	Lawyers	Economicsts	Data/information managers	Researchers & technicians	Graduate & undergraduate students	Interest groups (Consumer groups, farmers, NGOs) Associations	Mass medial/ extension workers	General public, politicians
Harmonization of biosafety related sectoral laws/ policies including international agreements	✓		✓	✓		✓					✓	✓	✓
Regulatory training (legal, policy, enforcement, inspection, etc.)	✓	✓	✓	✓	✓	✓							
Preparation and presentation of LMO export or release applications/ dossiers			✓			✓			✓				
Review of applications and the accompanying dossiers			✓	✓		✓							
Administrative practices (including handling of requests for LMO imports or releases)		✓						✓					
Decision-making practices, including assessment and integration of socioeconomic considerations	✓	✓	✓	✓							✓	✓	✓

TRAINING NEEDS	MAJOR TARGET GROUPS												
(KEY COMPETENCES-KNOWLEDGE AND SKILLS REQUIRED)	Decision/ polity-makers	Government regulators	Scientists/technical, advisors & experts	Enforcement officials	Customs officials	Lawyers	Economicsts	Data/information managers	Researchers & technicians	Graduate & undergraduate students	Interest groups (Consumer groups, farmers, NGOs) Associations	Mass medial/ extension workers	General public, politicians
Drafting/ use of technical manuals & guidelines			✓	✓	✓	✓		✓	✓				
Procedures to be applied to LMO transboundary movements (including information on neighboring countries)	✓	✓	✓	✓	✓	✓		✓		✓			
Documentation requirements for LMO shipments		✓	✓	✓				✓					
LMO detection & quantitative analysis			✓		✓	✓			✓	✓			✓
Cost/ risk-benefit analysis	✓	✓				✓					✓	✓	✓
Systems for identification of LMOs including traceability procedures			✓	✓	✓				✓				
Public awareness and participation	✓	✓	✓					✓		✓	✓	✓	✓
Data and information managment, including use of the BCH		✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓

framework as well as obligations with respect to international agreements particularly Cartagena Protocol on Biosafety:

- **Public awareness activities:** Public awareness programmes are required to educate and provide working knowledge to various stakeholders. Massive audience and language friendly communication tools, training methods and modules need to be developed in order to reach out to maximum targets. Implementation of regulations also requires great awareness at the grassroots level and a strong extension network, which can carry forward the message. This requires capacity building in terms of both infrastructure and human resource development at the grassroots levels. Some of the suggestions in this regard include:

  - Both print and electronic media should be used for awareness programmes through the existing networks in the country such as agricultural extension offices and departments, nutrition education departments, health education programmes etc., which are traditionally trusted by the target groups.

  - Network of scientific communicators to be created who will interact with the media as well as deliver regular talks to different categories of stakeholders.

  - Regulators need to be trained about risk communication strategies as per international guidelines.

  - Development of TV, radio educational programmes on biosafety issues in collaboration with the local as well as national level agencies.

  - Primers/brochures/booklets/FAQs/glossary of terms targeting various stakeholders and in different languages to be extensively circulated.

- Regular interaction with media, political leadership and other stakeholders for sensitization on important issues to ensure circulation of authentic information.

- Awareness and participation of students in schools and universities through interactive programmes and circulation of literature in easy to understand language and formats.

- **National Workshops:** There is an urgent need to target stakeholders across the country by organizing events such as:

  - Series of events for custom, port, plant quarantine officials etc. with the focus on the basics of GMOs/ LMOs, biosafety issues, identification procedures, national regulatory framework, international commitments etc. Visits to scientific institutions should also be organized.

  - Series of workshops for scientists of state agricultural universities, agricultural research institutions and related organizations focusing on:

    - Environmental risk assessment procedures
    - Management of field trials
    - Risk communication strategies

  - Series of workshops for scientists of health and nutrition organizations on

    - Food safety assessment procedures
    - Communication strategies

  - Consultations/workshops on post release monitoring procedures and emergency measures for unintentional movement of LMOs.

  - Series of events for health and food inspectors to sensitize about developments and regulations in the area.

- Programmes for training the trainers on biosafety issues for wider outreach and dissemination of science based information.
- National consultations among various stakeholders particularly with those involved in trade and transboundary movements on various articles of Cartagena Protocol particularly Article 7-8 (AIA procedures), Article 15 (risk assessment and management), Article 18 (documentation requirements) and Article 27 (liability and redress).
- Regular inter-ministerial consultations on crosscutting issues regarding Cartagena Protocol and other international agreements particularly WTO
- National workshops on various crops under development (one crop at a time) to study its characteristics in a comprehensive manner.
- National consultations for development of guidelines in the area of phytopharma, transgenic animals, transgenic fish etc.

The suggested approach in organizing above events is to have coordination at the central level for interaction with the local/regional organizations for conducting nationwide events in order to have uniformity and complimentarity with the national approach. Involvement of representatives of both public and private sector should be encouraged.

- **Regulatory strengthening:** Training of the regulators is extremely important for effective implementation of the regulatory framework. This includes capacity building of the members of various statutory committees, secretariats operating these committees in DBT and MoEF, DBT nominees in IBSCs and senior/middle level officers in concerned ministries and the departments. Some of the suggestions include:

- Brainstorming sessions may be organized for GEAC and RCGM members along with national and international experts on latest developments in the areas of research as well as international regulations and experiences of other countries.

- Officials handling biosafety issues in secretariats operating the statutory committees such as RCGM in DBT and GEAC in MoEF may be encouraged to participate in various events.

- Regional IBSC consultations may be organized on a regular basis to discuss the problems being faced by IBSCs and understand their information needs. Experts can be invited in these consultations for deliberations on the latest issues for guidance to IBSCs. Mechanisms to provide regular updates to IBSCs on the decisions taken as well as developments in the regulatory framework may be operationalized.

- Similarly consultation among SBCCs and DLCs may be regularly organized including interaction with officials from central Ministries, members of RCGM and GEAC and leading experts to discuss the problems being faced, understand their information requirements and provide updates on both development and regulatory fronts.

- In addition to strengthening the capacity of the statutory committee members, senior and middle level officers of other concerned Ministries and Departments such as Ministry of Agriculture, Ministry of Health, Ministry of Food Processing Industries, Ministry of Commerce etc. need to be apprised of the information on GMOs through resource materials on biosafety issues such as newsletters, bulletins, brochures, leaflets etc.

- **Laboratory training:** There is an urgent need to hold a series of seminars that would serve as brainstorming sessions in specific research areas pertinent to GMO biosafety. These would include questions of immediate concern for GMOs already commercialised or close to the commercial release stage. The comparison of strategy and results obtained worldwide would help define question requiring further research in the country. The seminars may be held in both the areas of food and feed safety evaluation and environmental risk assessments. The topics for food safety assessments may be toxicity, allergenicity, nutritional enhancement etc. whereas the topics for environmental risk assessment could be assessment of horizontal gene flow; impact on non target organisms and studies of their interactions with pests and pathogens; impact of novel organisms on agronomy and farming practice, effect on microbial populations; means for reducing or managing risk etc. Strategies to generate biosafety data in the local agro-ecological background should be discussed to make consolidated and coordinated plans for research. It is extremely important to consider redeploying of researchers working in the traditional subjects as agronomy, botany, microbiology, food toxicology and plant breeding and genetics to take research in biosafety. Such seminars that will expose them to various biosafety issues followed by focused training programmes would go a long way in capacity building in the area of biosafety research.

  Training programmes on good laboratory practices are also required to understand the importance of biosafety. The researchers working in State Agricultural Universities (SAUs), universities, research institutions etc. should be exposed to such practices by organizing programmes conducted at selected institutions. The Centres of Plant Molecular Biology could take a lead in this direction in association with institutions such as ICGEB, which have excellent facilities.

- **Updation of rules/guidelines:** In line with developments in the GMOs taking place at a rapid pace and the transition of the world trade norms due to various international agreements, such as Cartagena Protocol, WTO and Codex, there is an urgent need to review and update the provisions of national rules and guidelines as well as notify additional policies/rules/guidelines.

  Rules 1989 for the manufacture, use/import/export and storage of hazardous micro organisms/genetically engineered organisms or cells (under Environment Protection Act, 1986), including its annexures may be updated keeping in view the recommendations of Swaminathan Committee, Mashelkar Committee, National Environment Policy and Draft National Biotechnology Strategy . Rules and guidelines applicable in other countries may be compiled and analysed by Committees constituted on specific issues. Interaction with international experts may also be a part of consultative exercise.

  Detailed guidelines for new GMOs and products thereof as well as newer applications of existing GMOs e.g. transgenic animals including livestock and fish, use of plants and animals for production of pharmaceuticals/biochemicals, clinical trials of plant/animal based pharma products etc. need to be developed. Issues such as delivery system for plant based recombinant edible/injectable vaccines to the farmers need to be regulated taking into consideration the requirement of storage, in terms of temperature and other physical parameters of the edible plant including its transportation.

- Studies and surveys: Studies and surveys are important instruments for collecting information for planning various activities as well as implementing the same. Some of the areas which need to be urgently taken up are:

- Study on review of guidelines for transport of LMOs
- Study on global status, impact and cost implications of labeling.
- Baseline surveys for developing protocols for risk assessment particularly ecological issues such as impact on non-target organisms for sustainable use and conservation of biodiversity.
- Baseline surveys for assessment of awareness among the user segments such as consumers, farmers, processors etc.

- **Publication/documents/websites/video films:** Information on issues related to GMOs/LMOs needs to be provided in variety of formats such as resource material on specific topics, brochures, pamphlets, booklets, peer reviewed scientific publications, review articles/current expert opinions, conference proceedings, reports and documents form international organizations etc. These can be disseminated both through the print and electronic forms. The regulations/ decision documents from the national approval committees available for public access, successful case studies and experiences of the users are rich sources of information in identified risks and management options for particular GM crops and products. These can be also used in preparation of publications/video films etc. Some of the suggestions for immediate consideration include:

  - Handbooks for various regulatory bodies
  - Resource material on biosafety issues for specific stakeholders
  - Manuals on risk assessment and management procedures
  - Manual on AIA procedure
  - Manuals on various detection methods and approaches for LMOs
  - Newsletters/ Bulletins
  - Video films on successful case studies

- CDs/videos on regulatory requirements
- Dedicated websites on biosafety

- **Study tours:** Study tours/exchange programmes as well as participation in the international conferences should be regularly undertaken by scientists, regulators etc. to get exposed to the international developments and procedures. For example, Government of Australia has enacted new Gene Technology Regulation Act and has approved 25 GM products including food products. It has a well planned consumer awareness programmes and also trained the science communicators. Canada has well defined risk assessment and management systems in place. Mexico is a mega biodiverse country and centre of origin for maize and it has approved GM maize for cultivation. It is important to study how the regulatory authorities are taking precautions to ensure the conservation of its land races. Several such interesting models should be studied by exchange programmes i.e. interaction with the regulators and scientists by visiting them and/or inviting in India.

- **International conferences:** The following international conferences are suggested for meeting the immediate capacity building requirements:

  - LMOs testing methods, facilities and equipments including both private and public sector
  - Risk assessment and management procedures including case studies by different countries
  - Regional conference (Asia or Asia Pacific) on understanding and harmonization of biosafety rules, guidelines and priorities/ approach for effective implementation of Cartagena Protocol.
  - Regional conference on labeling approaches

- **Directory of resource persons:** For undertaking such wide ranging capacity building activities, there is a need not only to develop a critical mass of experts at all levels, but also provide information about these experts for organizing of training programmes. A roster of 50 Indian experts will be available at BCH but for a vast country like India, there is an urgent need to prepare and continuously update a directory of resource persons. The directory may provide information on the experts classified on the basis of various subject areas as well as locations.

- **Compendium of Biosafety Training Programmes:** There is a need to have a compendium of existing biosafety training and education programmes as it would help to improve accessibility to available training and education opportunities to stakeholders/professionals who require such training and also provide a general overview of who is providing what training. It would also enable training institutions to announce their new programmes and to have an overview of the programmes offered by other institutions and plan accordingly. Compendium needs to be a dynamic, flexible and up to date resource and not a static list. In this regard, it is suggested that the compendium may be a searchable database, which will allow users to search for courses that meet their specific needs and competencies they require. It may clearly have search options to specify whether the course/seminar is a standalone programme or part of a formal degree programme. It may contain basic summary information about the different courses and a link to the respective websites for further detailed information. Common formats may be developed and all the training institutions (both government and private) invited to provide information to the compendium using the common format.

- **Training programmes:** Training programmes, both short term and long term need to be organized to provide both theoretical and practical training. Some of the suggestions in this regard are:

  - Training programme for in service officials such as technicians in food testing laboratories, seed testing laboratories, public analysts, plant quarantine officials etc. at designated laboratories/ research institutions for duration ranging from 1-4 weeks depending on the level of training requirements.

  - Distance training programmes for beginners as well as advanced training modules.

  - Special postgraduate diploma/degree course on risk assessment and management, biosafety regulations etc.

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