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Issue on Biosafety Frameworks in South Asia

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BIOTECHNOLOGY - DEVELOPING THE FRAMEWORK FOR SAFE USE

There is an ongoing debate between the risks that biotechnology may pose to human health and the environment and its potential to assist agriculture and food production. It is therefore an extremely important issue in the South Asian region, with its rich biodiversity which could be at risk, but which is a predominantly agriculture-based region facing the problem of adequate food supplies in the future.

There are several areas of concern in biotechnology. How safe are genetically modified foods for humans? Questions have been asked such as whether transgenic food will spread allergens, introduce toxins or change the nutritional composition of the products. What impacts will GM crops have on the environment? Issues such as the impact of the transgenic organisms on non-target species have been highlighted. The socio economic effects of biotechnology have also been addressed, especially the impact of genetically modified crops on agriculture. Issues such as the role of biotechnology in controlling agriculture inputs to farms as well as the contribution of bioengineered organisms towards sustainable agriculture have been debated and discussed.

With lucrative markets such as the European Union turning GM products away, GM producers are looking at developing countries as consumer markets for both genetically modified foods and seeds. Agricultural biotechnology is being seen by many of the developing countries as a solution to a problem facing them all: pressures on agricultural and natural resources by population expansion. The solution to them is based on the high-yielding and pest-resistant varieties promised by GM companies, alongside independent research of their own.

A report to the UN on achieving Millennium Development Goals (MDGs) sets out clear goals for reducing poverty, hunger, disease, illiteracy, environmental degradation, and discrimination against women. The central finding of the millennium development project is that to achieve the MDGs, huge and in many cases better policy initiatives and institutional mechanisms have to be placed at ground level. If countries are hoping to achieve some measure of food security and thereby alleviate poverty through biotechnology, an adequate and effective biosafety framework is a capacity building effort that fall in line with the MDGs.

With the adoption of the Cartagena Protocol on Biosafety, and the pressure on countries to meet this issue head-on, the importance of the biosafety framework as a regulatory framework becomes more important to solve the common problems that are faced by the South Asian Regional countries. A biosafety framework, if properly developed and implemented, can allow counties to protect themselves against the risks attached to the use and movement of genetically modified products, while benefiting from their positive aspects.

Given the diverse nature of each country's needs and capabilities, each country's framework should be unique and address the situation of each State. However, information sharing on each country's approach may assist another in developing their own. This newsletter therefore seeks to discuss the current regulatory and capacity building efforts undertaken by the member countries of SACEP Bangladesh, Bhutan, India, Maldives, Pakistan, Nepal and Sri Lanka.

Mahboob Elahi

In this Issue

COMING ISSUE: RECOVERING FROM THE TSUNAMI DISASTER

FAO recommends guidelines to monitor environmental effects of GM crops

A consultation of experts convened at the UN Food and Agriculture Organization (FAO), recommended that any responsible deployment of Genetically Modified (GM) crops needs to comprise the whole technology development process, from the pre-release risk assessment, to biosafety considerations and post release monitoring.

Environmental goals must also encompass the maintenance and protection of basic natural resources such as soil, water and biodiversity. In this way monitoring could become the key element in generating the necessary knowledge to protect agro-systems, rural livelihoods and broader ecological integrity. Potential hazards associated with GM cropping - according to the scientists - have all to be placed within the broader context of both positive and negative impacts that are associated with all agricultural practices.

Involving farmer groups

Environmental organizations, farmer groups and community organizations should be actively and continuously engaged in this process. These stakeholders - the workshop agreed - are absolutely intrinsic to the system. FAO is ready to facilitate this process along with other agencies and national and international research centres, encouraging the adoption of rigorously designed monitoring programmes.

Besides FAO and UNEP, the CGIAR Centres are expected to play an important role in partnership with national research centres. The consultation was organized in the light of the controversy and public concern over Genetic Modifications (GM). FAO asked a group of agricultural scientists from many parts of the world to provide clear preliminary guidelines on the most accurate and scientifically sound approach to monitoring the environmental effects of existing GM crops.

Protecting agrosystems and livelihoods

"FAO's aim is to provide a tool to assist countries in making their own informed choices on the matter, as well as protect the productivity and ecological integrity of farming systems" said Ms. Louise O. Fresco, FAO Assistant Director-General of the Agriculture Department. She added "the need to monitor both the benefits and potential hazards of released GM crops to the environment is becoming ever more important with the dramatic increase in the range and scale of their commercial cultivation, especially in developing countries."

The experts acknowledged that a great deal of data is already available. What needs to be done is to bring together and coordinate this volume of often scattered information. They also emphasized that monitoring the effects of GM crops on the environment is not only necessary but feasible even with limited resources when it is integrated with the deployment of these crops. The experts agreed that it is important to identify the most accurate existing data. They noted that field and traditional expertise should become a strong resource in addition to scientific expertise. These data could be used in indicators to measure the effects of GM crops on the environment.

Significant changes that might cause concern should be promptly notified. In this regard, a full stakeholder engagement - farmers, scientists, consumers, public and the private sector and the civil society - will be necessary and integral to the process. One of the difficulties in monitoring agriculture is the heterogeneity of farming systems in the different regions. The group of scientists recommended that the objective of environmental monitoring of GM crops should be nested within processes that address broader goals. There would be a need to adapt any methodology to the specific farming system through a well-designed process. Monitoring GM crops will provide information for policies and regulations, but mainly will give producers informed options in order to allow technologies to be adopted in a sustainable way.

Source: www.fao.org/newsroom/en/news/2005/89259/index.html

SAARC to promote regional cooperation in biotechnology

SAARC Member Countries have agreed to develop a Plan of Action for Cooperation in Biotechnology. Six areas have been identified for collaboration, including: Plant Tissue Culture, Medicinal and Aromatic Plants, Plant Biotechnology including Therapeutic and Edible Vaccines, and Diagnostics for Human Health, Aquaculture, and Human Resource Development. The Plan of Action will be based on concept papers being provided by the member States, and will be regional in nature, focussing on the aspects of cooperation. In addition, a concept paper on Developing an Institutional Framework for Biotechnology Cooperation is being finalized on the basis of comments received from the Member States, with a networking approach in mind. In addition, two reports have been prepared, one on selected rural technologies, the other on biotechnology, and are part of a set of four reports considered by the Technical Committee on Science and Technology. The reports will form the basis for development of regional strategies and future plans of action.

SAARC is also considering a proposal to draw up a regional framework for Biosafety Procedures and Protocols in the context of the rules and regulations prevailing in the Member States. Member States are in the process of sharing information in this important area. A concept paper on a regional framework for Biosafety Procedures and Protocols will be finalized.

Source: SAARC Website: http://www.saarc-sec.org

India to further develop biosafety regulations, policies

India is contemplating a national biotechnology regulatory authority similar to the Telecom Regulatory Authority of India, to address the regulatory issues relating to biotechnology. In addition, the national policy on biotechnology is expected to be ready by January 2005.

Of all the South Asian countries, it is India that appears to have advanced the most in the field of biotechnology and biosafety. It has already approved one GM crop for commercial use and is in the process of field trials for several other types. In biosafety, India had already established rules as early as the 1980s, and is in the process of strengthening its institutional capacity to face challenges posed by the coming into force of the Cartagena Protocol.

Possibly because of its own capability to conduct research in the field of biotechnology, and its more extensive acceptance of biotechnology that many other countries, India's legislative framework in biosafety appears to be quite advanced.

India formulated biosafety guidelines as early as 1989, and are known as the "Rules for Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or cells under the Environmental Protection Act (EPA)"; it constitutes the legally binding regulatory framework for genetically modified organisms (GMOs). These rules were followed by three sets of guidelines issued by the Department of Biotechnology (functioning under the Ministry of Science and Technology) in 1990, 1994 and 1998.

The first two set of rules deal with containment and safe laboratory practices for GMOs in the agricultural and pharmaceutical sectors, as well as the deliberate release of GMOs with emphasis on assessment and management of ecological and health risks that might result.

The last set of guidelines calls for toxicity and allergenicity data for ruminants from consumption of transgenic plants. The 1998 Rules also requires the generation of data on comparative economic benefits of a modified plant, meaning that there must be a demonstration that the transgenic crop is both environmentally safe and economically viable.

Overall, the overseeing of GMOs in India is divided between the Ministry of Science and Technology (who oversees research) and the Ministry of Environment which overseas commercial release of GMOs.

The Recombinant DNA Advisory Committee reviews biotechnology developments at national and international levels and recommends suitable biosafety regulations for India.

Indian cartoon on Genetically Modified Crops
Copyright: indiatogether.org

The Review Committee on Genetic Manipulation (RCGM) functions in the Department of Biotechnology (DBT) and its functions include:

- to issue guidelines for GMO research;
- to review the reports in all approved ongoing projects involving high risk category and controlled field experiments research in four areas namely human and animal health, agriculture, industry and environmental management;
- to visit sites of experimental facilities periodically where projects with biohazard potential are being pursued and also at a time prior to the commencement of the activity to ensure that adequate safety measures are taken as per the guidelines;
- to issue clearance for import/export of etiologic agents and vectors, germ plasm, organelles, etc. needed for experimental work/training and research.

The RCGM comprises of the Secretary, Department of Biotechnology, several research councils and other experts.

The re is also the Genetic Engineering Approval Committee (GEAC) under the Ministry of Environment and Forests (MOEF) which is responsible for the commercial release and use of GMOs. It examines and issues the clearance from the environmental side on a case by case basis for:

- activities involving large scale use of potentially hazardous microorganisms and recombinants in research and industrial production from environmental angle;
- proposals relating to the release of genetically engineered organisms and products into the environment including experimental field trials;
- production, sale, import or use of substances and products including food stuffs and additives including processing aids containing or consisting of genetically engineered organisms or cells or micro-organisms;
- import, export, transport, manufacture, process, use or sale of any hazardous microorganisms or genetically engineered

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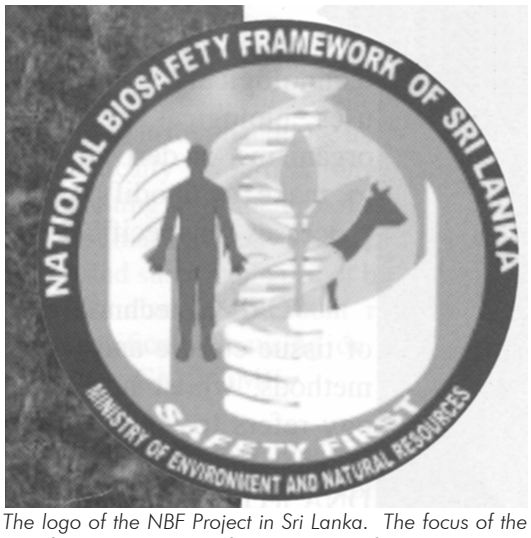
Sri Lanka in last stages of finalizing national biosafety framework

Sri Lanka is in the process of establishing a national biosafety framework (NBF) (by National Biosafety Framework Development Project under the Ministry of Environment and Natural Resources) that includes guidelines for laboratory-based experiments, for testing in the green house and for small and large scale field trials of genetically modified organisms (GMOs) and GM plants and for their commercialization and release into the environment or food chain, and for transboundary movement of GMOs in line with the Cartagena Protocol (ratified by Sri Lanka in 2004).



The logo of the NBF Project in Sri Lanka. The focus of the NBF formulation is on safety in the use of GMOs. Courtesy: Ministry of Environment and Natural Resources

A National Policy on Biosafety would also be a part of this framework, so that development, application and promotion of all biotechnologies can be done ensuring that there are no adverse impacts on conservation and sustainable use of biological diversity in the country as well as on human health and the environment.

The objective of the draft policy is to ensure adequate levels of protection in the safe use of modern biotechnology based on the precautionary principle, within the framework of sustainable development. The identified terms of reference for the biosafety framework policy were to: collect information on presently available policy documents relevant to biosafety; review policy documents and prepare draft structure for Sri Lanka; identify contents of policy instruments in terms of its structure; check for contradictions with other policy instruments; coordinate as much as possible with relevant ministries, institutes etc; review draft with relevant stakeholders and submit to the National Project Co-ordinator of the Biosafety Unit which would be then presented to the National Coordinating Committee (NCC). Currently the draft was open for public comments, comments taken and will be advertised again in all three languages for public comments before finalizing.

The biosafety framework is expected to address issues related to biosafety while developing national acts, regulations etc. that are relevant or currently in use to address issues on GM plants, animals etc. The final draft of the NBF would be prepared after considering and analyzing the existing laws, acts, regulations as well as the identified gaps in the legal regime and deciding on whether new laws will be necessary. This would be then subjected to strict scrutiny by the NCC before the final document is presented. At present, Sri Lanka has not yet passed any laws to specifically deal with GMOs. The only law that has the terms "genetically modified" and "living modified" is the Plant Protection Act, and that too, only in the interpretation section.

However, there are provisions in existing laws which could be successfully used to control, check and even ban the introduction of certain GMOs. There are around ten such laws which have provisions relating to the regulation of different GMO's. For example, the Intellectual Property Act provisions cover GM-technologies and their products as they are subject to patents and also because the Act patents GM-microbes. There are safety guidelines for activities related to Genetically Modified Organisms (GMOs) in laboratory and draft guidelines for import and release which needs to be amended accordingly. In addition, institutional aspects would be considered and a framework which includes an administrative and decision making system would be developed and technical and technological aspects of the biosafety framework would also be drafted.

However, there are no mechanisms to evaluate the potential risks associated with the range of genetically modified organisms and products in place.

The main part of the project activities during this period covers capacity building and so far national workshops have been conducted for institutional coordinators and NCC members, stake holder workshops as well as training workshops in risk assessment and management for institutional coordinators, and legal sectors, customs officials, ministries, farmer/ consumer organizations, non governmental organizations, government departments and authorities, universities, postgraduate institutes and research institutes, awareness workshops for school teachers, students, teacher trainers, PHIs, etc.

In addition a national database on biotechnology/biosafety and a website have been prepared. The website is currently online at www.biosafety.lk.

With assistance from Mr. Gamini Gamage, Director (Biodiversity) and Ms. Iresha Rajapakse, Environment Management Officer, Ministry of Environment and Natural Resources

References: *Executive summery, First National Report on Implementation of Article 6 of Conventions of Biodiversity; Caring for the Environment 2003-2007; Country Progress Report for Sri Lanka on National Biosafety Framework (NBF), Asia Sub-Regional Workshop on Development of a Regulatory Regime and Administrative Systems for National Biosafety Frameworks (NBFs) October 2003; Draft Sri Lankan National Policy on Biosafety 2004*

Bhutan beginning biosafety framework, emphasis on protection of biodiversity

Bhutan is now gathering information in preparation for drafting their draft their National Biosafety Framework (NBF), according to the National Environment Commission in Bhutan. The drafting of their NBF is in line with their obligations under the Cartagena Protocol, which they acceded to in August 2002.

According to the National Progress Report submitted during sub-regional workshops for Asia held in 2003 under the UNEP/GEF Project on Development of NBFs Bhutan has no enabling legislative framework, especially in the areas of biosafety and financial resources. The report states that "Access to and transfer of some economically important plant species including LMOs and GMOs are subject to restriction, but essentially without the legal framework to support its contextual application."

In a country report prepared for submission to the Asia Regional Workshop on Risk Assessment and Risk Management to Implement the Cartagena Protocol, held in 2002, Bhutan accepted the importance of the protocol given Bhutan's rich biodiversity and the "need to exercise caution and control when allowing the import and use of LMOs"

Bhutan's lack of any legal framework arises from the irrelevance of biotechnology as a tool for sustainable development of the nation. Bhutan, according to its progress report, meets 65% of its food needs. However, in the same report, it states that this goal of self-sufficiency is facing problems in the form of limited arable land, a high population rate and the increase in urban, non-farming communities which means that more and more of its food requirements are being imported. The report acknowledges that while Bhutan may be importing products containing LMOs/GMOs, "there is neither a technical capabilitynor required infrastructure to assess them". The report further states that this is made more difficult because of "lack of public awareness on this issue".

According to its country report to the 2002 workshop, Bhutan has identified the two main areas of capacity development and capacity building in which to take action. Under capacity development, activities include: 1) development of a legal framework and instruments to implement biosafety procedures 2) development of institutional capacities of existing institutions 3) strengthen the scientific knowledge base and documentation procedures in the country required for biosafety and biotechnology 4) build national scientific and technical capacity to deal with biotechnological research 5) develop appropriate information management systems, public awareness schemes and a Biosafety Clearing House Mechanism 6) monitoring and evaluation of LMOs 7) development of risk management protocols for LMOs 8) establish appropriate emergency measures for accidental movements of LMOs 9) training of field staff in the implementation of specialized biosafety activities.

Under capacity building, Bhutan is seeking primarily to: assess existing laws and regulation pertinent to the Protocol to identify major gaps and weaknesses; strengthen relevant existing institutions including coordination mechanism; develop national risk assessment and risk management capabilities; promote public awareness and education; develop human resources to deal with biotechnological resources and biosafety procedures; build capacities in monitoring compliance. Bhutan also needs to develop the institutional capacity to deal with the Protocol. Existing institutions which can deal with biotechnology issues include the National Environment Commission, the national focal point for environment policies and the national executing agency and legal entity responsible for the biosafety project.

There are also institutions under the Ministry of Agriculture, the Food Corporation and the National Biodiversity Center, which deal with, among other things, the conservation and sustainable utilization of agro-biodiversity. The Renewable Resources Research Centers which are integrated centers coordinating research in forestry, field crops, livestock and horticulture, and the Quality Control and Regulatory Services responsible for ensuring the quality of goods and products in Bhutan, are also institutions which can be used to govern issues relating to biotechnology and biosafety in Bhutan.

Source: National Progress Report in the third series of workshops under UNEP/ GEF Project on Development of Biosafety Frameworks, 2003; Country Report, Asia Regional Workshop on Risk Assessment and Risk Management to Implement the Cartagena Protocol, held in 2002.

Nepal yet to develop its biosafety framework

Nepal is yet to devise a biosafety framework, though the formulation and implementation of required policies, plans and legislation to protect its people, environment and biodiversity from the negative impacts of LMOs/GMOs is part of its Tenth five-year plan. According to its report to the third regional series of workshops under the UNEP/ GEF project on biosafety frameworks, while Nepal doesn't have separate legislation on biotechnology, there are other acts which address the issue such as the Export/Import control Act, the Food Act, the Plant Protection Act and the Livestock Feed Products Act.

Nepal is under a stronger obligation to implement national laws in relation to biosafety, because under its legal regime, international treaty obligations must be incorporated and internalized into domestic law. Nepalese law goes so far as to hold domestic laws inconsistent with international treaties, void in so far as the inconsistence.

Source: National Progress Report in the third series of workshops under UNEP/GEF Project on Development of Biosafety Frameworks, 2003.

Bangladesh enacts guidelines, draft act on biosafety

Bangladesh's biotechnology focus in the areas of increasing food production and overcoming constraints of agricultural productivity has led it to try and ensure that adequate biosafety laws are in place.

Currently, Bangladesh has a set of biosafety guidelines which were prepared in 2000 aimed to "ensure safe transfer, handling, use and transboundary movement of LMOs to safeguard human and animal health, environment, biodiversity and...socio economic welfare".

These specifically focus on:
• procedures and guidelines on the introduction, movement and field release of regulated materials;
• physio-chemical and biological containment procedures and facilities guidelines for classification of micro-organisms according to their risk assessment;
• good laboratory practices; good industrial large scale practices;
• lists of organisms according to different risk groups; framework for risk assessment;
• biosafety committees.

A biosafety act is also being drafted, which proposes the setting up of an authority called the Bangladesh Biosafety Monitoring and Control Authority (BMCA). The act has three sections on risk management, contained use and permit for field release of GMOs that shall be the responsibility of the BMCA. The draft act also has provisions for inviting prior public opinion before releasing a GMO.

Two other relevant acts are also being drafted, the Biodiversity Act and the Plant Varieties Act. The first act's main objective is to protect the biological and ecological environment of the country from the potential and actual pollution cause by the release of GMO in the environment.

Other objectives include provisions to determine access to and equitable benefit sharing of biological and genetic resources and related knowledge.

The act proposes the setting up of a National Biodiversity Authority (NBA) which appears to have fairly comprehensive powers in relation to GMOs and LMOS. Its functions would include the study and recommendation of policies and regulations on the use of biological and genetic resources.

It would also monitor the importation and introduction of GMOs and the research and processes of biotechnology and GE to protect the environment and citizens from biological pollution, hazards and dangers of such technologies.

Chickpea germplasm. Bt chickpea is one of four crops on which Bangladesh is reported to be conducting biotechnological research Photo © CGIAR and ICRISAT

Bangladesh approves four biotech crops

Bangladesh has reportedly approved the development of four biotechnology crops under the National Agriculture Research Council (NARC). The four crops are drought and saline tolerant rice, late blight resistant potato, fruit and shoot borer resistant eggplant and pod borer resistant chickpea.

The NBA is also to have authority to declare unlawful any material, research facilities and experiments related to GMOs that exist within Bangladesh without its permission.

The second act on plant varieties regulates the commercial transaction of plant varieties including new plant varieties in Bangladesh.

The country also set up its National Institute of Biotechnology to accelerate research activities in the field of biotechnology. Its activities would include research work on priority problems, networking important projects, human resource development and policy planning i.e. acting as a national focal point on biosafety, bioethics and biosurveillance.

There is also a National Committee on Biotechnology in Bangladesh (NCBB) which recently formulated the country's first biotechnology policy.

At one point, the media reported that there was a delay in constituting the NCBB after the Ministry of Environment and Forestry requested that it be brought under their purview instead of under the Ministry of Science and Technology. The Ministry of Environment was the focal point for the implementation of the Cartagena Protocol.

It was later agreed that the Science and Technology Ministry would lead biotechnology research while Environment and Forestry Ministry would lead biosafety.

Source: National Progress Report submitted to the Third Series of Subregional Workshops (2003/2004) under the UNEP/GEF Project on Development of National Biosafety Frameworks; Choudhury, Naiyyum and M. Serajul Islam. "Biotechnology in Bangladesh", National Institute of Bangladesh;

Pakistan's biosafety guidelines have yet to be approved

Pakistan's guidelines which were formulated in 2001 covers several aspects, namely: procedures for evaluation of project proposals with biosafety implications; procedures and guidelines for the introduction, movement and field release of regulated materials; physicochemical and biological containment procedures and facilities.

There are several institutions within the biosafety framework, the first of which is the National Committee on Biosafety in Pakistan (NCBP), created in 1998 by the Environment Ministry. The NCBP is responsible for: identifying and evaluating potential hazards involved in GE experiments and the risks associated with GMO release into the environment; recommending measures to minimize risks; formulating and reviewing national policies and guidelines; supervising implementation and developing working arrangements with the quarantine services and other institutions in the evaluation; monitoring and review of projects. It also assists in the development of technical expertise, facilities and other resources for quarantine services and risk assessment, recommends the development and promotion of research programs to establish risk assessment protocols and assessment of long term environmental effects of biological research covered by the guidelines, provides assistance in the formulation of pertinent laws, rules and regulations.

The NCBP is also responsible for approving planned release of field testing, if: 1) the organism is genetically modified, whether produced locally or imported from abroad; 2) organism is not genetically modified but is exotic and non-indigenous to Pakistan and maybe potentially harmful.

There also need to be Institutional Biosafety Committees (IBC) in every organization intending to do work with GMOs and forms the link between project proponents and the NCBP. The IBC undertakes the assessment and review of field test proposals to identify potential hazards to human health and the environment and advises the project leader on their proper amendment; reviews the qualifications and experience of personnel involved in the field testing; ensures competence, acceptable professional practices and adequate supervision of project staff. There is also a 3-member Scientific and Technical Review Panel (STRP) whose responsibility is biosafety review and risk benefit analysis, and which is made up of experts whose expertise area is relevant to the submitted proposal.

Overall, there is National Biosafety Expert Committee which was set up for several reasons including: review and update of existing guidelines/legislation in the field of biosafety; review and improvement of the voluntary code of conduct for the release of organisms into the environment; assessment of the risks associated with the development, handling and use of LMOs; recommendation of measures for management, safe transfer and movement of LMOs; suggestion of measures for strengthening the linkages between relevant organizations and implementation of recommendations; review and assessment of the national capacity building requirements for safety in biotechnology, risk assessment and management; suggestion of measures for the implementation of the protocol; extending support and assistance to the Ministry in matters relating to biosafety.

The guidelines cover the regulation of field work in the following manner: experiments made during laboratory work must be repeated and results verified from tests performed at lab level; precise and accurate information/data on the stability, expression and hereditary transmission of trans genes under field conditions must be gathered; viability of GMOs under field conditions must be assessed; adaptive or evolutionary potential of GMOs under changing environmental conditions must be assessed; the overall environmental impact must also be assessed. The criteria for evaluating work under containment includes: transformation protocol; genetic and physiological analyses of donor organisms and GMOs; adequacy of the facility and laboratory to ensure that no viable material escapes into the environment; the biosafety protocol. There must also be greenhouse/screenhouse studies so that the potential ecological impacts, genetic stability of GMOs, and reaction and interaction with other organisms are found before they are released into the natural ecosystems.

The guidelines also sets out the format for formulating the proposal for field testing of GMOs. There are also provisions for sanctions on non-compliance which include: withdrawal of all or applicable grants, tax incentives; liability for evident consequences of failure to comply with provisions of guidelines; issuance of NCBP of public statements on noncompliance, etc. There is also a public participation: mechanism: notice of NCBP approval is published for three weeks, followed by a 30 day commenting period. Comments are then forwarded to the proponent, who has 15 days to respond.

Pakistan's guidelines, however, have been delayed by the Ministry of Environment, which is eliciting the views of stakeholders, ministries, organizations, and provincial departments concerned on biosafety guidelines. This was because of risk factors of GMOs on human health and safety. The main reasons of concern are the impacts of GMOs on public health and safety. The Ministry is reported to feel that as the general public will be the end consumer, the views must be considered.

Main sources: *Nasim, Anwar. "Biosafety Guidelines in Pakistan". Presentation, "GMO Detection: Capacity Building on Biosafety of GM Crops, June 2004, Pakistan", organized by FAO;* ***Other sources:*** *"Scrutiny of biosafety guidelines stressed". The Dawn (Internet edition), August 22, 2004; "More time needed to formulate biosafety rules: official", The Dawn (Internet Edition), August 24, 2004.*

Maldives winding up its national biosafety framework

Maldives' Biosafety Framework is expected to be completed this month. The draft national biosafety framework is currently in the final drafting stages. The National Biosafety Framework will have a national biotechnology policy as well as regulatory system that includes identification of nodal agencies and administrative procedures. The drafts were planned for the end of last year.

According to Maldives' country report at the third series of subregional workshops under the UNEP-GEF project to develop biosafety frameworks held in October 2003, Maldives' primary concern appears to be the impact that the free movement of GMOs might have on the country's biodiversity, and the need of an biosafety framework to prevent this.

The country's National Biodiversity Strategy and Action Plan (NBSAP) of 2001 has as one of its important elements the control and management of exotic species for the conservation of the country's marine and terrestrial biodiversity. The NBSAP recommends establishing appropriate sanitary and phytosanitary measures for conservation of biodiversity. It has also recommended formulating quarantine laws and other regulations to control import of alien species, pests and diseases and to adopt risk assessment techniques for identification and control of potentially harmful species.

In its report, Maldives states that it is seeking to take a precautionary approach to the introduction, use and dissemination of GMOs. As an island nation, Maldives feels that it is particularly threatened by GMOs of marine and coastal origin, and therefore believes that there is a need for regional cooperation. Maldives, while feeling that it lacks the capacity to develop biotechnology products, believes that it may be a transit point or destination of GMOs.

The project to develop a National Biosafety Framework is coordinated by individuals from different government authorities and NGOs, under the supervision of the Environment Research Centre (ERC)of the Ministry of Home Affairs and Environment.

Currently, Maldives has no laws or regulation addressing biosafety issues. A national survey on biosafety conducted by the ERC identified several gaps that needed to be addressed, including: capacity building in the areas of food safety and biotechnology research; information exchange to ensure better understanding, and harmonization of standards and regulations to allow free movement and fair trade practices; public awareness of all aspects of biotechnology to ensure safe judgement.

Source: National Progress Report submitted to the Third Series of Subregional Workshops (2003/2004) under the UNEP/GEF Project on Development of National Biosafety Frameworks

Non-GM iron rich rice shows encouraging results in field trials

In the midst of the controversy surrounding the genetically engineered 'golden rice', a non-GM type of iron rich rice has been showing results in several studies conducted by the International Rice Research Institute (IRRI).

The strain, which was found by accident by IRRI scientists experimenting for rice capable of thriving in degraded soils and cold, was found to contain 21 parts per million of iron, about double the normal iron content of rice, and it also had about 34 parts per million of zinc. According to IRRI, not only is it high in these minerals, but also has good flavour, texture, cooking qualities and is high yielding.

IRRI's genebank in Los Banos, Philippines. This facility contains the most comprehensive collection of rice genetic resources on earth. Source: CGIAR and IRRI www.cgiar.org/newsroom/photos/

The rice was field tested on a group of 27 nuns, chosen because of their disciplined lifestyles and moderate diets. Preliminary tests showed that the serum ferritin levels in the blood had increased, in some as much as two to three times. This led to a larger trial involving 300 nuns, a study which concluded in 2003. According to reports, those who consumed the high iron rice took in around 20% more iron that those who ate normal rise.

There was a reported average 10% increase of body iron by 10%. Parallel tests at Cornell and IRRI confirmed the study results that minerals in the strain remained after processing and eating.

According to an Asian Development Bank Review, the next step is trials in a community setting and a trial is scheduled for Bangaladesh during 2004-2005.

According to WHO statistics, South East Asia has the highest prevalence of iron deficiency anaemia. In India, over 80% of pregnant women suffer from the condition, followed by Bangladesh with around 70%.

Source: "'Mom killers' and convents - iron enriched rice", PDI, October 26, 2004; 'The Sisters of Nutrition', IRRI, April 3, 2003

Program for Biosafety Systems (PBS) Partnership for Biosafety Capacity Development in India

The *Program for Biosafety Systems* (PBS) promotes the appropriate application of agricultural biotechnology for developing countries by addressing the issue of biosafety. A consortium led by the International Food Policy Research Institute (IFPRI, Washington DC, USA), the goal of PBS is to effectively address biosafety within a sustainable development strategy. PBS does this by taking a comprehensive approach that looks at biosafety as a system beyond just regulatory development, and promotes linkages between biosafety policy and the development, access, and use of biotechnology applications in an environmentally sustainable fashion.

PBS works at both national and regional levels in East, West and Southern Africa, and, in Asia, in Bangladesh, India, Indonesia and The Philippines, incorporating components addressing policy, capacity building and outreach, regulatory package development assistance and environmental risk research. Financial support is primarily provided by the US Agency for International Development, USAID. A substantial part of PBS is formed by a competitive grants program supporting biosafety research addressing the intersection of agricultural biotechnology and biodiversity in developing countries, the Biotechnology-Biodiversity Interface program.

The Biotechnology and Biodiversity Interface (BBI) program was initiated by USAID in 2001, with the award of 5 grants to researchers studying various issues including transgenic fish, gene flow in rice and the impact of Bt maize on soil micro-organisms. This year, the BBI program became part of PBS. In September, four new BBI projects were selected: environmental risk management of genetically engineered sorghums in Mali and Kenya, submitted by the International Crops Research Institute for the Semi-Arid Tropics (ICRISAT, with its headquarters in India); baseline susceptibility and genetic diversity among eggplant shoot and fruit borer populations, by the Maharashtra Hybrid Seed Company (Mahyco, India); investigation of secondary ecological effects of Bt corn in The Philippines, by the National Institute of Molecular Biology and Biotechnology (BIOTECH) University of the Philippines Los Banos; risk assessment and management options for stacked-gene transgenic crucifers in India and Indonesia, by Cornell University

PBS also organizes an active program of training and outreach activities. PBS held its first regional biotech food safety course in New Delhi in June 2004, in cooperation with Michigan State University (MSU) and The Energy and Resources Institute (TERI). The course was designed to provide food safety education and information with a broader goal of creating awareness among various stakeholders to help them make science-based decisions for the development and commercialization of biotech products in Asia. Twenty-six participants from Bangladesh, India, Indonesia and the Philippines, with a range of backgrounds from scientists and academics to regulators and NGO representatives as well as the media attended the course. The course covered a range of topics including food hazards and the evaluation process as well as risk communication and outreach and other safety issues regarding biotech foods. The course provided ample opportunity for participants to have open frank discussion on the topic and share their experiences and exchange ideas for moving biotech and food safety standards forward.

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Participatory Assessment of Social and Economic Impacts of Biotechnology

Virginia Tech is leading a project funded by the U.S. Department of Agriculture (USDA/CSREES) to assess the social and economic impacts of biotechnologies. One component of that project is focused on the impacts of rice biotechnologies in Asia.

Rice is the most important source of calories for nearly half of the world's population. Within Asia, rice provides more than 30 percent of the total calorie supply; poor populations are especially reliant on rice as a source of nutrition. Asia accounts for 90 percent of the world's rice production and consumption. With increasing global populations, demand for rice in the region is expected to increase about 70 percent over the next three decades, implying a need to raise yields and grain quality to meet future nutritional demands.

One approach being considered to improve rice production in Asia is biotechnology. Traits such as increased resistance to insects, drought tolerance, herbicide tolerance, enhanced photosynthesis, and enhanced nutrient content are just some of the ones that scientists are attempting to incorporate into rice.

Rice biotechnology research is underway at the International Research Institute, in national agricultural research systems and in the private sector to develop these traits. Potential agricultural productivity and nutritional gains associated with agricultural biotechnology are accompanied by a set of risks and concerns over human health, environmental safety, and preservation of local cultures. Therefore informed public opinion and sound policies require identifying the costs, benefits, and tradeoffs associated with these crop technologies.

The objectives of our project are to: (1) elicit and document stakeholder expectations and concerns, (2) develop and apply a framework to assess the positive and negative

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IUCN carries out capacity building on Cartagena

The Biosafety Capacity Building Initiative, Asia, of the IUCN-Regional Biodiversity Programme (RBP) is aimed to assist in furthering the implementation of the Cartagena Protocol on Biosafety in Asia. This project is developed from the recognition of both the possible benefits and risks that biotechnology offers, as well as RBP's firm belief in building partnerships in the Asia region. RBP encourages and supports the further development of the Protocol as well as national action plans that include risk management and strategy analysis. The Capacity Building Initiative focuses on the promotion of awareness and encouragement of dialogues, as well as on capacity enhancement in Asia for Cartagena implementation.

RBP has promoted awareness on biosafety by preparing publications (such as the 'Biosafety Resources Kit' which includes legal, regulatory, and technical information and reports, as well as the Biosafety CD-ROM) and hosting and participating in international forums. The Programme has created and distributed agenda briefs and recommendation papers for meetings of the Intergovernmental Committee for the Cartagena Protocol (ICCP) and the Meeting of the Parties for the Cartagena Protocol (MOP). The briefs serve to illustrate the issues and opinions recognized by the region as fundamental considerations for the implementation of the Protocol in Asia.

RBP has worked since 2001 to create an interim regional clearinghouse on biosafety. This initiative has fostered the development of a regional network of experts on biosafety, while providing a platform for the transfer of relevant information to interested organizations, individuals and governments. The Programme also focuses on creating opportunities for raising awareness and networking through the organization of workshops, training programs and the development of local language materials. Some of their recent activities include the identification of trade and WTO implications on issues of biosafety as well as socio-economic impacts of biotechnology in Asia.

The Programme is currently working with 14 countries in Asia to develop regulatory frameworks for biosafety, as well as building capacity and support for their implementation. RBP has also directly assisted with the development of national biosafety guidelines for Sri Lanka, Lao PDR, Vietnam, Maldives and Cambodia. They have also produced publications such as 'Risk Assessment and Risk Management in Implementing the Cartagena Protocol' to enhance the capacity of countries to implement and use risk assessments in their Protocol implementation programs.

Recognizing the need for continued communication and support, RBP is setting the research agenda for biosafety in Asia and advancing collaborative capacity building initiatives such as a regional harmonization of biosafety provisions. With many countries in Asia interested in responsibly utilizing the benefits of biotechnology, they will continue to play an essential role in the promotion of awareness and the encouragement of dialogues on biosafety, as well as building capacity at individual and institutional levels.

Established in 1996, the IUCN – Regional Biodiversity Programme, Asia (RBP) aims to assist countries in the region effectively implement the Convention on Biological Diversity (CBD). RBP is a significant regional initiative that encourages, advises and supports 14 countries in Asia through a partnership approach.

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*Participatory...**Continued from page 9*

economic and social impacts of agricultural biotechnologies, and (3) develop educational materials to extend information to the public.

Method and Approach

The project utilizes both qualitative and quantitative research methods to meet our objectives. To gauge the level of knowledge, attitudes, and perceptions about rice biotechnology held by stakeholders, expectations and concerns have been elicited using one-on-one interviews, focus groups, and surveys in the U.S., the Philippines, and Bangladesh. In Asia these surveys targeted likely policy influencers – representatives from civil society who tend to play a leading role in molding public opinion. Economic impact assessments are a major component of the project, quantifying the level and distribution of benefits and costs in models that consider benefits accruing to input suppliers, consumers, and rice producers in different locations. One analysis takes a macro-level approach – examining aggregate welfare effects, and impacts on Asian nations' economies and world markets. Another investigation assesses the impacts in Bangladesh that such technologies may elicit at the individual household level, with respect to increasing local incomes and decreasing nutritional vulnerability. Both of these investigations are on-going.

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Report on the Needs and Present Status of the Capacity Building in Biosafety in Asia published by FAO

The Regional Office of the Food and Agricultural Organization released in May 2004 a report highlighting the needs and current status of capacity building in biosafety of GM crops in Asia.

The report, written by Dr. Anupam Varma, outlines approaches to build capacity in participating countries in the context of Cartagena Protocol on Biosafety. The key areas include: human resources; regulatory mechanisms; policies and programs; financial requirements; regional collaboration; development of time frame for all key areas.

The document also includes other areas such as: financial status of biotechnology and biosafety programs; sustainability of the initiative, environmental issues, weediness (unintentional transboundary management through gene flow or intentional farmers exchange across the borders), strengthening of policy advocacy, harmonization with UNEP-GEF and ASEAN project on biosafety, farmers awareness, categorization of GMOs, listing of biosafety laboratories, biosecurity.

The document is available at the FAO's Asian BioNet Website at http://asiabionet.org/documents/benchmark.htm.

India...Continued from page 3

organisms/substances or cells;
- scale up or pilot operations for facilities using genetically engineered organisms/micro-organisms mentioned in the schedule.

Institutional Biosafety Committees (IBSC) have to be set by every institution involved in biotechnology research. Its functions include the overseeing of research; the seeking of approval for certain categories of risk activities, ensuring adherence to biosafety guidelines; preparing an emergency plan and informing other relevant bodies about experiments.

There is also the State Biotechnology Coordination Committee to be established in each State and its functions are: to periodically review safety and control measures in institutions handling GMOs; to inspect and take punitive action in case of violations through the State Pollution Control Board or the Directorate of Health.

District Level Committees (DLCs) monitor safety regulations in installations; investigate compliance with guidelines and report violations to the SBCC or GRAC; act at district level to assess damage and institute control measures in relation to GMO release.

There is also a Monitoring and Evaluation Committee (MED) to undertake field visits at field sites and assist the RCGM in collecting and analyzing field data.

Despite its fairly comprehensive legislative and regulatory structure, India is further seeking to strengthen its institutional capacity, given the possibility of increased movement of LMOs after the coming into force of the Protocol.

In a presentation by the Biosafety Capacity Building Cell of the Ministry of Environment (MoE) in April 2004, an MoE representative stated that India needs to strengthen its Research and Development institutions by developing multi-disciplinary expertise, strengthening laboratories, and conducting training to improve skills in handling equipments and directed research.

Growing rice in paddy lowlands. Rice forms the staple food of most of the South Asian countries, but rapid population increase coupled with depleting resources is threatening this food resource. Countries are now looking at biotechnology as a possible solution, but its capacity to solve food shortage is under intense debate. Photo © CGIAR and IRRI

The MoE representative also said that India needed to:
- develop information sharing through networking, focus on database development and web management of information dissemination;
- enhance capacity in assessment of risks through protocol and guidelines for various scenarios;
- develop standards/limits and training in risk assessment and management;
- increase awareness building through awareness programs and an introduction of some type of public consultation mechanism.

Sources: Gupta, Aarti. "Governing Biosafety in India: The Relevance of the Cartagena Protocol." Belfer Center for Science and International Affairs (BCSIA) Discussion Paper 2000-24, Harvard University, 2000; Gupta, Aarti. "Ensuring 'Safe Use' of Biotechnology: Key Challenges", EPW Review of Science Studies, July 06, 2002; Hota, Dr. Manoranjan. "India: Capacity Building in Biosafety." Second Conference on Biotechnology for Asian Development - Regional Cooperation for Ensuring Access and Capacity Building, New Delhi. April 2004; "Regulatory body for biotech likely", Financial Express, December 13, 2004

SACEP expresses its deepest sorrow at the recent Tsunami tragedy which has taken the lives of so many people in the region, and conveys its condolences to those who have lost loved ones and homes. While the impacts on human lives, property and the environment are beyond comprehension, SACEP believes that the region can rebuild shattered lives and the coastal communities in these countries through understanding and cooperation as well.

MANUAL ON ASSESSING ECOLOGICAL AND HUMAN HEALTH EFFECTS OF GMOs

A Manual on Assessing Ecological and Human Health Effects of Genetically Engineered Organisms is available on the website of the Edmonds Institute, a public interest nonprofit group focusing on understanding and sharing information about environmental, human rights and human health, economic impacts of technology and intellectual property policies. The manual is a revision of an earlier manual, also compiled by several scientists, which aimed to a handbook for both consumers and policy-makers to evaluate likely impacts of GE organism in a variety of settings and applications. The manual takes the form of a series of flowcharts and worksheets.

The Manual is only one of the activities of the Institute, which has had other publications, and activities aimed at spreading awareness on biotechnology. The Institute also makes available to biosafety focal points, regulators, and researchers in the Global South and Eastern Europe special complimentary copies of Genetically Engineered Organisms: Assessing Environmental and Human Health Effects, a highly-regarded compendium of biosafety research published by CRC Press. The book includes chapters by scientists who have done cutting edge research in botany, entomology, plant pathology, and other agricultural and environmental sciences.

The Institute's current emphasis is on: (a) biosafety and the legally-binding international regulation of modern biotechnologies, (b) intellectual property rights and just policies for the maintenance and protection of biodiversity and (c) exploration of the ethical implications of new technologies. The Institute conducts many activities in the area of dissemination of information on biosafety, including research, publishing of policy analysis and scientific thought pieces and sponsoring of public workshops.

It also disseminates information about and criticism of technology assessment, encourages pro bono research and policy analysis by scientists and scholars, and seeks to create alliances and coalitions with like-minded organizations and individuals. Since the 90s, the Institute has held workshops on biosafety throughout the world, and its representatives have appeared before various international groups concerned with biosafety and biosafety capacity building.

For more information, contact: Ms. Beth Burrows, Director at beb@igc.org or write The Edmonds Institute, 20419-92nd Avenue West, Edmonds, Washington 98020 USA; http://www.edmonds-institute.org

SACEP thanks all individuals and organizations who contributed articles for this issue. The next issue will be a special issue focussing on:

Post Tsunami Recovery and Rehabilitation

The tsunami disaster that affected so many people in the South Asian region has left many questions unanswered, mostly surrounding the failure to warn people of the impending destructive waves, and how the post-disaster scenario is to be handled. Many things have to be rebuilt: lives, buildings, infrastructure and not least, the natural resource base on environment in sectors like agriculture, fisheries, tourism, wildlife.

One of the most pressing issues is the establishment of an early warning system in the region. This issue will look at how this is being attempted, as well other requirements for an effective system of prevention, including the raising of public awareness and rapid response on the part of the public and the authorities. We will also focus on damage assessment, how the countries of the region will be recovering, on the plans for recovery and rehabilitation. We will also look at disaster management and rehabilitation strategies.

For information, comments and suggestions, please contact:
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