Report of the Subregional Workshop

for Asian Countries on:

the Development of a Regulatory Regime

and

Administrative Systems

October 19 -22, 2003, Shiraz,

Islamic Republic of Iran

ABBREVIATIONS

BCH	Biosafety Clearing House
CBD	Convention on Biological Diversity
CMS	Convention on Migratory Species
COP	Conference of the Parties
GATT	General Agreement on Tariffs and Trade
FFP	(LMOs intended for) food or feed, or for processing
GEF	Global Environment Facility
GMO	Genetically Modified Organism
ICCP	Intergovernmental Committee for the Cartagena Protocol on Biosafety
IPPC	International Plant Protection Convention
IUCN	International Union for Conservation of Nature and Natural Resources
LMO	Living Modified Organism
MOP	Meeting of the Parties
NBF	National Biosafety Framework
NCC	National Coordinating Committee
NGO	Non-Governmental Organisation
NPC	National Project Coordinator
SPS	Sanitary and Phytosanitary
TBT	Agreement on the Technical Barriers to Trade
TRIPS	Agreement on the Trade-Related Aspects to Intellectual Property Rights
UNCCD	United Nations Convention to Combat Desertification
UNCLOS	United Nations Convention on the Law of the Sea
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme
UNFCCC	United Nations Framework Convention on Climate Change
WTO	World Trade Organisation

INTRODUCTION

1. The United Nations Environment Programme (UNEP) - Global Environment Facility (GEF) Project on the Development of National Biosafety Frameworks (NBFs) is one of the main components of the GEF Initial Strategy for assisting countries to prepare for the entry into force of the Cartagena Protocol on Biosafety, approved by the 16th GEF Council in November 2000. The project, which was initiated in June 2001 for a three-year duration, is designed to (a) assist up to 100 eligible countries to prepare their NBFs; and (b) to promote regional and sub regional collaboration and exchange experience on issues of relevance to the NBFs. The overall objective of the project is to prepare countries for the entry into force of the Cartagena Protocol by, *inter alia*, assisting in the implementation of the following activities:

    (a) Assessing current technological capacity to manage biosafety issues, and the implications of this for implementation of an NBF;
    (b) Strengthening national capacity to develop national regulatory biosafety frameworks;
    (c) Strengthening national capacity for competent decision-making on notifications and requests relating to living modified organisms (LMOs), including the establishment of administrative systems to assist in this;
    (d) Applying other measures, according to the Protocol, taking into account the work of the Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP);
    (e) Supporting regional and sub regional collaboration, including harmonization of the implementation of national regulations;
    (f) Raising public awareness and improving information flow to the public on the issues involved around the release of LMOs, to promote informed debate and to ensure transparency with respect to the regulation of LMOs;
    (g) Providing all stakeholders with an opportunity to be involved in the design and implementation of the NBF.

2. The project is coordinated by the UNEP-GEF Biosafety Development Project Team. A regional coordinator for each region is available within the Team, to provide advice and support to countries throughout the implementation of their national projects to develop NBFs, which are intended to last a maximum of 18 months.

3. In parallel with the work with individual countries, the Biosafety Team has already held regional workshops in Africa (Kenya, 16-19 January 2002), Central and Eastern Europe (Slovakia, 5-9

February 2002), Asia-Pacific (China, 4-8 March 2002) and Latin America and the Caribbean region (Buenos Aires, 8-10 May 2002), in order to improve countries' understanding of the key issues of the development of NBFs. The workshops were targeted at National Project Coordinators (NPCs) of participating countries or potential NPCs from countries yet to join the project.

4. To assist progress at the sub regional level, a series of 12 training workshops have been planned from November 2002, to help build capacity in: the decision-making process (risk assessment, risk management, etc.); public participation; administrative systems; and regulatory systems. The following six sub regional groupings would be addressed: Francophone Africa: Anglophone Africa; Asia; Small Island Developing States (SIDS); Latin America; and Central and Eastern Europe, including Central Asia. The rationale behind the subregional workshops lay in the country-driven preference for more regional meetings; the need to promote networking within a region and subregions; a desire to help to meet special development needs; the need to increase opportunities for participation; the need to optimise scarce human resources; and the desire to achieve economies of scale.

5. The first subset of six subregional workshops, dealing with risk assessment and management, and public awareness and participation, was held in the Anglophone Africa (Namibia, 12-15 November 2002), Latin America (Mexico, 10-13 December 2002), Asia (Malaysia, 21-24 January 2003), the Small Island Developing States (SIDs; Fiji, 18-21 February 2003), the Francophone Africa (Senegal, 22-25 April 2003, and the Countries of Central and Eastern Europe, the Caucasus and Central Asia (CEECCA; Lithuania, 27-30 May 2003).

6. It was decided that the second subset of six workshops, scheduled for October 2003 - May 2003, would deal with the "Development of Regulatory Regime and Administrative Systems".

7. The first in these series of workshops, the Asian Countries Subregional Workshop: Development of Regulatory Regime and Administrative Systems, was held from 19 to 22 January 2003 at the Homa Hotel, Shiraz, Islamic Republic of Iran. The Workshop was convened by the UNEP/GEF Biosafety Project Team, in collaboration with the Government of the Islamic Republic of Iran.

8. A list of participants is attached as Annex I to the present report.

Opening of the Workshop

Introduction to the Workshop

9. The plenary session of the Workshop was opened at 8.30 am on Sunday, 19 October 2003. Mr. Nizar Mohamed, Regional Coordinator for Asia and the Pacific, UNEP-GEF Biosafety Unit, welcomed the participants and expressed gratitude to the Government of the Islamic Republic of Iran and to its Department of Environment for hosting the Workshop, and for the assistance and support provided in the logistical and administrative arrangements. He looked forward to a productive workshop over the next four days, and encouraged participants to actively participate in the discussions.

10. The participants agreed to follow the programme of work as set out in Annex II to the present report. Mr. Mohamed briefly laid out a set of ground rules for the Workshop as contained in Annex III to the present report, and requested the participants to observe them.

Opening Ceremony

11. Mr. Frederick Lyons, United Nations Resident Coordinator and UNDP Resident Representative, welcomed participants to the workshop. He gave an overview of the United Nations' commitment to Sustainable Development originating from the Earth Summit in Rio de Janeiro in 1992, which culminated in the conception of Agenda 21 and the establishment of the Convention on Biological Diversity (CBD) along with the United Nations Framework Convention on Climate Change (UNFCCC), and the United Nations Convention to Combat Desertification (UNCCD). He also highlighted a number of collaborative national and regional efforts of the UN agencies on capacity-building related to the environmental conservation. Recognising that the effective implementation of the Cartagena Protocol on Biosafety would promote health, safety, sustainable development and poverty reduction, he congratulated the convening of the workshop and wished for a successful deliberation.

12. The Deputy Governor of the Fars province then welcomed the participants to Shiraz. He gave a brief account of the environment, flora, and fauna of the province, and highlighted the importance of the conservation of biological diversity for the region as well as for the country as a whole. He noted the significance of holding this workshop in Shiraz, Iran, as part of the country's contribution to the global efforts on environmental conservation. He gave his best wishes for the workshop, and expressed a vision to improved cooperation in the Asian region, and further assistance from the UNEP-GEF Biosafety team.

13. In her address to mark the formal opening of the proceedings, H E Dr. Ebtekar, Vice President of the Islamic Republic of Iran and Director of the Department of Environment, welcomed all the participants to Iran and to Shiraz, a city of historical and cultural significance for human civilisation. She expressed her support in promoting dialogue and further understanding among Asian countries that shared environmental conditions and faced similar concerns for the region.

14. She pointed to the appropriate use of biotechnology as an important issue for the region and for civilisation, pointing out the need for a fine balance between technological advancement, improvement of agriculture, human health and human life on one hand, and taking the necessary precautionary and regulatory steps in order to promote sustainable development on the other. She considered that the ratification of the Cartagena Protocol on Biosafety by as many countries as possible was one of the main ways to achieve this fine balance.

15. She noted that the government of Iran has ratified the Protocol and is working, with assistance from UNEP-GEF to develop an NBF, so that a legal framework could be established in accordance with national policies and priorities while implementing the Protocol and promoting the appropriate use of biotechnology.

16. Pointing to the recent developments in the global debate on the genetically modified food and crops, in particular to the report of the British Royal Society on its 3-year long field trial experiment on the environmental effects of genetically modified crop agriculture, she stressed that such emerging considerations and new scientific findings helped allow each country to make its own decision and take necessary actions. She encouraged all developing countries to ratify the Protocol, develop their NBFs, promote public understanding, and implement the use of the BCH, in order to take advantage of the benefits of biotechnology while avoiding any potential negative effects, including any impacts on trade.

17. She hoped that a fruitful deliberation in the workshop would achieve an outcome that was beneficial for the region, and that would promote cooperation on the improvement of the environment, human health and living standards, as well as on the promotion of multilateralism and sustainable development.

Introduction to the UNEP-GEF Global Biosafety Development Project and the Implementation projects

18. Mr. Christopher Briggs, Global Programme Manager, UNEP-GEF Biosafety Unit, gave a presentation on the UNEP/GEF Biosafety Project, describing the process leading to the adoption of

the Cartagena Protocol and the history of the Biosafety Enabling Activity Project. He noted the adoption of the GEF Initial Strategy by the GEF Council, and enumerated its main objectives and proposed activities. He drew attention to the starting date of the UNEP-GEF Global Project on the Development of NBFs in June 2001 and to its overall objectives. Following the second meeting of the Intergovernmental Committee for the Cartagena Protocol (ICCP), the GEF Council had approved the pilot projects to provide support in the implementation of NBFs.

19. After describing the different levels of the project (global, regional, subregional and national), he explained that the initial set of four regional workshops had been held in 2002 to improve the understanding of the key issues involved in developing NBFs. Twelve subregional training workshops were planned, and the first in the series that covered the topic of risk assessment and management, and public awareness and participation, were held in six subregions between November 2002 and May 2003. The second series of six workshops would cover administrative systems and regulatory systems, this workshop being the first of this series.

20. He summarised the progress made at the national level by the 121 participating countries on board, and elaborated on the stages at which the Asian countries were undertaking at the moment. He added that an independent evaluator had conducted the mid-term review of the project. A request had also been made to the GEF Secretariat for the further expansion of the number of countries and for an extension of the project period to take into account those countries that experienced delays in joining the project.

21. Mr. David Heron, Implementation Project Task manager, UNEP-GEF Biosafety Unit, presented the overview of the demonstration projects to provide support in the implementation of NBFs and reported the progress of the demonstration projects in eight countries. He briefly outlined the projects, which included countries undertaking the initial activities and convening their start-up workshops. Working with the countries participating in the pilot implementation project had so far identified the need for a broad-based dialogue and careful planning of fine-tuned activities that suited each beneficiary country, and taking the current experiences and lessons into account, the project expected to implement further activities at the national level in the near future. The project also developed supporting documents and established network to other ongoing database activities in parallel to the pilot project. Preparation of new project proposals for additional countries was also underway.

Expectations and concerns

22. Participants were invited to express their expectations and concerns in connection with the outcome of the Workshop. The resulting comments are summarized in the table contained in Annex IV to the present report, as well as the comments made at the closing session of the Workshop, assessing whether the expectations had been met.

Introduction to CBD Article 8g and 19, and the Cartagena Protocol on Biosafety

23. Ms. Camilla Mathiesen, Junior Professional Officer, Secretariat for the CBD, reviewed the historical context and elaborated the main provisions of the Cartagena Protocol on Biosafety, emphasising that this was the starting document for the development of NBFs for every participating country. She reminded the participants that the Protocol entered into force on 11 September 2003 and had, at the moment, 65 countries and one regional economic integration organisation as Parties to the Protocol. She also informed that the first Conference of the Parties acting as the Meeting of the Parties (COP-MOP1) to the Cartagena Protocol on Biosafety would take place on 23-27 February 2003.

Overview of key components of National Biosafety Framework

24. Mr. Giovanni Ferraiolo, Regional Coordinator for Latin America and the Caribbean, UNEP-GEF Biosafety Unit, presented the five aspects of the NBFs which were considered as key components by the Biosafety Team: biosafety policy; regulatory regime; system to handle requests; follow-up activities; and public awareness and participation. While stressing that there was no single model or a best solution for what an ideal NBF should contain, he noted that these key components were usually the common features of existing NBFs. He described each key component and highlighted that they would need to be addressed in the course of the NBF project, in order to develop appropriate policy, legal, administrative and technical instruments for the safe use of modern biotechnology.

25. During the discussion, the participants considered various aspects of the Cartagena Protocol and how they could be reflected in their NBFs. Particular reference was made to the scope, public awareness and participation, interpretation of the precautionary approach, relationship with non-Parties, failure of notification, socio-economic considerations, and ensuring adequate protection. The question of how to relate biosafety with poverty-reduction was also raised.

26. It was reiterated that there were no standard models or a single method to address many of these issues, and it was up to each country to consider whether to apply the minimum requirements of the

Protocol or to apply different emphases and extend them to a higher degree of regulation than that of the Protocol. The development of NBF was a dynamic and iterative process that required revision and amendments to reflect any recent scientific developments or changes in the national policy. Such revision could occur during and after the life of the UNEP-GEF project.

Regulatory Regime

Sharing of regional experiences on NBF development

27. Mr. Mohamed introduced the session on regulatory regime by presenting a synopsis of the experiences with NBFs in Asian countries participating in the UNEP-GEF project. He summarised the common starting points of the countries in the region and listed a number of options for possible regulatory regimes and administrative systems that countries have considered. Each country's NBF project was based on their national development plans and/or sectoral policies. He also pointed the main challenges encountered by countries in the course of the NBF projects, which included: overlapping mandates, lack of institutional capacity, conflicts between different sectoral laws and regulations, strengthening enforcement, and promotion of subregional cooperation and harmonisation.

28. Following this introduction, participants from four countries in the region gave presentations on their national efforts in the development of national biosafety regulatory regimes. Three countries, Indonesia, the Republic of Korea and Jordan are participating in the current UNEP-GEF NBF Development project, while Malaysia, having developed its NBF without external funding, is now working with UNDP-GEF to implement its NBF. The presenters highlighted their ideas and approaches for their NBF process with an aim to share these experiences with other countries in the region.

29. The representative of Indonesia summarised the state of biotechnology, current regulations, new regulations planned for the future, and the adjustments needed to current regulations for ensuring compliance with the Cartagena Protocol on Biosafety. Activities included the establishment of a national biosafety committee, incorporation of compulsory public participation procedures, and BCH provisions. He also summarised the regulatory flow of the proposed executive order.

30. The representative of Jordan presented the progress of the Jordanian NBF project. He summarised the process involved in the establishment of the NCC comprising a number of ministries, academia and consumer/farmer associations. He also outlined other project activities such as the development of training manuals and the convening of training and consultative national workshops. He also

summarised the process for the drafting of a national bylaw and explained the rationale for selecting a bylaw as well as the provisions included in the bylaw.

31. The representative of the Republic of Korea introduced the main biotechnology act and a number of ministry-level regulations in the country, and highlighted the multidisciplinary and de-centralised system consisting of many ministries involved in the regulation of LMOs in their different capacities. He also presented the problems encountered and remedies sought during the process of integrating various ministerial roles, including addressing the possible conflict with WTO agreements.

32. The presentation by the representative of Malaysia first demonstrated the grounds for the country's choice for the regulatory system, weighing the options between sectoral and cross-sectoral system against existing laws. This process resulted in the establishment of a national commission on biosafety, and the drafting of a national biosafety bill. She characterised the role of the national biosafety bill as supplementing existing sectoral legislation, while addressing gaps, conflicts and/or any overlaps among the existing laws related to biosafety.

33. The participants showed a keen interest in the variety of approaches taken by the four countries, raising a wide range of questions and discussions among the counties in order to learn from their experiences. The main issues of discussion concerned the composition, function and responsibilities of various committees and technical teams; how to maintain independence of the national biosafety board; and how to overcome the difficulties of cooperation among different ministries/departments and sectoral laws. A number of participants were also eager to consider how to incorporate the inputs of NGOs and the public as well as socio-economic considerations at the national regulatory level in practical terms, including convening different special-interest workshops.

34. The discussion continued to focus on how to compare the options of amending existing laws and developing a new law, and how to reach a balance between the two to suit the interest of the country. Participants attempted to learn in detail how the Malaysian cross-sectoral biosafety bill could work in harmony with the existing laws by supplementing them, although it appeared to supersede them in the legal context. The speaker from Malaysia stressed that in order to avoid the risk of overlap between existing law and the new bill, it was important to request different ministries to review the new bill in relation to their own sectoral laws, and provide feedback; this required patience and persistence.

Rights and Obligations under the Cartagena Protocol on Biosafety

35. Ms. Mathiesen from the CBD Secretariat outlined the practical aspects of Protocol provisions that were underlined in the recent notification from the CBD on the requirements that need to be fulfilled on entry into force of the Cartagena Protocol (SCBD/BS/CS/WD/jh/36477), as well as the guidelines for national participation in the BCH (SCBD/BS/RH/jh/38460). Stressing the importance of the domestic regulatory framework in implementing the Protocol, and in particular ensuring transparency throughout the implementation process, she elaborated the general rights and obligations of the Parties under different provisions as well as some of the immediate capacity needs to allow effective implementation of the Protocol. She also touched upon the key items for discussion at the COP-MOP1.

Other international instruments and national obligations and rights

36. Ms. Tomme Rosanne Young, Senior Legal Officer, IUCN Environmental Law Centre, reviewed the need for the coordination and harmonisation of international agreements at the national level, and the types of international instruments that might need to be considered when developing an NBF in line with the Cartagena Protocol on Biosafety. She pointed out national sovereignty as the important element of the functions of international law, along with other possible conflicts or problems that a country may encounter in attempting an integrated regulatory implementation process.

37. She drew attention to a multitude of instruments and processes, including those under the CBD system (equitable benefit-sharing, technology transfer, liability and alien invasive species), trade and commercial systems (GATT, TBT, SPS, TRIPs, and the dispute settlement process), environmental instruments (UNFCCC, UNCCD, UNCLOS, Ramsar Convention, CMS, and the Rio Declaration), as well as various regional bilateral and multilateral instruments. In charting relevant commitments to these instruments, countries must be aware of their status of membership as well as that of neighbouring countries, the scope and operation of the law, and any relevant international negotiations that are in progress. She concluded by stressing the importance of identifying relevant opportunities for regional cooperation and special trade requirements while evaluating the national implementation of international legislations.

38. Participants discussed how these international instruments could be balanced with their obligation towards the Cartagena Protocol, with particular questions on alien invasive species and trade-related international instruments. Questions regarding access to private-sector technologies by developing countries, and the use of transboundary environmental impact assessment were also raised.

Elements of a regulatory regime

39. In introducing the agenda item on the elements of a regulatory regime, Mr. Julian Kinderlerer, Professor of Biotechnology Law, Sheffield Institute of Biotechnological Law and Ethics, stated that the scope, objectives, and definition were the main starting points when drafting or reviewing a national biosafety legislation. Since legal documents were explicit by nature, the rationale behind excluded items must be thought out as well as the included items at this starting point. He added that the regulatory regime must not be in conflict with, but was not limited to, the provisions of the Protocol. For example, countries may choose to supplement their national law with enhanced considerations for socio-economic issues or food and feed safety.

40. Formulating a legally functional regulatory regime might be a difficult and complicated task, particularly when the subject matter lay under the auspices of several government ministries and agencies. He identified some aspects for a biosafety administrative system that might need to be put in place by law in order to ensure a synergy between the concerned ministries and agencies. Another important issue of concern for a legally functional regulatory regime was whether and how to use the existing national laws and international obligations. A close examination of any new national regulatory regimes was vital for each country, in order to avoid any possible conflicts that might arise with existing national, regional, and international laws.

41. Ms. Young took Mr. Kinderlerer's points further by examining the "general provisions" of a legal document. She strongly recommended that the contents of a legal document be thought out thoroughly before the legal technicalities were incorporated. She then ran through the possible rationale and conceptual approaches behind the possible options within the general provisions of objective, scope, definitions, institutional arrangements, and obligations.

42. The countries must search for their initial vision - an answer to why a particular legal document needed to be written – in order to guide the direction of the legislative and administrative processes. She also emphasized that laws must generally be accessible, understandable, and practicable. Consequently, a conscious decision must be made in the choice of the type of primary and secondary legislative tools as well as in the choice of governmental function and level that would assume the legal authority, in order to clarify roles, responsibilities and requirements for the cooperating ministries. She concluded by reminding the participants that the first stages of drafting a new legislation must also take into account that the legislative tools might need to be revised and amended from time to time to reflect the changes in the national biosafety policy or the emergence of new knowledge. .

43. In the discussion following the two presentations, the participants considered how responsibilities could be balanced between the legal authorities and the applicants, particularly when a conflict or disputes arose or when new scientific information became available. They also discussed how the synergy can be attained between various ministries, how to work with existing laws in the interim when a biosafety act was being prepared, and how to incorporate consideration for international trade implications at the national level.

44. Participants undertook an exercise on the essential elements of a hypothetical objective and scope for a regulatory regime in biosafety, taking into consideration international and national obligations and what is already covered by existing legislation. Ms. Young introduced the focus group questions:

i. What are the possible national objectives of a legal framework addressing biosafety?

ii. For each listed objective, identify:

- Priorities (essential? Or optional? And why?)
- Impact of including or excluding this objective?

iii. Starting from the minimum scope, what are the positive and negative impacts of enlarging the scope to address issues or objectives listed in 1 or 2 above?

45. The participants were divided into six focus groups to discuss and prepare a summary of their deliberations. Each group subsequently presented the outcome to the plenary in a written form, as seen in Annex V of the present report. A selected panel of resource persons commented on the outcome of the focus group discussions. The main comments were positive, with suggestions for a deeper consideration into the details of each general provision item.

Operational provisions of a regulatory regime

46. Bearing in mind that thee objectives, scope and structure were the basis of a biosafety regulatory regime, Mr. Heron stated that the draft regime must also be tested for clarity, transparency, consistency, workability, enforceability, and adaptability. In introducing the discussion on the operational provisions, he explained that many existing biosafety regimes contained four common elements: carrying out a risk assessment, application of adequate safety measures, request for permits for certain activities, and procedure for decision-making.

47. He described the thought processes and underlying principles behind the operational procedural elements using four categories of uses: contained measures, release into the environment, marketing and import/export. He demonstrated the complexity of determining the level of safety requirements

for the different organisms and activities, and suggested some options for the regulatory tools and administrative steps that might be required for putting the safety measures in place.

48. Following the presentation, the participants discussed to clarify a number of issues under this agenda item, particularly on transparency, legal authority, auditing process, differences between containment and confinement, and on ensuring that the operational procedure remained consistent with the scope.

49. In an experience-sharing exercise, South Korea, Indonesia, and the Philippines made presentations on the relevant features of their regulatory regimes followed by a discussion by participants.

50. The main features of the biosafety regulatory regime in South Korea included an enhanced precautionary principle, no special distinction for FFP and contained use, and a special distinction on experiment, research and exhibition. The participant from Indonesia described the rationale behind the type of national regulatory regime chosen in her country and gave an overview of the proposed Executive Order, listing the pros and cons of the chosen system. The presentation on the existing and the proposed new biosafety regulations in the Philippines included the overview on the national committee on biosafety, its composition and roles, the responsible agencies for safety assessment and compliance, and the different processes for contained use, field test, and propagation.

51. Mr. Kinderlerer summed up the discussion, reminding the participants that although the absolute minimum requirement for the operational provisions was that of the Protocol, countries could gradually add much more according to their specific national needs.

Other elements or considerations when developing an NBF

52. Ms. Young identified the "other elements or considerations" as those that did not fit into the essential and the operational provisions, although this did not mean that these elements were unnecessary. She divided the "other elements" into three categories: generally essential provisions, provisions found in fewer biosafety laws, and those required for legal/stylistic reasons. She then elaborated on the details of each category, providing the grounds for inclusion in the regulatory regime.

53. The participants were then asked to suggest various topics for "other elements" to be discussed in focus groups. . The suggested elements for discussion were:

- Enforcement and monitoring;

- Addressing ethical concerns;
- Access to information and public involvement;
- Responding to new information;
- Confidentiality; and
- Liability and redress.

After prioritisation by participants in the plenary, the following three issues were selected, each topic being discussed by two groups:

- Enforcement and monitoring;
- Liability and redress.
- Confidentiality, access to information and public involvement;

54. For each topic, the focus groups attempted to answer the following questions:

- Question 1 – "What were the key issues to be considered?"
- Question 2 – "What were the lessons to be learned?"

The summary of the resulting outputs of the focus group discussions is contained in Annex VI of the present report.

Choices on the regulatory regime

55. Mr. Kinderlerer illustrated the different approaches for choosing a regulatory regime. He explained that there were many general laws in a given country that controlled the everyday practice of its citizens and would inevitably affect how a new regulatory regime functioned in that country. He noted that the choice of a regulatory regime for some countries might also be affected by the historical (including colonial) contexts in which their national legal systems were originally shaped. He felt that, as the whole "body of law " of each country must be taken into account when developing a new legislation, understanding the concept of the philosophy of law might be useful.

56. He described the differences between the various "laws". Primary legislation included statute law, secondary legislations could be regulations as specified in a primary legislation or ministerial/presidential decrees, and guidance was a less-stringent form of legislation. He briefly touched upon other legal glossary and approaches that might be useful in choosing a national regulatory regime for biosafety. He listed the types of biology-related laws that might exist in a given country and gave the examples of countries that made their decisions on using such existing laws or on employing a completely new law.

57. Noting that the biosafety laws in the developed countries had evolved over a long period of time, he stressed the need to think about the minimum set of requirements that were of utmost concern for the

developing countries at the present time, so that it may be used as transitional/interim measures while the long-term goals of the national biosafety regulatory regime could be matured gradually into a legal form.

58. The participants discussed how existing laws might be utilised by amending or supplementing them with a new law. They exchanged their country experiences on the choices of their regulatory regimes, and suggested that in order to find where new laws were required, it might be useful to look for sectoral gaps in existing laws. Mr. Kinderlerer closed the discussion by reminding the importance of taking many complex factors into account when developing a regulatory regime, and showing his appreciation for the insightful contributions given by the countries.

Administrative Systems

Introduction to administrative systems

59. As the workshop moved from the topic of developing a regulatory regime into the topic of establishing an administrative system, Mr. Heron gave an overview of some key functions of the biosafety administration process: ensuring administrative and technical completeness, decision-making process including issuing of decision documents, and enforcement. He then described each step in detail, highlighting roles and responsibilities of the "applicant" against those of the government and listing possible skills needed to undertake the necessary activities. He stressed the need for a transparent system throughout the administrative system for the benefit of the administrators themselves. A better understanding among the applicants, the public and government agencies would vastly improve the administrative workload of the processes.

60. He introduced the focus group discussion questions based on the "ICCP implementation toolkit" contained in the notification on the requirements that need to be fulfilled at the date of the entry into force of the Cartagena Protocol (SCBD/BS/CS/WD/jh/36477). He went through some of the administrative systems requirements and considered the multiple steps required to fulfil them, such as: who designates the authorities, who communicate the output, and how to manage the internal coordination between the government ministries/agencies.

61. The participants were again divided into six focus groups to discuss one of the three topics of the ICCP implementation toolkit: administrative tasks (initial and future), legal requirements and/or undertakings, and procedural requirements (AIA and Article 11). The six groups prepared a summary of their deliberations, and the two rapporteurs for each topic produced a synthesised report for presentation to the plenary as contained in Annex VII of the present report.

62. During the discussion, participants considered how to deal with monitoring requirements, public awareness and participation purposes, and with the monitoring of field trials. In summarising the exercise, Mr. Ferraiolo noted that much of the administrative system seemed to be in place in many countries, and that coordination was the major challenge where different agencies were working separately. There seemed to be a general concern among the participants on the monitoring activities, particularly on who should be involved and how they should be conducted. He emphasised the need for a clear understanding of each administrative step.

Administrative systems related to decision-making for the Advance Informed Agreement

63. In introducing the agenda item, Mr. Gbedemah described the Advance Informed Agreement (AIA) procedure as the main feature of the Protocol. He stated that lengthy negotiations had taken place to finalise its precise procedure, and each step had been thoroughly thought out. He outlined each step of the regular AIA notification process with a sample timeframe as prepared in the form of a "checklist" during the UNEP-GEF Subregional Workshop on risk assessment and risk management.

64. He also touched upon some additional considerations for AIA raised during the previous subregional workshop, particularly on the treatment of confidential information, using BCH to obtain and report relevant information, informing neighbouring countries, public awareness and participation in the decision-making process, and making provisions for appeal and monitoring.

Administrative systems related to Article 11 of the Cartagena Protocol on Biosafety

65. Mr. Kinderlerer introduced the agenda item on the administrative system related to the procedure for LMOs intended for food or feed, or for processing (FFP) as described in Article 11 of the Cartagena Protocol on Biosafety. Starting from the historical background on why the commodities/FFPs came to be treated separately from the other LMOs, he described the procedure summarised in Article 11 as an indirect notification process, where the Party only had to inform the BCH of approval for domestic use[1]. He interpreted each subclause and referred to Annex II to clarify the information required concerning FFPs under Article 11.

66. In an exercise on the development of an LMO-FFPs, he asked the participants to draw a diagrammatic representation on how their country currently implemented, or planned to implement, Article 11. He reminded that the processes for import and export of FFPs should both be represented in the diagram. Each country presented the diagram to the plenary for viewing.

[1] **Corrigendum: Report summary changed to improve clarity from: "where the applicants did not have to seek any prior permission from the importing Party but only had to inform the BCH (May 2005)**

67. Mr. Kinderlerer commented that although most countries had placed the applicant at the start of the diagram, the national FFP procedure described in Article 11 of the Protocol was not triggered by an applicant or a notifier informing the importing country. He clarified that after informing the BCH and meeting the labelling requirements, the exporter was allowed to send LMO-FFPs without the importing country's approval or awareness. Participants discussed on the need for a special provision dealing with transit of FFPs, on introducing stricter FFP requirements than that of Article 11, and on how to ensure that Parties and exporters meet the requirements of the Protocol.

Cross-cutting issues

68. In order to identify the cross-cutting issues of interest to the workshop, Mr. Mohamed asked the participants to brainstorm for the topics that they would like to discuss, which were then narrowed down to four items for the focus group discussion:

- Problems of small countries;
- Financial resources for NBF;
- Conflict between trade and environment; and
- International standards for RA.

The outcome of the deliberations by the four focus groups was presented to the plenary.

69. The focus group on the international standards for risk assessment focussed on capacity-building, training and identifying needs, and listed priority areas of setting up international facilities, developing possible regional risk assessment guidelines, using BCH for communication, and searching/using international expertise.

70. The focus group on small countries described some common problems, such as the difficulty of monitoring and screening imports, lack of in-house human and technical capacities, delicate import-export balancing, and concerns about dumping by larger countries. The group identified, as their key needs, training among decision-makers, bilateral agreements with large neighbour countries to monitor borders, infrastructure development, and network-based management. A proposal for setting an annual biosafety day to raise general awareness was also suggested.

71. The focus group on financial resources identified the lack of funds as a general problem among all the countries. Acknowledging that foreign assistance could not be relied on in the long run and self-sustainability was the ultimate goal, the group underlined that the focus must shift to national

sources. Possibilities for generating revenue from the application fees and mobilising additional funding from bilateral/regional cooperation were also discussed, including the possible GEF implementation project in the future. In order to secure GEF approval in this regard, the group suggested submitting a recommendation from the COP/MOP to the GEF Secretariat requesting further financing.

72. The focus group on trade and environment recognised the uneasy relationship between the two issues, with proponents of each issue often at the opposite ends of the discussion. Establishing harmony was therefore a difficult task, and concluded that further attempts must be made to ensure that trade and environment were mutually supported, with sustainable development on top of the national agenda. Recommendations by the group included the use of regional instruments, preventing the use of environmental standards as trade barriers, introducing a "polluters pay policy", raising public awareness on eco-labelling, harmonisation of compliance under WTO agreements and MEAs, raising awareness at national levels, ensuring effective and clear definitions of related terms, and checking for the effective compliance of national laws.

Panel discussion on sub-regional cooperation

73. In opening the panel discussion, Mr. Keneti Faulalo, Assistant Regional Coordinator for the Pacific Region, UNEP-GEF Biosafety Unit, shared his experience in the Pacific and SIDS subregional institutional levels, particularly focussing on the regional mechanism for risk assessment to overcome the lack of capacity at the national levels.

74. The participant from the Philippines spoke on the subregional projects undertaken by ASEAN committee on Science and Technology. Although it does not currently run projects related to biotechnology, she suggested seeking cooperation among the ASEAN countries in order to draw experiences of those countries that are relatively more developed in the regulation of biotechnology.

75. The participant from Iran welcomed the idea of cooperation among her subregion, particularly in the area of institutional and human capacity, networking and exchange of scientists and scientific information. Harmonisation of administrative systems might also be envisaged.

76. The participant from Bangladesh described existing activities under the South Asia Regional Cooperation (SARC), particularly on the coordination of biodiversity departments in the member countries, sharing experience, expertise and responsibilities. In order to promote human health and environmental conservation, learning the status of all SARC countries and identifying subregional problems was suggested as an important step.

77. The representative of the Regional Office for Asia Pacific, UNEP congratulated the UNEP-GEF team for the holding of the present workshop, noting that it was one of the many successful initiatives of the UNEP family in this region. Noting the tremendous amount of existing biodiversity in this region, he described some of the major priority areas of UNEP Regional Office for Asia Pacific. On the issue of subregional cooperation, he gave an overview of ASEAN, SACEP, SPREP, and INSPEC, among the various subregional functions working with UNEP.

78. Following the panel presentation the participants discussed various related issues. Countries that did not fit into the existing subregional initiatives showed their concern, while larger, more-developed countries showed willingness to cooperate with smaller, developing countries of the region. Promotion of cost-effective methods of technology transfer and the importance of learning about the scientific/regulatory status of neighbouring countries were stressed as key starting point of cooperation.

Concluding Session of the Workshop

79. On 22 October 2003, the Workshop held its concluding plenary session.

Expectations and Concerns – Revisited

80. At the closing session of the Workshop, Mr. Mohamed invited the participants to again go through the list of expectations and concerns that they had drawn up at the very opening of the Workshop four days previously, to see which of them had been met or not. Participants acknowledged that some of the things were still at the starting point and were not discussed or worked on in detail during this workshop. The results of the feedback from participants for the expectations and concerns are given in Annex IV.

Evaluation Exercise and Closure of the Workshop

81. Mr. Mohamed informed participants that their comments on the Workshop would provide important feedback to help the Biosafety Team further refine the process, and invited them to complete the evaluation form provided for the purpose. The results of the evaluation by participants is given in the evaluation report in Annex VIII.

Closure of the Workshop

82. After a closing speech by the Director of the Department of Environment in Fars province, Mr. Briggs, on behalf of the Biosafety Team, thanked all participants for their hard work. He expressed his particular appreciation for the Government of the Islamic Republic of Iran and the Fars province for hosting the Workshop and for their hospitality, and thanked all who had participated and who had worked in front of, and behind the scenes. In return, the participant of Iran thanked the UNEP-GEF team and the resource persons. After the customary exchange of courtesies, the Workshop was closed at 5.30 p.m. on Wednesday, 22 October 2003.

Annex I: List of participants

(intentionally removed from this report published on the web)

Annex II: Workplan

Asia Workshop on developing a Regulatory Regime and Administrative Systems for National Biosafety Frameworks (NBFs)

Shiraz, Iran 19-22 October

Day 1

08.30	Start of workshop
8.30 – 8.40	Introduction to workshop
	Ground rules for workshop
8.40 – 9.20	Introduction of participants
9.20 – 9.30	Expectations and concerns
9.30 – 10.10	Official opening of workshop - Welcome speech by UN Resident Coordinator in I R Iran - Speech by the Governor of Fars province - Opening speech by H E Dr Ebtekar, Vice-President, I R Iran
10.10 – 10.30	Coffee break
10.30 – 10.50	Introduction to the UNEP-GEF Global Biosafety Development Project and Implementation projects
10.50 – 11.10	Introduction to CBD Art. 8g and 19, and the Cartagena Protocol on Biosafety
11.10 – 11.30	Overview of key components of National Biosafety Framework
11.30 – 12.15	Plenary discussion
12.15 – 14.00	Lunch
14.00 – 14.20	Overview of regional experiences on NBF development
14.20 – 15.00	Four country presentations
15.00 – 16.00	Plenary discussion on regional experiences with NBF
16.00 – 16.20	Coffee break
16.20 – 16.50	Introduction to national obligations and rights under the Cartagena Protocol
16.50 – 17.10	Introduction to other international instruments and to national obligations and rights that may affect NBF regulatory systems
17.10 – 17.40	Plenary Discussion
17.40	Close of Day 1
19.30	Dinner hosted by Governor or of Fars province

Day 2

08.00 – 09.30	Elements of a regulatory regime - presentations
09.30 – 10.30	Focus group discussions

10.30 – 11.00	Coffee break and viewing of focus group outputs
11.00 – 12.00	Plenary discussions and summing up
12.00 – 13.00	Lunch break
13.00	Departure for field excursion to cultural site – Persepolis
18.30	Dinner hosted by UNEP-GEF project

Day 3

08.30 – 09.10	Presentation on Operational provisions
09.10 – 09.50	Plenary discussion with examples from Asia
09.50 – 10.00	Summing up of discussions
10.00 – 10.20	Coffee break
10.20 – 11.00	Introduction to other elements
11.00 – 12.00	Focus group exercise on other elements
12.00 – 12.30	Plenary discussions
12.30 – 14.00	Lunch break
14.00 – 14.40	Choices on a regulatory regime
14.40 – 15.40	Plenary discussion
15.40 – 16.00	Coffee break
16.00 – 16.30	Introduction to Administrative systems
16.30 – 17.30	Focus group discussions
17.30 – 20.00	Dinner Break
20.00 – 21.30	Presentations on different approaches by countries and other stakeholders

Day 4

08.30 – 08.45	Report back from Day 3 focus groups
08.45 – 09.15	Plenary discussion and summing up
09.15 – 09.30	Flow chart for decision-making from risk assessment and management workshops
09.30 – 10.00	Plenary discussion on flow chart
10.00 – 10.20	Coffee break
10.20 – 10.50	Introduction to Administrative systems
10.50 – 11.50	Focus group discussions
11.50 – 12.20	Plenary discussion
12.20 – 14.00	Lunch break
14.00 – 14.10	Brainstorming to identify cross-cutting issues
14.10 - 15.10	Focus group discussions
15.10 – 15.30	Coffee break

15.30 – 16.00	Plenary on focus group discussions
16.00 – 16.40	Sub-regional cooperation – panel discussion
16.40 – 17.00	Responses to 'Expectations and concerns'
17.00 – 17.10	Evaluation and
17.10 –17.20	Closure of workshop

Annex III: Ground rules

The following four major pillars of ground rules were agreed:

1. Courtesy
2. Respect
3. Assertiveness
4. Trust

Annex IV: Expectations and Concerns

Outcome from the Workshop

Expectations	Concerns
Learn about other countries experiences in developing or implementing regulatory regime ***	Time too short to develop NBF+
Learn about experiences of other countries in the region in developing (or that have completed) their NBF ***	
Learn how to work with neighbouring countries and develop sub-regional cooperation**	
How to start NBF project***	
How to move from Phase 0 to Phase +	
What to consider in developing an NBF (with reference to risk assessment, public participation and socio-economic issues) *	
Share experiences on NBF***	
NBF developed as a country-driven process**	
How to develop risk assessment guidelines+	
Tools for NGOs to participate+	
How to implement and enforce regulation***	
Learn about other international agreements**	

Notes

*** Indicates that participants judged that their expectations were met to their satisfaction;
** Indicates that participants judged that their expectations were met partially
* Indicates that participants judged that their expectations were not met to their satisfaction.
+ Issues not addressed by the workshop

Annex V: Exercise on the essential elements of a national biosafety regulatory regime

Focus group outputs

Questions:

i. What are the possible national objectives of a legal framework addressing biosafety?

ii. For each listed objective, identify:

- Priorities (essential? Or optional? And why?)
- Impact of including or excluding this objective?

iii. Starting from the minimum scope, what are the positive and negative impacts of enlarging the scope to address issues or objectives listed in 1 or 2 above?

Focus Group 1

(essential):

1. Protection of plant, animal, human health, environment and biodiversity, sustainable development, in ethically and socially justifiable way
2. Safe use of biotechnology

(optional):

1. Capacity-building
2. Equal distribution of benefits
3. Enhance cooperation
4. Protection of local products
5. Conservation

Why

1. Protection should be primary concern
2. Protection of local products
3. Ensure safety of new technologies

Impacts of enlarging the scope

1. Clearer (+)
2. Most of the optional objectives actually can be considered included in (1) or (2)

Focus Group 2

Question 1

- Environmental protection (maintenance, biodiversity, precautionary)
- Human health
- National welfare (social aspect, economic aspect)
- Safe use of biotechnology
- Sustainable development (present generation, future generation)
- To promote biosafety

Question 2: priority

- Environmental protection
- human health
- national welfare

Why?

- Our existence depends on environment
- Economic development will not be sustained
- Elements of sustainable development

Question 3
(negative)

- If objective is too large, regulation can't cover all of the elements
- If too large, not focussed
- If too large, need additional resources

(positive)

- Enlarged scope will help to get vision in the future
- Enlarged scope can accommodate other agreement i.e. WTO
- Can improve environmental protection and human health
- Can regulate domestic activities, i.e. research & development.

Focus Group 3

Question 1 & 2: National objectives

1. Safety – protection of human health
2. Conserve biodiversity
3. Protection of environment
    - Protection from imports
    - Protection from local GMOs
    - Control of hazards in labs
    - Consider exports
    - Public participation
    - Control adverse effects of LMO
    - Safe handling…
    - Precautionary approach
    - Regulating use of GMOs in agriculture

Question 3:

	Impact include	Impact exclude
1. Biodiversity	Conserve	Loss of biodiversity Invasive Pollution Weediness
2. Human health	Prevent unknown adverse effects Explore new treatments	New problem occur (allergen, toxins)
3. Environment	Prevent deterioration	Containment Pollution Lab-hazards
4. Protection from imports	Regulate imports	Unknown imports

Focus Group 4

Objective:
To regulate:

- Transboundary movement of GMO & product of GMO
- Release of GMO into the environment
- Handling & use & transportation of GMO & product of GMO
- Contained use of GMO
- Invasive alien species

To reduce risks to human health, protection of the environment & biodiversity

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Focus Group 5

Objective (possible)

1. Protection of biodiversity
2. Protection of environment
3. Protection of human health
4. Ethical issues
5. Trading in GMOs
6. Safe use of biotechnology

Essential	Optional	Why?
protection of biodiversity		Sustainable use of biodiversity Conservation of GR
	Protection of environment	Small-scale
Human health		Humans are the main concern
	Ethical issues	Respect the people's beliefs
Trading		
Safe use of biotechnology		

Protection of environment

Negative & Positive: complimentary/conflict of existing laws
Positive: NBF will capture the unique characteristics of each country

Ethical

Positive: NBF will capture unique national characteristics
Negative: discourages development of the technology
Positive encourage development of technology
Negative: difficult to implement
Negative: difficult for harmonisation/collaboration

Focus Group 6

Objective of the legal framework

- Ensuring public health and safety
- Protecting the environment and conservation of natural resources
- Maximise benefits and minimise risks arising from modern biotechnology

By means of:

- Regulating (controlling), dealing, transporting, transboundary movements and use of LMOs and products thereof; contained use and release into the environment as well as design and performance of biotechnology experiments

Note:
In special cases, identification of LMOs, capacity-building and public awareness may constitute the parts of the objectives.

Annex VI: Exercise on the other elements of a national biosafety regulatory regime

Focus group outputs

Group 1: Enforcement

K*ey issues*

- Capacity and infrastructure
- (Balancing biotechnology vs. biosafety)
- Administrative systems (including competent authority/ies)
    - coordination
    - penal code (corruption)
    - violation
    - decision-making
    - etc.
- Awareness, education and participation
- Implementation systems
- Legislation
- Finance
- Labelling and traceability

Lessons learnt

- "Illegal " releases of LMOs
- How to deal with stakeholders (NGOs, churches, industry, etc.)
- "Escape" of GMos (LMOs) into the environment
- Lack of proper and timely monitoring
- Illegal domestic development and production of LMOs
- Preparedness and emergency measures
- (Risk) management options
- Impacts to beneficial organisms
- Crossing and hybridisation with related native plants/animals
- Amendment and revision (law, guidelines, etc.)
- Magnitude of task dealing with labelling

Group 2: Enforcement

- Appointment of enforcement authorities
    - Who appoints?
    - New authority vs. existing authorities (agriculture, forestry, food, health, environment, etc.)

- Terms of reference for enforcement authority:
    1. Power to investigate
    2. Power to enter and inspect (with and without warranty)
- Search
- Sampling
- Power to prosecute (sanction of AG/PP)
- Penalties

Monitoring

1. periodical reporting
2. review of decision

Group 3: Liability and Redress

Key issues

1. Items not under the Protocol
2. Basis or components to measure redress
3. Liability to whom? Redress to whom?
4. Non-Party liability
5. Long-term effects – who is liable after approval?
6. Strict liability
7. Shared responsibility
8. Transfer of liability
9. Liability for illegal/accidental movement of LMOs
10. Procedures to prove liability, i.e. use of laboratories, research institutes, experts
11. Retroactivity
12. State liability

Lessons Learnt

1. LMO product liability should be included especially when dealing with developing countries
2. A guarantee fund
3. Protection of traditional/indigenous species/strains and farming systems, cultural and social systems
4. Traceability and labelling in connection to liability
5. Reward system

Group 4: Liability and Redress

1. *Key issues*
   - International (state) liability
   - Corporate liability
   - Liability to individuals
   - Liability to State

   Legal "nature" of liability - Strict vs. "ordinary"
   - Strict liability: eliminates problems of governments' burden of proof
   - Existence of harm/link to defendant covered by "normal" environmental and biomedical jurisprudence

   Different recovery for categories of defendants

2. Who can claim damages for harm to biodiversity?
   - For harm to biodiversity?
   - For community/social harm?
   - Government only? NGOs? Legal/natural person?

3. What about harm to protected area (for example) caused by another Ministry's approval of introduction?
   - Where "cause" is insufficient information?
   - Where sufficient AIA?

4. How does international liability relate to domestic?
   - Bilateral liability agreement with trade partners?

5. Control of use after permit – planting of LMO-FFPs

Group 5: Confidentiality, access to information and public involvement

Key issues:

- Mechanisms
- Representation of the public (stakeholders, definition of public)
- Necessity for public involvement
- Kind of information to be divulged to public
- Mechanisms (effectiveness?)
  - Practice, attitude and knowledge
  - Use of BCH (national focal points)
- Tools for public participation
  - Media (education; radio and TV; journalism)
  - workshops
- kind of information…
  - criteria
- NGO involvement
- Feedback mechanism from public (e.g. websites)
- Involvement of relevant institutions
- Budgetary provisions to undertake the activities
- Participatory decision-making
- Capacity to run the system
- Importance of KT

Lessons learned

- In terms of confidentiality, take into consideration national laws, negotiations with country decisions
- IPR consideration in confidentiality issue
- Develop mechanism to check accuracy of information
- Newspaper publication (2 consecutive weeks) posting of project information sheet in strategic areas where field test will be carried out
- Public involvement should have timeline
- No limit for tools for public involvement, but limiting factor is budget

Group 6: Confidentiality, access to information and public involvement

1. LCD/information communication technology
2. Mass media
3. Technology transfer
4. Public information centre
5. Market information
6. Information disseminations
   - Publications
   - Study tours
   - Workshops
   - Training
   - Seminars
7. Labelling
8. Capacity building
9. Transparency
10. Accountability

11. BCH
12. Awareness raising
13. Degree of confidentiality
14. Coordination among public/private/academic stakeholders

Lessons learned

1. Low effectiveness and efficiency of public involvement
2. Low participation of all stakeholders because of lack of information
3. "Bottom-up" approach has been effective
4. Lack of information for consumers
5. Lack of training of trainers
6. lack of technical knowledge on biosafety -> improvement is needed
7. limitations of capacity-building on:
   - HRP including managers
   - Facility
   - Financial resources
8. ***Regional/international cooperation necessary for NBF development (information-sharing)

Annex VII: Exercise on the administrative systems of a national biosafety regulatory regime

Analysis of the ICCP "Implementation Toolkit"- Focus group outputs

Focus Group on Reporting requirements

1. Status:

Our group composed of representatives from the Islamic Republic of Iran, Sri Lanka, Bhutan, Laos, Thailand, and the Philippines. We discussed the basic requirements, specifically Articles 17, 19, 20 of the Cartagena Protocol that need to be complied with by the Parties, prior to its entry into force on 11 September 2003.

Based on the discussions that ensued, it became apparent that very little has been done to comply with these obligations. The most that these economies have accomplished so far was the designations of national focal point and national competent authorities. I said authorities because in the case of the Philippines, there are four representing the science sector, agriculture, environment and health.

We somehow managed to achieve certain level of compliance despite the lack of resources, as most economies have in place steering/national committees that addresses work on genetic engineering and set up policy on biosafety. But it is not clear as to whether or not these committees are indeed the legal authority to implement and monitor compliance with these obligations.

On the key issues identified during the discussions that led to the delay in compliance is that various economies have varying approaches and that there is lack of coordination between and among the concerned agencies, in most cases nobody knows who should be the focal point and in some, everybody wants to be the leader.

2. What needs to be done:

There is a need to establish a well-coordinated procedural mechanism for coordination at various levels to ensure that the obligations of the Protocol are complied with.

To be candid about it, these activities will need financial resources. Also there is a need to establish the BCH.

Focus Group on Risk Assessment

1. Status of Risk Assessment in countries: From 15 countries 8 in place, 7 no system.

Country	Status	Comments
Indonesia	In place	
Iran	No system	No imports
Myanmar	No system	

Bhutan	No system	RA in other areas
Mongolia	No system	
R of Korea	In place	
Bangladesh	In place	As guidelines, to be completed
Sri Lanka	No system	
DPR Korea	No system	
Philippines	In place	
Viet Nam	In place	
Cambodia	In place	For food only
Lao	In place	
Syria	In place	Draft guidelines
Nepal	No system	

2. What needs to be done and how?

- Lobby /awareness programme for policy makers in order to ensure that they understand and support the development of biosafety policy
- Establish/development of scientific standards and norms
- Development of policies and regulations, guidelines (including definitions)
- Establish/nominate governmental competent authority (authorities) with clear responsibilities
- Establish independent biosafety scientific committee (advisory body)
- Capacity building, including training for risk assessors and trainers of risk assessors
- Capacity building in terms of scientific and technical expertise
- Coordination among in-country institutions
- International cooperation for exchanging experience of risk assessment, including cooperation with non-parties, including assistance from international institutions
- Establish networking
- Evaluation/ long-term monitoring of RA procedures (Periodic review of the system)
- Financial support

<u>Focus group on promotion and facilitation of public awareness, education and participation concerning the safe transfer, handling and use of LMOs, taking also into account risks to human health</u>

Promote and facilitate public awareness and education: current status

- Create inter-agency NCC to ensure active participation of stakeholders in the NBF development process, and in building awareness among agencies (e.g. Technical Working Group on Public Awareness)
- Coordinate with concerned Ministries (e.g. education)
- Promote biotechnology and biosafety
- Establish national internet-based BCH

- Use of websites, mailing lists, TV, printed materials (books, newspapers, posters, pamphlets, brochures, etc.)
- Biosafety Day
- Conduct orientation-seminars and workshops
- Involve various stakeholders (national scientific associations) to raise level of awareness
- Promote awareness through formal education (e.g. inclusion in school curricula in high school and university levels)
- Stakeholder consultation

Public Participation: current status

- Consumer associations
- National Biosafety Committee
- National Competent Authority
- National Committee of all stakeholders
- Major stakeholders (government, academe, industry, civil society, etc.)

What needs to be done and how it might be done

- Establish BCH
- Establish capacity (e.g. train staff, build appropriate infrastructure)
- Prepare and integrated and comprehensive public awareness campaign for stakeholders (e.g. Local councils, religious leaders)
- Train trainers
- Disseminate information publicly
- Use of questionnaires to solicit public opinion

Annex VIII: Workshop Evaluation by Participants

Introduction

The Asian Countries Subregional Workshop on the development of a regulatory regime and administrative systems, was held from 19 to 22 October 2003 at the Homa Hotel, Shiraz, I R Iran. The Workshop was convened by the UNEP/GEF Biosafety Project Team, in collaboration with the Government of the I R Iran.

At the end of the workshops, participants were asked to evaluate the workshops both in terms of the expected results from the workshop and in terms of workshop organisation and design. The purpose of the evaluation by participants was to:

1 Provide feedback to the Biosafety team on the workshop so that the lessons learned, in terms of content and format, could be used to improve the design of future workshops;
2 Provide an assessment by participants of the quality of the inputs from the Biosafety team;
3 Enable the Biosafety team to assess the extent to which the workshop achieved its stated objectives;

Methodology

The form used for evaluation (see below) of the workshop asked participants to give a quantitative indication, on a scale of 1 to 6, of their assessment of:

1 The expected results from the regulatory regime and administrative systems workshop, Section A, questions (i) to (x).
2 An overall assessment of the workshop, Section B, questions (i) to (ix).

The rating for each question, on a scale of 1 to 6, was converted to a percentage figure based on the mean of all the responses for that particular question. This figure, in conjunction with the range of scores for each question, gave an indication of the overall assessment by participants for each of the questions. The assessment was graded as follows:
>80% - excellent / very useful
75-80% - very good / useful to very useful
70-75% - good / useful.

In addition, participants were also asked to give a short written assessment of the overall workshop. This allowed them the opportunity to comment on any aspect of the workshop. All evaluation forms were anonymous so that respondents were free to give their honest opinion of the workshop.

Results

The overall evaluation by participants of the workshop was very good, with an overall rating of 77% (±3%), and all participants gave positive feedback on the contents and organisation of the workshop. The results also showed that participants considered the workshop to be successful in achieving the expected results in terms of learning about the development of a regulatory regime and administrative systems for their NBF.

Nearly 80% of respondents answered the assessments carefully, assigning scores that showed significant variation between their answers to different questions. This indicated that participants had thought through the questions before assigning scores to each of the questions. However, comparison of the variation within the answers from each respondent showed that 15 participants (approximately 20% of the total) gave scores whose variation was significantly less than the average. This result indicates that these 15 respondents may not have carefully considered their

responses to each question (for whatever reason) and had assigned scores without a thorough assessment of their response to the question. This introduced a source of error to the evaluation; however, since only 20% of respondents were affected, this is unlikely to make a significant difference to the overall results of the evaluation.

The results for the technical and overall assessments are discussed below under Parts A and B; this is followed by a discussion of the written comments from participants.

Part A: Regulatory and Administrative Issues

The evaluation of this workshop is discussed under each of the ten questions in the evaluation form (see annex IX). These questions are based on the expected results from the workshop as formulated by the biosafety team. The numerical results are also summarised in a chart (Figure 1).

The overall rating for the technical aspects of the workshop was 76% ±3; this indicated a high level of satisfaction by participants of the technical content of the workshop. The results for individual areas of the workshop are discussed below under each question (see Figure 1 below):

(i). Improved understanding of national rights and obligations under the Cartagena Protocol and other international agreements that may impact on an NBF.
The purpose of this question was to find out if participants had improved their understanding of the national rights and obligations resulting both from the Cartagena Protocol and other relevant international agreements. This is an important aspect of the training and was designed to help participants see the development of their regulatory regime within the broader context of relevant international agreements, and was therefore carried out in the early stages of the workshop. This question received a rating of 75% ±16% indicating that most participants found this aspect of the workshop to be useful to very useful.

(ii). Improving your understanding of the specific needs of your country in terms of national priorities and policies in setting up the regulatory regime and administrative systems for your NBF.
The purpose of this question was to see if participants were able to better understand the need to develop their biosafety regulations within the overall context of their national priorities and policies. Although there was no specific part of the training that addressed this aspect, both the session on regional experiences and focus group discussions allowed participants an opportunity to discuss this topic. The responses to this question gave a rating of 76% ±16% indicating that again participants found the workshop to be useful in improving their understanding of the national policy context in developing their NBF.

(iii). Improved understanding of what are the main elements of a regulatory regime for an NBF.
This question addressed one of the main aims of the entire workshop, i.e. whether participants had improved their understanding of the main elements of a regulatory regime that they would need to include in their NBF. An understanding of the overall concept of the regulatory regime is necessary if participants are to develop the specific provisions needed for a workable regime. The rating given by participants for this aspect of the training was very good at 80% ±16%, indicating that most participants found the workshop to be very useful in improving their understanding of this crucial aspect of the training.

(iv). Improved understanding of the different approaches that can be taken in developing a regulatory regime for an NBF.
This question was designed to find out if participants considered that the presentation at the workshop and the plenary discussions on this topic had given them a better understanding of the

choices involved. The results showed that the respondents gave a rating of good to this question, 76%±17%.

(v) Improved understanding of what General provisions that need to be included in the regulatory regime of an NBF.
This question sought to find out whether participants thought that the presentation on the general provisions that needed to be included in their regulatory regime and the subsequent focus group discussions had helped them to understand what general provisions they needed to include in their draft regulations. The results indicated that participants found this session to be useful, with a score of 75% ±17%.

(vi) Improved understanding of what Operational provisions need to be included in the regulatory regime of an NBF.
This question sought to find out if participants had found this session, the presentation plus the plenary discussions, to be useful in improving their understanding of the operational provisions in a regulatory regime. The score for this session was slightly higher at 78% ±17%, indicating that participants had found the session to be useful to very useful.

(vii) Improved understanding of what other elements or consideration need to be included in the regulatory regime of an NBF.
This question addressed the next session of the workshop which included both a presentation on the subject and focus group discussions, The results, 77% ±16% indicated that participants found the session to be useful to very useful in improving their understanding of this subject.

(viii). Improved understanding of the linkages between a regulatory regime and administrative systems in an NBF.
The purpose of this session was to help participants to understand the linkages between the regulatory regime and the administrative system in formulating their NBF; this session was intended to provide the interface between the two topics covered by the workshop. The results showed that respondents gave a rating of useful, 75% ±14%, to this session.

(ix) Improved understanding of the legal and administrative requirements for AIA in your NBF.
This question sought to determine whether participants had improved their understanding of the legal and administrative requirements for AIA in their NBF. The responses to this question showed that participants found the session to be only useful in improving their understanding of requirements for AIA, with the lowest rating for any question at 71% ±18%. These results, supported by the results of the exercise on AIA and FFP (see main report) indicate that participants find this complex topic hard to understand and that this session of the workshop needs to be strengthened.

(x). Improved understanding of the legal and administrative requirements for Article 11 (FFP) in your NBF.
This question addressed the parallel issue of FFPs and whether participants felt that they had improved their understanding of the legal and administrative requirements for Article 11 on FFPs. The results surprisingly showed a higher rating of useful to very useful for this session – a rating of 79% ±16. The results indicate that although participants had found the presentation on this subject to be more useful than that on AIA, there was still some misunderstanding about the differences between AIA and FFP as shown by the results of the exercise on FFP (see text of main report).

Figure 1: A - Regulatory & Administrative Issues

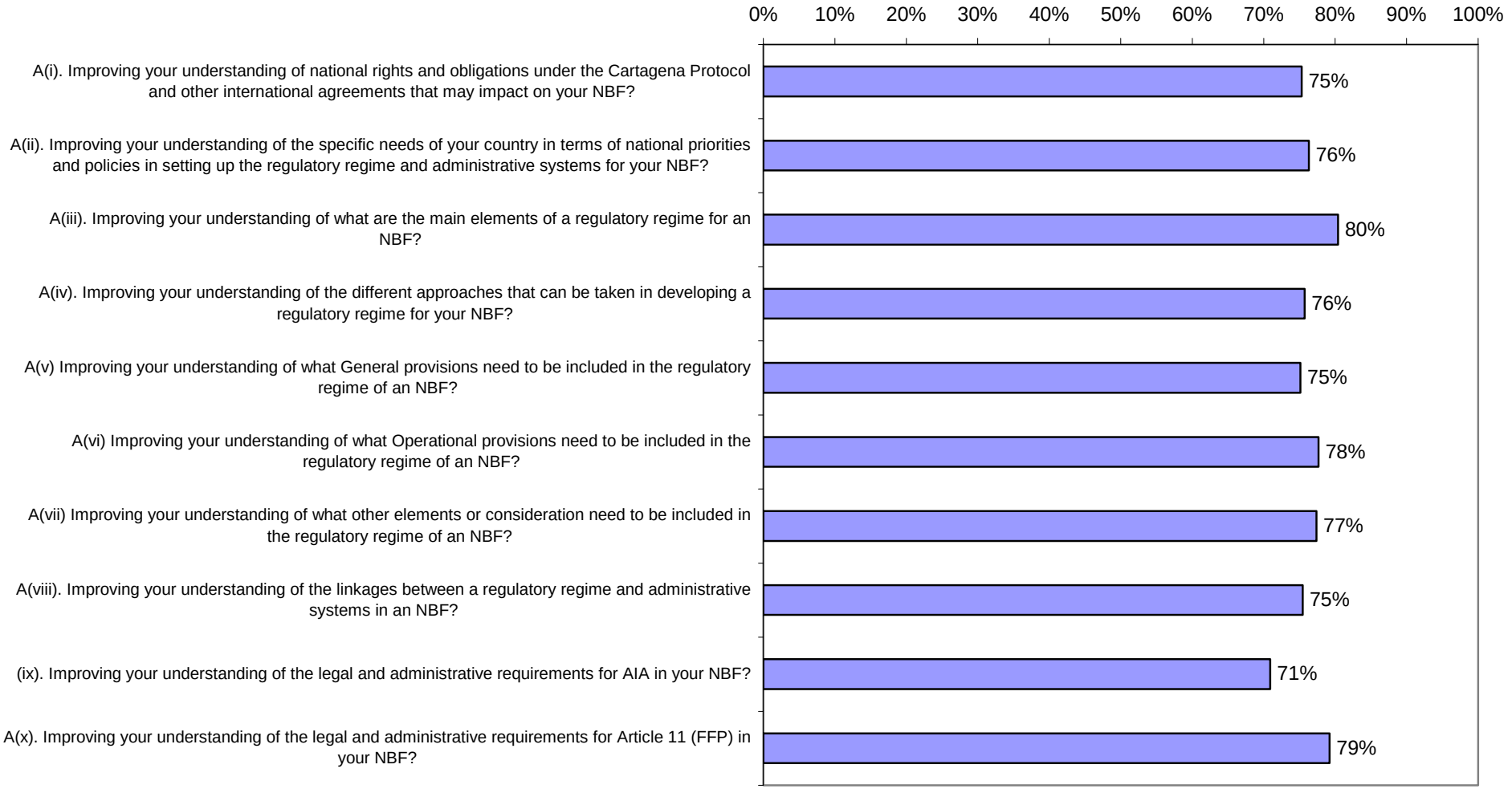
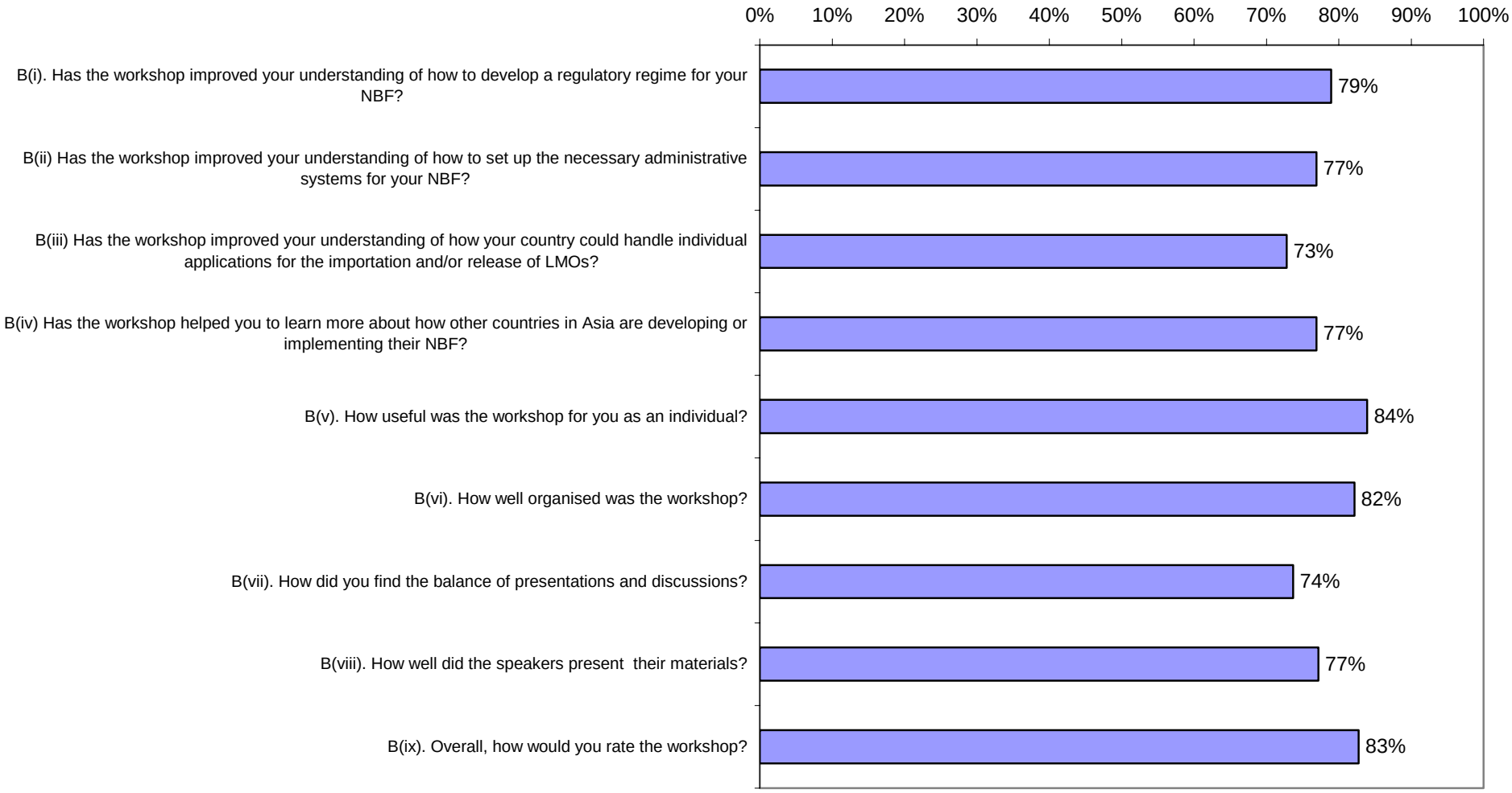


Figure 2: B - Overall Workshop Assessment



Part B: Overall workshop assessment

The evaluation of this workshop is discussed under the nine headings based on the nine questions in the evaluation form (see annex IX). These questions are based on the expected results from the workshop and are intended to give the participants' evaluation of the overall workshop, as well as focusing on its organisation. The overall assessment of78% ±4% indicating a high level of satisfaction with the workshop as a whole, including its organisation and the participants' assessment of the overall contribution of the workshop to their understanding of their NBF.

The numerical results are also summarised in a chart (Figure 2).

(i). Improved understanding of how to develop a regulatory regime for an NBF.

This question sought to find out if participants considered that the workshop had managed to achieve one of its major aims, i.e. to help them improve their understanding of how to develop one of the pillars of their NBF, a regulatory regime. The responses to this question indicated that participants had found the workshop to be very useful in improving their understanding of this concept, with a rating of 79% ±16%. Thus the workshop was successful in achieving one of its main aims.

(ii) Improved understanding of how to set up the necessary administrative systems for an NBF.
This question sought to find out if participants considered that the workshop had managed to achieve its other major aim, i.e. to help them improve their understanding of how to develop one of the pillars of their NBF, an administrative system. The responses to this question indicated that participants had found the workshop to be useful to very useful in improving their understanding of this concept, with a rating of 77% ±15%. Thus the workshop was successful in achieving its second main aim.

(iii) Improved understanding of how a country could handle individual applications for the importation and/or release of LMOs.
This question addressed a practical outcome of the workshop, i.e. whether participants had found that the workshop had helped them to better understand how their NBF systems would work in practice. There was no session specifically designed to address this aspect in the workshop as this was intended as one of the practical outcomes of the entire workshop. The results showed that the rating was significantly lower at 73% ±14% indicating that participants found that the workshop was only useful in improving their understanding of how to handle applications for import and/or release.

(iv) Helped participants to learn more about how other countries in Asia are developing or implementing their NBF.
This question addressed one of the main objectives of the workshop, which was to promote an exchange of experiences between countries in Asia on the development of their NBF. The intention had been to provide a forum for exchange of experiences throughout the workshop by allowing participating countries to discuss their own experiences in order to illustrate various points raised by the presenters. The results showed that the participants found the workshop to be useful to very useful in promoting this exchange of experiences and gave a rating of 77% ±16%.

(v). How useful was the workshop for you as an individual?

This question sought to find out if participants had found this workshop to be useful to them as individuals. This is an assessment of the workshop from their viewpoint as individuals and is in many ways one of the most important questions in evaluating the overall success or otherwise of the workshop. The participants gave this question the highest rating of any for this workshop at 84% ±17%, indicating that participants had found the workshop very useful to them as individuals

(vi). How well organised was the workshop?
This question addressed the organisational aspects of the workshop rather than the technical inputs and discussions. The overall rating for this question was 82% ±20%, indicating a high level of satisfaction for the organisation of the workshop as a whole. The standard deviation of ±20% in responses indicates that there was a significant degree variation in the responses to this question, indicating that some participants had indicated a higher level of satisfaction whilst some others had been less satisfied.

The results for this question is a compliment to both the Iranian hosts for the workshop organisation team for their excellent efforts in organising the workshop and facilitating the travel of participants, as well as selecting an excellent venue for the workshop.

(vii). How did you find the balance of presentations and discussions?
This question was designed to address one of the main features of an interactive workshop, i.e. the balance between presentations to convey difficult concepts and discussions to draw out experiences and opinions from participants. The results indicated that participants found this aspect to be only useful with a rating of 74% ±18%. These results indicate that this aspect of the workshop would need to be strengthened in future workshops.

(viii). How well did the speakers present their materials?
This question asked participants to assess the speakers in terms of how well they presented their materials in order to provide feedback on the quality of the presentations. The results indicated that participants rated this aspect at 77% ±16% indicating that they found the presentation materials to be useful in helping them to understand the concepts.

(ix). Overall, how would you rate the workshop?
This final question sought an general evaluation of the workshop as a whole from the viewpoint of the participants. This question received the second highest rating of any of the questions, 83% ±14%, indicating that most of the participants found the workshop to be very useful. These results indicate that participants, as the intended clients, gave the entire workshop a rating of excellent.

Written comments from participants

Participants were asked to provide written comments on the workshop in order to enable a more qualitative assessment to support the quantitative evaluation. This assessment focussed on three questions and the responses from participants are summarised below under each of the questions.

(i) What did you consider to be the most helpful part of the workshop?

A number of participants gave examples of what they found to be the most helpful about the workshop, commenting on various aspects of the workshop. The most common comment was about the contents of the sessions on the regulatory regime; 15 respondents (i.e. 20% of the participants commented specifically on how much they like these sessions on the regulatory regime. These comments were made in the context of the treatment of the regulatory regime in developing the NBF. One participant commented that:

"Opportunity to learn about how NBFs are developed in a systematic manner"

A number of participants expressed their appreciation of the quality and clarity of the presentations; specific praise was given to the presentations by all three of the main presenters, David, Julian and Tomme; this supported the quantitative evaluation in question B (viii) above.

Another aspect of the workshop that gave rise to the most positive comments were the focus groups, which were mentioned specifically by 9 respondents indicating the popularity of this methodology. The sharing of experiences with other countries was also mentioned as a positive aspect of the workshop by a further 9 participants; this supported the quantitative evaluation in question B (iv) above.

(ii). What did you find the least helpful about the workshop?

Fewer specific comments were made in this section. Some comments mentioned the absence of specific training in risk assessment (not one of the objectives of the workshop) while others spoke of more relevant shortcomings such as the lack of practical examples in some presentations, and the absence of hands-on training. At least one respondent asked for more time for country presentations whilst another complained about the length of presentations. The most common complaint was about the travel arrangements where a number of participants mentioned long transit times and the difficult routings for people.

(iii). What suggestions do you have for improving future workshops?

Participants made a number of suggestions for improving the workshop. Specific suggestions included:

- Improved travel and logistical arrangements, selecting a venue that is easier to reach for all countries in Asia (4 respondents);
- Reducing the length of sessions so as to allow more time for discussions in focus groups and presentations of the results of focus groups;
- More hands-on training working through practical examples;
- Handouts for presentations should be given out before the presentations;
- More time for discussion of country experiences (10 respondents) and more practical examples of case studies to illustrate various points:

"I think future workshops should be oriented to presentations with as many practical examples and case studies as possible"

I. Conclusions

The evaluation of the workshop by participants indicated that, from their perspective, the workshop was successful in achieving its main aims in promoting their understanding of how to develop the regulatory regime and administrative systems for an NBF. In particular, the assessment of the workshop in terms of its usefulness to participants was high as was the overall organisation of the workshop.

However, there were certain aspects of the technical contents and organisation of the workshop that need further strengthening in future workshops:

- The assessments indicated that the administrative aspects of the NBF were not covered as well as the regulatory aspects and the balance between these two components will need to be looked at closely in developing this series of workshops.
- Many participants were not clear about the differences between the procedures for AIA and FFPs (as shown by the exercise on drawings of procedures for FFPs, and this session will need to be revised and strengthened for future workshops.
- The use of practical examples and case studies, particularly from the region, will need to be improved so that concepts are illustrated by examples that are meaningful to participants.
- Although this workshop included more case studies and sharing of regional experiences, this still needs to be further strengthened, particularly through greater involvement of regional resource persons.
- The quality of presentations was praised by a number of participants but consideration should be given to complementing these presentations with more regional experiences, perhaps by calling on participants with experience in developing their national regulatory systems to contribute their experiences. This would require a more interactive approach to presentations rather than the current practice of formal presentations followed by a discussion session.

Annex IX: Workshop Evaluation Form

UNEP-GEF Biosafety Sub-Regional Workshop on the Development of a Regulatory Regime and Administrative Systems for National Biosafety Frameworks (NBFs) for Asia

Homa Hotel, Shiraz, I. R. of Iran, 19-22 October 2003

Instructions:

1. Please take a few minutes to help us to evaluate our workshop by answering the following questions.
2. *In each case, indicate your answer by **circling the number** which best describes your assessment of the workshop.*

Part A: Regulatory and Administrative issues

On a rating of 1 to 6, assess how useful the workshop has been in::

(i). Improving your understanding of national rights and obligations under the Cartagena Protocol and other international agreements that may impact on your NBF?	1 2 3 4 5 6 Not Useful Useful Very Useful
(ii). Improving your understanding of the specific needs of your country in terms of national priorities and policies in setting up the regulatory regime and administrative systems for your NBF?	1 2 3 4 5 6 Not Useful Useful Very Useful
(iii). Improving your understanding of what are the main elements of a regulatory regime for an NBF?	1 2 3 4 5 6 Not Useful Useful Very Useful
(iv). Improving your understanding of the different approaches that can be taken in developing a regulatory regime for your NBF;	1 2 3 4 5 6 Not Useful Useful Very Useful
(v) Improving your understanding of what General provisions need to be included in the regulatory regime of an NBF?	1 2 3 4 5 6 Not Useful Useful Very Useful
(vi) Improving your understanding of what Operational provisions need to be included in the regulatory regime of an NBF?	1 2 3 4 5 6 Not Useful Useful Very Useful
(vii) Improving your understanding of what other elements or consideration need to be included in the regulatory regime of an NBF?	1 2 3 4 5 6 Not Useful Useful Very Useful
(viii). Improving your understanding of the linkages between a regulatory regime and administrative systems in an NBF;	1 2 3 4 5 6 Not Useful Useful Very Useful
(ix). Improving your understanding of the legal and administrative requirements for AIA in your NBF?	1 2 3 4 5 6 Not Useful Useful Very Useful
(x). Improving your understanding of the legal and administrative requirements for Article 11 (FFP) in your NBF?;	1 2 3 4 5 6 Not Useful Useful Very Useful

B: Overall workshop assessment:

Please rate the overall workshop on a scale of 1 to 6 by circling the appropriate number:

(i). Has the workshop improved your understanding of how to develop a regulatory regime for your NBF?	1 2 3 4 5 6 Not Useful Useful Very Useful
(ii) Has the workshop improved your understanding of how to set up the necessary administrative systems for your NBF?	1 2 3 4 5 6 Not Useful Useful Very Useful
(iii) Has the workshop improved your understanding of how your country could handle individual applications for the importation and/or release of LMOs?	1 2 3 4 5 6 Not Useful Useful Very Useful
(iv) Has the workshop helped you to learn more about how other countries in Asia are developing or implementing their NBF?	1 2 3 4 5 6 Not Useful Useful Very Useful
(v). How useful was the workshop for you as an individual?	1 2 3 4 5 6 Not Useful Useful Very Useful
(vi). How well organised was the workshop?	1 2 3 4 5 6 Not Useful Useful Very Useful
(vii). How did you find the balance of presentations and discussions?	1 2 3 4 5 6 Not Useful Useful Very Useful
(viii). How well did the speakers present their materials?	1 2 3 4 5 6 Not Useful Useful Very Useful
(ix). Overall, how would you rate the workshop?	1 2 3 4 5 6 Not Useful Useful Very Useful

Your personal comments on the Workshop:

(i). What did you consider to be the most helpful part of the workshop?

(ii). What did you find the least helpful about the workshop?

(iii). What suggestions do you have for improving future workshops?

Please hand your completed form to one of the organisers before leaving the room. Thank you