E/CN.16/2001/Misc. 2
26 April 2001

ENGLISH ONLY

COMMISSION ON SCIENCE AND TECHNOLOGY
FOR DEVELOPMENT
Fifth session
Geneva, 28 May–1 June 2001

PANEL ON LEGAL AND REGULATORY ISSUES IN BIOTECHNOLOGY

3 - 5 July 2000
Geneva

Summary report by the UNCTAD Secretariat*

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* This paper summarizes the panel's discussions; it does not necessarily reflect the views of the UNCTAD secretariat.

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EXECUTIVE SUMMARY

The panel examined issues related to intellectual property rights (IPRs), biosafety and other policy areas relating to the transfer and diffusion of biotechnology in the key sectors of agriculture, health and environment. The objective of the meeting was to identify the key issues and capacity-building needs that must be addressed in respect of building legal and regulatory frameworks for biotechnology. The meeting recognized that policy regimes are needed which encourage the inward transfer of biotechnology appropriate to national needs, but which at the same time manage or constrain the import and development of those technologies that present unacceptable threats. There is also a need to integrate and harmonize biotechnology-related regulations and policies with obligations under international agreements.

In respect of technology transfer and diffusion, the meeting recognized that a large amount of information and new knowledge is available in the public domain, although there are still some problems in respect of access to it. The Internet was acknowledged to be an extremely valuable source of new technological information, and policies and initiatives that expand Internet use in developing countries were seen as crucial. In respect of proprietary technology, the issue of finding appropriate new mechanisms, including bioprospecting arrangements, through which to acquire the technologies was discussed. It was reported that, although the costs of the new technologies are often high, the extremely rapid developments in biotechnology mean that new innovations quickly come down in price. Where cost appears to be more significant is in building capacity to absorb the technology, and in maintaining the necessary infrastructure for its use and further development.

It was clear from the country reports that many developing countries have been experiencing problems in resourcing the implementation of the Agreement on Trade-related aspects of Intellectual Property Rights at a national level, in terms of both financing and human expertise. This has in very many cases meant that countries have had to request more time for implementation from the World Trade Oorganization. At the same time, many developing countries have yet to decide their position on, or are firmly opposed to, IPRs for living matter. It was recognized that many organizations, including international agencies, are interested in the area of IPRs for traditional knowledge, although the extent of their activities was not clear. The panel felt that there was a need for more coordinated reporting of the activities of interested organizations, and suggested that this might be a role for the Commission.

The panel discussed the appropriate timing for developing countries to formulate and implement national biosafety regulations, depending on their level of technological development. It was clear that there are two fundamental arguments on this issue one supporting a reactive approach, the other supporting a proactive approach. However, it was noted that countries that have become or are preparing to become, parties to the Cartagena Protocol on Biosafety must introduce institutional structures and procedures that are commensurate with its terms and conditions. Also, it was pointed out that national regulations need to go beyond implementation of the Cartagena Protocol. Unfortunately, resources to formulate and implement biosafety regimes are scarce in many developing countries. The concerns here include a lack of trained personnel and institutions, and poor legal infrastructure, to assess and manage risks in those countries. It was noted that a wide range of

scientific expertise is needed in order to develop meaningful regulations and procedures, including enhanced capacity in molecular biology, ecology and physiology.

It was recognized that better access to information and knowledge would greatly facilitate acquisition, development and diffusion of biotechnology, and also the development of legal and regulatory frameworks to manage the technologies. Objective information about biotechnology should be provided by academics, Governments and the mass media in a form that is understandable to the general public. Key recommendations to improve the dissemination of information included support to improve information technology infrastructure, the development of national policies aimed at building effective networks and linkages between technology users and producers, and the identification of national, regional and international focal points.

The meeting recognized that many developing countries felt a need for continuing international assistance in building regulatory capacity for biotechnology. This could also be a role for national, regional and international focal points. The CSTD could provide direct assistance by initiating and overseeing the development of a regulatory model to serve as a basis for developing countries to establish appropriate regimes for biotechnology management.

Finally, the panel highlighted some areas in which improved understanding is needed at national and international levels in order to support capacity building in biotechnology. These include the problem of technology absorption in developing countries, the potential of bioinformatics to contribute to increased transfer of public domain knowledge, and the role of IPR regimes in encouraging the inward transfer of technology, particularly in respect of biotechnology.

INTRODUCTION

The United Nations Commission on Science and Technology for Development (CSTD), at its fourth session in May 1999, selected as the substantive theme for its inter-sessional period 1999–2001 "National Capacity Building in Biotechnology", with particular attention to be paid to agriculture and agro-industry, health and the environment. The panel meeting held was the second of three substantive panel meetings organized by the CSTD to address biotechnology issues relating to capacity building, legal and regulatory regimes, and public awareness and participation.

The panel examined issues related to intellectual property protection, biosafety and other policy areas relating to the transfer and diffusion of biotechnology in the key sectors of agriculture, health and environment.

The objective of the meeting was to identify the key issues and capacity-building needs which must be addressed in respect of building legal and regulatory frameworks for biotechnology. On the basis of its discussions, the panel produced a set of recommendations for measures and mechanisms by which successful development of these regimes can be undertaken.

1. MANAGING THE OPPORTUNITIES AND CHALLENGES

The characteristics of modern biotechnology provide both opportunities and challenges for developing countries. The new technologies have a wide range of potential applications, and many are knowledge- rather than capital-intensive. If countries are able to build capacity in their national innovation system, biotechnology has the potential to support national efforts for food security, improved health care, increased export potential and environmental sustainability. On the other hand, two key characteristics of modern biotechnology present major challenges to developing countries. First, these technologies have been mainly developed in the northern industrialized countries, and to a large extent in the private sector. This raises concerns about the applicability of new biotechnology to developing country problems; possible mechanisms by which to select and acquire the more appropriate technologies; and the potential barriers to access to technology. Second, biotechnological developments have, in some cases, raised ethical concerns and fears about adverse impacts on human and environmental health. Scientific manipulation of living organisms at the genetic level is still a relatively new area of biotechnology, where the long-term impacts of such manipulation are still uncertain, and where the potential for misuse of the technology has raised serious moral questions.

The Chairman's opening remarks provided a summary of the current developments in biotechnology which have highlighted some of the issues for discussion. These developments include the recent announcement concerning the "race" between the Human Genome Project a multinational public sector research consortium and a private United States based biotechnology firm to sequence the human genome in its entirety. Before the recent announcement on the human genome, it was the genetic modification of crops and processed foods which had dominated the media coverage of biotechnology. With respect to this, it has often been difficult to separate "facts" from "media sensationalism". For example:

- To what extent are the perceived risks of biotechnology "real", and how much is just the normal human fear of the unknown?
- Are all applications of biotechnology potentially threatening? If not, which technologies are considered "safe"?
- In what ways do the perceived risks from biotechnology need handling differently from those relating to other technologies used in food production and health care?

These are just some of the questions which must be addressed by policy makers at national level in order to build an effective regulatory framework.

The Chairman concluding his remarks by stating that the complex task for policy makers at national level is the development of a policy and regulatory framework which encourages the inward transfer of biotechnology which is appropriate to national needs, but which at the same time manages or constrains the import and development of those technologies which present unacceptable threats. These threats might be to human, animal or environmental health, to socio-economic welfare, or to moral and ethical standards. This task is of course complicated by the need to integrate and harmonize biotechnology-related regulations and policies with:

- Other national, and in particular, sectoral, policies and regulations such as those in agriculture, health, trade and industry and environment; and
- Obligations under international agreements, including the Convention of Biological Diversity (CBD) and the World Trade Organization (WTO) Agreements.

This may require policy formulation to be approached in a more holistic way.

1.1 A new approach for biotechnology development

The resource person[1] reported to the panel that studies on technological development at Harvard University's Center for International Development have produced two main conclusions in respect of the impact of globalization on public policy in developing countries.

The first conclusion reached studies is that most of the public policy recommendations which have been provided to developing country Governments, and in fact those *generated by* developing country Governments, are based largely on classical views about technology transfer that were developed in the 1950s and 1960s. These were, perhaps, relevant to the transfer of mechanical technologies. However, it is now argued that in areas such as biotechnology and information technology (IT), the classical views of science and technology really do not represent a true picture of the situation. Therefore, a new approach to technology transfer is needed.

The second conclusion is that while studies on technology and development have always recognized that technological developments present both opportunities and

[1] Professor Calestous Juma, Director, Science, Technology and Innovation Program Centre, Center for International Development, Harvard University, United States.

challenges, the analysis is almost always focused on the challenges rather than the opportunities. From the body of existing literature on technology and development a very pessimistic picture emerges in respect of the potential for developing countries to progress technologically. Available evidence contradicts this, however. For example, in IT and computer software, some countries are emerging to play a key role in the global economy. It is argued that this can also be the case with biotechnology. It is therefore suggested that a positive approach be taken to biotechnological development, one which gives sufficient weight to the opportunities provided.

The resource person went on to identify some key characteristics of biotechnology, and outline their implications for public policy.

First, biotechnology draws on a wide range of expertise. At one end of the spectrum, expertise in genetics is needed, and at the other end, expertise in for example information technology. Therefore, investments only in some areas, such as genetics or molecular biology, are not sufficient to enable a country to play a significant role in using the knowledge that is available. In this respect, there is a need to ensure the safe and sustainable use of these new technologies, as well as of expertise in other areas, such as ecology.

Next, biotechnology is a knowledge-intensive technology. This has implications for institutional organizations. It is clear from those countries, including developing countries, that have advanced fastest in biotechnology that countries that invest in creating a knowledge base in key strategic fields have a much better chance of entering the field.

The third characteristic that distinguishes biotechnology from mechanical inventions is that the product and the process are very often integrated. The unique feature of biotechnology is that life itself provides both a product and a process. Therefore, the period of time for getting to the market place is much shorter than in the case of, say, chemical inventions, where there is often a long research and development (R&D) time lag involved in developing the process. This characteristic also introduces discontinuities, whereby new products come in very quickly to displace existing products and processes. The classic example is where genetic engineering threatens to displace conventional plant breeding as a set of techniques and skills that have been built up over a long period. This in turn has consequences at an institutional level, in particular, where a tension emerges between the need to introduce new technology and reluctance to abandon existing capacity in older technologies. It may favour institutions that are more flexible, and that have invested in diverse areas of expertise.

Another key point is that, unlike mechanical inventions, biotechnology is very much driven around programmes that are predefined by a particular objective. For example, a decision is taken to develop certain pest-resistant crops, or to develop a diagnostic kit for a particular disease, and then efforts are made to mobilize the required knowledge, worldwide, around that particular product. The weakness in many developing countries is not so much the lack of expertise as the lack of ability to establish programmes and sustain them over a long period.

Finally, it is self-evident that much of the work, whether it is in agricultural biotechnology or the pharmaceutical sector, is being driven by the private sector. This is

widely seen as an obstacle, and many analysts are preoccupied with looking at how to bring technological development back into the public sector. What might be a more useful focus for policy analysis is the potential for developing new, appropriate and complementary roles for the public and private sectors in developing countries. Regulatory regimes need to take this into account.

The resource person concluded by offering two broad views on the implications of a new approach.

First, it changes the way in which policy advice is given at the national level. The predominant advice on these issues has generally come from the legal profession. However, in order that policies reflect the rapidly changing technical complexities involved in modern biotechnology development, continuous input of scientific expertise is needed.

Second, important questions are raised about the relationships between Governments and, for example, universities and private sector firms. Any policies in this area have to be the product of a consensus (based on public–private sector dialogue) among industry, government and the universities, as well as civil society, because of the interests of the public in these issues.

1.2 Agriculture

The resource person[2] outlined the current and future problems for agricultural production, with special reference to the Latin American and Caribbean region. He reported that in Latin America average crop yields are already falling behind those of world leaders, and that it is possible that as much as thirty per cent of cereals consumed by the year 2020 will have to be imported. This is because the expected population increase is higher than the anticipated capacity for food production, taking into account the limitations on further expansion of agricultural land, and predicted levels of land degradation. It was therefore recognized that biotechnology is likely to play an important role in sustainable agriculture. On the other hand, the introduction of genetically engineered crops into tropical ecosystems merits careful oversight and monitoring. Given the high level of crop and other plant biodiversity in the region, the countries of Latin America and the Caribbean need to address the uncertainties surrounding the long-term impacts of transgenic crops on their ecosystems, including potential losses to biodiversity.

Already, around six per cent of field trials worldwide are conducted in countries in Latin America and the Caribbean, with the largest concentrations in Argentina, Brazil, Chile and Mexico. Whilst the region must utilize the new technologies in order to enhance agricultural productivity, the potential risks must be evaluated objectively.

[2] Dr. Ivan Rodrigo Artunduaga Salas, Head, Biosafety and Genetic Resources Unit, Colombian Agricultural Institute, Bogota.

1.3 Health

The resource person[3] summarized the importance of the work on the Human Genome Project for the future treatment of genetic diseases, and the opportunities which the emerging knowledge provides for developing countries.

Until recent years, the approach to understanding genetic diseases was to investigate a particular disease, and look at the genetic basis for it. Much work has been done, but the whole investigative process had to be undertaken for each individual disease. A new approach was therefore needed, and this was the intention of the Human Genome Project. This project has discovered great number of new functions, which provide opportunities for new therapies, new drugs and new understandings of how humans function. In addition and perhaps this is the main reason genome research has become so popular the genome technologies, and the transfer of those technologies between countries, have greatly boosted the detection of disease genes.

One factor in the rapid progress towards understanding the human genome has been, and continues to be, the availability of increasingly sophisticated information technologies to process and disseminate information. It can reasonably be expected that in ten years' time it will be completely standard for all biologists to access, on the Internet, the DNA sequence of most of the organisms which they are studying. Bioinformatics provides opportunities for developing countries to use the gene sequence databases on the Internet, even where they cannot afford laboratory-intensive research.

Another area with great potential is pharmacogenetics a combination of pharmacology and genomics which is concerned with medication and dosages. Expectations from progress in pharmacogenetics are more effective drugs, fewer side effects, prevention of overtreatment and longer-term, greater understanding leading to better therapies and even new preventive approaches.

2. OVERVIEW OF ISSUES FOR DISCUSSION

The meeting noted that biotechnology policy needed a holistic approach. There were also discussions on the degree of integration between the issues identified for consideration by the panel, namely technology transfer and diffusion, intellectual property rights, and biosafety and bioethics.

Many members of the panel felt that the issues identified should be dealt with separately during the course of the meeting. It was agreed that generally applicable recommendations would be a likely outcome of the discussions, together with specific recommendations for each topic, where appropriate. One panel member pointed out that the CSTD was the only UN body with such an integrated approach to biotechnology which constituted a great strength for the current programme.

[3] Professor Gert-Jan van Ommen, Department of Human and Clinical Genetics, University of Leiden, Netherlands.

2.1 Technology transfer and diffusion

Two aspects of technology transfer were highlighted. The first was the international transfer of technology, usually from industrialized to developing countries. The second was the diffusion of technology, both imported and locally developed, from the importing or innovating organization into the wider economy. In order to build capacity to utilize the potential of biotechnology to address national needs, it is crucial that policies and regulations are able to effectively encourage both the international transfer and the diffusion of the technologies. And yet, the effectiveness of the various mechanisms of, and incentives for, technology transfer are still not clear, despite many decades of study on this issue.

A resource person[a] described the "classical" view of technology transfer, which is characterized by a linear model. The general assumption of this model is that technologies are usually developed in, and for, the industrialized world. After some time, the technology is "transferred" to, usually, a few developing countries that are capable of using it. It may then be adapted to, or enhanced for, local conditions. Having been adapted, it will logically diffuse into the local economy. This was the prevalent model for most of the colonial period, when much of the technology was designed for natural resource extraction. In the context of technology embodied in machinery, it was not an unrealistic model. But under this model the initial patterns of technology transfer are usually associated with people learning how to use the imported technologies, and policy recommendations commensurate with this model still persist. And yet, past evidence does not support the persistence of this classical view. Evidence suggests that many countries imported equipment, but no learning took place, and there was no local adaptation of the technologies. In fact, a large share of the foreign debt of African countries is accounted for by borrowing to import equipment and technology that were never able to function effectively under local conditions. Thus, there is a significant degree of technological failure associated with the "classical" model. It can therefore be argued that, for the emerging technologies, and particularly biotechnology, there is a need to abandon this approach. This has significant policy implications in respect of identifying, understanding and overcoming potential obstacles to successful technology transfer.

A move away from the "linear" model requires a different perspective on modes and mechanisms for technology acquisition from the international market, and for diffusion within a national economy. Particularly, it suggests the need to refocus policy initiatives in the host country in the direction of new mechanisms for the acquisition of technology, including:

- New forms of licensing arrangements for proprietary technologies;
- Enhancing access to publicly available knowledge, for example through IT, research and partnerships;
- Encouraging development of host country private enterprises to participate in the acquisition and development of biotechnology;
- Finding means and mechanisms to harness the scientific expertise of nationals residing outside the country to support national objectives.

[a] Professor Calestous Juma.

With respect to diffusion of technology within the country, the concentration of technological development in public sector research organizations has both advantages and disadvantages. On the one hand, it was noted by a resource person that the countries which had successfully developed biotechnology had a major input from their universities in this process. On the other hand, "traditional" public sector incentives do not always take into account the need to diffuse innovations into the commercial sectors.

2.2 Intellectual property rights

It has been traditionally reasoned that a strong regime for intellectual property rights (IPRs) will encourage the inward transfer of technology. However, there is in this respect a shortage of empirical evidence.

A resource person[a] reported that, in fact, many statistics and case studies show that the role of IPR regimes has often been exaggerated with respect to technology transfer. IPRs have often been seen as the major obstacle to technology transfer, and this is particularly the case with more advanced technologies such as biotechnology. In fact, there are two arguments against this view, which are supported by the evidence from developing countries that have successfully entered into new areas of technology:

- Where there is national capacity to make use of proprietary knowledge, the capacity to negotiate and pay royalty fees also generally exists. Furthermore, evidence shows that budgets for training and managerial expertise far exceed royalty fees as a proportion of total costs in technology transfer projects. The logical conclusion is, therefore, that the main savings to be made in respect of technology transfer are from prior investment in human resource development, which would lower these training costs.
- With knowledge-intensive technologies such as biotechnology, there is a huge amount of knowledge already in the public domain. Developing countries which have advanced in biotechnology in recent years are those which have developed the expertise to utilize this freely available knowledge.

However, the resource person also indicated two areas where IPRs assume a greater importance. First, discussions with large firms in industrialized countries suggest that they are reluctant to transfer some technologies, even under licensing agreements, where contractual obligations may not be fully enforceable in the receiving country. The existence of an effective IPR regime in the receiving country would provide some reassurance for these firms.

Second, IPRs are usually associated with privately owned technology, but the fact that this technology becomes public-domain knowledge on the expiry of the patent (or some other form of IPR) is often overlooked. Patent offices in developing countries can therefore act as a source of scientific and technical information, and can monitor the expiry of patents. This, rather than their role in protecting local innovations, can justify the establishment of patent regimes in economic terms.

[a] Professor Calestous Juma.

2.2.1 Implementation of the TRIPS Agreement

Since the establishment of the World Trade Organization and the conclusion of its Agreements, much of the policy debate about the role of IPR systems in technology transfer has been superseded by the need to conform to WTO provisions on IPR. For the countries that are member States of the WTO there is an obligation to implement the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Specific issues which relate to biotechnology include:

- The patenting of human genes;
- IPRs for plants.

(i) Human Genes

The resource person[c] reported that the Human Genome Organisation (HUGO) has produced two statements on the patenting of human genes. In the first, in 1994, the organization supported a balance between the promotion of scientific progress by early public release of new knowledge, and the need for intellectual property protection (IPP) to ensure continued investment in research. In March 2000, HUGO updated this statement. In determining the stage of research where patenting should be possible, HUGO expresses the view that DNA sequences of unknown function should be regarded as "pre-competitive information" and should be in the public domain. Where DNA sequences are isolated and their functions known, they may become patentable.

However, there have now been calls internationally for a review of the situation, supported by the Governments of the United States and some European countries, with a view to more strictly limiting patenting in respect of human genes.

(ii) Plants

Article 27.3(b) of the TRIPS Agreement requires that plant varieties be protectable as intellectual property. The options which have been used to effect this, worldwide, are:

- Plant patents;
- One of the UPOV Conventions;[4]
- *Sui generis* systems (particularly, plant breeder's rights laws);
- A combination of more than one of these.

Plant breeders rights are just one option for introducing a *sui generis* system for the protection of IPRs on plant varieties as required by TRIPS. An issue which has merited considerable attention in recent years, especially since the coming into force of the Convention on Biological Diversity, is the possible introduction of new IPR regimes to protect both national sovereignty over plant genetic resources and the rights of indigenous

[c] Professor Gert-Jan van Ommen.

[4] The Union for the Protection of Plant Varieties (UPOV), formed during the 1960s to harmonize plant breeders' rights at an international level, currently has two Conventions in force: many long-time members of UPOV still adhere to the 1978 Convention, but new members are now required to adopt the revised 1991 text, which gives wider rights of protection to plant breeders.

peoples regarding their traditional knowledge about these resources. The option of introducing a *sui generis* system as laid out in Article 27.3(b) of the TRIPS Agreement is seen as a potential mechanism for such protection.

2.2.2 IPRs for traditional knowledge

The issue of *sui generis* systems is also considered important as a possible means of protecting traditional knowledge and innovations, and this subject was also included in the panel's discussions.

A representative from UNCTAD gave an overview of work currently being undertaken at UNCTAD in the area of genetic resources and protection of traditional knowledge. The speaker identified two major concerns for developing countries with respect to the protection of traditional knowledge. First, there are risks that traditional knowledge will be lost as indigenous peoples become more integrated into modern society. Second, existing traditional knowledge which is not legally protected as intellectual property can be exploited by modern science and industry without adequate recompense to the indigenous and local communities that are the custodians of the knowledge.

Existing forms of IPRs should be explored as mechanisms for protecting traditional knowledge, although there are some inherent problems. Two characteristics of traditional knowledge present fundamental challenges for existing forms of IPRs. First, it is "traditional"; i.e. handed down from generation to generation rather than being newly generated, and therefore does not meet the innovative criteria of conventional IPR regimes. Second, the knowledge is often held by, or on behalf of, communities, whereas existing forms of IPRs confer legal rights on individuals or other clearly identified activities. The existing systems in the communities themselves for protecting traditional knowledge are customary and common-law regimes. But the increasing interaction between the communities and outside actors, who are not bound by these regimes, means that customary and common laws are no longer sufficient.

The resource person[a] presented an alternative approach to protecting traditional knowledge as intellectual property. This view suggests that, before trying to develop an entirely new form of IPRs, existing IPR regimes should be exhaustively tested to see whether they may be suitable for protecting traditional knowledge and/or genetic resources, at least in some aspects. For example, some countries, including Spain, have routinely named the origins of plant-related patents in their patent applications. In this approach, emphasis should be on defining needs and the potential for protection of traditional knowledge at the national level according to the specific local needs and characteristics of the IPR regime which prevails before trying to devise a new system at the global level. The resource person further suggested that, in fact, developments in genomics may have a very significant impact on the potential economic value of both traditional knowledge and genetic resources which may render these initiatives to legally protect them fruitless.

[a] Professor Calestous Juma.

2.3. Biosafety and bioethics

The wide-scale introduction of genetically modified crops has given rise to public concerns about the environmental and health impacts of these crops and their related food products. In consequence, developing country Governments are trying to build capacity to scientifically evaluate and manage the technologies involved.

UN agencies and other international organizations have frequently been asked to assist developing countries in capacity building. In support of this, the international community facilitated the negotiation of the Cartagena Protocol on Biosafety, which sets out agreed procedures for the international movement of living modified organisms. The provisions of the Protocol are not exhaustive, even in terms of the potential physical risks to human, plant and animal health. Going beyond these risks, the rapid development of advanced biotechnologies and the commercial introduction of their products results may also have social, economic and ethical impacts. These risks, which are not inherent in the technology but may be associated with choices about its application, are not as yet covered by the Protocol. These issues were discussed under the topic of "bioethics".

2.3.1 Biosafety

National regimes must be commensurate with the terms and provisions of international agreements to which a country is a party. For many countries, these will include both the Agreement establishing the World Trade Organization and the Convention on Biological Diversity.

Negotiations for an internationally binding protocol, which would focus on the transboundary movement of living modified organisms (LMOs), were started in 1996 under the auspices of the Convention. It was anticipated that the eventual Protocol would provide both a blueprint for a national biosafety regime and some effective protection against the importation of LMOs while a national regulatory framework was being built. After five years of negotiation, the text of the Protocol was agreed at a meeting in Montreal in January 2000 and opened for signature at the CBD's Fifth Conference of Parties held in Nairbobi in May 2000.

In areas where consensus could not be reached between the negotiating parties at the final session in Montreal, compromises were made in the provisions and wording of the final text.[5] These compromises are likely to present significant challenges for implementation. The first limitation of the Protocol is that it applies only to the transboundary movement of LMOs, and not to the release of LMOs developed within national borders. Second, under the Protocol, some classes of LMOs are excluded from its scope, such as pharmaceuticals,[6] and others are exempt from its provisions for Advanced Informed Agreement (including mandatory Risk Assessment). This latter category includes LMOs in transit, and those that are intended for direct use as food or feed, or for processing. It is therefore likely that national regimes for biosafety will go beyond implementation of the Protocol.

[5] It should be noted that several issues remained unresolved in the final text, including issues of liability and redress, and socio-economic considerations arising from the import of LMOs. These issues are subject to further negotiation by an Intergovernmental Working Group.

[6] Those that which are already regulated by other international agreements.

One potential problem in developing a national regime for biosafety based on the principles of the Cartagena Protocol is that the provisions of the latter do not supersede countries the obligations under the WTO Agreements (if, of course, a country is a member of the WTO). The wording of the Protocol leaves the relationship between it and other international agreements unclear. If and when conflicts arise, they, the WTO or the CBD, will probably be subject to interpretation on a case-by-case basis, but it is unclear whether dispute settlement mechanism will be used.

There are four relevant WTO Agreements in respect of biosafety the General Agreement on Tariffs and Trade (GATT), the TRIPS Agreement, the Agreement on the Application of Sanitary and Phytosanitary Measures, and the Agreement on Technical Barriers to Trade. There are provisions in these Agreements to allow the restriction of imported technologies and products on the ground of risk to public order or morality, or to human, animal or plant health. In the case of the TRIPS Agreement, the restriction extends only to the patentability of the technology or product, and does not prevent its import or distribution. Any restrictions introduced on the basis of the provisions of the Agreement on the Application of Sanitary and Phytosanitary Measures and the Agreement on Technical Barriers to Trade are subject to a requirement that currently available scientific and technical information supports the restriction. Similarly, Article XX of the GATT allows for restrictive measures on the basis that they do not constitute "a disguised restriction on international trade".

There is one crucial aspect where all these WTO Agreements differ from the Cartagena Protocol. In the WTO Agreements, the onus is on the country introducing the biosafety measures to justify them. In effect, it must prove that the technology poses risks to human, animal or plant life or health on the basis of currently available scientific information. In contrast, the provisions of the Cartagena Protocol, particularly in respect of the Advanced Informed Agreement procedure, are explicitly based on the Precautionary Principle, as described in Appendix III (Risk Assessment) of the Protocol:

> "Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable level of risk."

This holds that an absence or lack of scientific certainty about the potential risks of a technology cannot be used to justify claims that it is safe. In this case, the onus is on the technology-exporting country to prove that the technology does not pose a threat to human, animal or plant life or health.

However, the Precautionary Principle is not without its problems. Its implementation is likely to prove complex, and potentially problematic, not least in respect of possible disparities between obligations under the Protocol and those under the WTO. One final point here is that, so far, no disputes have arisen on this basis, and there is no consensus on whether disparities between the CBD and WTO will emerge in future.

Other international organizations concerned with biosafety regulation and capacity building include the Food and Agriculture Organization (FAO), the United Nations Industrial Development Organization (UNIDO), the Organization for Economic Co-operation and

Development (OECD), and the Codex Alimentarius Commission. In terms of direct measures which support national regulation, the greater part of international assistance has so far been in providing internet-based information. However, "hands-on" training courses in risk assessment are run by the International Centre for Genetic Engineering and Biotechnology (ICGEB), an agency founded by UNIDO, with headquarters in Italy and India.

A representative of the ICGEB reported that this agency undertakes specific activities to support biosafety capacity building at national level. The Biosafety Unit of the ICGEB provides two main categories of services: dissemination of information and capacity building in areas related to biosafety and risk assessment. Unfortunately, ICGEB is unable to provide financial support for participants from those countries that are not full members. This may prevent or constrain the benefits of ICGEB's activities in those countries which are in most need.

2.3.2 Bioethics

Advances in biotechnology have raised, or increased, a number of moral and ethical concerns about the potential misuse of new technology. Many of the major fears about the potential of new genetic knowledge and the application of genetic engineering concern human health and genetics. However, bioethics is now also concerned with environmental ethics, and with the potentially adverse social and economic impacts of advanced biotechnologies, particularly the introduction of genetically modified crops.

A resource person[c] stated that, in respect of the Human Genome Project, there are concerns that developments are too rapid and are not explained to the outside world. The speaker reported that the Human Genome Organization (HUGO)[7] has an ethics committee, which has made an inventory of concerns relating to the Human Genome Project (HGP), as follows:

- Discrimination/stigmatization, and potential misuse of information to promote racism;
- Loss of access to discoveries for research purposes due to commercialization of new knowledge;
- "Reduction" of humans to their DNA sequences, and the attribution of all our problems to our genes;
- Lack of respect for the values, traditions and integrity of populations, families and individuals;
- Inadequate links/communication between the scientific community and the public.

The stakeholder community (that is, all those potentially affected by decisions made to promote or restrict a particular technology application) will reflect not only a wide variety of views, but also different levels of knowledge about the complex technologies concerned, and of philosophical and/or theological understanding. This makes the issue of public awareness critically important.

[c] Professor Gert-Jan van Ommen.

[7] HUGO is a coordinating committee within the Human Genome Project.

3. REGIONAL AND COUNTRY REPORTS

The first CSTD panel meeting on biotechnology held in Tehran Islamic Republic of Iran, recommended that capacity needs assessments for biotechnology be undertaken at national level in developing countries and countries with economies in transition. This recommendation derived from the recognition that developing and managing biotechnology requires a holistic approach to identify key issues and areas of application which require resources and capacity building. Several countries were able, at the meeting, to briefly report on national programmes which have already been designed to address these objectives.

In some countries, including Slovakia and the Republic of Korea, explicit medium- to long-term (10–15 years) biotechnology programmes have been established with the specific aim of building long-term policy and technical capacity. In each of these countries, the programmes are jointly operated by two or more ministries, and a national biotechnology advisory council has been set up to provide expert input to the responsible ministries. On the other hand, an alternative approach has been taken in Cuba, where national strategies for biotechnology development have been integrated into the existing framework for science and technology. In all cases, the Government was the sole or major provider of funding for the programme.

In other countries, early attempts to implement national programmes have foundered because of resourcing problems, where the public sector is the main source of financing. One potential approach in such a situation is to start with a relatively modest programme, and build from there. This has been done in Ghana, for example, where the Biotechnology Development Programme under the Ministry of Environment, Science and Technology was initiated in 1998 with a project to involve stakeholders in setting priority areas for biotechnology development and assessing existing capacity to address those areas.

3.1 Technology transfer and diffusion

Country reports highlighted the problem of a lack of systematic understanding of the process of technology transfer and diffusion at national level. Many countries reported that biotechnology was being developed mostly in the public sector research system. Transfers through private enterprises were few, and generally involved more mature technologies such as tissue culture and brewing techniques.

Most international technology transfer was effected through public sector research collaborations with overseas research institutes and universities, which were often funded by donors. This has sometimes caused problems in targeting biotechnology to address local needs, in cases where local input into the initial project design was absent. One country reported that overseas experts had been hired as a mechanism for transferring specifically desired technologies, and several countries had devised scholarship schemes to train local scientists at overseas institutions in particular disciplines. Bioprospecting arrangements had not been used as a mechanism for technology transfer in any of the reporting countries, although policy or legislative regimes in this area were under consideration in some countries. Another problem was that in some cases, transfer of advanced biotechnology had been inhibited by a lack of national biosafety regulations.

Private sector enterprises tended to receive technology mainly from overseas parent companies. Even in the public sector, technology transfer was generally reported as being from North to South, with no South–South transfer reported.

Diffusion appeared to be a significant problem. In some countries, knowledge is shared among research institutions through collaborations and workshops, although in one country's national programme specific provision is made to promote the development of biotechnology in the private sector.

3.2 Intellectual property rights

In Sri Lanka, the existing legislation on IPRs is contained in a single law, the Code of Intellectual Property Act of 1979. Amendments to legislation to bring it into line with the TRIPS Agreement are not yet complete, and a decision is still to be made in respect of plant variety protection. The two options being considered are to adopt UPOV 1991, or to develop a *sui generis* system. The panel member from Sri Lanka reported that the National Intellectual Property Office is poorly staffed and equipped, and proper searches are rarely possible. Capacity for enhanced training of personnel hardly exists.

Proposals to amend Romania's existing patent law (1991) to bring it into line with TRIPS provisions are currently being debated in Parliament. Since 1998, plants have been patentable, although there are exceptions to the exclusive rights of the patent holder with respect to (i) use for personal or non-commercial purposes; and (ii) experimental use, including as a basis for new varieties. A national register of plant variety patents has also been established, with unworked patents becoming subject to compulsory licensing after five years.[8]

In the Republic of Korea, IPR protection relevant to biotechnological innovations includes both patents and utility models, and intellectual property protection for micro-organisms is allowed. However, a report by the Swiss International Institute for Management and Development (IMD) ranked the Republic of Korea's degree of IPR protection in 1997 extremely low – 38th out of 46 countries included in the report.[9] The proportion of patents (over all fields of innovation) held by local innovators has been increasing rapidly in recent years. The local share of biotechnology-related patents grew at an annual rate of 15.6 per cent between 1991 and 1997. Statistics for 1999show that residents' share of total patents in the area of biomedicines was around 40 per cent.

Paraguay had already introduced a plant breeders' rights regime before the TRIPS Agreement came into force. The Seeds and Varieties Protection Act was introduced in 1994. This protects the IPRs of plant breeders for between 15 and 18 years, although under this law protected varieties can be used as a base for the research and development of new varieties, and farmers have the right to re-use saved seed. In 1995, the law was presented to UPOV for analysis. UPOV approved Paraguay's membership of the organization in 1997.

Jamaica is generally upgrading its IPR regime. It has recently become a signatory to the Paris Convention. National legislation on plant varieties protection is being drafted,

[8] More details on the Romanian IPR system can be found on the Internet at URL: http://www.osim.ro

[9] The IMD produces the annual *World competitiveness Report.*

guided by a UPOV model. The panel member from Jamaica reported that concerns have been expressed that this drafting is being driven by external pressure rather than local need. Furthermore, it is taking up scare resources, and it is still unclear whether these investments will be justified in respect of socio-economic development. Since there are few local innovations, the investment of resources is mainly for the purpose of attracting inward technology transfer.

Few panel members were able to report signficant developments in their own countries in respect of intellectual property protection for traditional knowledge. In fact, many countries have first to undertake a substantial amount of research in order to fully assess their genetic resources and the traditional knowledge associated with them.

In Jamaica, for example, ethnomedical and ethnobotanical research has started which is intended to facilitate the recording/preservation of traditional pharmacological knowledge. In other countries, such as Sri Lanka, where initiatives are under way to develop legislation on access to genetic resources and benefit sharing as part of CBD implementation, progress is reported to be slow.

The Costa Rican Biodiversity Law, introduced in 1994, is a broad protection regime which establishes procedures for accessing both genetic resources and associated knowledge and practices. Under this law, bioprospecting agreements must ensure that consent is obtained from the custodians of the genetic resources and knowledge, and that profits from their use are equitably distributed.

In Peru, a register of collective knowledge related to biological resources is being compiled. Access to the register, when it is complete, will require the permission of the indigenous people from whom the knowledge was obtained. Furthermore, commercial use of the knowledge will be allowed only through licensing agreements.

The Andean Pact introduced a broad-spectrum biodiversity regime in 1996 the Andean Community Decision 391. This regulates access agreements for genetic resources and traditional knowledge, and provides for contractually agreed benefit sharing in respect of the traditional knowledge components of bioprospecting activities. However, the Andean Community is also considering the introduction of a new *sui generis* system to legally protect traditional knowledge. One purpose of this system would be to encourage the holders of the knowledge to make it available as a database.

3.3 Biosafety and bioethics

A resource person[b] gave an overview of the situation in the Latin American and Caribbean region in respect of biosafety regulations. He reported that the majority (63 per cent) of countries in the region have not yet formulated and implemented biosafety regulations. These countries include the Dominican Republic, Ecuador, El Salvador, Guatemala, Honduras, Nicaragua, Panama, Venezuela and most of the Caribbean countries.

Among the countries which have introduced specific measures to manage biosafety, there are wide differences with respect to the scope of regulations, the approach taken (that is,

[b] Dr. Ivan Rodrigo Artunduaga Salas.

the development of an entirely new regime, or building on existing regulations), the institutional arrangements and mandates for implementation, and the types of regulatory mechanism used. Biosafety Committees or Commissions have been set up in these countries. Their membership tends to draw from a wide range of agencies, including ministries (especially agriculture, health, environment, commerce, and foreign relations), the scientific community, civil society, agricultural producers, non-governmental organizations, consumers, environmentalists and the private sector. Except in Brazil, these Committees act in an advisory capacity only. In Brazil, in addition to making recommendations to ministries, the Technical Commission for Biosafety has the final decision to authorize or prohibit field trials.

In Paraguay, an inter-institutional Biosafety Commission has been in place for three years, and procedures have been established for it to handle applications for the introduction of genetically modified organisms. The Commission, which is made up of representatives from the agriculture and health ministries, universities and non-governmental organizations, acts in an advisory capacity to the two key ministries that have the authority to authorize or reject applications. To date, only one such application has been received for the experimental releae of several herbicide-tolerant soya varieties and this was approved.

In Cuba, a National Centre for Biological Safety was established in 1996 under the Ministry of Science, Technology and Environment. This body is responsible for coordination and implementation of regulations and agreements on biosafety. Other relevant organizations and programmes are the Centre for the State Control of Medicine Quality, the National System for Veterinary Medicine and the National System of Plant Health. In 1999, a Decree-Law on Biological Safety was passed which regulates the use, storage, handling, transport, import and export of biological agents, including genetically modified organisms and DNA fragments. In the same year, the Government established, by Resolution, an Official List of Biological Agents affecting humans, animal and plants, including their classification into risk groups. A further Resolution was passed this year the General Rule on Biological Safety, which establishes the functions and procedures for biosafety organizations and officers, including procedures for handling and moving samples. An authorization procedure has been approved to regulate applications for approval of releases of biological agents, including the granting of licences. Furthermore, Cuba has already introduced university course modules in biosafety, including specialized modules in respect of human health, veterinary medicine and plant health. In addition, a Master's level degree course in biosafety has recently been approved.

The Republic of Korea has drafted a Bioengineering Safety Law, which is currently under consideration. If adopted by Parliament, it will become effective from October 2001. In the current text, provisions are made for:

- The establishment of a Bioengineering Safety Committee, which would include representation from nine ministries and some outside professionals, and would be chaired by the Prime Minister;
- Regular formulation of five-year biosafety plans by the Government;
- Inspection and regulation of facilities for bioengineering research and development;
- Procedures regulating the production and import of, and trade, in LMOs;

- Government designates agencies responsible for biosafety evaluation.

In Pakistan, a new regime for biosafety has been developed which includes very comprehensive guidelines on procedures for various risk categories, together with the institutional structures for their implementation. These proposals, which are in draft form, are currently being circulated and are publicly available for comment. In Pakistan, biotechnology was first developed in centres of excellence. After some time, these centres wished to undertake field trials. Also, overseas firms wanted to start field trials in local conditions for their transgenic seeds. The present draft biosafety regime was developed in response to these requirements. There have been no releases of GMOs in the country to date.

In Sri Lanka, the Ministry of Environment has appointed committees to study issues related to biosafety and bioethics, but so far no regulatory mechanisms have been introduced. With respect to controlling the import of GMOs, existing seed import controls and capacity are insufficient; for example, the regulatory agencies involved do not have laboratory facilities for this. However, within the country, there is at present no research directed at transgenic plants.

A slightly different approach to biosafety has been taken in Slovakia, where a cross-sectoral Slovak Commission for the Convention on Biological Diversity has the mandate to support biosafety initiatives. Legislation has not yet been introduced, and it has been suggested that, in the interim, EU laws on GMOs be observed. In the meantime, the Commission has obtained for distribution a translation of the International Technical Guidelines on Safety in Biotechnology, prepared by the United Nations Environment Programme (UNEP). Under the national programme, implementation of legislative measures is scheduled, as a priority, for the first phase in 2001–2003.

A National Commission on Biological Safety was established in Romania earlier this year, under a Government Ordinance, made up of representatives from ministries, regulatory agencies and public sector research institutes. The Ordinance laid out specific terms of reference for the Commission's scope and procedures, which have still to become operational.

In Ghana, a National Biosafety Council was set up early in 2000, under the auspices of the Ministry of Environment, Science and Technology, which brings together expertise from universities, research institutes, ministries, industry, the legal profession and farmers. It will be responsible for policy development, monitoring biotechnology activities, developing capacity in biosafety, and international collaboration on biosafety issues. Owing to limited technical capacity, it will not try to develop an entire regulatory regime from scratch, but will draw on a variety of existing guidelines, including UNEP's 1995 International Technical Guidelines for Safety in Biotechnology, and national policy models from other countries, especially developing countries.

Ethiopia has also prepared a comprehensive draft law on biosafety for consideration by Parliament, but institutional arrangements are not yet in place.

4. DISCUSSION

4.1 Technology transfer and diffusion

It was recognized that a large amount of information and new knowledge is available in the public domain, although there are still some problems in accessing it. The Internet was acknowledged as an extremely valuable source of new technological information, and policies and initiatives that expand Internet use in developing countries were seen as crucial. However, some countries still have difficulties because of the language barrier. It was suggested therefore that journals, electronic databases and other sources of scientific information available on the Internet in only one language (most commonly, English) be "mirrored" in other major world languages.

In respect of proprietary technology, the issue of finding appropriate new mechanisms through which to acquire the technologies was discussed. The bioprospecting agreement between InBio (Costa Rica) and Merck was commended as a good example because of the proactive approach by Costa Rica. It was stated that there is a greater willingness than is generally believed on the part of large companies to transfer technologies to developing countries at little or no cost, and this should be explored. Also, it was pointed out that although the costs of new technologies are often high, the extremely rapid developments in biotechnology mean that new innovations quickly come down in price. The cost of importing proprietary technologies is therefore not, perhaps, the major barrier to technology transfers.

Where cost appears to be more significant is in building capacity to absorb the technology, and in maintaining the necessary infrastructure for its use and further development. It was indicated that linking developing country organizations to the Internet is probably less of a problem than the ability of those organisations to pay the telephone bills in order to get "on line". This is one aspect of trying to understand the systemic nature of technology development, where targeting resources at one particular capacity-building activity does not ensure success. One panel member reported that his Government had found that enhancing human resource capacity had been insufficient to develop the technology, and was now actively seeking to understand the complex processes behind successful technology transfer and development.

One part of this process is the participation of the private sector. It was reiterated that most of the biotechnology being used or developed in developing countries is in the public sector, and it was suggested that there may be some structural problems in many of these countries which inhibit the private sector's participation in research and development. Even when the private sector is involved in technology acquisition, it is generally more mature biotechnologies which are transferred. Another concern was the need to ensure that appropriate biotechnologies were transferred or developed locally. It was pointed out that many technologies which might address the critical developing country concerns regarding subsistence farming would not be likely to receive the attention of private firms, especially those in industrialized countries, where so much of the technology is based. Mechanisms for South–South collaboration in these areas might provide some solutions.

4.2 Intellectual property rights

There was a concern that development of IPR regimes in developing countries in order to conform to the TRIPS Agreement would not provide sufficient benefits to those countries to justify the substantial resources expended. It was reiterated that there is little evidence to show that stronger IPR protection will result in more technology transfer to developing countries. Furthermore, on a global scale, it was noted that only a small proportion of patents held worldwide 4 per cent are owned by developing country innovators, including those from newly industrializing countries.

The costs of implementing the TRIPS Agreement, in both time and resources, has made implementations very difficult, and most developing countries have had to request an extension beyond the 1 January 2000 deadline. One area of particular contention is the adoption of the 1991 UPOV Convention in order to conform to the TRIPS requirement for IPRs for plants. It was noted that while many developing countries find the 1978 Convention acceptable, the revised Convention is not generally favoured. However, there is pressure on developing countries to become parties to this Convention, simply in order to fulfil the requirements of the TRIPS Agreement. At the same time, many developing countries have yet to decide their position on, or are firmly opposed to, IPRs for living matter.

Sui generis IPR systems for plants have been developed in some countries, including India, South Africa and Nicaragua. However, these may be unacceptable to the WTO or some of its member States. For example, Nicaragua's system, which gave prominence to the terms and objectives of the Convention on Biological Diversity, was opposed *inter alia* by UPOV. This raises the whole question of *sui generis* systems' acceptability within the WTO, despite the wording of Article 27.3(b) of the TRIPS Agreement. The CBD has called for the WTO to recognize the importance of *sui generis* systems, although it has not been possible to come up with concrete guidelines at a global level for such systems.

However, it was suggested that, given the likely unacceptability of these systems to the WTO, more efforts should be made with UPOV to revise its own Convention and make it more acceptable to developing countries.

What was clear from the country reports and discussion was that, first and foremost, many developing countries have been experiencing problems in resourcing the implementation of the TRIPS Agreement at national level, in terms of both financing and human expertise. This has in very many cases meant that countries have had to request more time for implementation from the WTO. With respect to IPP for plants, country reports indicate that various forms of IPR are used: patents, utility models, UPOV and *sui generis* systems. However, those countries that had less developed regimes at the time the TRIPS Agreement came into force (1995) have been under more pressure to adopt UPOV as a "simple" means of protecting plant innovations because of the time and resources needed to implement the TRIPS Agreement.

It was noted that there are several problems in using existing IPR regimes to protect traditional knowledge, particularly:

- The non-exclusivity of the knowledge between countries, communities and individuals, where most existing forms of IPR are designed to protect individual or corporate rights;
- The evolving nature of the knowledge over time, which makes it difficult to claim inventiveness;
- The lack of documentation in respect of traditional knowledge.

Some *sui generis* models have been developed, including one from the Organization of African Unity. However, it was pointed out that, because of the deadline for TRIPS implementation in many countries, these models may have come too late. Many countries have already adopted one of the UPOV Conventions (1978 or 1991) in order to fulfil their obligations under the TRIPS Agreement, and this reduces the impetus to develop a new *sui generis* system. Another problem in respect of TRIPS implementation is that it is unclear whether *sui generis* systems will be accepted by the WTO as "effective", as specified in Article 27.3(b) of the TRIPS Agreement.

It was noted that, at present, most arrangements which involve access to genetic resources and traditional knowledge are effected through simple contracts, which raises the question whether *sui generis* contracts already provide an adequately effective system.

It was recognized that many organizations, including international agencies, are interested in the area of IPP for traditional knowledge, although the extent of their activities and progress was not clear. For example, a representative of the CBD Secretariat pointed out that the CBD had been actively working on the subject for several years, but was unable to report significant progress. Some organizations noted that although there seem to be many international forums for debate, there is little practical development. The panel felt that there was a need for more coordinated reporting of the activities of interested organizations, and suggested that this might be a role for the Commission.

4.3 Biosafety and bioethics

(i) Biosafety

Where regulations have already been developed, this has generally been in response to domestic developments in biotechology, rather than in response to international concerns or in anticipation of future needs. For those countries that have yet to establish national competent authorities, and/or regulations and guidelines, implementation of the Cartagena Protocol seems to be the starting point.

A question was raised concerning the appropriate timing for developing countries to formulate and implement national biosafety regulations, depending on their level of technological development. It was clear that there are two fundamental arguments on this issue one supporting a reactive approach, the other supporting a proactive approach.

On one hand, it was suggested that capacity building in the use of biotechnology should precede the introduction of biosafety regimes on the ground that there is little point in spending resources to regulate technology which is not used in the country. This "reactive" approach has been predominant in countries which are now advanced in biotechnology. The

opposing argument is that biotechnology is developing very rapidly, whereas the development of biosafety regimes has been slow, which would favour a proactive approach to developing such regimes. No consensus on this subject was reached.

However, countries which have become, or are preparing to become, parties to the Cartagena Protocol on Biosafety must also be prepared to introduce institutional structures and procedures which are commensurate with its terms and conditions. It was also pointed out that national regulations need to go beyond implementation of the Cartagena Protocol. The Protocol is limited in that it only covers transboundary movements of GMOs, not their release within national borders, and it only applies to some classes of GMOs.

Unfortunately, resources for formulating and implementing biosafety regimes are scarce in many developing countries. The concerns here include a lack of trained personnel and institutions, and poor legal infrastructure for assessing and managing risks in the these countries. It was noted that a wide range of scientific expertise is needed in order to develop meaningful regulations and procedures, including enhanced capacity in molecular biology, ecology and physiology.

The main concern with regard to developing risk assessment procedures was that they need to be ecosystem-specific. Lack of detailed knowledge about specific ecosystems will make effective risk assessment very difficult. One problem in this respect is that research, for example on the impact of insect-resistant transgenic crops on monarch butterflies, is producing different results. Laboratory tests have indicated a strongly adverse impact, but in field conditions the results have been very different.

These difficulties will also make risk assessment a costly process in terms of human resources, funding and time. It was pointed out that risk assessments undertaken by the innovating organizations themselves are not really acceptable, although these organizations may be best placed to provide the necessary expertise and other resources. In respect of the international transfer of genetically modified organisms, the Cartagena Protocol states that the receiving country does not have to carry out the risk assessments, but may require the exporter to undertake an independent assessment. Therefore, risk assessments for domestic innovations would seem to be more of a problem.

National regulations are still only part of the solution. The issue of monitoring the implementation of biosafety regulations was discussed, with particular reference to illegal planting of transgenic crops. Regulations are often very difficult to enforce, as has been found in Brazil, where it is estimated that 3 million hectares of transgenic soybeans have been planted illegally. This problem is also found in Paraguay, where illegally planted crops are estimated to account for about 10 per cent of all crops under cultivation. It was mentioned that in Colombia, diagnostic kits to detect transgenic crops have recently come into use. One problem with the use of such kits is that as the number of different genetic modifications and resulting products increases, the number of different kits needed is likely to increase to unmanageable proportions. However, against this argument, it was pointed out that with the continuing development of DNA chips[10] it will become possible for one such chip to test for many conditions. Furthermore, these kits are likely to bring costs down.

[10] DNA chips, or microarrays, contain many DNA segments in a single array. This allows for diagnosis of many conditions in a single kit. Existing diagnostic kits are designed to test for one specific condition.

It was suggested the costs of biosafety implementation could be kept down through, for example, regional cooperation. It was pointed out that the Andean countries have drawn up a common pact on transboundary movement of GMOs, where different countries share some of the same ecosystems. Regional pacts are also useful for harmonization of biosafety standards between countries. Another suggestion was that developing countries should cooperate at a subregional level if independent development of biosafety regimes at national level may be too costly. However, agreements at regional level may be difficult to reach.

Given some of the very complex and potentially costly requirements of formulating and implementing national biosafety regimes, the discussion turned to the role of the international community in assisting developing countries. It was pointed out that, for too long, global discussions have focused more on trade in genetically modified commodities and less on trying to share experiences and expertise relating to national regulations and guidelines. As a result, it was claimed, UNEP's very useful initiative in developing basic standard guidelines in 1995 has not been followed up. It was suggested that the real problem with biosafety regulations is their implementation at national level, and that this is where guidance is now needed.

It was further argued that different countries will probably use different instruments to implement the Cartagena Protocol, as well as handling biotechnology developments within the countries, according to their prevailing socio-economic and trade concerns.

However, some members of the panel felt strongly that where capacity to develop and manage biotechnology does not exist in some developing countries, there is still a need for regulatory systems to manage potential risks from imports, legal or otherwise. This is where the international community needs to provide support, and address the problems of the contradictions and inconsistencies in international agreements. It was further argued that one of the main problems with international agreements is that they are negotiated without reference to scientific evidence, and this also needs to be addressed. One suggestion was the establishment of international bodies and facilities to undertake monitoring of GMOs on a worldwide and regional basis. Another issue identified was that some important areas of contention at the international level, particularly a mechanism to handle liability in cases of adverse impacts from biotechnology, are unresolved.

Given the lack of resources, and the complexities of both fulfilling international obligations and meeting national needs, it was finally suggested that a two-pronged approach to biosafety may be appropriate: one short-term and the other long-term. The international community could organize training to facilitate implementation of international regulations and build long-term capacity. At the same time, coordination and dissemination of national models for implementation would give assistance to those countries that have the least capacity to formulate biosafety regimes.

(ii) Bioethics

None of the members of the panel reported specific initiatives related to bioethics in their countries, although in some countries public awareness and interests had been taken into account in the development of biosafety regimes more generally.

A question was posed, in respect of stigmatization and potential misuse of genetic information, about how to differentiate between the terms “genetic variation” and “genetic disease” (Down’s syndrome was given as an example). It was suggested that such a differentiation was extremely difficult, and would perhaps be a matter of individual interpretation. This raised the issue of the appropriateness of state intervention and regulation in the field of clinical genetics.

Whilst the discussion on bioethics was very much focused on human health concerns, it was also noted that there are many socio-economic issues related to new developments in agricultural and industrial biotechnology. The example was given of the ongoing development of genetically engineered synthetic cocoa butter. The future commercialization of such a product would adversely affect countries such as Côte d’Ivoire and Ghana, where a large per centage of foreign exchange earnings are dependent on cocoa.

It was agreed that these issues all clearly point to a need for public awareness, either to enable informed individual choices to be made, or for individuals to participate effectively in public decision-making. It was pointed out that public information on biotechnology, particularly genetic engineering, has tended to be oversimplistic and present extreme positions both negative (such as the coining of the phrase “Frankenstein foods”) and positive (the claims that “transgenic crops will feed the world”). It was argued that there is a need for information to be more widely published, not only in scientific journals but also in forms suitable for the mass media, so that a balanced view is presented to the general public. Furthermore, monitoring of new developments in biotechnology should take into account different ethical perspectives.

5. CONCLUSIONS AND RECOMMENDATIONS

The discussions highlighted two major areas of concern with respect to the regulation of biotechnology development. The first relates to the need for improved information and knowledge flows to support capacity-building efforts. The second, which takes account of the lack of capacity to manage biotechnology in most developing countries, relates to international efforts to support oversight and regulatory harmonization. Furthermore, the panel identified some key areas where greater understanding is needed, particularly about existing barriers to biotechnology development. The consolidated recommendations from this meeting have therefore been divided into the following

- Information and knowledge flows;
- Legislative and regulatory framework;
- Further studies.

5.1 Information and knowledge flows

It was recognized that better access to information and knowledge would greatly facilitate acquisition, development and diffusion of biotechnology, and also the development of legal and regulatory frameworks to manage these technologies. Objective information about biotechnology should be provided by academics, Governments and the mass media in a form that is understandable to the general public.

The following areas were highlighted for attention:

- Access to electronic databases and other Internet-based information sources;
- The availability of objective information on issues relating to biotechnology, including current international debates, in forms which can easily be understood by non-experts;
- The need for mechanisms to select (from the huge volumes of available information on biotechnology) and disseminate information which is most relevant to capacity building and policy formulation;
- The problem of information held and disseminated in different languages;
- The sharing of information and expertise through networks;
- The ability of developing country researchers to use available information to generate new knowledge, and to diffuse that new knowledge effectively.

In respect of these areas, the following recommendations were made:

(i) Global databases

The establishment of "global" databases would give central access to all similar (i.e. on the same theme) major databases, including those in languages other than English. It was suggested that the possibility of establishing a central website facility under the auspices of the CSTD be explored. Such a website would link competent international organizations and national institutes relevant to the development and management of biotechnology. The UNCTAD secretariat is currently undertaking the development of this type of web facility, and this could provide a basis for further enhancement in support of CSTD activities and recommendations.

Another option would be to encourage and support, including through initiatives to mobilize resources, an expanded database which would involve:

- Access, on a reduced "block fee" basis, to databases which can currently be accessed only by paying a separate fee to each one;
- A translation facility for databases held in different languages.

(ii) CSTD standing committee

The CSTD should establish a small standing committee to collect, analyse and package information on biotechnology for dissemination on the UNCTAD website. The CSTD should request funding for this committee from the United Nations Economic and Social Council and also commitment from other bodies that could undertake work associated with the initiative. The objective of the committee would be to deliver impartial information on important biotechnology issues such as:

- The Human Genome Project;
- The effect of intellectual property protection on biotechnology development in poorer countries;
- Techniques for ensuring biosafety;

- The current debates with respect to harmonizing multilateral agreements which impact on biotechnology development.

The committee could also:

- Promote dialogue and consultations among leaders from Governments, industry, academia and other sectors on the role of biotechnology in development;
- Follow up on CSTD recommendations;
- Raise funds for the implementation of those recommendations.

(iii) Regional/sub-regional focal points

Consistent with the recommendations of the first panel on capacity building, it was recommended that regional mechanisms could be set up to help countries build capacity for biotechnology development, including the dissemination of information and building public awareness. These could also act as focal points in respect of other recommendations relating to regulatory oversight (included in the next section). The CSTD could provide an outline proposal on the structure and roles of these regional mechanisms for consideration by the relevant United Nations regional commission.

(iv) Improvement of information technology infrastructure

The key area for national capacity-building in respect of information flows is the facilitation of access to new knowledge through building up information technology infrastructure. Access to the Internet is an increasingly important resource for technological development, and programmes should be established with international support where necessary to improve such access. It is known that several major foundations are funding initiatives to improve Internet use in developing countries, particularly those in Africa. The World Bank's InfoDev programme in Africa is also significant. The CSTD may specifically recommend that these and other organizations mobilize resources for addressing some of the contextual problems of Internet access in developing countries, such as the high cost, and low reliability, of telecommunications systems; the scarcity of web server facilities; problems of power supply and equipment failure; and unequal distribution of Internet access, with few facilities existing outside capital cities.

(v) Networks and collaborative links

Networks and collaborative research links were recognized as important mechanisms for information and knowledge transfer, and it was recommended that national policies should promote the establishment of such links. Furthermore, careful attention should be paid to ensuring the most effective utilization of these links in respect of knowledge and information transfer. Policies should therefore:

- Promote, in particular, user–innovator networks, including links between industrialized and developing countries, and links between the public and private sectors;

- Encourage collaborative research agreements which provide an equitable sharing of benefits, it being recognized that such benefits should extend beyond financial reward to include technology transfer;
- Not only ensure the allocation of resources to create new knowledge, but also give support to mechanisms to diffuse, or market, this knowledge.

5.2 Legislative and regulatory framework

Members of the panel felt that while developing countries and countries with economies in transition should develop regulatory regimes for biotechnology according to national contexts, there is also a need for extensive international support to ensure effective implementation of biotechnology regulations. The following recommendations and suggestions for further consideration were made:

(i) Capacity building

Capacity building for risk monitoring, assessment and management is needed. International agencies such as ICGEB and UNEP, and the international financial institutions can play an important role in building capacity. Subregional groups and centres of excellence for risk assessment could be one option for reducing costs and providing expertise needed at national level.

(ii) International oversight and regulatory harmonization

It was suggested that mechanisms should be established, at regional and/or global levels, to support the harmonization of basic agreed safety standards, or benchmarks, in respect of, for example, the conduct of field trials of GM crops. Efforts must be made to resolve the potential disparities between rights and obligations under various international agreements particularly the WTO Agreements and the CBD/Cartagena Protocol. The following proposals were made to facilitate these efforts:

- Work should be undertaken under the guidance of the CSTD to develop a regulatory "model". *This model could serve as a basis for developing countries to formulate, harmonize, integrate, implement and monitor policies for the selection, acquisition, adaptation, development, diffusion and management of biotechnology.* It could also help members develop regulatory regimes which are consistent with international protocols.
- There should be international support for CSTD regional and subregonal workshops to harmonize national regulations within regions/subregions, using the regulatory model mentioned above.
- Independent international monitoring and assessment of activities involving GMOs should be undertaken, perhaps under the auspices of UNEP or of the Secretariat of the Convention on Biological Diversity, which is already developing a global clearing-house mechanism for information on GMOs.

(iii) National policies for biotechnology regulation

Institutional responsibility for implementing biosafety regulations was one key issue raised. Procedures such as risk assessment will rely heavily on scientific expertise, but at the same time there are concerns that the scientists themselves should not become "self-regulating" in respect of biotechnology. One reason is that there are social, moral and ethical implications related to new biotechnologies, including their potential misuse. Regulatory regimes should take these into account. A major task for national policy is therefore to identify members of the stakeholder community for biosafety policy formulation, and ensure a balance of various types of expertise and objectivity. Processes such as national capacity needs assessments, recommended by the previous panel, would provide a mechanism for identifying those stakeholders.

It was noted that the issue of liability and redress, in respect of adverse impacts of imported GMOs, has not yet been settled at the international level, and that therefore national legislation might need to address this concern. The progress of the Intergovernmental Committee on the Cartagena Protocol on the liability issue should be monitored by the CSTD, particularly with respect to identifying a dispute mechanism.

5.3 Further studies

Several issues emerged, particularly in respect of technology transfer and diffusion, for which further understanding is needed at national and international levels in order to support capacity building in biotechnology. The panel members therefore feel that the following areas of research are deserving of support by international organizations, including UNCTAD, bilateral donors and national Governments:

Studies which will give a better understanding of:

- Problems with technology absorption in developing countries;
- Factors which affect the implementation of biosafety regulations once these are in place; it was noted that regulatory regimes may be necessary, but are not in themselves sufficient;
- The potential for *sui generis* systems of intellectual property protection (IPP) to ensure the equitable sharing of benefits from the biotechnology-related use of traditional knowledge and plant genetic resources;
- The potential impact on technological development, including technology transfer and diffusion, of new IPR regimes which allow IPP for living matter. This would help developing countries and countries with economies in transition to formulate domestic policies as well as appropriate positions for international negotiation for example, in respect of future reviews of the TRIPS Agreement.

SUMMARY

The recommendations of the panel stressed that better coordination and more even distribution of knowledge and information are critical to the successful development of biotechnology in developing countries and countries with economies in transition. This applies equally to scientific data and knowledge, to information on the policy debates and to initiatives at international level. It is expected that the UNCTAD website can be used as a significant resource in this respect. Over and above the need for better dissemination of information on a global scale, the need for enhanced public awareness within countries about the potential risks and benefits of modern biotechnology was strongly emphasized by the panel. The final CSTD panel on biotechnology in 2001 will take up this issue as its main theme.

ANNEX I

List of participants

CSTD Panel members/representatives

Prof. Bernd Michael Rode	Austria
Ms. Marleen Bosschaerts	Belgium
Mr. Syargei Katsko	Belarus
Prof. H. Hogbe Nlend	Cameroon
Dr. José Rodriguez Due as	Cuba
Mr. Mamo Mulugeta	Ethiopia
Mr. Eberhard Hauser	Germany
Dr. Joseph R. Cobbinah	Ghana
Mr. Cécé Kpoghomou	Guinea
Prof. Dr. Yoedoro Soedarsono	Indonesia
Dr. M. Molanejad	Islamic Republic of Iran
Dr. Arnoldo K. Ventura	Jamaica
Dr. Kong Rae Lee	Republic of Korea
Dr. Tariq ur Rahman	Pakistan
Mr. Victorio Oxilia	Paraguay
Ms. Rolanda Predescu	Romania
Prof. Štefan Morávek (Chairman)	Slovak Republic
Mr. D. Jesús Martinez Frias	Spain
Prof. Dr. Vijaya Kumar	Sri Lanka
Dr. Ali Abaab	Tunisia

Permanent missions in Geneva

Mr. Arnaldo Abeti	Italy
Mr. Felix Grishaev	Russian Federation
Mr. David José Vivas Eugui	Venezuela

Resource persons

Dr. Ivan Rodrigo Artunduaga Salas	Colombian Agricultural Institute, Colombia
Prof. Gert-Jan van Ommen	University of Leiden, Netherlands
Prof. Calestous Juma	University of Harvard, United States

Observers and invited guests

Mr. Sam Johnston	Convention on Biological Diversity, Canada
Ms. Edda Rossi	Ministry of Foreign Affairs, Chile
Mr. Giovanni Ferraiolo	ICGEB, Italy

Mme Anne-Marie Colandrea	Mission of the Holy See, Geneva
Père Masimo de Gregori	Mission of the Holy See, Geneva

ANNEX II

List of documents and presentations

Resource persons

Prof. Calestous Juma	Promoting biotechnology acquisition and development: the broad policy context
Prof. Gert-Jan van Ommen	The Human Genome Project: Issues arising for technology transfer, intellectual property rights, and bioethics
Dr. Ivan Rodrigo Artunduaga Salas	Biosafety regulations related to transgenic plants in Latin America and the Caribbean region

CSTD members

Dr. Joseph Cobbinah	Status of biosafety in Africa
Dr. José Rodriguez Due as	Bioethics and biosafety in Cuba
Mr. David José Vivas Eugui	Reunion de la OMPI sobre propiedad intelectual y recursos genéticos: Los conocimientos tradicionales, sus innovaciones y practicas, y la necesidad del establecimiento de una protección de propiedad intelectual adecuada
Mr. Syaregei Katsko	Biotechnology in the Republic of Belarus: National policy and regulation
Prof. Vijaya Kumar	1. Technology transfer and diffusion in Sri Lanka 2. IPR, plant breeders rights and *sui generis* systems: current situation in Sri Lanka 3. Biosafety and bioethics issues in Sri Lanka 4. IPR for plant genetic resources and developing country concerns
Dr. Kong Rae Lee	Biosafety and biodiversity in the Republic of Korea.
Mr. Mulugeta Mamo	National biotechnology policy of Ethiopia
Mr. Victorio Oxilia	Legal and regulatory issues in Paraguay

Ms Rolanda Predescu	The IPR protection system and biosafety-related legal and institutional framework in Romania: A brief overview
Dr. Tariq ur Rahman	National biosafety guidelines in Pakistan
Mr. Juan L. Ramos	Environmental biotechnology, biochemical and genetic basis for biodegradation and questions posed by the use of recombinant and non-recombinant strains in the environment
Prof. St fan Morávek	National programme for the development of biotechnologies and the biotechnological industry in the Slovak Republic
Dr. Arnoldo Ventura	Regulatory issues in biotechnology: The Jamaican case

Observers and invited guests

Mr. Giovanni Ferraiolo	The work of the International Centre for Genetic Engineering and Biotechnology in building capacity for biosafety

UNCTAD

UNCTAD Secretariat:	Regulation and management of biotechnology in developing countries and countries with economies in transition
Mr. Rene Vossenaar	UNCTAD's work on biotechnology and the protection of traditional knowledge
Ms. Simonetta Zarrilli:	Genetically modified organisms and multilateral negotiations: A new dilemma for developing countries.