

# Towards a Framework for Socio-economic Aspects in Biosafety Protocol

The Article 26 of the Cartagena Protocol on Biosafety (CPB) requires the Parties to have in place mechanisms to incorporate socio-economic considerations while reaching a decision on the import of living modified organisms (LMOs) and encourages the Parties to cooperate on research and information exchange on any socio-economic impacts of living modified organisms.

The “Nagoya Kuala Lumpur Supplementary Protocol” and “Decision BS V/3” of the COP MOP-5 have provided fresh impetus to the discussions on the socio-economic considerations. It is now held that the manufacturers are also accountable for damages arising out of the use of LMOs, a proposition that was vehemently opposed till the deliberations at Nagoya last year. The Parties are also required to cooperate in the capacity building process by sharing the research and information and best practices. In pursuant to the COP MOP-5 Decision and as a preparatory work for next COP-MOP (in 2012) online global and regional conferences have already been organized by the Secretariat of Convention on Biodiversity (CBD) on socio-economic considerations and a workshop is proposed on capacity building for the research and information exchange on socio-economic impacts of LMOs later this year.

In this context, this Policy Brief aims at providing an overview of the socio-economic aspects that are already there in the decision making process in different countries and at identifying phases in the commercialization of LMOs where different socio-economic factors are considered for identifying the capacity building requirements. From a regulatory perspective assessing the safety, efficacy and effectiveness of the LMOs are important. Safety and efficacy are technology dependent factors and hence can be assessed by quantifiable results with tested and accepted methodologies. Safety assessment includes environmental assessment and food safety assessment, and the science of risk assessment provides guidance in this. The methodologies, good practices and protocols have been standardized and international organizations like WHO, OECD and Codex Alimentarius have issued guidelines that are globally accepted and practiced.

Efficacy of a LMO can be tested by measuring the expected outcome with the actual outcome under the specific conditions. For example, if the expected outcome is 70 per cent reduction in targeted pests on account of the impact of the Bt toxin from the LMO, this can be tested and verified whether the reduction is there as is being projected. The

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expected efficacy is estimated, based on the models and laboratory experiments while the efficacy under controlled conditions may be different. As efficacy has direct and indirect impacts, like increase in yield and reduction in use of inputs, it has implications in assessing the socio-economic (SE) aspects of LMOs. Effectiveness on the other hand is dependant on the actual performance of LMOs or their usage under different conditions and contexts. Factors that are not related to the technology per se influence the performance. For example, the cost of LMOs (for example, Bt cotton seed), use of inputs, factors like condition of the soil, handling/management of technology are some of the factors that can affect the performance of LMOs in agriculture. Thus, it is possible that the same technology embedded in a LMO can lead to different outcomes on account of these factors, under different conditions and contexts. For understanding the SE impacts this has to be borne in mind as effectiveness has implications in terms of the SE impacts.

The Cartagena Protocol on Biosafety establishes the right of Parties to take into account the socio-economic considerations arising from the impact of LMOs on the conservation and sustainable use of biodiversity. Article 26 of the Cartagena Protocol enables countries to take into account the socio-economic considerations in biosafety decision making. Article 26 of the Cartagena Protocol on Biosafety states:

*1. The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities. 2. The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities.*

In developing countries, like India, where a sizeable population is dependent on agriculture, the socio-economic impact

assessment is as essential as scientific and technical assessment. Many developing countries are centers of origin of diversity, and the potential adverse impacts of LMOs on biodiversity and traditional agriculture have to be taken into account when deciding on permitting use of LMOs. This includes field trials of LMOs also as unintended consequences of such field trials may adversely affect the *in situ* conservation and use of plant genetic resources. The Taskforce on Agricultural Biotechnology, headed by Dr. M.S.Swaminathan, had recommended: 'As India is endowed with rich agro-bio diversity, important centres of origin and diversity should be protected so as to conserve precious agro-biodiversity in their pristine purity. A case in point is the Jeypore tract of Orissa, which is very rich in rice genetic resources. Such areas should be earmarked as "Agro-Biodiversity Sanctuaries", along the pattern of wild life sanctuaries and National Parks. In such areas, the cultivation of GM crops should be prohibited.' It also suggested that some regions which are centers of rich biodiversity should be kept free from GMO cultivation 'until more data are available on the long-term impact of the introgression of transgenic material into native biodiversity'.<sup>1</sup>

From a commercial view also this is important as non-GM crops, particularly cereals, are important sources of export revenue for many developing countries. It has been pointed out that Article 26 of CPB is perhaps one of the most significant aspects of the Protocol, from the perspective of developing countries, since it takes into account the latter's concerns (Chaturvedi *et al.*, 2007).

### **Overview of Socio-economic Considerations**

A number of countries have already incorporated socio-economic considerations in the decision making. They have adopted different approaches for the inclusion of such considerations. A country wise analysis of such provisions would give a better understanding on the issues involved in the socio-economic analysis.

**Table 1: Status of Countries with Socio-economic Considerations**

Countries	SE Provisions	Ratification to CPB
Cambodia	No	Yes
India	Yes	Yes
Japan	No	Yes
Malaysia	Yes	Yes
Austria	Yes	Yes
Belgium	Increasingly considering new criteria	Yes
Spain	No	Yes
France	Yes	Yes
Norway	Yes	Yes
Egypt	Yes	Yes
Zimbabwe	Yes	Yes
Sudan	Yes	Yes
Liberia	Yes	Yes
Bolivia	Yes	Yes
Colombia	Increasingly considering new criteria	Yes
Honduras	Yes	Yes
Mexico	Yes	Yes
South Africa	No	Yes
Cameroon	Yes	Yes
Uganda	Yes	Yes
Kenya	Yes	Yes
Australia	Yes	No
New Zealand	Yes	Yes
Canada	Partially Yes	No
Brazil	Yes	Yes

**Source:** Own compilation using information from BCH CBD and other sources.

Norway has adopted a very comprehensive approach on the socio-economic issues in its decision making. The Norwegian Gene Technology Act 1993 intends to ensure that production and use of LMOs take place in an ethical and socially justifiable way, in harmony with the principle of sustainable development and without detrimental effects on health and the environment. It requires deliberate release of LMOs only when its safety on health and environment is proved and that the use of LMO should be beneficial to the community.<sup>2</sup> Malaysia has in place a system that involves the analysis of the impact of LMOs on the changes in the existing social and economic patterns and means of livelihood of the communities that are likely to be affected by the introduction of the living modified organisms or products of such organisms; and it also analyses the effects to the religion, social, cultural and ethical values of communities arising from the use or release

of the living modified organisms or products of such organisms.<sup>3</sup>

Laws in Cameroon mandate studies on ethical and socio-economic impacts. Such studies are expected to take into account impacts on traditional market and export earnings, health and production systems. In Austria the decision makers are allowed to ban the marketing of products which are considered 'socially unsustainable' referring to social, economic, and ethical aspects.<sup>4</sup> Austria had banned on the import of two types of GM maize - MON 810 and T25 - in 1999 on account of concerns on their effects on non-target organisms, development of resistance to toxins by target organisms and cross pollination with wild relatives and conventional crops. Sudan requires the risk assessment to include the evaluation of direct and indirect risks, in the short, medium or long term, to human health,

2. As required by Gene Technology Act 1993, Norway. <http://www.regjeringen.no/en/doc/laws/Acts/gene-technology-act.html>

3. These requirements are under the National Policy on Biological Diversity 1998 and the Biosafety Act 2007.

4. [http://ec.europa.eu/food/food/biotechnology/reports\\_studies/docs/Austria\\_impacts\\_en.pdf](http://ec.europa.eu/food/food/biotechnology/reports_studies/docs/Austria_impacts_en.pdf)

5. As required by The law on Biosafety of Genetically Modified Organisms in Mexico, 2005. See GEUM, 2008 for details.
6. [www.ec.gc.ca](http://www.ec.gc.ca)
7. Australian Government Report on The Office of the Gene Technology Regulator (OGTR) <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf>
8. Hazardous Substances and New Organisms (HSNO) Act, New Zealand. <http://www.hsno.govt.nz>
9. The Brazil Biosafety Law No. 11.105 (2005) <http://www.ctnbio.gov.br/index.php/content/view/12847.html>

biodiversity, social and economic conditions, and ethical values resulting from importation, exportation, restricted use, and release or marketing of genetically modified organism or a product of a genetically modified organism. These are some of the countries which are having a very comprehensive view on socio-economic analysis.

There are a few other countries which have socio-economic considerations in their regulations, though not very comprehensive as in those countries discussed above. In Mexico, the purview of the analysis includes impacts on traditional agriculture, indigenous and local communities, human health, environment and biodiversity.<sup>5</sup> In Argentina the socio-economic analysis is confined to the impact on exports. France requires the assessment of impact on economic, ethical and social aspects. Canada requires for the assessment of LMOs regarding human health, environment, sustainable development and economic growth (*The Canadian Environmental Protection Act (CEPA), 1999*).<sup>6</sup> Zimbabwe requires socio-economic analysis when considering import of LMOs for food, feed and processing. In Australia, the Gene Technology Act 2000 requires for the assessment and management of risk to public health and safety of people and the environment.<sup>7</sup> New Zealand's HSNO (Genetically Modified Organisms) Amendment Act 2002, requires for the establishment of a Bioethics Council to conduct research on environmental and socio-economic impacts on LMOs.<sup>8</sup>

In Bolivia, the New Constitution of the State states that the international relations and the negotiation, signing and ratification of treaties will be guided by the principle of prohibition of the import, production and marketing of genetically modified and toxic elements, that can damage health and the environment, for ensuring food security and sovereignty of all the people. It also requires that the production, import and commercialization of LMOs be regulated by law (Government of Bolivia, 2011). Brazil's regulatory mechanism separates technical risk assessment and assessment of other aspects by establishing two different bodies. A technical

body (CTNBio) deals with technical issues like biosafety, environmental and health impacts and approves use of GMOs. National Biosafety Council, an autonomous body, takes decisions on commercial use if social or economic issues arise during the evaluation process. This bifurcation separates technical risk assessment from political issues.<sup>9</sup>

In India, its biosafety system provides for evaluation of the economic benefits of LMOs through systematic evaluation of agronomic performance. The Government of India has commissioned case studies to assess the socio-economic and environmental implications of transgenic crops, such as Bt cotton and Bt eggplant. Under the Revised Guidelines for Research in Transgenic Plants and Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts 1998, it has been specified that data should also be generated on economic advantage of the transgenic over the existing varieties. Though there is an environmental objective, most of the provisions have a direct bearing on agricultural production practices as also on the trade and commerce. The Act, on lines of the CPB, aims to 'ensure an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, taking into account the risks to human health, and specifically focusing on transboundary movements' (Chaturvedi, *et al.*, 2007). India is now developing a comprehensive regulatory framework by establishing an Authority to regulate biotechnology.

There are regional frameworks also for the incorporation of socio-economic considerations in the decision making. European Union (EU) has the most advanced regional framework for the socio-economic analysis. The EC Directive 90/220/EEC provides for an approval process and labelling and packing requirements for all GM food, which aims to avoid the adverse effects on human health and the environment that could result from a release of LMOs into the environment or food chain. In 1997, the EC

brought out the 'Novel Foods Regulation' which governs the market release of finished products made from or containing, components of LMOs. The objective of the regulation is to protect consumer rights, so that the marketed products should not engender the consumer, misled the consumer, and, nutritionally or otherwise, substantially differ from the food it is intended to replace, to the detriment of the consumer.

The EU's position on socio-economic considerations has been that such efforts should define a robust set of factors to properly capture the actual *ex ante* and *ex post* socio-economic consequences and, different approaches should be explored to capture the multi-dimensional aspects of socio-economic issues (European Union, 2011). Like the EU, the African Union and the Andean Community also provide regional approaches for the socio-economic analysis. The African Union Model Law defines socio-economic conditions as 'the economic, social or cultural conditions, livelihoods, knowledge, innovations, practices and technologies of indigenous and local communities including the national economy.' This Model Law indicates that the SE assessment is necessary before approval and takes the position that GM technologies that have a negative impact on SE conditions should not be developed or released.<sup>10</sup> The New Partnership for Africa's Development (NEPAD) has initiated the African Biosafety Network of Expertise (ABNE) through its African Biosciences Initiative in Africa. The main objective of ABNE is the provision of biosafety resources for African regulators in decision making on safe use, deployment and management of biotech products that are locally developed, imported and adopted in Africa (Makinde *et al.*, 2009). The Andean Community's Regional Biosafety Strategy includes socio-economic considerations that may be adopted by member countries in their respective laws but does not provide any guidance on implementation.

Some countries are already in the process of incorporating socio-economic provisions in

their domestic legislations. The draft National Biosafety Frameworks of Honduras and Nigeria indicate that their socio-economic considerations would include changes in social and economic pattern; impacts on biological diversity, traditional crops and sustainable agriculture; impacts on likely substitution on traditional crops; social and economic costs; impacts on livelihoods of communities; and effects that are contrary to the social, cultural, ethical and religious values. The proposed system in Bangladesh also has almost similar considerations: it does not have the impacts on religious values while it has included additional considerations such as impact on gender, food security, poverty alleviation and right to choice (Zepeda, 2009).

In the Philippines, the Executive Order No. 514 of 2006 requires that the competent authority, (the National Committee on Biosafety of the Philippines (NCPB)), to frame detailed guidelines for the conduct of socio-economic impact evaluation, though no such guidelines have been finalized. The current version is still under consideration of the office of the council of State. Uganda and Kenya have pending legislations having provisions relating to socio-economic considerations (Collier and Moitui, 2009). Thailand had the SE provisions in the previous version of the draft biosafety law, but in the later draft it was deleted because it was considered that biosafety should concern mainly of scientific basis. The current version is still under consideration of the office of the council of state

It is very important to have conceptual clarity on socio-economic considerations. The ABNE points out that '...national biosafety regulatory systems in considering socio economic issues should address definitional issues and spell out the decision making rules and regulations upfront and these must be consistent with international obligations. Also needed is a clear indication of when and how socioeconomic considerations will be analyzed and factored into the decision-making process.'<sup>11</sup>

It is also equally important that proper methodologies are developed for capturing

10. African Model Law On Safety in Biotechnology (2002), Organisation for African Unity (OAU)

11. Socio-Economics ABNE Policy Brief No 1 ABNE (2010) [www.nepabisafety.net](http://www.nepabisafety.net)

relevant information on the socio-economic considerations. According to Fransen, *et al.* (2005) “Careful research clarifying the socio-economic issues related to biotechnology is essential, but is not in itself sufficient to integrate the socio-economic considerations into biosafety decisions. To build on a credible research methodology that yields excellent information and analysis, mechanisms must be designed and implemented so that the results of socio-economic assessments are in fact taken into account in regulatory decisions about biosafety”.<sup>12</sup>

An important study on the socio-economic analysis in Norway, which is perhaps having the most advanced system for the incorporation of socio-economic considerations, (Rosendal, 2009)<sup>13</sup> shows some of the drawbacks in the Norwegian system. The study aimed at analyzing how the criteria of ‘sustainable development’ and ‘social utility’ are met in the Norwegian Gene Technology Act. The information provided by the applicants is very relevant for assessing global impacts and ecological limits, but the data is generated in own research department of applicants and hence is confidential, which prevents the peer review. The study also found that there are many interpretations which are significant and have implications of scientific development. Societal utility is a complicated concept that requires consideration of many points such as whether the technology is beneficial to small or large farms, whether the technology is likely to have any effect on employment, food security, landscape aesthetics, or human and animal health and welfare, and an assessment of who will benefit from the technology. The study found that the applicants had carried out little research to identify how GM crops might contribute to sustainability and societal utility around in the world. The study further suggests in the Norwegian context, which are relevant for other countries also, that: *one*, there is a need to identify how ethical issues and public perspectives and values affect the framing and conduct of risk assessments and the management of LMOs; *two*, there is a need to take a more integrated approach to LMO

applications and risk issues to account for the present lack of scientific understanding; *three*, there is a need to evolve regulations (like labelling to protect human health and consumer rights) to address long-term concerns for environmental consequences; and *four*, there is a need for a legal analysis of the scope and types of requirements that are required in investigating socio-economic considerations. There is a need for using meta-analysis of different studies on issues like costs and benefits of GMOs and it is important to note that short-term studies may not necessarily capture long term effects.<sup>14</sup>

A major challenge in using the socio-economic aspects in decision making lies in developing the appropriate capacity to identify the important elements among various SE issues and assess their relevance in terms of the objectives of the policy. There can be any number of issues, associated values and preferences that form part of the SE aspects, ranging from impacts on labour to conservation of traditional lifestyles and traditional agricultural practices. Assessing the impacts on each of these is difficult and it is better to evaluate them in terms of criteria in a broader context and identify the interfaces and linkages than looking at individual issues only.

For example, if the policy framework considers sustainable development as the criteria to evaluate the impact of GMOs and incorporates this in decision making, then it is better to identify the relevant criteria and map the linkages.<sup>15</sup> According this report, the production and use of GM crops must contribute to more sustainable agriculture and nine criteria have been identified for this.

The above discussion shows that there is no ‘one size fit all’ and the socio-economic, factors involved in the analysis vary across countries and situations. It is for the countries to identify what are the appropriate SE aspects they want to prioritize in decision making and what criteria should be applied to evaluate them. For example, if freedom of choice for both consumers and farmers is considered as an important objective, then policy makers

12. Fransen, L. *et al.* 2005 *Integrating Socio-Economic Considerations into Biosafety Decisions: Role of Public Participation* Washington:D.C: World Resources Institute

13. This study was commissioned by the Norwegian Directorate for Nature Management in Trondheim.

14. A Meta Analysis on Farm-Level Costs and Benefits of GM Crops, Robert Finger *et.al* (2011), *Sustainability* 2011, 3, 743-762

15. Socio-Economic Aspects of GMOS COGEM Report 090929-01 The Hague: COGEM

can think of options like labelling, making available non-GM seeds as measures to promote that objective.

However, there are certain elements that are relevant for almost all the countries at different stages of the commercialization of LMOs. The following section provides an overview of these stages and the elements that are most relevant in each stage.

## **Socio-economic Considerations and Assessment of LMOs**

### *Regulatory perspective*

For the regulator the two stages - testing for environmental and health safety, and, testing for effectiveness - are important.

#### *Testing for environmental and health safety*

In this stage the environmental impact and health safety assessments are done. Many countries have mandated them. For example, the Canadian Environmental Protection Act (CEPA) 1999, requires for assessment of LMOs at the pre-release stage for the safety on human health and environment. Similarly, the law on Biosafety of Genetically Modified Organisms in Mexico (2005) requires assessment of LMOs on human health and biological diversity prior to their release. The proposed legislation in India establishes a risk assessment regime to evaluate the environmental impacts of LMOs.

#### *Testing for effectiveness*

Some socio-economic impacts would become visible only in the long run; for example, appropriate dissemination of technology and safe handling of LMOs. During the production phase, consideration of certain factors such as impact of LMOs on the usage of inputs, employment, subsistence farmers, landscape management, post-harvest loss, co-existence and contamination, organic farming and biodiversity, and ecosystem services, becomes important. In the context of Gene Technology Act of Australia, it prohibits the production if LMOs unless it is safe to workers, general public and environment. Brazilian Biosafety Law (2005)

also requires assessment of the impacts on human, animal and plant health and the environment while cultivation and development of LMOs.

The dissemination of technology should be accompanied by training in safe handling of LMOs and adherence to norms stipulated by regulators. It has been observed in the Indian contexts that farmers are not adequately informed on the handling of Bt cotton and many farmers do not practice refuge cultivation (Chaturvedi, *et al.* (2007); Joseph (2007); Stone (2011); Dev and Niranjana (2007).

As products based on LMOs are used in different sectors, the regulation should take into account the need to have co-ordination between different regulators with clear demarcation of their powers to assess and regulate different aspects. For example, an authority regulating clinical trials and safety of drugs will have the powers to regulate those aspects of drugs based on LMOs and not all activities related to development, testing and marketing of drugs based on LMOs. Similarly, the environmental impact assessment of seeds based on LMOs can be handled by one authority while evaluation through large scale field trials and approvals for cultivation based on yield performance and other criteria can be handled by another authority. But to avoid turf wars and to ensure that the regulatory bodies get a holistic picture, and take informed decisions, the regulatory regime can have a body with representatives from different regulators. The draft law in India envisages a similar structure with different authorities handling different stages of evaluation for a product.

A comprehensive framework to capture the inter-linkages between the various socio-economic factors is required. Incorporation of such socio-economic factors is easier said than done. It would require clarity in the thinking on what factors are to be considered at which phase, identification of relevant indicators, and devising of appropriate methodologies to capture the impacts of LMOs.

## Other Issues

### Traceability and labelling issues

Traceability of LMOs is at the heart of the socio-economic considerations during the marketing phase. Traceability of LMOs and labelling of LMO products would ensure not only that the products can be easily withdrawn from the market in case of unforeseen adverse effects on human health or the environment, but it also provides correct information to those involved in trade and marketing and for the consumer. This would require clarity on the threshold values for the presence of adventitious LMO material and administrative capacities in ensuring segregation. Traceability and labelling becomes all the more important if the product is to be moved across the borders. For example, European Union has very strict standards on GMO labelling. Regulation (EC) No 1830/2003 requires all food and feed stuffs made of LMOs to maintain labelling throughout the food chain. The foodstuffs and feedstuffs from non-LMOs would be exempt from labelling obligation if they do not exceed the threshold of 0.9 per cent and if their presence is adventitious and technically unavoidable. If a country wants to export to the European Union products intended to be used as food or feed, it will have to ensure labelling and traceability of LMOs. For example, some shipments of honey from Canada, where bees can feed on GM Canola and GM food labelling is not required, were rejected by Germany in 1999 on account of GM content crossing the permissible limits (Malone, 2002). In the context of marketing of LMOs, Art. 29 of Directive 2001/18/ the European Union requires that ethical considerations (apart from the effect on human health and on environment) may be taken into account when LMOs are placed in the market (European Union, 2010).<sup>16</sup>

There are countries like Cameroon, Malaysia, Mexico and Argentina which have the socio-economic analysis in place to gauge the potential impacts on export of LMOs. Similarly, countries like Norway, Zimbabwe, Malaysia, Mexico, Canada and Bolivia have

legislations for monitoring import of LMOs for the socio-economic considerations. New Zealand, under its Hazardous Substances and New Organisms Act (1996), prohibits the import of LMOs unless they are safe for human health and environment.<sup>17</sup> Australia has prohibitions on import of LMOs unless it satisfies safety requirements and risk assessment procedures so that it doesn't have any risk bearing on workers, general public and the environment. While in Japan's Food Sanitation Law 1947 (amended in 2006) requires that Genetically Modified Foods may not be imported or marketed unless they are certified by the safety examinations and do not have any adverse impact on health of human beings.<sup>18</sup> African Union Model Law has a provision which requires that the import of LMOs should have no risk bearing on human health, biological diversity and the environment; should contribute to sustainable development; should not have any adverse socio-economic impacts; should adhere to the ethical values and concerns of communities; and does not undermine community knowledge and technologies (African Model Law On Safety in Biotechnology, 2002).

### Long-term monitoring

Some socio-economic impacts become visible only in the long run; for example, impact on existing social and economic pattern. Assessment of the impact on existing social and economic pattern is an important aspect of the socio-economic considerations in Malaysia (BioSafety Act 2007). Again, the law on Biosafety of Genetically Modified Organisms in Mexico (2005) requires for the monitoring of LMOs (posterior to the release) on human health, environment and biological diversity. The post production monitoring has two objectives: *one*, to investigate the occurrence of any potential adverse effects of a LMO that were identified during the pre-release phase and to assess their significance; and *two*, identify the occurrence and impact of unanticipated adverse effects of LMOs that were not predicted in pre-release assessment. Subsequently, the post-production monitoring would determine if (a) any unanticipated

16. <http://www.ec.europa.eu/food/food/biotechnology/reports>.

17. Hazardous Substances and New Organisms Act (1996), Ministry for the Environment, New Zealand. <http://www.mfe.govt.nz>

18. Food Sanitation Law prepared by Standards and Evaluation Division, Department of Food Safety, Ministry of Health, Labour and Welfare, Japan.

effects are occurring; (b) the observed effects are adverse; and (c) the adverse effects are caused by the release of the LMO.<sup>19</sup> In order to operationalise the post-production monitoring, the baseline data of the receiving environment is required.

Establishing a baseline requires monitoring of the system prior to the LMO release. In order to detect not only the immediate effects but also the delayed effects associated with the release of a LMO, sufficient time periods should be allowed for monitoring. The post-production monitoring would cover not only the impacts of LMOs on the socio-economic factors, which have been considered at the pre-release, production and marketing phases, but also additional factors such as impact on income distribution, persistence of income benefits, impact on non-target effects (mammals, birds, invertebrates), impact on secondary pests, impact on green house gas emissions and impact on protected areas.

However, all these activities at different stages as well as incorporating of the SE aspects in decision making can be possible only if countries possess sufficient capacity to make studies, integrate biosafety concerns and the SE issues in decision making and in evaluating policy options and choices.

### Capacity Building Measures

The Cartagena Protocol on Bio-Safety recognized the urgent need to address the critical capacity building measures of developing country parties, and parties with economies in transition for effective implementation of the protocol. The Article 26(2) of the Protocol urges the parties to cooperate on the research and exchange of information on the socio-economic impact of Living Modified Organisms (LMOs). The fifth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Bio Safety (held in Nagoya, Japan, 11-15 October 2011) adopted decision BS-V/3 on 'Status of capacity-building activities'.<sup>20</sup> The decision included section IV on 'Cooperation on identification of capacity-building needs for research and

information exchange on socio-economic considerations'.<sup>21</sup>

In decision X/1 at the tenth Conference of the Parties, the Executive Secretary was requested to provide technical assistance to Parties with a view to supporting the early ratification and implementation of the Nagoya Protocol. Henceforth, the Global Environment Facility (GEF) was invited to provide financial support to Parties to assist with early ratification of the Nagoya Protocol and its implementation. A series of awareness-raising and capacity-building activities will be conducted by the Secretariat over the next biennium in order to support the ratification and early entry into force of the Nagoya Protocol. As part of these awareness-raising and capacity-building activities, the Secretariats of the Convention on Biological Diversity (CBD) and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) jointly organized a capacity-building workshop on access and benefit-sharing on 4-5 June 2011. It was also aimed to contribute to the identification of the capacity-building needs and priorities of Parties in the implementation of their obligations under the Nagoya Protocol and to build on the experience and lessons learned from the implementation of the ITPGRFA. This workshop follows the signature of a Memorandum of Understanding between the Secretariats of the CBD and the ITPGRFA to further enhance collaboration in areas of mutual interest within their mandates and it foresees, *inter alia*, jointly undertaking workshops, seminars and other events on access and benefit-sharing as well as in other areas.<sup>22</sup> The capacity building needs of countries would vary depending on the socio-economic considerations that are relevant for each country. However, there are some core areas where capacity building is necessary for those countries which are in the process of incorporating the socio-economic considerations in the decision making on LMOs. The core areas are discussed below.

19. Adapted from FAO, 2011.

20. [http://bch.cbd.int/protocol/cpb\\_art26/bsv3.shtml](http://bch.cbd.int/protocol/cpb_art26/bsv3.shtml)

21. <http://www.UNEP/CBD/BS/COP-MOP/1/INF/2>

22. <http://www.cbd.int/icnp1/workshop>

### *Establishment of Technology Assessment Units*

23. <http://www.unep.org/GC/GC23/documents/GC23-6-add-1.pdf>

24. <http://www.fao.org/docrep/012/i1033e/i1033e.pdf>

25. [http://bch.cbd.int/protocol/cpb\\_art26/portal.shtml](http://bch.cbd.int/protocol/cpb_art26/portal.shtml)

26. Building Bio Safety Capacities, FAO's Experience and Outlook, 2009.

The Bali Strategic Plan for Technology Support and Capacity-building was approved by the 23rd session of United Nations Environment Programme (UNEP) Governing Council in February 2005. The Plan was first adopted by the High-level Intergovernmental Working Group on an Intergovernmental Strategic Plan for Technology Support and Capacity-building Plan constitutes an inter-governmentally agreed approach to strengthen technology support and capacity building in developing countries, as well as countries with economies in transition. In support of the implementation of the Bali Strategic Plan, UNEP has developed an inventory of its capacity building and technology activities across all UNEP Divisions, including those undertaken directly by its Regional Offices.<sup>23</sup> Conducting technology needs assessment for socio-economic consideration must be done through a consultative process that will engage all relevant stakeholders, and other government agencies. Technology needs assessment entails identification and evaluation of technologies and practices, and reforms that can be implemented in different development sectors for the reduction of risk involved in LMOs. Technology needs assessment leads to a clarification of technical barriers, strategies, policies and option that a country could implement to get a clear idea about the Socio Economic consideration on LMOs.

### *Legal and Administrative Mechanisms*

To develop regulatory frameworks for biotechnology, to address biosafety issues, and to enable countries to meet the requirements of the Cartagena Protocol, FAO has supported capacity building measures in several countries. FAO has supported several countries, including Bangladesh, Nicaragua, Paraguay and Sri Lanka, in developing national biotechnology policies and strategies, and provided legal assistance to Benin, Bolivia, Grenada, Paraguay and Swaziland.<sup>24</sup> Since more and more crops are getting commercialized, it is necessary to strengthen the legal and Administrative mechanism

through the active participation of other governmental agencies.

### *Support of Resources*

The UNEP-GEF (Global Environment Facility), Global Project for Development of National Bio Safety Frameworks is in the fifth year of implementation and now includes 126 countries. The last country to join the project was Bosnia & Herzegovina in June 2006. To date, 68 countries have posted their draft national biosafety frameworks. The project has developed support tool kits for each of the major phases in the development of an National Bio Safety Frameworks (NBF), and has also coordinated four regional and twelve sub-regional workshops to promote collaborations and exchanges of experience on Bio Safety.<sup>25</sup> Constrains in resources is the major hurdle to adopt capacity building measures on SE consideration on LMOs of most of the countries. Even if most of the countries have already included the Bio Safety Framework, strengthening the resource base through the transfer of resources from developed countries to the developing countries is important. It can be possible only through the strong involvement of the government funding agencies.

### *Economic Impact Assessment*

The project supported by FAO in Uganda was to strengthen the capacities in biosafety and to enable the government to use biotechnology for enhancing incomes of farmers from agriculture and to improve the food security.<sup>26</sup> Economic impact assessment is also needed to assess the impact of LMOs on issues such as trade and tourism, crop management, labour-cost, etc. The assessment should also capture the impact of LMOs on economic benefits and there distribution.

### *Environmental and Health Assessment Capacity*

The Project "Vietnam: Preparation of the Initial National Communication (INC) on Climate Change to the UNFCCC - GF/2200-97-54" financially and technically supported by UNEP/GEF was successfully completed in

2002. This INC of Viet Nam was submitted to the UNFCCC Secretariat in November 2003. Within the framework of this INC, the GHGs inventory for 1994 and GHGs emission projection to 2020 were carried out; different GHG abatement options in energy, agriculture and forestry sectors were developed; the potential impacts of climate change on some major economic activities and adaptation measures were evaluated; and the GHGs mitigation strategies through socio-economic development plan were also presented.<sup>27</sup> Here the important consideration is the environmental and cultural impact of LMOs. Therefore, the technical and scientific capacity to evaluate the impact of LMOs on human as well as animals is also unavoidable.

The decision, BS-IV/16, under the Cartagena Protocol invited the Coordination Meeting for Governments and Organizations Implementing or Funding Bio Safety Capacity-Building Activities to consider further possibilities for cooperation in identifying needs for capacity-building among Parties for research and information exchange on socio-economic impacts of living modified organisms. It also invites the parties and other governments to submit to the Bio Safety Clearing-House, their capacity-building needs and priorities regarding socio-economic consideration. It urges the Parties, other Governments and relevant organizations to submit to the Executive Secretary relevant information on socio-economic considerations, including guidance material and case studies as well as, institutional arrangements and best practices; and it also invites the United Nations Environment Programme and other organizations to conduct additional case studies to document experiences and lessons learned in different regions.<sup>28</sup>

In the efforts at the capacity building in biosafety at various levels, the socio-economic considerations have been taken into account. Although most of the capacity building measures give more importance to scientific, technical and regulatory aspects of biosafety, the SE aspects have also been given due importance in some of them.

The international organizations like United Nations Environment Programme (UNEP) and Food and Agriculture Organisation (FAO) can give more importance to enhancing the capacity building measures in view of the SE consideration in LMOs. However, the capacity building measures with external assistance alone would not be sufficient as countries need to develop capacities and capabilities in biosafety regulation. This means that countries should strengthen their regulatory capacities and also invest in human resources development, setting up laboratories and identifying the best practices in biosafety that are relevant to their needs without resorting to too much of regulation for the sake of regulation. It is not necessary that capacity building measures should be undertaken only by international agencies like FAO or UNEP or development aid agencies like USAID.

Developing countries that have acquired sufficient regulatory capacity in biotechnology can help other developing countries in this. South-South cooperation in capacity building, particularly in the SE aspects is both necessary and desirable. It is high time that major developing countries like India, Brazil and South Africa come together and establish an agency that can play an important role in capacity building in other developing countries.

As our analysis shows, many countries have incorporated the SE considerations, but have not framed definitive guidelines on this or have given more importance to technical aspects of biosafety while not taking into account the SE issues.

Thus, there is a need to develop capacity building in using the SE considerations in decision making. As more and more countries are using biotechnology for socio-economic development, it is essential that they develop the regulatory regimes that are sensitive to the SE issues. It is also in the interest of developing countries to use the Article 26 in such a way that use of biotechnology results in sustainable development and contributes to biodiversity conservation and sustainable use of genetic resources.

27. UNEP/GEF project "Vietnam: Expedited financing for measures for capacity building in priority areas (Phase II)".

28. <http://www.cbd.int/doc/newsletters/bpn/bpn-issue01.pdf>

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