EVALUATION REPORT OF THE UNITED NATIONS ENVIRONMENT PROGRAMME/GLOBAL ENVIRONMENT FACILITY PILOT BIOSAFETY ENABLING ACTIVITY PROJECT

by

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LIST OF ACRONYMS

AIA	advanced informed agreement
DNA	deoxyribonucleic acid
GMO	Genetically Modified Organism
IRRO	International Information Resource on the Release of Organisms into the Environment
IUCN	World Conservation Union
LMO	Living Modified Organism
MSDN	Microbial Strain Data Network
NEA	National Executing Agency
ONT	Organism with Novel Traits
SIDS	small island developing States
UNEP	United Nations Environment Programme

EXECUTIVE SUMMARY

Background

This evaluation was undertaken by Dr. Julian Kinderlerer of the University of Sheffield, United Kingdom, during the period November to December 1999. It covers the two components of the project:

(a) Support to the preparation of National Biosafety Frameworks by 18 countries (Bolivia, Bulgaria, Cameroon, China, Cuba, Egypt, Hungary, Kenya, Malawi, Mauritania, Mauritius, Namibia, Pakistan, Poland, Russia, Tunisia, Uganda and Zambia);

(b) Organization of a series of awareness-raising regional workshops on issues related to biosafety and biotechnology. These were held in Havana, Cuba; New Delhi, India; Nairobi, Kenya; and Bled, Slovenia.

The evaluation of the project involved:

(a) An examination of all country reports submitted to United Nations Environment Programme (UNEP) in relation to the development of National Biosafety Frameworks;

(b) Visits to Bulgaria, China, Kenya and Mauritius and discussions with officials responsible for the projects in Poland, Russian Federation while at a meeting of the Central and Eastern European Countries in Bulgaria, December 1999;

(c) An examination of the reports emanating from all the workshops held in the four regions, plus reports of the Consultative Meeting of the Countries participating in the pilot project and the Second Steering Committee meeting held in Cairo, Egypt, 24-26 May 1999;

(d) The consultant also gives a brief explanation of the appropriateness of the project in relation to relevant provisions of the Convention on Biological Diversity (such as Article 8g) and relevant aspects of Chapter 16 of Agenda 21 (Environmentally sound management of biotechnology).

Project implementation

The project was implemented by UNEP in association with National Executing Agencies (NEAs) of the respective countries (for the national level component).

The three primary stages in the implementation of the project in each individual country were as follows:

(a) The current use of modern biotechnology within the borders of the country, collecting information on what was being done in national institutions, whether government, university or private industry, and the level of awareness of biosafety within the institutions;

(b) The structures required for a risk assessment and audit of these assessments in order to ensure the safe use of modern biotechnology;

(c) The means by which the safe use of modern biotechnology could be promoted. This was often interpreted as the promotion of use of biotechnology, tempered by a need to involve the public in the development of strategies to ensure biosafety.

UNEP also collaborated with the International Information Resource on the Release of Organisms into the Environment Microbial Strain Data Network (IRRO/MSDN) and four institutions designated by respective host Governments for the organization of regional workshops.

Evaluation

This was an ambitious project that was successfully executed over a period of 16 months (originally planned for 12 months). Out of 18 countries in the pilot project, 17 prepared National Biosafety Frameworks. The consultant is satisfied that the countries have identified the national systems needed to ensure the safe adoption and application of products of modern biotechnology. But, many had not separated their role in promoting the technology from that of audit and safety assessment. The report suggests that it is important, in order to maintain public acceptance of a government's objectivity, that a clear separation of duties and activities is maintained and the consequential necessary national capacities developed for the execution of the respective roles. These countries now require further support for capacity-building initiatives that would enable them to implement the biosafety frameworks in the light of the provisions of the Protocol on biosafety. The UNEP International Technical Guidelines for Safety in Biotechnology, which were used by the participating countries as a guide, may also need updating or reviewing to take into account the Biosafety Protocol provisions.

The consultant observes that all the regional workshops were held and that a wide spectrum of stakeholders was involved. The regional workshops were successfully conducted, productive and worthwhile. The workshops provided a good understanding and appreciation of the type of assistance that the countries might need to ensure the transparent and safe consideration of the use of products of modern biotechnology. All the workshops concluded that strong regulatory authorities and efficient systems are needed to give users confidence in the safety of products on the market. It was recognized that there is a need for development and/or strengthening of national as well as subregional capacities, including the development and/or strengthening of national as well as subregional capacities, including the development of human resource infrastructure to attempt risk assessment, management and monitoring of LMOs at national, subregional and regional levels.

A recurrent theme of the participants at the regional workshops and of the officials and experts in the 17 countries participating in the national level component was their genuine and honest commendation of UNEP for conceptualizing and executing the project and the Global Environment Facility (GEF) for funding it. Both the regional workshops and the Consultative Meeting of the Participating Countries as well as the steering committee members of the pilot project underlined the importance of extending further UNEP/GEF financial and technical support beyond the pilot project and to include additional eligible countries.

It is observed that the timescale for the project was severely limiting, and most countries were not able to complete the full legislative process of getting their National Biosafety Frameworks legally adopted by their parliaments. However, the preliminary work done towards producing legal

systems for safe biotechnology applications demonstrated a commitment to the project and towards ensuring that modern biotechnology is, so far as is possible, conducted in a safe manner.

The impetus of the project provided countries with the possibility of establishing a regulatory framework and of kick-starting the use of biotechnological techniques and options in those countries since research and development in the area of biotechnology was lagging, relative to industrialized countries.

Accordingly and most commendably, a majority of the countries involved in the project have passed or drafted new legislation to control the use of LMOs/GMOs within their borders. This type of exercise may extend to other areas of biodiversity and protection of the environment - a very important and welcome development.

The level of public participation and involvement in the project in respect of the national level component, differed substantially among the countries, largely reflecting differing traditions, difficulties caused by the size and geographical conditions of the countries, the number of languages and educational deficiencies.

Having been an ambitious project, attempting much within a very short time-frame, the achievements attained indicate a well-managed project. The sub-project documents and the UNEP biosafety guidelines provided a framework for the work involved in this project and the individual participating countries were provided with timetables and detailed guidance for delivery of various aspects of the project. The consultant was impressed that the structures instituted by UNEP ensured that where countries failed to meet their obligations, the system was flexible enough to ensure that money was withheld. In some circumstances small amounts of extra finance were required, and again, countries were impressed with the flexibility of the system. Task managers at UNEP were clearly willing to talk with country representatives and provide flexibility in interpreting the needs of countries within the framework set by the project.

In an extended or expanded future programme or project, more realistic timescales need to be identified. If need be, the terms of reference could be scaled down or drafted to ensure that countries are fully aware of what is readily achievable within the set time-frames, and within the funds that may be provided.

Framework for cost norms

The identification of cost norms was one of the goals of the project. This has turned out to be very complex and perhaps virtually impossible. Variety in climate, physical and social geography, the number of local languages needed to bring awareness of the benefits and risks of biotechnology to all stakeholders should be taken into account in the design of the biosafety systems to be implemented in the respective countries and in deciding on a level of funding support to be provided to the countries.

The rate of adoption of modern biotechnology applications may differ considerably and significantly from country to country. Whereas the adoption of technology itself may be cheap, and could be readily implemented at the laboratory stage by many countries, it is not the case with respect to risk assessment and risk management. Consideration of the potential hazards of any new LMO to human health or the environment may be very expensive, and the

investments required for the commercial exploitation of these novel LMOs may be substantial.

Fortunately, in the wake of the project activities at national level, and consequent awareness raised during both the regional workshops and the biosafety Protocol negotiations, a majority of countries would not be starting from scratch, that is from a complete absence of environmental legislation or total lack of some capacity for assessment of the impact of LMOs. However, there is strong need for strengthening national capacities and urgent need for establishing and/or strengthening subregional centres of expertise with the relevant capacities, facilities and human resources to support national level risk assessment and risk management initiatives.

From the experience gained and lessons learned in the pilot project, four types of broad assistance may be identified namely:

(a) Support to the development of National Biosafety Frameworks through a consultative and participatory process involving a wide spectrum of stakeholders nationwide ($ 18 million);

(b) Support to the implementation of National Biosafety Frameworks by 25 countries, including those that participated in the UNEP/GEF Pilot Biosafety Enabling Activity Project, and other countries that are at various stages of finalization of their National Biosafety Frameworks prepared on their own initiatives ($ 14,840,000);

(c) Support to subregional and regional awareness-raising workshops on issues related to biosafety and biotechnology ($ 5.2 million);

(d) Support to the establishment or strengthening of subregional and regional centres of excellence for biosafety and biotechnology ($ 7,780,000);

(e) Support to integrated, multi-pronged global, regional and subregional medium-sized projects on biosafety ($ 20 million).

Accordingly, a crude estimate of funding needs required for accelerated capacity-building initiatives in the immediate short-term (two years) in respect of the critical mass of target countries may be given as $ 65,820,000 starting from July 2000. This would facilitate enhancement of biosafety at the national, subregional and regional levels in the identified critical mass of 85 countries, as further outlined below.

Conclusions and recommendations

There can be no doubt of the importance of this enabling project in the eyes of the participating countries. There was considerable evidence that in many cases it had vastly exceeded its remit. The vast majority of country representatives believed that this was the type of project that the countries would have had to undertake. However, if left entirely to Governments for funding, it would have been greatly delayed, much slower and less effective. Certainly, a majority of the project activities at national level would not have taken place without the UNEP/GEF support. While limited funds are available in some of the countries for fundamental research, or applied research and development, most developing countries have been slow to provide funds for research into biosafety, or for the setting up of mechanisms by which the safe use of the technology could be assured. Establishment of subregional and regional centres of expertise and nodes for supply and exchange of information, the training of scientists to use the technology

safely, and to think about the consequences of their work, were seen to be of extreme importance and urgency.

The need expressed by those participating in this project for the funds allocated to them, and the impetus that they have experienced from its implementation, have been clearly demonstrated in this project. The countries involved in the project are fearful of being unable to complete the process started. They believe that much has been accomplished, but that there is much to accomplish in the area of biosafety and biotechnology in relation to biodiversity. If they are to set up strict regulatory systems, there needs to be enforcement and laboratory and field facilities that are capable of testing and validating the presence or absence of modified organisms. It is acknowledged that the project has stimulated a new approach to biotechnology by national and international organizations and that it has stimulated regional cooperation. It would be a great pity if these 17 countries were unable to continue the good work started in the course of a single year.

In the consultant's view, it is crucial for the future of biotechnology that a project similar to this one is funded in those countries that have yet to develop a consistent framework for the safe use of this science. If at all possible, as many as possible of those countries involved in this project should continue to be involved, acting in some ways as mentors to newly involved countries so as to allow the rapid build-up of expertise in this area. The experience gained and expertise developed as well as lessons learned should not be lost. Many more countries should benefit from similar input of funds and expertise as are available through this project. Many of these countries have applied for funding for their own National Biosafety Frameworks.

The follow-up project for new countries would then be similar to that already achieved, requiring a survey of the expertise and use of both biotechnology and of biosafety. An assessment of the need for an overall biosafety framework would then follow.

In order to effectively fulfil its functions as a complement to the Protocol on Biosafety, and to further guide the countries in the preparation of the National Biosafety Framework in the light of the provisions of the Protocol on Biosafety Frameworks in the light of the provisions of the Protocol on Biosafety, it is strongly recommended that consideration be given to the review of the UNEP International Technical Guidelines for Safety in Biotechnology.

I. INTRODUCTION

1. This is a report of an evaluation of the pilot project that aimed to set up National Biosafety Frameworks in 18 countries and the development of systems for cross boundary movement of living modified organisms (LMOs). Biosafety in this context involves the development of systems to ensure:

(a) Safe use of modern biotechnology, whether for foods or feeds, primarily but not solely in relation to their impact on the environment; and

(b) That the possible environmental impact of imported foods, feeds or LMOs has been considered and the risks taken into account before importation.

2. The project had two components:

(a) Preparation of National Biosafety Frameworks in each of eighteen participating countries, including a survey of capacity for both biotechnology and for safety assessment; and

(b) The organization of a series of eight workshops that explored both risk analysis and management and transboundary movement of LMOs. The workshops involved many more countries than participated in the preparation of National Biosafety Frameworks.

3. It was a very ambitious project, for all of this was to be accomplished within 12 months. In the event, the project was completed over 16 months.

4. The task manager, in close collaboration with the programme officer, Division of Environmental Conventions of UNEP, implemented the pilot project within UNEP/GEF. Eighteen individual National Executing Agencies in the participating countries attempted to implement the project within their territories. This project was approved by the GEF Council at its meeting of 4 to 6 November 1997. It was designed to promote a comprehensive understanding of, and approach to, biosafety issues by countries within their region or subregion in order to safeguard biological diversity under in situ conservation against possible adverse impacts from LMOs with novel traits resulting from biotechnology. The project was directed at improving and strengthening national instruments for environmental management. The prime mechanism for implementation of the project was the development of National Biosafety Frameworks in the context of the implementation of the UNEP International Technical Guidelines for Safety in Biotechnology and any future international agreement on biosafety such as a Protocol to the Convention on Biological Diversity.

II. NATIONAL BIOSAFETY FRAMEWORKS

5. The countries that participated in the programme were chosen because of their different sizes, geography and geographical locations and level of socio-economic development. The Russian Federation and China have both the largest land area (52% and 30 % respectively of the land area of the participating countries) and the largest populations, with China having 76% of the population of the participating countries. At the other extreme, Mauritius has only 0.01% of the area of the Russian Federation and 0.8% of its population. Its gross domestic product per capita is, however, at least twice as large. In addition, it was recognized that the countries were at very different stages in the development of biotechnological applications. The

primary focus in the development of the use of modern biotechnology has been in medicine and agriculture.

6. The participating countries were Bolivia, Bulgaria, Cameroon, China, Cuba, Egypt, Hungary, Kenya, Malawi, Mauritania, Mauritius, Namibia, Pakistan, Poland, the Russian Federation, Tunisia, Uganda and Zambia. They were expected to start in April 1998 on the preparation of a National Framework using the UNEP International Technical Guidelines for Safety in Biotechnology as a guide. It was hoped that this would result in a harmonized approach to risk assessment and risk management of modified organisms both within the individual countries and within each region. Pakistan was unable to start the programme and eventually withdrew.

7. The objectives of the participating countries were (from the report by China on its implementation of the project):

(a) To assess the existing national capacity and roles in environmental release of LMOs and their products and to develop methods, techniques, standards, guidelines, indicators for assessing and monitoring the risks, and control measures for those risks likely caused by the transportation, release, commercialization and application of LMOs;

(b) To facilitate the national capacity-building for biosafety management and formulate a package of needs, including the development of human resources, the establishment of management mechanisms, the formulation of relevant policies and regulations, the development of relevant technical guidelines and management procedures;

(c) To promote the establishment of the institutional arrangements and operational mechanisms for biosafety management and develop human resources for biosafety management through formulating and implementing a series of training plans to upgrade the expertise in this field, in particular technical staff and managers for risk assessment and risk management of LMOs and their products;

(d) To undertake publicity activities at the national and local levels to increase the understanding and concern of the public and major decision makers of the potential benefits and risks of biotechnology application;

(e) To increase the public awareness of biosafety and facilitate the formulation of relevant laws, regulations and rules and supervise their enforcement;

(f) To enhance international cooperation and communication on scientific research, legislation, information exchange and personnel training in the field of biosafety.

8. There were, therefore, three primary stages in the implementation of the project in each individual country. The authority implementing the project had to identify:

(a) The current use of biotechnology within the borders of the country, collecting information on what was being done in each institute, whether government, university or private industry, and the level of awareness of biosafety within the institutes;

(b) The structures required for a risk assessment and audit of these assessments in order to ensure the safe use of the technology; and

(c) The means by which the safe use of biotechnology could be promoted. This was often interpreted as the promotion of the use of biotechnology, tempered by a need to involve the public in the development of strategies to ensure biosafety.

9. Table 1, below, identifies the tasks required of each of the countries in identifying their needs and producing a framework for biosafety. The establishment of a task force was reported as having been completed by all countries within the first quarter following the beginning of the project. Most were in the process of stocktaking and assessment. By the end of the project, all participating countries except Pakistan had identified their needs, had held a number of national workshops, often with invited representatives of other countries in the region or international experts and had begun the process of considering a possible legal framework for biotechnology research, development, commercialization and import and export. All the countries had discovered a very wide range of biotechnology applications, although few of these involved recombinant DNA technology. The national workshops were designed to review the assessments of their capacity for modern biotechnology and safety assessment, and to investigate the principles of risk assessment and risk management.

Table 1: Tasks

Establishment of task force
Stock taking and assessment
Survey of existing biotechnologies and status of safety
Survey of existing cooperative programmes
Survey of existing mechanisms of risk assessment/ management
Survey of extent and impact of release of LMOs
Identification and analysis of options
National workshop to review findings of assessment
Awareness workshop on risk assessment and risk management principles
Awareness workshop on monitoring and enforcement mechanisms for national controls
Planning and preparation of National Biosafety Framework
Preparation and circulation of draft National Biosafety Framework
Public awareness workshop on the National Biosafety Framework
Finalization of National Biosafety Framework in light of feedback received
Printing, publication and dissemination of the National Biosafety Framework
Project coordination, monitoring and evaluation

10. The stocktaking process required each country to attempt to identify the legal restraints in existence (if any) for controlling the use or import of the products of biotechnology. When completed, the assessment provided the starting point for necessary changes, regulations or guidelines.

11. There are very few special laws in place for ensuring the safe use of modern biotechnology, although many of the countries had legal systems that could be used to control many aspects of this technology. At the end of the project, only Cuba and Hungary had formal new laws in place, but considering the time that it normally takes to draft legal instruments, gain agreement of the executive, obtain a place in the legislative queue and present these complex laws to national parliaments, that is not surprising.

12. What is more important is that the mechanisms needed to implement any law or guidelines should be in place, and that there should be recognition of

the need to consider the safe use of the biotechnology. It may be that, like most Western European countries before 1990, voluntary systems are in place to assure safe use of genetically modified organisms (GMOs) within an environment and to reassure the public and media that any novel organism or product used within the borders of a country has been assessed and has not been permitted unless considered as safe as it is possible to make it. The system should be capable of identifying risk, of identifying any environmental impact both of using the technology and of using traditional or current systems rather than new varieties in the future. At the close of the project all countries appeared to be in this position.

13. In reviewing the process, it was necessary to consider:

(a) The current use of biotechnology within their borders;

(b) The means by which the safe use of biotechnology could be promoted;

(c) The structures required for risk assessment and audit of such assessments in order to ensure the safe use of biotechnology.

14. In order for the system to work, it will eventually be necessary to ensure that there is:

(a) A regulatory system (e.g. legally binding regulations and/or non-binding guidelines);

(b) A means of implementing the system, probably through some form of peer review system involving scientific expertise drawn from those working in the field within the individual countries, or where necessary, by use of outside expertise;

(c) A decision making system that must include impact assessment (at least risk assessment) and audit;

(d) An information system both to maintain public acceptance of that used in their region and to ensure that decisions are based on knowledge;

(e) An enforcement system to ensure compliance with any decisions made and to allow monitoring of that which is happening in the field; and finally,

(f) Some form of validation system if testing is required to identify the presence or concentration of either GMOs or LMOs.

All of these criteria have been used in examining the reports submitted to UNEP/GEF by the participating countries.

15. The consultant was satisfied that all countries had identified the systems needed to ensure the safe use of the technology within their borders but many had not separated their role in promoting the technology from that of audit and safety assessment. It is crucially important that a clear separation is maintained between assessing or auditing risk and promoting the use of biotechnology in order to maintain public acceptance of governments' objectivity.

16. In order to consider the diverse mechanisms by which each of the countries built their frameworks, it was important to identify common elements needed for a comprehensive biosafety framework. In particular, it was considered necessary to identify the following items in each country’s report.

Although the list below simply identifies the issues that should have been considered within each framework, different countries will have interpreted these in very different ways.

(a) The objectives of the regulatory system (e.g. protection of human health and the environment, conservation of biodiversity etc.) and the mechanism proposed to meet these objectives;

(b) The scope of the regulatory system:

(i) What is covered —— GMOs, novel organisms, and non-living products thereof; whether products that contain neither gene nor gene product and those whose characteristics are unchanged (as, for example, maize oil) are covered within the legislation. In this context there was a need to ensure that only products that were intended to fall within the scope of the regulatory system did so. Beer and wine, for example, are products of biotechnology. Would the rules require their control; if so, was this intended? Most countries have chosen not to alter the regulatory system for products or processes currently used, reserving the system for new products. In doing so, they have chosen to use the techniques of modern biotechnology as a trigger for regulation. The use of a trigger has been much criticized, for it lacks a scientific justification. Products that fall within this regulatory system are chosen on the basis of the process by which they are formed, rather than a real risk. The criticism is based on an assumption that the drawing of lines to separate that which is regulated and that which is not should be derived from scientific criteria. The use of scientific criteria may be justified, but is inconsequential when drafting legislation;

(ii) Which activities are covered? For example, is it only the impact on the environment that is within the scope, and hence primarily a consideration of any activity that might result in uncontained or unconfined use of the modified organism, or is it any use? Should the legislation address unintended or inadvertent escapes from containment, or is the intention of the user sufficient to identify that which falls within the regulatory system? Does the import or export of the organism fall within the scope of the regulatory system?

(c) The mechanisms through which regulatory systems are implemented, including identification of an organization that will act as the authority to which notification should be given. Does the system differ depending on the type of activity? Contained use could be regulated at a local level whereas release would be regulated through a national authority;

(d) The legislation currently in place that would apply to the use of GMOs;

(e) Rules for non-compliance including the setting up of a supervisory inspection system if and where necessary must be specified so that applicants for permission to use LMOs or GMOs are aware of their responsibilities;

(f) Mechanisms for review and amendment of the regulatory system should be in place at the outset, for both the technology and our understanding of biosafety are in flux. It is likely that the techniques currently used to modify organisms will change during the next few years.

Knowledge of the structure of the genome of individual plant species, and of differences between alleles and the consequent impact on the physiology of the plant may allow directed mutations in genes already present rather than the insertion of genes from other organisms, for example. Should legislation be flexible enough to cover these changes?

(g) To maintain public acceptance of biotechnology, it may be necessary to have mechanisms for public information, and/or participation in the decision-making process (e.g. input into the review system or appeal) within the framework;

(h) The manner in which neighbouring countries are involved in the assessment process or the mechanisms for informing these countries of problems that might arise in the event of an accident or loss of control of a modified organism within the environment.

17. It was very clear that most of these issues had been addressed at the Regional Workshops (see below) and that almost all the countries in the project were aware of, and able to identify, the mechanisms they would wish to put into place in order to achieve the aims and objectives.

III. REGIONAL WORKSHOPS

18. The global component of the programme was achieved through the organization of eight regional workshops in each region, namely Africa (Nairobi), Asia/Pacific (New Delhi), Latin America and the Caribbean (Havana) and Central and Eastern Europe (Bled, Slovenia). Two back-to-back workshops were held in each of the four centres. The workshops were attended by representatives from a large number of countries in each region (see Table 1), many more than participated in the capacity-building segment of the project. They addressed risk assessment and management of LMOs concentrating primarily on their impact on the environment. Issues of transboundary movement of the organisms, including mechanisms for the supply and exchange of information between importing and exporting nations, constituted a major part of the workshop agenda. The workshops aimed to provide a clear understanding and appreciation of biosafety issues and to place the UNEP International Technical Guidelines for Safety in Biotechnology in perspective.

Table 2 Regional Workshops

Region	Venue	Date	Countries
Latin America and the Caribbean	Havana, Cuba	26-30 October 1998	17
Central and Eastern Europe	Bled, Slovenia	11-15 November 1998	16
Africa	Nairobi, Kenya	23-27 November 1998	30
Asia-Pacific	New Delhi, India	7- 11 December 1998	16

19. The purpose of the regional workshops was to promote greater awareness, understanding and appreciation of biosafety and biotechnology issues by countries, in particular, developing countries and countries with economies in transition. They allowed the exchange of views and information on biosafety by countries, the scientific community, relevant non-governmental organizations and the private sector. Workshop 1 covered issues related to risk assessment and risk management of LMOs resulting from biotechnology,

including environmental impact assessment. Workshop 2 focused on issues related to the transboundary transfer of LMOs, including appropriate mechanisms and modalities for the supply and exchange of information regarding biosafety. The workshops aimed at considering issues of importance to building capacity at each of national, subregional, regional and global levels. Throughout the workshops it was emphasized that the governments must invest, innovate and develop resources to ensure that their economies benefit from biotechnology not only in agriculture, but also in health care and in industry. The impact of the introduction of the new technology on economies was also addressed, with the possibility of loss of markets, jobs, and changes in agricultural and cultural practice.

20. Government nominated representatives from countries within each region attended the workshops. Also attending were Government representatives of developed countries, the scientific community, United Nations organizations, the biotechnology industry and other organizations. All key stakeholders attended.

21. The workshop participants were apprised of international initiatives to ensure biosafety, including the discussions concerning a possible Biosafety Protocol to the Convention on BiologicalDiversity. They were able to discuss the many issues of concern that all had about the new technology, especially as undercurrents of a backlash in Western Europe were already beginning to appear, and were reassured that their state of preparedness for the influx, mainly through import, of new varieties of transgenic food and crops was similar to other countries in the region. The background to the development of the UNEP International Technical Guidelines was explained, particularly the aim of helping countries in the development of capacity to undertake risk assessment and information systems. They constituted part of the UNEP/GEF Pilot Biosafety Enabling Activity Project. A draft agenda, used at each of the workshops, is attached in Table 3.

22. At each of the workshops, the participants were able to identify what was known about biotechnology in their region. There was great variation in the state of biotechnology in African countries, with Egypt, South Africa and Zimbabwe the only countries in which research in modern biotechnology was known to be proceeding. Central and South America are leaders in the use of modern biotechnology, both in research and in commercialization, with Argentina, Brazil, Chile, Cuba and Mexico well advanced in using modern biotechnology both in medicine and agriculture. Like South and Central America, Asia was well advanced in using biotechnology and had also been involved for some years in setting up mechanisms for assessing the safe use of the technology. In Central and Eastern Europe, research in the use of the technology was well advanced, but little progress had been made in the commercialization of the products of their own technology. It was known that the introduction of novel products from other markets was imminent in a number of these countries, and there was bitter debate about some of the East European countries allowing new transgenic crops to be imported and grown without any apparent review of their safety. It was noted at all the workshops that the commercialization of transgenic crops represented the fastest introduction of a new technology in the history of agriculture, perceived to be due to the likely benefit to be gained by farmers using the new varieties. It was emphasized that for trade to succeed, stakeholders needed to have confidence in, and understand, that which had been done, so that they could make their own cost-benefit analyses and make informed decisions about the industrialization of the technology, although what constituted stakeholders may have been improperly understood. Are consumers part of this process?

23. All the workshops concluded that strong regulatory authorities and efficient systems are needed to give users confidence in the safety of products on the market. It was evident that indigenous technologies needed to be developed and protected, and the ethical issues needed to be handled by strong regulatory structures that could make unbiased assessment of the safety of any introduction.

24. Principles and mechanisms of risk assessment were considered at each of the workshops. In most cases, it was suggested, an independent national biosafety committee considers applications for the use of modified organisms on a case by case basis, either performs a risk assessment or audits that performed by applicants, and then advises an appropriate ministry or executive commission representing a variety of Government departments of the scientific assessment made and its conclusions. It is then up to government to decide on permitting the particular use. This model separates the advice based on a scientific assessment of risk (and/or benefit) and the political decision.

25. Much of the science relating to the interaction of ordinary plants with their environment are unknown, so the risk assessment may often be based on experience and scientific intuition rather than scientific fact. It was suggested that risk analysis, therefore, works best with public involvement and dissemination of information. The evaluation of risks is difficult because of both the lack of information and because of different interpretation of the available data by those from different disciplines. The need to take precaution into account was extensively discussed. Industries views were aired, primarily that products will not sell if the public is not satisfied, if public interests are not protected and if the risks of the product are not thought to have been evaluated properly and in an independent manner. In general, industry welcomed the development of sound legislation at national, regional and international level. It became very clear that the information required of applicants for permits to use transgenic organisms by national authorities throughout the world was almost identical, but that the interpretation of that data was different. The need in some systems to balance risk, benefit, and even consequences of not using the new technology could be compared to other systems where risk alone was considered, and precaution dictated a slow and careful appraisal of many experiments.

26. The second workshop considered issues related primarily to transboundary transfer of LMOS. It was clear that movement of goods was partly governed by existing trade and safety agreements, which were carefully considered. It was recognized that there would be a need for countries to interact, at the very least at a regional level. The meetings considered unintended movement of modified organisms across national borders due to natural dispersal or to breakdown in confinement systems. The delegates expressed concern at possible environmental impacts of modified organisms about which their Governments may be unaware. GMOs were seen to have the capacity to spread new characteristics within an ecosystem, and in some ways could not be considered equivalent to the introduction of alien species. The general view of those attending the workshops was that a precautionary principle should be applied, LMOs were considered a special risk when released into the environment and that, following risk analysis, risk management should be put into place to minimize risk to the environment. Both labelling and the problems of complex transshipments were discussed and flagged for consideration during the process of agreeing a Protocol to the Convention on Biological Diversity. It was recognized that there is a need for development of national capacities, including the development of human resource infrastructure to attempt risk assessment, management and monitoring. The Protocol to the Convention on Biological Diversity was expected to contain provisions for capacity-building in many of the participating countries. This could include training of those

using the technology (in cooperation with the private sector) and training in risk assessment and management for the safe use of these new technologies.

27. The workshops provided those participating with an insight into the many different ways the countries that have already developed assessment and management systems have approached the problem, and provided the springboard for each country to decide on the manner in which biotechnology would be developed within their borders.

28. It was the view of those involved in the workshops that they were successfully conducted and provided the representative countries with a great deal of useful and important advice and information. The meetings provided a forum for individuals from many countries to meet and discuss matters of mutual concern. These meetings demonstrated the lack of knowledge and thought about biosafety amongst many of the participants, and demonstrated the need for thought about the problems that might arise from the introduction of the products of biotechnology into a new environment. The issues raised, and the conclusions drawn, have been borne out by the impact of the public rejection of the technology in Western Europe, and therefore, the anxiety and questioning of the use of the technology in less developed countries.

29. The commendation of UNEP and GEF for organizing the workshops appears to have been unanimous and honest, and all participants believed that the workshops had been a productive and worthwhile exercise. They provided an understanding and appreciation of the assistance that countries might need to ensure the transparent and safe consideration of the use of the products of modern biotechnology.

30. Participatory workshops of this sort, involving a wide range of experience and expertise, provide a necessary springboard for further action, and it is essential that any further project uses similar workshops to provide a basis for countries to decide on the appropriate manner of regulating the introduction of the products of modern biotechnology.

31. The costs of the workshops are detailed in Table 3 below. On average it cost $4400 for each participating country, which does not seem excessive. The Latin American workshop, held in Cuba, was significantly more expensive than the other meetings.

Table 3: Workshop costs

Region	Cost ($)	Countries	Cost per country ($)
Latin America and Caribbean	95,700	17	5,629
Asia/Pacific	70,000	16	4,375
Central and Eastern Europe	53,650	16	3,353
Africa	125,000	30	4,167

Table 4: Provisional agenda for regional workshops

Item 1:	Introductory remarks.
Item 2:	Biotechnology: benefits, opportunities and possible environmental, health and socio-economic impacts.
Workshop 1	Theme: Issues related to risk assessment and risk management of LMOs and ONTs including their environmental impact assessment, for enhancement of biosafety
Item 3:	International efforts on biosafety:
(i)	UNEP Biosafety Guidelines activities and other relevant international activities on biosafety.
(ii)	Biosafety Protocol within the framework of the Convention on Biological Diversity.
Item 4:	State of the art of biotechnology in the region
Item 5:	Trends in commercialization and international trade of biotechnology products:
(i)	Agriculture
(ii)	Health
(iii)	Environment
Item 6:	Risk assessment and risk management.
Item 7:	Regulatory oversight for the safe development and commercialization of biotechnology products (from research and development to field testing and marketing):
(i)	Biotechnology industry regulatory procedures, guidelines and perspectives
(ii)	Country experiences in regulation and administration
(iii)	Regional experiences
(iv)	Non-governmental organizations' views and perspectives on regulation
Workshop 2	Theme: Issues related to transboundary transfer of LMOs and ONTs including appropriate mechanisms and modalities for supply and exchange of information, for enhancement of biosafety
Item 8:	Transboundary movement of GMOs:
(i)	Current trade and challenges in commercialization of biotechnology products
(ii)	Unintended movement
(iii)	Regulatory approvals
Item 9:	Country case studies:
(i)	Building of acts - compiling/formulating/enacting legislation, directives and regulations - (in respect of contained uses, releases, movements)
(ii)	Review of applications for field releases and commercialization
(iii)	Information exchange and public participation
(iv)	Data harmonization/Data validation
(v)	Setting up of national regulatory frameworks
Item 10:	Supply and exchange of information:
(i)	Mechanisms and modalities
(ii)	Global information exchange mechanisms
(iii)	Regional exchange mechanisms
(iv)	Data harmonization
Item 11:	Public awareness, education and participation
Item 12:	Regional and national needs for the implementation of UNEP Guidelines and biosafety agreements in light of scientific and regulatory issues and information exchange requirements.
Item 13:	Workshop recommendations and adoption of the proceedings.

IV. THE APPROPRIATENESS OF THE PROJECT IN RELATION TO RELEVANT PROVISIONS OF THE CONVENTION ON BIOLOGICAL DIVERSITY (SUCH AS ARTICLE 8g) AND RELEVANT ASPECTS OF CHAPTER 16 OF AGENDA 21.

32. Biotechnology probably began when the first human realized that keeping the best seed from a crop for planting the following year would constitute a better use of the product than its consumption. The use of biology to modify foods to make them more palatable, or to make usable clothing and shelter is centuries old, and is familiar, we take it for granted, not even aware that most of our foods have benefited from biological processing. Few modern crops bear much relation to the ancestral plants from which they are derived. Very few individuals question traditional uses of biological systems to produce food, feed or clothing, even though they may pose significant risks to the user. Traditional breeding techniques to increase resistance to environmental stress or increase yield are accepted as natural and therefore good in almost all societies that think about the safety of foods or industrial processes. There are many products and plant varieties on the market that could not have been achieved naturally, if that is defined as not requiring human intervention in the fertilization process. On the other hand, the intervention by humans in a process in order to modify a variety of traits, may be seen as unwholesome or unnecessary interference, and in particular, as posing risks and hazards that are not, apparently, present in the natural system. Many scientists argue that the use of a paintbrush to physically move pollen from one plant to another is similar to the use of modern recombinant techniques to physically move genes between organisms that are not sexually compatible, but those opposed to modern biotechnology do not accept the argument. The green revolution that has occurred in the last half of the twentieth century owes much to deliberate selective and artificial techniques.

33. If the manufacture of transgenic organisms is similar to traditional breeding methods long used there is no need for specific safety controls, laws or guidelines. The safety systems in place for ensuring the safe use of new varieties of plants or animal crossbreeds would suffice. The control at country borders of novel species that might be invasive in a new environment would then be the same whether the organism had been modified or otherwise. Unfortunately, there are few controls over the products of traditional breeding or border controls to ensure the safety of novel imported species. Legal systems could be instituted to ensure the safe use of all novel organisms introduced into an environment, or the use of modern biotechnology could be used to act as a trigger resulting in some form of regulation. All of these strategies have been used by countries around the world, and there is a clear need for countries to identify their needs and the best way in which the safety of introductions can be assured.

34. The invention of new techniques in biology during the late 1960s and early 1970s caused many scientists to start thinking of the implications of their research and the possible dangers that might result from the ability to move genetic information from one organism to another. Prominent scientists indicated their concern during the early years of this new science in graphic terms. Joshua Lederburg is quoted as telling the US Committee on Disarmament in August 1970 [1]/ that these new approaches for the understanding and manipulation of living organisms had potential implications for human progress of very great significance …… to these long standing threats would now be added new ones, potentially of our own invention. Sydney Brenner wrote to the

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[1]/ Wright, Susan (1994) Molecular Politics Developing American and British Regulatory Policy for Genetic Engineering, 1972-1982 University of Chicago Press, ISBN 0-266-91066-0. Page 69.

Ashby Committee (1975) [2]/ that it cannot be argued that this is simply another, perhaps easier way to do what we have been doing for a long time with less direct methods. For the first time, there is now available a method which allows us to cross very large evolutionary barriers and to move genes between organisms which have never had genetic contact. (quoted in Wright, 1994) [3]/. Wright also quotes Alan Bullock in the early 1970s as saying that … the public will say this is so much a Pandora's box you are giving us, and it is so evident that it will be misused, that we had just better stop the fundamental research. I can hear people saying: We just can't tolerate the problems that are going to be created by genetic engineering, and we will shut it down as a gift too destructive to the ordinary inventions and the ordinary mores of human life. This early concern was enough to initiate an unusual process, the instigation of safety guidelines and legislation that was proactive rather than reactive. In July 1974, a letter was published in all of Nature, Science and the Proceedings of the National Academy of Science concerning the contained use of modified organisms, signed by prominent scientists working in the field. Scientists were asked (for the time being) not to manufacture organisms which might carry unknown or novel antibiotic resistance or where the manufactured bacteria could make toxins. They were also asked to hold back on experiments involving animal virus DNA. This letter was interpreted to be a call for a moratorium on the use of the technology, even though it only asked for a partial delay on particular experiments. It proposed that a scientific conference be held to review scientific progress in this area and to further discuss appropriate ways to deal with the putative hazards posed by the technology. The letter also proposed that it should be a committee nominated by the National Institutes of Health in the United States that should prepare guidelines for the safe use of the new technology.

35. The positive benefits of the technology and the possibility of problems that might prove disastrous were appreciated from the start, and some countries instituted legal systems to ensure the safe use of biotechnology from as early as the late 1970s.

36. Recognizing that biotechnology can contribute to the improvement of agriculture, fisheries, forestry, health care and environmental management, governments represented at the Earth Summit in Rio de Janeiro in June 1992 undertook to consider international cooperation on issues relating to the safety of modern biotechnology in order to maximize the benefits that could accrue and minimize any risks to the environment and to human health. The commitment included sharing experience, capacity-building and international agreement on principles for the safe use of the technology. Agenda 21 (Chapter 16) defines biotechnology in optimistic terms as the integration of the new techniques emerging from modern biotechnology with the well established approaches of traditional biotechnology. Biotechnology, an emerging knowledge intensive field, is a set of enabling techniques for bringing about specific man-made changes in deoxyribonucleic acid (DNA) or genetic material, in plants, animals and microbial systems, leading to useful products and technologies. The technology was expected to make a significant contribution in enabling the development of, for example, better health care, enhanced food security through sustainable agricultural practices, improved

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[2]/ Ashby Committee (1975) Report of the Working Party on the Experimental Manipulation of the Genetic Composition of Micro-Organisms, January 1975, United Kingdom CMND 5880

[3]/ Wright, Susan (1994) Molecular Politics Developing American and British Regulatory Policy for Genetic Engineering, 1972-1982 University of Chicago Press, ISBN 0-266-91066-0. Pages 75 (see also page 142)

supplies of potable water, more efficient industrial development processes for transforming raw materials, support for sustainable methods of afforestation and reforestations, and detoxification of hazardous wastes. The Chapter identifies an absolute need to increase the availability of food, feed and renewable raw materials by whatever means possible. This is interpreted not only to increase food supply, but also to improve food distribution while simultaneously developing more sustainable agricultural systems. It is clear that much of the improvement in food supply needs to take place in developing countries. There is recognition in Chapter 16 that governments should take the lead (with the assistance of a variety of organizations at regional and international levels and with the support of non-governmental organizations, private industry and academic and scientific institutions) in improving plant and animal breeding and modifying micro-organisms to enhance output. There is also recognition of the need to ensure that the needs of farmers, the socio-economic, cultural and environmental impacts of modifications and the need to promote sustainable social and economic development are taken into account. Environmental protection is recognized as an integral component of sustainable development. The increase in the use of chemicals, energy and non-renewable resources by an expanding population is recognized as a major threat to sustainable use of land and resources. Biotechnology is one of many tools that can play an important role in supporting the rehabilitation of degraded ecosystems and landscapes.

7. The introduction of modern genetic techniques into industry has proceeded with little interest or protest amongst the public. Many pharmaceuticals and even food additives have been produced for some time using recombinant micro-organisms, modified to produce a large amount of a particular chemical under laboratory and industrial conditions. Although some countries, particularly in Western Europe, have instigated controls to ensure the safe use of the micro-organisms (and in some cases have then followed the modern biotechnology lead by introducing safety legislation in relation to unmodified organisms within the factory or laboratory environment), there has been little public abhorrence of food ingredients produced in this way. The United Kingdom, for example, has decided to use human factor VIII produced using modified micro-organisms rather than that derived from human serum. Many countries have tended to rely on the legal systems already in place for ensuring the safe industrial use of transgenic organisms, expecting that these will not survive in the wild should they escape.

38. The Convention on Biological Diversity requires participating countries to conserve biological diversity, to use biological resources sustainably and to ensure the equitable access to and sharing of any benefits arising from the use of genetic resources. That biological diversity is distributed unevenly is recognized. If biodiversity is to be conserved, this imposes a heavier burden on the South, at a time when the use of biological resources is of paramount importance for developing countries in achieving development. The Convention recognizes that this burden, in turn, can only be alleviated by additional contributions (not only financial) from the industrialized North and through increased partnership between both developed and developing countries (Glowka et al, 1994). It is in this context that Article 8(g) was written. Establish or maintain means to regulate, manage or control the risks associated with the use and release of LMOs resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health. This requires countries to set up internal arrangements to ensure the safe use of organisms within their own borders. Article 19 provides for consideration of a possible Protocol to the Convention on the cross-boundary transfer of LMOs, and in paragraph 4 requires the provision by an exporting country of information about the safe use and safety

regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms to the Contracting Party into which those organisms are to be introduced. The Convention does not define LMOs, and there was a general view during the negotiations that led to the Convention that many of the concerns directed towards GMOs, invasiveness, spread of introduced characteristics or even the production of toxic by-products in foods, could equally well be applied to traditionally produced organisms (Glowka et al, 1994, page 45).

39. Article 19 of the Convention, Handling of Biotechnology and Distribution of its Benefits, is also of importance in the context of this project, as the Conference of the Parties had decided that a Protocol to the Convention on biosafety should be developed (Decision II/5 of the second meeting of the Conference of Parties to the Convention on Biological Diversity, Jakarta, Indonesia, November 1995). It was recognized that significant gaps in knowledge in relation to modified organisms remain, particularly in relation to interaction between these organisms and the environment. The Governing Council of UNEP in its decision 18/36 of 26 May 1995 on biological diversity affirmed the desirability of contributing to international efforts on biosafety including the development of International Technical Guidelines for safety in Biotechnology.

40. It is against this background that the Governing Council adopted its decision 19/16 of 7 February 1997 on biosafety, requesting the Executive Director to continue to promote the implementation of the UNEP International Technical Guidelines, particularly in developing countries, with regard to the provisions for exchange of general information given in the Guidelines (about National biosafety mechanisms, risk assessment and risk management procedures and the mechanisms for approval for marketing products either consisting of modified organisms or products containing ONTs).

41. The provision of the new types of foods containing GMOs in the United States of America and Canada has been almost without problems. Few public concerns have yet appeared or been expressed. However, their introduction into Europe, and particularly the United Kingdom, during 1998 lead to an unexpected public and media reaction that has almost made the use of such products in Europe impossible during 1999. Products derived from both maize and soya beans have been routinely added to the majority of processed foods sold in European supermarkets and it is these two crops that form the vast majority of genetically modified plants commercially available. The concern that genetically modified foods are unsafe permeates much of European thinking. Support for their marketing has plummeted in the United Kingdom, for example. A recent United Kingdom Parliamentary Committee report comments that paste produced from genetically modified tomatoes initially outsold the non-GM variety by 2:1. During 1998 the volume of sales declined and since Christmas [1998] it has reduced to a very low level indeed, (House of Commons Science and Technology Committee, 1999, paragraph 22). During the first six months of 1999 in Britain, there had been a continual series of press reports implying that eating GM food would lead to all sorts of serious diseases (House of Commons Science and Technology Committee, 1999, paragraph 29). The attention paid by the media to foods produced using modern biotechnology has been sustained over a long period and almost totally hostile with headlines using pejorative terms such as ‘Frankenfoods’. The coverage has stressed the technology used to make these foods, rather than the products. Concern over the impact on the environment has been the primary concern but fears about the long-term safety of eating modified foods and about the speed of entering the unknown have been powerful messages to the public (Christian Aid, 1999).

42. The impact of the concerns in Europe on countries in which regulatory structures are not yet in place has been important. The concern expressed in Western European media about both the possible deleterious effects of eating these new foods and at the possible environmental effects came at about the same time as countries involved in this project were in the process of setting up their national frameworks, and ensuring public participation in the regulatory systems they were considering instituting. That which is unacceptable in Western Europe might be deemed to be unacceptable in developing countries, even though the risk analysis might (correctly) provide a very different conclusion. There has been a scientific consensus about the issues that need to be taken into account to form a science-based assessment of risk; the need to take public perception into account is a new factor in the assessment process.

43. There have been laws for a very long time that limit the transfer of organisms from one country to another or even between states of a single federal country. This is due to fears of being unable to control an organism introduced (without careful consideration) into a new and possibly hospitable environment, but it is only the advent of modern biotechnology that has caused a large number of countries to consider the introduction of regulation to control the introduction of novel organisms into food, feed or the environment regardless of the traits that have been incorporated into them. Experience has readily demonstrated that organisms deemed benign in one ecosystem may be invasive when introduced into another. It is only the advent of modern biotechnology that has caused a large number of countries to consider the introduction of regulation to control the introduction of novel organisms into food, feed or the environment regardless of the traits that have been incorporated into them.

44. It was within this context that the development and implementation of the pilot programme may be reviewed and national frameworks appreciated.

V. EVALUATION

45. The evaluation of this project involved:

(a) An examination of all country reports submitted to UNEP/GEF in relation to the development of National Biosafety Frameworks;

(b) Visits to Bulgaria, China, Kenya and Mauritius and discussion with officials responsible for the projects in Poland and the Russian Federation while at a meeting of the Central and Eastern European Countries in Bulgaria, December 1999;

(c) An examination of the reports emanating from all the workshops held in the four centres, plus reports of the steering committee for the project.

A. To what extent do the results of the project meet the identified needs of the countries?

46. It rapidly became clear both in discussions with individuals from many different areas within each of the participating countries visited, and in examining country reports, that this project was seen to be of crucial importance in ensuring the safe use of the technology, and of assuring those not versed in biotechnology of the safety of products imported into their countries. The need for a consideration of the issues raised by either the development of indigenous biotechnology or where products are imported from or exported to other countries was clearly recognized. Many of those interviewed were concerned that exports to other countries required them to assure the safety of products produced using the new technologies even where the development of the new foods had taken place elsewhere. Although this stressed the perceived safety of exported foods, environmental concerns were also recognized as important to their customers.

47. On many occasions it was indicated that the project had allowed a much more rapid assessment of both needs and current capabilities than would have been possible without the assistance provided through the project. Even where the capacity to utilize biotechnology had long been demonstrated, as in China, the project provided the environmental and other agencies with an opportunity to map that which was happening, and provided an impetus to allow the development of a framework of regulation and guidelines.

48. In those countries where development of the technology was lagging relative to the industrialized countries, the impetus of the project provided both the possibility of establishing a regulatory framework and of kick-starting the use of biotechnological techniques. It was exciting to hear of the manner in which the project had enabled a new vision of this science. A project that had as its primary impetus the assurance of safety may well have helped in the more general implementation of the Convention on Biological Diversity and of bringing developing countries into a realization of both the potential benefits and risks of applying biotechnology in its many spheres of application.

49. The level of support amongst those organizing the project for the programme in the various countries was exhilarating. Their enthusiasm was such that countries present at the meeting of Central and Eastern European

countries in Bulgaria not involved in the project indicated some jealousy. All the countries visited talked about an urgent need for capacity-building in the fields of regulations, administration (in particular in the setting up of national databases) and science based risk assessment and risk management. They also recognized the importance of publicly available information. Even though most of the representatives of the Central and Eastern European countries had only been involved in the global part of this project, they were aware of the implications of the setting up of formal frameworks for biosafety and in their report underlined the importance of continuing the UNEP/GEF Pilot Biosafety Enabling Activity Project.

50. The countries visited had had very different starting points. China was well advanced in the utilization of modern biotechnology, and may be second only to the United States in the number of hectares on which genetically modified crops are being grown. The Chinese Government stated that the project had helped them to implement their obligations stipulated by the Convention on Biological Diversity and helped to actively promote research into biosafety. China believed that experience and lessons obtained from the project will provide a reference for other countries which will undertake projects similar to the project. They believed strongly that this project was appropriate and completely consistent with the spirit embodied by relevant contents of the Convention on Biological Diversity and Agenda of twenty-first century. The report of the Chinese Government, which echoes much said elsewhere, provides ample evidence for the enthusiasm expressed by those in Eastern Europe. The project had stimulated Chinese biosafety research and management, and the needs have basically [been] identified through the implementation of the project, particularly those about policies, regulations, technical guidelines for risk assessment and risk management of LMOs and national capability-building in the field of biosafety management. The project was said to have stimulated the establishment of bodies and mechanisms for the biosafety management of China and has laid a solid foundation for formulating relevant policies and regulations for biosafety management. The Chinese expressed concern at the problems of identifying principles of risk assessment, but at least the project had enabled this to be discussed openly amongst experts from many countries and attempts to be made to resolve differences. There is a lack of data which allows full risk assessments; there is a shortage of experienced scientists and administrators and this is acute because of the range of disciplines needed to consider the risks but the project had enabled scientists and administrators from many disciplines to meet and discuss the risks to their environment. Before the project, biosafety was the exclusive preserve of scientists, but this project had extended the range of people involved. The involvement of so many disciplines (even lawyers) had been important, for by reacting to one another they believed they had moved the subject forward. The collection of information in a single place, especially in a country the size of China, was an enormous step forward, allowing a thorough foundation for good guidelines and regulation to be in place.

51. Kenya was in a very different position, with little use of modern biotechnology but with an expectation of using the techniques learnt in both food and medicine. They believed that they had much in common with many developing countries, particularly in Africa. Kenya recognized that there are as many as 35,000 known species of plants and animals and countless micro-organisms in their environment and their exploitation needs careful consideration and management. They also recognized that the country largely depends on rain-fed agriculture. There is a desperate need to increase human and financial capacity in biotechnology to add value to the human and genetic resources of the country. Kenya, like many other developing countries, has limited capacity for the implementation of a National Biosafety Framework.

They lack the critical mass of people and the availability of information or facilities relevant to the use of the science. The project had enabled the country to identify enormous gaps in knowledge, and an appreciation of biosafety needs. The results of the country survey indicated that few institutions had adequately trained personnel in order to assess the risks of that which they were doing, particularly were there to be intended or unintended releases of LMOs. The Kenyan Government has recognized that this poses great danger both to human health and to biodiversity, and although unhappy with the survey results, it was now poised to do something about the problems that had been unearthed. Their research indicated that there were gaps in knowledge both in state funded institutions and universities and in the private sector and non-governmental organizations, where there was lack of awareness on the part of companies on the products that they deal with. The survey had been extremely useful, even as an educational tool. Even scientists have become aware of the safety issues. The project had allowed them to identify the absolute necessity of providing training on risk assessment and management to a large body of scientists and industry. They had also identified the need for the public to be sensitized on biotechnology and biosafety through media, press conference and stakeholder workshops. The insurance industry, hospitals and Government ministries all displayed a lack of awareness of biotechnology and biosafety industries. Even in research and educational institutions the level of awareness of the need for biosafety was poor, with few institutional biosafety committees in the institutions in Kenya. The survey also showed that few institutions had anyone trained adequately to assess risk or manage the resulting problems when they occurred. The Kenyan Government, having participated in the project and identified much that is good in their country, is convinced of the need for biosafety and for capacity-building in both personnel and infrastructure. The increase in awareness of the needs for Kenya amongst Government officials is an important by-product of the project. They were proud of that which had been achieved during this project, and acknowledged a desperate need to proceed to educate all stakeholders in the issues of biosafety and the need to protect biodiversity. The project has resulted in Guidelines and the establishment of a National Biosafety Committee. This project has gone a long way in assessing the current situation in the country and has identified the requirements for increasing the capacity for safety in biotechnology.

52. The development of biotechnology in Uganda is still relatively modest, but the documents submitted to UNEP in relation to the project indicate a strong intention to establish an adequate biosafety framework with the aim of allowing the general public, private and public sector institutions and education to benefit from biotechnology for food supply, health care and environmental protection.

53. Mauritius was again different, for it has many non-native species of plants and animals that have been introduced during the centuries. It is also a free port, which poses difficulties in controlling imports and exports. The scientific base is small, but the need for discovering the uses to which biology was being put in the country, and the raising of awareness of biosafety in the context of biodiversity, and the many issues these had raised (including the need to protect their intellectual property) convinced those involved of the importance of the project. They echoed many of the issues raised by the Chinese and the Kenyans.

54. Although the timescale was severely limiting, and most countries were unable to complete and adopt a framework, the preliminary work done towards producing legal systems for safe biotechnology demonstrated a commitment to the project and to ensuring that modern biotechnology is (so far as is possible) conducted in a safe manner. The survey of biotechnology expertise,

enabled by the funds available from the project, has proved to been an extremely useful and important tool for governments, allowing the identification of needs and priorities for both biosafety and for science. The primary criticism, heard many times, was the time limitation, where all the work had to be completed within one year. Kenya exemplified the problem, saying that the first three months of the one-year project were used simply to organize and get it started.

55. The excitement generated by the project appeared on occasion to result in unfortunate juxtapositions. In some countries, the role of national biosafety committees often included promotion of the use of biotechnology as well as either performing a risk assessment on products produced in the country or imported, or auditing the risk assessment performed by applicants to produce or release modified organisms into the environment. The nuance of both supporting and judging products seemed to be lost in enthusiasm.

56. Public involvement in the project differed substantially in the different countries, largely reflecting different traditions, but also reflecting difficulties caused by, for example, the size of the country (China or the Russian Federation compared to Mauritius or even Namibia [correcting for population density and distribution]). In many countries the range of different languages used and educational deficiencies made it difficult to ensure full participation by the public.

B. An analysis of the quality and usefulness of the project's outputs, determining outputs attained and their contribution to the achievements of the results, as well as, the overall objectives of the project

57. The following observations are pertinent:

(a) A survey of the use of biotechnology within the countries borders proved extremely useful, whether in large countries like China and the Russian Federation where much was being done but little had been identified by the national authorities, and in small or less developed countries where the survey has served to stimulate the scientific output of the countries and provide the basis for scientific capacity-building;

(b) The surveys have also demonstrated the range of safety measures taken in various institutions and private companies in the participating countries. Different standards were being applied in different institutions in many countries. These results will therefore, allow the imposition of common standards, important where there will eventually be a need for inspection and enforcement of guidelines and regulations;

(c) The formation of National Biosafety Organizations has been important in getting many individuals working in different disciplines and with different expertise to talk to each other about the same problems. This factor alone will be of lasting value;

(d) The National Biosafety Organizations have had the opportunity to think about legal frameworks and guidelines which might be implemented to ensure the safe use of biotechnology. In many countries the project has enabled the education of important politicians, which in the long term will benefit the adoption of the science and its safe use. In Namibia, for example, the President and Prime Minister of the Republic addressed the national workshops;

(e) Most countries involved in the project have passed or drafted new laws to control the use of LMOs within their borders. This may extend to other areas of biodiversity and the protection of the environment, again important;

(f) The need for subregional and regional collaboration is very clear, as modified organisms do not respect country borders. The similarity of terrain in many regions and the lack of sufficient expertise in any one country may result in significant collaboration amongst those countries involved in this project, and those who will have to attempt similar projects to bring themselves up to the level of self-knowledge achieved by project participants.

58. There can be no doubt of the importance of this enabling project in the eyes of the participating countries. There was considerable evidence that in many cases it had vastly exceeded its remit. The vast majority of country representatives talked to believe that this project would have had to be done, but it would have been much slower and less effective. Funds are available in some of the countries for fundamental research, or applied research and development, but countries have been slow to provide funds for research into biosafety, or for the setting up of mechanisms by which the safe use of the technology could be assured. The training of scientists to use the technology safely, and to think about the consequences of their work was seen to be of importance.

C. Were all stakeholders involved in the implementation of the activities?

59. The country reports indicate that strenuous efforts were made to involve a variety of stakeholders in the processes, whether at national or at the regional workshops. The regional workshops did include representatives of industries, primarily in agriculture, and non-governmental organizations. Consumers, farmers and the general public from the regions did not attend, although press coverage of many of the meetings was extensive and led to important debates within some of the countries in which the regional workshops were held. It is difficult to see how the regional workshops could have been organized to involve more of those who have a clear stake in the use of the technology.

60. It was important, therefore, to ensure that national workshops were designed to involve public participation where possible. In some countries this was considered difficult because of the huge variation in national languages (for example in Kenya) or simply the size of countries. Namibia was able to have two national workshops that involved scientists from many disciplines and workers from many industries. The workshops were open to the public who were welcome to join in the debates and politicians were not only invited, but attended a significant proportion of the meetings. In reading the reports submitted, there was a clear commitment of many of the countries to involve as many of those who might benefit from the technology and those who might lose from its implementation to become involved in the setting up of national frameworks. Perhaps the most heartening part of the reports is that in all cases scientists from many disciplines (including the social sciences) who had seldom met with one another came together to identify the problems of assessing and managing risk. There was an indication, however, in some of the countries reports that definitions of stakeholders differed. The need to talk with consumers is in many cases a new concept.

61. The gender balance was again important, for in many rain-fed agricultural economies women play a major role in farming, and in all

economies women are the primary purchasers of the products of the technology. Africa and Latin America led in this respect, for many of the prime movers in the national frameworks were women (including Kenya, Mauritius, Namibia and Cameroon) but it was clear that women had been involved in all the national committees and consultative processes.

D. How effective was the assistance provided by United Nations Environment Programme?

62. This question was asked of many of the countries visited. UNEP representatives had attended all of the national workshops, had provided important assistance during the process when approached, but had not been involved in the day-to-day running of the individual projects. UNEP had been involved in the regional workshops, providing the basis on which national frameworks could be built. The consultant was not informed of any complaints regarding the process by which UNEP monitored the project, nor was there any concern expressed about the appropriateness of the assistance provided by the task managers. The resource personnel at the workshops and the manner in which the workshops had been organized was generally praised, although there had been some concern at the short timescales often provided for organizing and holding meetings.

E. The effectiveness of the organization structure, management and financial systems that affected the implementation of the project

63. There were many different problems faced by the participating countries in this project, many of which have already been discussed in earlier parts of this report. The difficulties encountered by countries depended very much on the amount of science or preparedness for commercialization of modern biotechnology before the project started, the level of awareness of the need for safety both to human health and to the environment and the number of and range of experience of scientists and others interested in the fields of biotechnology or biosafety. A major issue, raised many times, was the size of countries like China and the Russian Federation and therefore, the many authorities at both local and national level that needed to be informed and consulted. In many instances internal structures needed to be constructed, in others the basic governmental structures were already in place.

64. The eight workshops that attempted to identify the major problems of risk assessment and management provided an excellent springboard that could have been used by the participating countries in their development of national frameworks, and provided the basic information that allowed for the possibility of regional and subregional collaboration.

65. UNEP/GEF provided a framework for the work involved in this project, and in consultation with individual participating countries provided timetables for delivery of aspects of the project. The consultant was impressed that the structures implemented ensured that where countries failed to meet their obligations the system was flexible enough to ensure that money was withheld. In some circumstances small amounts of extra finance were required, and again, countries were impressed with the flexibility of the system. Task managers were clearly willing to talk with country representatives and provide the flexibility in interpreting the needs of countries within the framework set by the project.

66. This was an ambitious project, for it attempted much within a short space of time. All were concerned at how quickly they had to respond, and in many cases felt that they had somehow failed for new legislation was not yet

on the statute book. The achievements within the year, however, indicate a well-managed project with excellent results. In retrospect, more realistic timescales need to be identified, without any necessary increase in the funds available, or the terms of reference of the project need to be carefully drafted to ensure that countries are aware of that which can be achieved in the timescale.

67. Many of the countries involved in the project are small, at least in terms of the biological and biotechnological expertise. Many different disciplines are needed to ensure an adequate risk assessment, risk management and monitoring regime. The science base in many developing countries is limited, and it is important that attempts are made to bring countries together within a subregional or regional structure so that expertise and information can be shared. National Biosafety Organizations may be able to consult or involve experts from within the region, on a confidential basis to ensure as full as possible coverage of the many disciplines. The lack of confidence in their own expertise was often evident amongst the scientists. National jealousies could be avoided if structures could be set up to involve individuals rather than attempting to institute a regional or subregional framework for biosafety.

68. It is difficult to identify the manner in which the project could have been approached in a different manner. Each country interpreted their responsibilities slightly differently, but provided the basic information upon which to build a framework. The need for a survey to identify the manner in which biotechnology is being used in individual countries and the level of appreciation of safety issues was a fundamental precursor to the institution of a safety framework.

69. The major issue that many of the countries will face is that of the import of LMOs grown or produced elsewhere. There will have to be estimates of the potential for harm to the ecology of the receiving environment or to human health of these imported products. The need to be vigilant to ensure that such products do not normally enter until rigorous safety analysis has been attempted needs to be stressed. The project could have provided more information and guidance on this issue.

70. There are few individuals with an understanding of legal issues and biotechnology. The World Conservation Union (IUCN) Law Centre in Bonn is an example of such expertise that needs to be brought to the attention of participating countries to provide them with a base on which to build new laws and regulatory structures. A draft law available to the consultant included a clause that, if it were to become law, would forever stop the use of modern biotechnology (shown below). Assistance in drafting, taking into account that produced elsewhere, might well be a significant contribution to this debate:

> ''No person shall import, release, make contained use or offer for sale a genetically modified organism or a product of a genetically modified organism without the approval of the Competent Authority…
>
> No approval shall be given unless there is firm and sufficient evidence that the genetically modified organism or its product poses no risks to human and animal health and environment''

71. The bill drafted by Cameroon, for example, was a comprehensive and detailed document with a clear overall structure that in principle contained many of the elements that might be expected in biosafety regulation. There

are, however, many inconsistent elements and duplications and in many instances the level of technical detail is excessive for primary legislation. Hungary, on the other hand, has used a system involving a framework law and implementing decrees on technical issues that provides the flexibility needed in an area as diverse and rapidly changing as biotechnology. However, where such a system is put into place, it is important also to ensure (as they have) that there are safeguards for consistency and for accountability.

72. It has long been argued that science based risk assessment is fundamental to the safe use of biotechnology. There must be an understanding amongst all stakeholders that the scientific assessment is only as good as the data upon which it is based, and at best is able to assure that the modified organisms are as safe as those from which the product is derived. To achieve this level of assurance requires input from a very broad range of scientists. To assure public acceptance of the assessment requires that social scientists, industry and non-governmental organizations, farmers and food retailers, politicians and opinion formers be involved in the decisions. Any structure that recognizes that only scientists have a valid input is likely to fail. The project has helped in bringing many of these crucial elements together to talk about the issues raised by the use of the new technology.

VI. RECOMMENDATIONS

73. The need expressed by those participating in this project for the funds allocated to them, and the impetus that they have experienced from its implementation, has been clearly demonstrated in this document. The countries involved in the project are fearful of being unable to complete the process started. They believe that much has been accomplished, but that there is much to accomplish in the area of biosafety and biotechnology in relation to biodiversity. If they are to set up strict regulatory systems, there needs to be enforcement and laboratory and field facilities that are capable of testing and validating the presence or absence of modified organisms. The consultant agrees with their general view that the project has stimulated a new approach to biotechnology by national and international organizations and that it has stimulated regional cooperation. It would be a great pity if these 17 countries were unable to continue the good work started in the course of a single year. The project has also succeeded in extending the understanding of biological diversity and the need to preserve and enhance that which exists in these countries. Although this is a consequence of that done it is important in its own right, and must be encouraged.

74. Success or otherwise in this project is hard to judge. The experience of the large relatively developed countries has been very different from that of less developed but more homogenous countries. The experience gained by all these countries should not be lost, but should be transferred in a coherent manner to other countries that will face similar problems. The diversity of legal systems used in developed countries to ensure biosafety should provide a range of models on which all countries can base their own new guidelines or legal structures.

75. It is crucial for the future of biotechnology, in the consultant's view, that a project similar to this one is funded in those countries that have yet to develop a consistent framework for the safe use of this science. If at all possible, as many as possible of those countries involved in this project should continue to be involved, acting in some ways as mentors to newly involved countries so as to allow the rapid build-up of expertise in this area. It will also be important to many of these countries to continue the

good work already done, and allow the imposition of the frameworks planned during the pilot phase.

76. The consultant therefore recommends that a new project that involves the countries that were involved in the pilot project, is instigated, permitting:

(a) The extension and implementation of the frameworks that have been designed during the pilot programme;

(b) These countries to act as mentors for those new to the organization of a national framework for biosafety.

77. On the other hand, there are many more countries that could benefit from similar input of funds and expertise as that available through this project. Many, I understand, have applied for funding for their own National Biosafety Frameworks. It is essential that all countries have the capacity to assess the risks (and benefits) of biotechnology, and a new project to provide the necessary expertise is essential.

78. In order that countries are able to decide on the mechanisms most appropriate for their circumstances, the project must provide training in techniques of risk analysis, assessment management and impact analysis. This training needs to be directed at scientists who would bear the brunt of the assessment requirements. However, identifying the many stakeholders and ensuring that all have an input into the process is critical. Provision of training for drafting of legislation and guidelines would also be important to ensure a clear understanding of the legal framework that exists and the mechanisms by which it could be extended to provide any required regulation. Administrators who have to implement the frameworks need training and sharing of experience.

79. The consultant therefore recommends that a new project involving many more developing countries (including those with economies in transition) be instigated to provide the necessary training and experience in risk analysis, assessment and management. The project must take into account the need to translate the assessments into workable legal frameworks. It must also take into account the need to preserve and enhance the biodiversity in each country.

80. The project for new countries would then be similar to that already achieved, requiring a survey of the expertise and use of both biotechnology and of biosafety. An assessment of the need for an overall biosafety framework would then follow, leading to the institution of a National Biosafety Framework that clearly identifies the needs of the country or region.

81. This assessment of the pilot project has demonstrated that many countries lack the full range of expertise in assessing or managing risk, both within government or academic institutions. This could result in the same people being involved in the projects and their assessment unless great care is taken. To achieve both public acceptance of the mechanisms implemented for impact analysis (including risk assessment and management) and to assure countries to which products are exported that the assessment has been rigorous and fair, it may be necessary to:

(a) Ensure that as much of the information as is consistent with commercial confidentiality is in the public domain;

(b) Ensure that the decisions (and the reasons for such decisions) of the authorities are public; and

(c) Use expertise from outside the country, either through regional authorities or a system of peer review.

82. Public awareness and public education should, therefore, form a part of the development of a framework for biosafety in each country.

83. No country is isolated from its neighbours, and in many of the countries participating in the project there were very extensive land borders. The use of LMOs in any country cannot (in general) be isolated, and there is clearly a need to identify risks to neighbouring countries and to inform those countries of risks about which they may have been unaware.

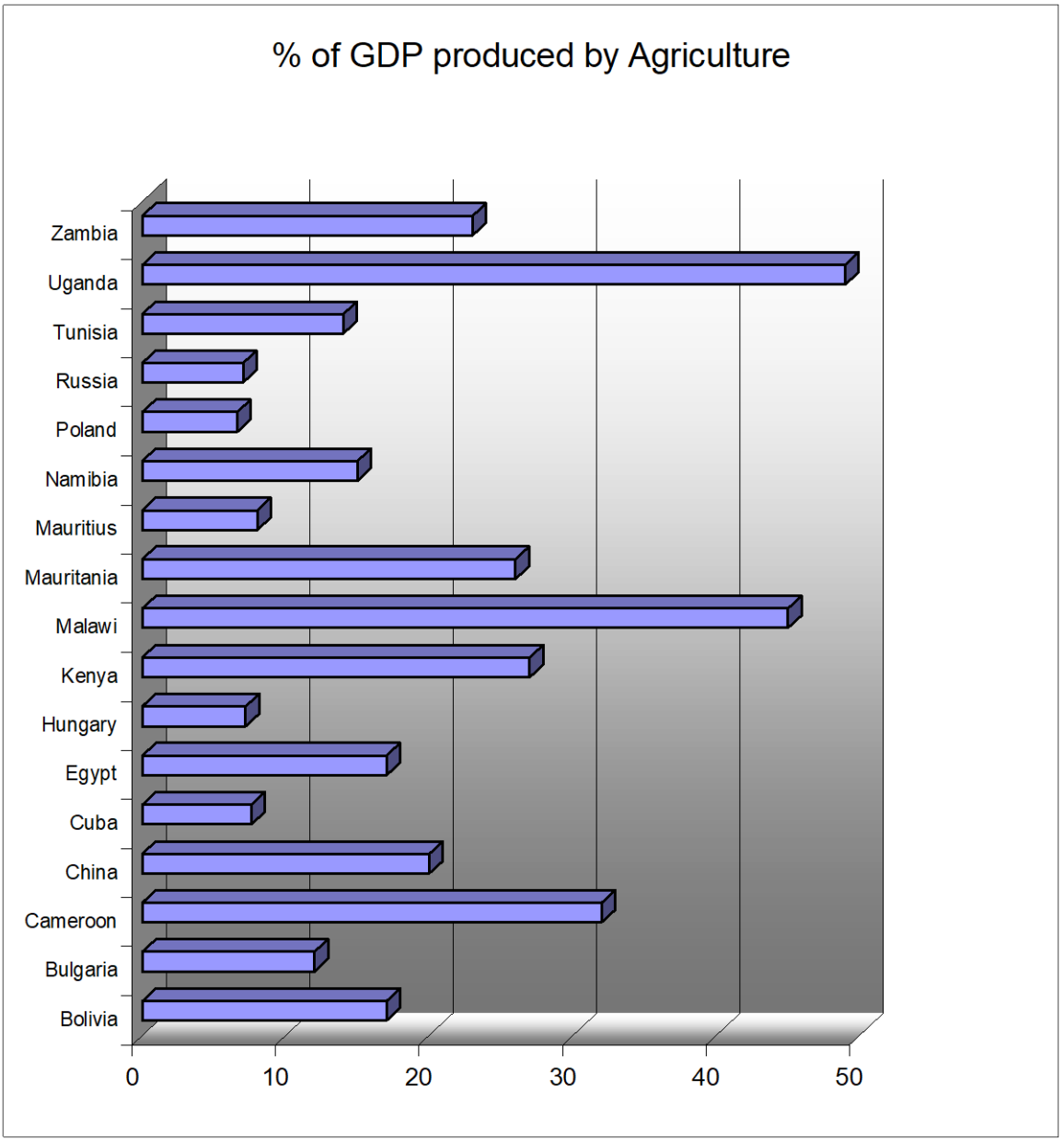
84. In the light of paragraph 81 and 82 (c), a new project must attempt to strengthen regional ties between countries, either by assisting in setting up regional networks or by helping to set up regional systems provided with the necessary authority to oversee the development of biotechnology within the region.

85. This project has provided important new insights into the problems faced by countries in implementing a framework. It is not the function of a report of this nature to identify in detail the structures that might be put into place in order to properly meet the needs of countries that may have to implement new biosafety provisions in order to meet the terms of a Protocol to the convention. In order to effectively fulfil its functions as a complement to a possible Protocol on Biosafety, and to further guide the countries in the preparation of the National Biosafety Framework, it is strongly recommended that consideration be given to a review of the UNEP International Technical Guidelines for Safety in Biotechnology

VII. FRAMEWORK FOR COST NORMS AND IDENTIFICATION OF ISSUES THAT MIGHT BECOME IMPORTANT IN ANY NEW PROJECT

86. The terms of reference required the consultant to consider the provision of cost norms in respect of the priorities for capacity-building in biosafety, for enhancement of safety in biotechnology at national, subregional and global levels. The consultant discussed this problem in detail with many of the representatives of the various countries, and reluctantly came to the conclusion that this is an almost impossible task.

87. Area and size of population must clearly be part of the consideration for criteria for funding. The size of countries cannot, however, be used as a simple criterion on which to base funding. Variety in climate, physical and social geography must be taken into account in deciding on expenditure. The number of local languages needed to bring an awareness of the benefits and dangers of biotechnology to all stakeholders may have a significant effect on the design of any framework. China’s population dwarfs all other countries, representing 76% of the people in the countries participating in the project (and with an area equal to nearly 28% of the participating countries). Russia is huge, both in area (nearly 51% of the land area of all the countries involved in the project), and in population. (9% of the total). However the budget was distributed, these two countries were likely to be anomalous.



Source: CIA World handbook 1999.

88. Should the degree of development of industries that use biotechnology play a part in deciding on funding for the development of a framework? If agriculture is the major area of concern in relation to the impact of biotechnology on biodiversity a criterion upon which funding may depend could be the extent of agricultural land, or the contribution made to the national economy by agriculture. If it is likely (in the future) that forest trees will be subject to modification using modern biotechnology, then the size of the forestry industry should also be taken into account.

89. The use of modern biotechnology may differ significantly in different countries. The technology itself is cheap, and can readily be implemented at the laboratory stage at little cost relative to other new technologies. The assessment of risk, consideration of the potential hazards of any new organism and the commercial exploitation of these varieties may however, be very

expensive. In addition, the majority of countries were not starting from a complete absence of environmental legislation.

90. Expenditure budgeted for in the programme is detailed in Table 5. The following paragraphs provide a critique of the budgeted expenditure.

Table 5: Partial Breakdown of Programme Budget

	Personnel Costs ($)	Training ($)	Equipment ($)	Miscel-laneous ($)	Total ($)
Bolivia	39,500	26,000	1,500	24,000	91,000
Bulgaria	29,000	31,000	1,500	23,500	85,000
Cameroon	32,000	33,000	1,500	27,500	94,000
China	91,000	100,000	2,000	51,000	244,000
Cuba	23,680	34,400	9,875	12,045	80,000
Egypt	37,500	30,000	1,500	26,000	95,000
Hungary	24,000	30,000	1,000	44,000	99,000
Kenya	36,000	37,000	1,500	21,500	96,000
Malawi	21,500	30,000	1,500	17,000	70,000
Mauritania	21,500	30,000	1,500	18,000	71,000
Mauritius	26,000	30,000	1,500	19,500	77,000
Namibia	41,720	20,000	1,500	15,500	78,720
Poland	28,000	28,000	1,500	24,500	82,000
Russia	62,000	100,000	4,000	64,000	230,000
Tunisia	29,000	36,000	1,000	31,000	97,000
Uganda	26,000	25,000	1,500	19,500	72,000
Zambia	23,000	23,000	1,500	18,500	66,000

91. Personnel costs includeed project coordination, the appointment of consultants and travel. Some countries chose to appoint consultants to review the status of biotechnology, others used the budget to pay part of the cost of personnel seconded by Government departments or research institutes to work on this project. Except for Russia and China, already identified as being much larger than the other countries both in population and area, the costs of personnel were very similar. There would appear to be a basic sum required to employ individuals for a project of this type, regardless of size of country. The average cost (excluding Russia and China) was approximately $30,000 with Russia employing twice and China three times the average. The equipment budget, expected to include expendable equipment (e.g. office supplies) was very similar for the different countries.[4]

92. How many people need to be employed in order to implement the project? Does this depend on the size of the country? The relationship between size and number cannot be simple, for it will depend on the infrastructure, the size of the agriculture and biotechnology industry, as well as population size. The more that has to be done, the more people are necessary. This part of the budget will also depend on the costs of employing people in a particular country.

[4]/ Cuba's expenditure appears anomalous —— used for the purchase of non-expendable equipment such as computers, and photocopiers; for most other countries equivalent expenditure appears under miscellaneous.

93. The training budget was spent solely on up to four workshops that provided for:

(a) Review of the findings of the survey of biotechnology activity within the country;

(b) The needs for risk assessment and management;

(c) Methods of monitoring;

(d) Public awareness.

94. This segment of the programme required more than one third of the total sum allocated, primarily for travel and subsistence of participants. Assuming four workshops were held in each country, an average cost of $9000 seems to have been a norm. The first three topics may be addressed at open workshops but do not specifically have an awareness-raising or education rationale. Two workshops are needed for scientific and legal reasons, one for a consideration of the results of the survey and suggestions about the framework, a second to review the draft framework and identify holes therein prior to drafting and submitting to the democratic process. An average cost of $10,000 would allow for some of the smaller countries to import experts from other countries, and provide the printed material necessary on which to base decisions.

95. The provision of workshops for raising public awareness or for education is very different. A more productive process may involve the participation of representatives of the media, providing both the rationale for using the technology and allowing the press to encounter those using the technology and those opposed to its use. The larger the country or the greater its language and cultural diversity, the more workshops may be needed to ensure public participation, although not if they only involve invited individuals. Public involvement in workshops can only be attempted through each meeting being open to anyone living in the part of the country in which the workshop is held, and through inviting attendance from organizations speaking for public viewpoints. If the workshops are for particular topics, then distributing them around the country to encourage people to attend, but only holding a few to address particular issues may be more effective. The advertisement and promotion of the safe use of biotechnology fell within the cope of a framework for biosafety. It may be that this may be costed as a basic figure to include publication of the national framework, its objectives and guidelines, and a further sum dependent on population corrected for the cost of living and, in particular, transport.

96. The first task during this pilot programme was a survey of activity using biotechnology (including modern biotechnology) within each country. The size and therefore cost of the survey depends crucially on the scientific and technical infrastructure and not necessarily on its population or physical size. Costs will greatly depend on how much is going on in the country, but that cannot be known until the survey is conducted. A case based on the number of universities and research institutes, which ought to be known, might provide the baseline for such a task.

97. Small countries, or those that have substantial land borders with other countries, need crucially to develop intraregional interactions. The attendance at workshops of adjacent countries is crucial, and the costs of involving representatives of these countries should be included in the budget. It is for the Governments of these countries to decide on who should attend

the workshops arranged by their neighbours, and to arrange for feedback within their own borders.

98. In many cases, a regional authority supported by the United Nations would be a better competent authority than local governments at the scientific evaluation stage. This would provide governments with an opportunity to decide on a regional report, but not remove decision from government. An equivalent system is that being suggested for Europe, where the Scientific Advisory Committees to the Commission provide detailed reports for consideration by the Commission and by individual governments. If this approach is taken, the setting up of regional scientific advisory boards requires an investment, but may provide the impetus to allow strong interaction at a regional level.

99. There will, therefore, be a number of phases in any new programme to provide countries with a worthwhile framework for biosafety.

A. International

100. The regional workshops organized by UNEP were an extremely successful approach to raising awareness of the need for biosafety frameworks at an international, regional and intraregional level. The average cost of $4,400 per participating country cannot be considered excessive as it provided an important starting point to the identification of need. There are many more areas that need to be addressed, including intellectual property issues, inadvertent or accidental transfer of modified organisms across international boundaries, and the modification of the UNEP International Guidelines on the basis of the Cartagena Protocol to the Convention on Biological Diversity. A number of international and regional workshops would constitute a cost-effective approach to capacity-building. The workshops should be designed to address specific issues and provide resources to allow countries to properly begin building their own infrastructure.

101. The need to ensure regional cooperation has already been stressed in paragraphs 83 and 85. Regional workshops to identify shared problems and to attempt to define shared structures to deal with these problems could be part of any new project. The cost might be similar to that assigned for the workshops identified in paragraph 100.

102. National workshops have already been addressed in paragraphs 93 and 94. The cost of running workshops in the pilot project was approximately one third of the total budget.

103. Funds should be allocated to ensure that countries that participated in the pilot stage are able to act as mentors to countries of a similar type and assist in the development of National Biosafety Frameworks.

B. National

104. The first priority will once again be to conduct a survey of activity in biotechnology. This should normally be costed as a sum based on the cost of living within a particular country, and adjusted on the basis of the number of research institutions and universities.

105. Drafting of the regulations, guidelines and laws should incur a standard basic cost, regardless of country unless a specific argument is made.

106. Should monitoring of the behaviour of modified organisms within an environment be included in the programme? It is clear that the monitoring of environmental impact is important, but it seems difficult to identify a norm for United Nations support for this activity.

107. Once established, the framework will have to be implemented and policed. Should the programme provide the means to

(a) Train those involved in the implementation of the terms of a biosafety framework?

(b) Assist in the setting up of a competent authority to oversee the implementation of the framework?

108. A major objective of the pilot project was to give GEF (among others such as, governments, institutions, the private sector), an idea of the kinds of assistance that countries might need to secure and enhance biosafety at national level within the subregional, regional as well as global context provided by the UNEP International Technical Guidelines for Safety in Biotechnology and the (forthcoming) Protocol on Biosafety. In considering the kinds of assistance required, due account should be taken of the potential benefits of the adoption and application of products of modern biotechnology, that is, LMOs or GMOs. It is also necessary to take into account the possible risks and adverse impacts such products may pose or cause to the environment and the ecosystems thereof, particularly in respect of the status of biodiversity of a country and/or its subregion. The types of assistance needed or recommended should also bear in mind the need for establishing appropriate national or subregional capacities to assess those potential risks that the products of modern biotechnology may pose to human health at the national, subregional, regional or global levels.

109. Above all, the provisions of the Protocol on Biosafety should be taken into account particularly those related to the implementation of Advance Informed Agreement (AIA) procedures. In respect of transboundary movement of LMOs and GMOs, it is essential that assistance provided recognizes the need for recipient countries to have both the opportunity and capacity to assess and manage risks posed by the LMOs and GMOs.

110. It is important that a critical mass of countries per subregion or region is targeted to receive such assistance and in this regard, a critical mass of 85 countries is envisaged. This number is based on a global figure of 50% of Parties to the Convention on Biological Diversity (currently 177 Parties) from developing countries and countries with transition economies. The critical mass of target countries, may be distributed as follows: Africa - 20; Asia/Pacific - 20; Latin America and the Caribbean - 15; Central and Eastern Europe - 15; and West Asian/Arab countries - 15. Factors for selection of target countries should include whether or how the countries have prioritized biosafety within their National Biodiversity Strategy and Action Plan, and whether they are or have:

(a) Megabiodiversity;

(b) Centres of origin;

(c) Endemic areas;

(d) small island developing States (SIDS);

(e) Arid or semi-arid or dryland ecosystems

111. A crude estimate of funding needs required for accelerated capacity-building initiatives in the immediate short-term (two years) in respect of the critical mass of target countries may be given as $ 65,820,000 starting from July 2000. This would facilitate enhancement of biosafety at the national, subregional and regional levels in the identified critical mass of 85 countries, as further outlined below.

112. From the experience gained and lessons learned in the pilot project, five types of broad assistance may be identified, namely:

(a) Support to the development of National Biosafety Frameworks through a consultative and participatory process involving a wide spectrum of stakeholders nationwide ($ 18 million);

(b) Support to the implementation of National Biosafety Frameworks by 25 countries, including those that participated in the UNEP/GEF Pilot Biosafety Enabling Activity Project, and other countries that are at various stages of finalization of their National Biosafety Frameworks prepared on their own initiatives ($ 14,840,000);

(c) Support to subregional or regional awareness-raising workshops on issues related to biosafety and biotechnology ($ 5.2 million);

(d) Support to the establishment or strengthening of subregional and regional centres of excellence for biosafety and biotechnology ($ 7,780,000);

(v) Support to Integrated, multi-pronged global, regional and subregional medium-sized projects on biosafety ($ 20 million).

1. Support to the development of National Biosafety Frameworks through a consultative and participatory process involving a wide spectrum of stakeholders nationwide ($ 18 million)

113. A time frame of about two years is needed by countries to develop effective National Biosafety Frameworks. This period would allow a series of workshops to be staged countrywide and time to initiate some capacity-building activities for the subsequent implementation of the National Biosafety Frameworks with respect to the UNEP Guidelines and the Provisions of the Biosafety Protocol at the national level. At the rate of $ 300,000 per country, a global figure of $ 18 million should be required during the 2-year period to fund a critical mass of 60 countries to prepare NBFs that would enhance biosafety. Refer to Table 6 for a breakdown of the budget.

2. Support to the implementation of National Biosafety Frameworks by 25 countries, including those that participated in the UNEP/GEF Pilot Biosafety Enabling Activity Project, and other countries that are at various stages of finalization of their National Biosafety Frameworks prepared on their own initiatives ($ 14,840,000).

114. A time frame of about two years is also needed by countries to implement various key aspects of their National Biosafety Frameworks including:

(a) Strengthening institutional capacity-building modalities;

(b) Implementation and enforcement of AIA procedures and related legislation governing LMOs/GMOs;

(c) Preparing technical manuals, guidelines, methodologies etc., for risk assessment and risk management;

(d) Building of human resource capacity in risk assessment and risk management of LMOs/GMOs;

(e) Training for scientists, lawyers, administrators and policy makers, etc., on relevant issues of biosafety;

(f) Promoting subregional, regional and international cooperation and collaboration for supply and exchange of information.

115. A similar exercise was done for estimating or quantifying the financial assistance required for this activity. On average $ 593,600 may be required per country to undertake the implementation of their National Biosafety Frameworks. Hence, the global figure to cater for 25 countries in this category would be approximately $ 14,840,000. Refer to Table 7 for a breakdown of the budget.

3. Support to subregional/regional awareness-raising workshops on issues related to biosafety and biotechnology ($ 5.2 million)

116. The envisaged workshops would cover issues related to the provisions of the recently adopted Cartagena Protocol on Biosafety, as well as those that have not been fully addressed therein, including, liability and redress, social economic considerations, modalities for practical implementation of the precautionary principle, among others.

117. The cost norms for this section can be calculated by the number of countries that would be involved in the process. This would include all developing countries and countries in transition that have ratified the Convention on Biological Diversity (Africa - 48; Asia/Pacific - 32; Latin America and the Caribbean - 31; Central and Eastern Europe - 21; and West Asia countries - 17).

118. From the experience gained during the Pilot phase, it is envisaged that in any of the four regions (Africa, Asia/Pacific, Latin America and the Caribbean, and Central and Eastern Europe) two to three subregional workshops and one regional workshop would be undertaken annually. As noted earlier, to stage a subregional or regional workshop, it would cost approximately $ 4,400 for each participating country. Hence a global figure of between $ 3.9 - 5.2 million is required for staging the awareness-raising workshops under this component.

4. Support to establishment or strengthening of subregional and regional centres of excellence for biosafety and biotechnology ($ 7,780,000)

119. Under this component, it is proposed to strengthen or establish a number of subregional and regional centres of excellence on biosafety and biotechnology. Through seminars and training programmes, selected centres of excellence in the respective subregion or region would facilitate development and realization of the following key aspects of capacity-building for enhancement of safety in biotechnology, research, development and application of LMOs/GMOs:

(a) Human resources and relevant expertise pertinent to issues of biosafety/biotechnology at national, subregional and regional levels ($ 2,860,000);

(b) National and subregional capacities to assess and manage risks associated with products of modern biotechnology ($ 1,760,000);

(c) Guidelines, methodologies and procedures for rapid assessment and management of risks and benefits of products of modern biotechnology, and review of applications for field trials and field releases, etc. ($ 1,400,000); and

(d) Networks for supply and exchange of biosafety information ($ 1,760,000).

120. For this purpose, 11 subregions could be identified wherein a subregional node or centre of excellence could be established or strengthened in each of the four regions, namely: Africa (Southern Africa, North Africa, Eastern Africa and West Africa); Asia/Pacific (South East Asia; South Pacific and West Asia/Arab countries); Latin America and the Caribbean (South America and Central America + the Caribbean islands); and Central and Eastern Europe (Balkan countries and Ex-Soviet countries). The level and kinds of assistance required would be based on the number of countries per subregion; how far advanced the countries are in terms of biosafety and biotechnology; human resource capacity; the cost of strengthening a centre of excellence where such an institution exists; the cost of establishing such a centre of excellence if necessary; and so on.

5. Support to integrated, multi-pronged global, regional and subregional medium-sized projects on biosafety ($ 20 million)

121. It is proposed that the GEF should envisage provision of support to a number of ad hoc medium-sized projects on biosafety that would encompass a combination of elements described under subheadings 1 to 5 such as the preparation and implementation of National Biosafety Frameworks, strengthening or establishment of subregional and regional centres of excellence and so on. At least 20 such integrated, multi-pronged global, subregional and regional projects judiciously selected and geographically spread would be able to cover and address many crucial aspects of safety in biotechnology world-wide at an approximate overall cost of $ 20 million. This would involve a wide spectrum of stakeholders, in particular governments, the private sector, the scientific community, non-governmental organizations and so on.

Table 6 Budget for the Development of National Biosafety Frameworks
(60 countries)

Budget item	Average amount pilot phase ($)	Average amount($) pilot phase (minus China and Russia)	Suggested amount for new phase($)	Comments (justification for difference compared to pilot phases)
Personnel	34,700.00	30,000.00	40,000.00	Able to support for full time officer and more survey personnel
Training	37,800.00	30,000.00	60,000.00	Five workshops at $12,000 each
Equipment	2,100.00	2,000.00	10,000.00	Estimated for one computer, one printer and one fax/photocopier
Miscellaneous	26,900.00	22,800.00	30,000.00	Held approximately at same amount
6% UNEP fees	6,090.00	5,088.00	8,400.00	
Total (per year)	107,590.00	89,888.00	148,400.00	
Over two years	215,180.00	179,776.00	296,800.00	
60 countries	12,910,800.00	10,786,560.00	17,808,000.00	

Table 7 Budget for the Implementation of National Biosafety Frameworks (25 countries)

Budget item	Suggested amount for new phase ($)	Comments
Personnel	100,000.00	Able to support for full time officer and more consultants/survey personnel as required
Training	100,000.00	Five workshops at $ 20,000 each and participation costs for regional workshops
Equipment	10,000.00	Estimated for one computer, one printer, one fax/photocopier and access to Internet
Miscellaneous	70,000.00	Includes printing costs and other technical support
6% UNEP fees	16,800.00	
Total (per year)	296,800.00	
Over two years	593,600.00	
25 countries	14,840,000.00	

VIII. CONCLUDING REMARKS

122. There can be no doubt of the importance of this enabling project in the eyes of the participating countries. There was considerable evidence that in many cases it had vastly exceeded its remit. The vast majority of country representatives believed that this was the type of project that the countries would have had to undertake. However, if left entirely to Governments for funding, it would have been greatly delayed, much slower and less effective. Certainly, a majority of the project activities at national level would not have taken place without the UNEP/GEF support. While limited funds are available in some of the countries for fundamental research, or applied research and development, most developing countries have been slow to provide funds for research into biosafety, or for the setting up of mechanisms by which the safe use of the technology could be assured. Establishment of subregional and regional centres of expertise and nodes for supply and exchange of information, the training of scientists to use the technology safely, and to think about the consequences of their work, were seen to be of extreme importance and urgency (para. 58).

123. The need expressed by those participating in this project for the funds allocated to them, and the impetus that they have experienced from its implementation, has been clearly demonstrated in this project. The countries involved in the project are fearful of being unable to complete the process started. They believe that much has been accomplished, but that there is much to accomplish in the area of biosafety and biotechnology in relation to biodiversity. If they are to set up strict regulatory systems, there needs to be enforcement and laboratory and field facilities that are capable of testing and validating the presence or absence of modified organisms. It is acknowledged that the project has stimulated a new approach to biotechnology by national and international organizations and that it has stimulated regional cooperation. It would be a great pity if these 17 countries were unable to continue the good work started in the course of a single year (para. 73).

124. In the consultant's view, it is crucial for the future of biotechnology that a project similar to this one is funded in those countries that have yet to develop a consistent framework for the safe use of this science. If at all possible, as many as possible of those countries involved in this project should continue to be involved, acting in some ways as mentors to newly involved countries so as to allow the rapid build-up of expertise in this area. The experience gained and expertise developed as well as lessons learned should not be lost. Many more countries should benefit from similar input of funds and expertise as that available through this project. Many of these countries have applied for funding for their own National Biosafety Frameworks (para. 74 - 79).

125. The follow-up project for new countries would then be similar to that already achieved, requiring a survey of the expertise and use of both biotechnology and of biosafety. An assessment of the need for an overall biosafety framework would then follow (para. 79 and 80).

126. In order to effectively fulfil its functions as a complement to the Protocol on Biosafety, and to further guide the countries in the preparation of the National Biosafety Framework in the light of the provisions of the Protocol on Biosafety Frameworks in the light of the provisions of the

Protocol on Biosafety, it is strongly recommended that consideration be given to the review of the UNEP International Technical Guidelines for Safety in Biotechnology.

ANNEX

Bibliography

Christian Aid (1999) Selling Suicide edited by Angela Burton, Christian Aid, PO Box 100, London, SE1 7RT. (http://www.christian-aid.org.uk/reports/suicide/index.html)

Glowka, L., Burhenne-Guilmin, F., Synge, H. (in collaboration with J. A. McNeely and L. Gündling) A guide to the Convention on Biological Diversity, Environmental Policy and Law Paper No. 30, IUCN Environmental Law Centre, Godesberger Allee 108-112, 53175 Bonn, Germany.

House of Commons Environmental Audit Committee (1999) GMOs and the Environment: Coordination of Government Policy Fifth Report HC 384-I ISBN 0 10 23019 9.

House of Commons Science & Technology Committee (1999) Scientific Advisory System: Genetically Modified Foods First Report HC 286-I ISBN 0 10 231499 3.
