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ACCESS TO GENETIC RESOURCES

Abstract of the international scientific conference on "Guidelines
for Access and Benefit-sharing – Initiatives and Perspectives for
Implementing the Convention on Biological Diversity"

Note by the Executive Secretary

1. At the request of the Government of Germany, the Executive Secretary is circulating herewith, for the information of the Conference of the Parties at its fifth meeting, the abstract of the international scientific conference on "Guidelines for Access and Benefit-sharing – Initiatives and Perspectives for Implementing the Convention on Biological Diversity", held in Germany on 17-18 April 2000.
2. The document is being circulated as it was prepared by the Government of Germany.

* UNEP/CBD/COP/5/1.

On 17.-18.04.2000, the German Federal Agency for Nature Conservation hosted an international scientific conference on

**„Guidelines on Access and Benefit-Sharing,
Initiatives and Perspectives for Implementing the CBD“**

which took place in Bonn. About 30 experts from European countries with a governmental, scientific, industry and research background discussed issues concerning guidance for access and benefit-sharing.

The following presentations/submissions were discussed:

- “Access to *ex-situ* Microbial Genetic Resources“ (Dr. Dagmar Fritze, Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH),
- “Access to and Transfer of Genetic Resources – Approaches within the German Association of Botanical Gardens” (Prof. Dr. Thomas Stützel, German Botanical Gardens Association)
- “Botanic Gardens Policy Guidelines on Access and Benefit-Sharing“ (Barbara Di Giovanni, Royal Botanical Gardens, Kew)
- “The Swiss Guidelines on the Utilisation of Genetic Resources“ (Alwin Kopse, Swiss State Secretariat of Economic Affairs, Bern)
- “The ASEAN Framework Agreement on Access and Benefit-Sharing“ (Dr. Andreas Drews, German Agency for Technical Cooperation (GTZ))
- “The Multi-stake-holder Approach and the Deliquescence of African States“ (Dr. Marcello Broggio, Plant Protection and Biotechnology Lab, Instituto Agronomico Oltremare, discussion keynote)
- “Guidelines of CBD and non-commercial basic academic research” (Prof. Dr. Michael Wink, Heidelberg University, Institute for Pharmaceutical Biology)
- „Seeding Solutions: The Struggle for Genetic Resources, International Policy Issues“ (Dan Leskien -as Member of the Crucible Group-, Friends of the Earth International)

The participants considered the Report of Panel of Experts on Access and Benefit-sharing, UNEP/CBD/COP/5/8, 2 November 1999 and the Note by the Executive Secretary on Access to Genetic Resources, UNEP/CBD/COP/5/21 (1 March 2000) and discussed further developments concerning guidelines on access and benefit-sharing. Abstracts of presentations and submissions are annexed for information.

Dr. Dagmar Fritze, Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH:

“ACCESS TO EX-SITU MICROBIAL GENETIC RESOURCES“

1. Provisions of the CBD of Relevance to Culture Collections

The demands of the CBD for maintenance and sustainable use of biodiversity, and the equitable share of knowledge, technology and benefits resulting from the use of biodiversity directly influence the work of *ex-situ* service culture collections whose custodial responsibilities need to be defined more clearly in future.

2. Peculiarities of Microbial Culture Collections

Introduction to the aims and scopes and the practical work of service collections of living biological material. Their policies for accessioning and distributing biological material for research and development. Some serve additionally as depositories for patent cultures.

3. Peculiarities of Microbial Cultures in Contrast to Plants and Animals

Microorganisms are ubiquitous and found in every ecological niche, performing recycling roles and interacting with other living forms in ways that we are only now beginning to understand. Their total numbers are unknown and their study *in-situ* is difficult. Microorganisms that are isolated from environment are typically conserved in culture collections and form the basis of much of our knowledge of microbial diversity and are the living archival material for future study. The *in-situ* conservation is not applicable to micro-organisms for a number of reasons.

4. The World Federation for Culture Collections (WFCC) and its Activities with Regard to Organization and Management of Culture Collections and Compliance with the CBD

The WFCC is a multidisciplinary Federation within the IUMS and the IUBS. Its objectives are the overall support of the activities of microbial resource centres, the promotion of a world network for information and communication and the exchange of microbial genetic resources. It represents the majority of *ex-situ* microbial resource centres; some 500 in 58 countries are listed in its World Data Centre for Microorganisms (WDCM). Through its committees a number of CBD related workshops and publications have been initiated.

5. The MOSAICC Project: Development of operational guidelines for the introduction of access and benefit sharing procedures

The CBD requires that prior informed consent (PIC) is obtained before collection of genetic resources and their deposit in a resource centre. Further, it requires that terms are defined at the time of deposit, which will cover distribution to third parties. Model Material Acquisition Agreements and model Material Transfer Agreements have been developed with respect to microbial cultures for the use of culture collections as well as of research scientists in their role of depositors or recipients of cultures.

ACCESS TO EX-SITU MICROBIAL GENETIC RESOURCES

I. Special characteristics which distinguish microorganisms from plants and animals

Microbial Genetic Resources:

- replicate frequently; this may lead to changing populations in the environment and, if not expertly preserved, also ex-situ
- cannot be accurately enumerated; estimation of 'base line' for inventorying purposes not possible
- may be transferred across borders by wind, water, the movement of animals or human beings
- cannot be tracked and monitored conventionally; are difficult to be fingerprinted for identity/non-identity checks; scope for piracy exists
- are unlikely to be depleted by sampling (however the loss of hosts could lead to the loss of dependent microbial species; examples known for fungi)
- have been recorded that strains of one and the same species may occur in a number of geographical locations; few species may occur in only one country
- have been shown to exhibit slight genetic variation within a species (isolates, strains), this also may depend e.g. on sampling time; thus individual isolates are of considerable significance in terms of genetic expression
- may be found equally in 'gene-rich' countries as in 'industrial' regions; microorganisms easily develop commercially valuable properties in response to environmental stress
- require special equipment, technologies and taxonomic skills for their study

II. Approaches how to tackle the issue of access to microbial genetic resources under the CBD have been made by

1. the World Federation for Culture Collections (WFCC) who compiled a respective Information Document (Background document to the UNEP/CBD/COP/3/Inf. 19 information document); (<http://wdcm.nig.ac.jp/wfcc/InfoDoc.html>)
2. the EU supported MOSAICC project (Micro-Organisms Sustainable use and Access regulation International Code of Conduct); (<http://www.belspo.be/bccm/mosaicc>)
3. individual Initiatives of Culture Collection

ad 1. The WFCC Information Document fully addresses the specific position of microorganisms. Information is provided on their nature, their rapid population change, their global distribution and relationships with other forms of life, and the consequences of such characteristics for inventorying, tracking and benefit sharing. Elements for inclusion into agreements relating to access to microbial genetic resources are presented and discussed.

It is recommended (among others) that

- access to microbial genetic resources should be protected for scientific research, taxonomy, education, development and health surveillance

- partnerships be encouraged between established and emerging microbial resource centres for training and the development of technical and administrative capacity
- consideration should be given to the development of a voluntary, internationally agreed Code of Practice (or Guidelines) for the deposit, access and distribution of microbial resources
- consideration be given to the possibility of developing International Depositary Authority status of Culture Collections (as presently in existence for patent strains under the Budapest Treaty) for the implementation of the CBD or introducing CBD registered CCs that are authorized to apply internationally agreed provisions
- microbiologists be involved in the development of national policies and international agreements to ensure practicability of measures in their application to microorganisms
- the legal situation with regard to ownership of microorganisms and working relationships between ratified and non-ratified countries be clarified
- the Parties to the Convention make full use of the expertise of WFCC members at the national level, particularly with regard to capacity building, training, taxonomic expertise, preservation skills, databases on microbial resources and existing WFCC Guidelines
- expert working groups be set up, consisting of representatives of the WFCC and other microbiological organizations, environmental lawyers and policy makers to assist in the development of policies and procedures for access to microbial genetic resources, capacity building and benefit sharing

ad 2. the MOSAICC project emerged from the recommendations of the WFCC document and aimed at the elaboration and diffusion of a code of conduct for the access to and sustainable use of microbial resources within the framework of the CBD. It is designed as a voluntary code of conduct. With a view to culture collection activities, it is foreseen to have this complex draft tested by collections to its practicability in daily work and potentially improved as seen necessary.

Model forms have been designed for the various stages from habitat to use of a microorganism. Their contents are discussed.

Isolation from nature (access in-situ)

- PIC application form for access
- PIC certificate obtained from competent authority or permission from landowner
- Material Transfer Agreement

Transfer from Culture Collections or from individual researchers (access ex-situ)

- Material Transfer Agreement
- Reference to original PIC or equivalent document

ad 3. Individual microbial culture collections have responded to the requirements of the CBD by developing general statements or inserts on their accession or delivery forms. These refer mainly to the questions of country of origin, PIC certificate, and final use of delivered material. However, it is stressed that there may be advantage in developing internationally acceptable guidelines.

Prof. Dr. Thomas Stützel, German Botanical Gardens Association

“ACCESS TO AND TRANSFER OF GENETIC RESOURCES – APPROACHES WITHIN THE GERMAN ASSOCIATION OF BOTANICAL GARDENS”

Germany has nearly 100 institutions, which can be called botanical gardens in a wider sense, about 50 % of which are university gardens. The rest are public gardens run by a city or a county as well as a small number of private institutions.

The spirit of the Biodiversity Convention is nothing new to German botanical gardens. German botanical gardens have always supported a balanced open system of giving and taking, far from commercial use and therefore from misuse.

For us changes due to the CBD are therefore not so much a change in spirit, but a change in practice. Now we have to keep formal control over our collections, which includes keeping the flow of material as well as the collections themselves as transparent as possible.

We are far from a convenient situation at the moment. The problem is not that we do not want to be more transparent, the problem is that we cannot.

At the Ruhr University Botanical Garden we do not have a full survey on our collections. One half of the supposed 15 000 taxa is registered either in an old card system which is totally out of date or is not registered at all. The other half is registered in an electronic database, which can be queried via the internet. The German botanical gardens own an online database which allows queries across all gardens which have joined in.

Our problem is that the manpower, which is sufficient to update the collection records is now responsible in addition for the documentation of material transfers and supervision according to the CBD. The consequence is that it is getting impossible for gardens to acquire new material, even in infra-German transfers of German resources.

This illustrates the need to establish a system which minimizes the amount of administrative work.

We would like to have a single standardized material transfer agreement (MTA) for all German botanical gardens. This agreement should have the character of an open list to which German gardens may assign to and have the status of national law. Material transfers between listed national institutions thus would not need further formal agreements, a reminder in the form of a standardized “license agreement” would suffice.

Our solution for the moment is to refrain from any aspects of commercial biodiversity research. However, it is unacceptable that access to plant material is restricted by patents or otherwise with the result that countries cannot use their own resources or have to pay license fees for them.

Solving difficult legal problems is not the task of a botanical garden or university administration, but of a national administrative institution. The German botanical gardens are willing to cooperate with national and international authorities to transform the “spirit of the CBD” into a functioning framework. This is underlined by our efforts for maximum transparency not only for national organizations but for all countries which act or might have acted as suppliers of plant material.

Barbara Di Giovanni, Royal Botanical Gardens, Kew:

“BOTANIC GARDENS POLICY GUIDELINES ON ACCESS AND BENEFIT-SHARING”

1. Context

The entry into force of the Convention of Biological Diversity (CBD) in 1993 and its subsequent ratification by 177 parties provides a new mandate for botanic gardens and presents them with both policy and practical challenges. For the *ex situ* collections held in botanic gardens to be of value to science and conservation, they must be maintained and improved. To achieve this, continued access to plant, fungal, microbial and animal genetic resources is essential. The exchange of genetic resources between botanic gardens is also necessary to facilitate taxonomic and other scientific research and to ensure that the levels of diversity held in *ex situ* collections are adequate for conservation. Additionally, botanic gardens act as an important “clearing house” as the genetic resources they collect may be supplied to a wide range of organisations including other botanic gardens, universities, research institutions and industry. The CBD and national laws on access to genetic resources have introduced certain legal obligations with which botanic gardens must comply. However, in some important respects, for example access to collections made prior to the entry into force of the CBD, there is little legal or policy guidance for botanic gardens. By taking a voluntary, proactive approach to find a clear and practical way to operate in the current situation, botanic gardens can help devise solutions which meet the requirements of the CBD and relevant national law, and which are appropriate to their activities. As there are some 1775 botanic gardens in the world, if each garden were to adopt its own approach on access to genetic resources and differing material transfer agreements, the exchange of materials could become extremely complicated and consuming. In order to facilitate access to genetic resources directly from countries of origin and through exchange with other botanic gardens, it is highly desirable that gardens harmonise their policies, practices and agreements.

2. Developing a harmonised approach

With this in mind, seventeen botanic gardens from Australia, Brazil, Cameroon, Canada, China, Colombia, Malaysia, Germany, Ghana, Mexico, Morocco, the Russian Federation, South Africa, the UK and the USA have been working together in a project coordinated by the CBD Unit of the Royal Botanic Gardens, Kew and funded by the UK Department for International Development. Botanic Gardens Conservation International and the International Association of Botanic Gardens have also taken part. The objectives of the project, which started in November 1997, have been to develop a harmonised approach for the participating gardens on access to genetic resources and the sharing of benefits that implements the letter and spirit of the Convention on Biological Diversity; to produce model material transfer agreements for the acquisition and supply of genetic resources by botanic gardens; and to prepare a publication explaining the choices made in their implications. A workshop is due to take place in Cartagena, Colombia, from 6-8 November 2000 in order to discuss implementation of the Common Policy Guidelines and will involve the original group, as well as any other botanic gardens or institutions that are interested in adopting the document. An explanatory note, which will be ready in December 2000, is being developed to accompany the Common Policy Guidelines.

Alwin R. Kopse, Swiss State Secretariat for Economic Affairs:

“SWISS PROPOSAL FOR DRAFT GUIDELINES ON ACCESS AND BENEFIT SHARING REGARDING THE UTILISATION OF GENETIC RESOURCES”

For many years, Switzerland has been actively involved in the discussion on access to genetic resources and the sharing of benefits arising from their utilisation. In order to gather useful information and to better understand the issues at a practical level, a survey had been conducted with the private sector and the research community regarding possible benefit sharing mechanisms used in connection with genetic resources. The results of this survey were reported to the COP IV (see document UNEP/CBD/COP/4/Inf. 16). The survey showed that one possible solution to address these issues is the elaboration of a set of guidelines. A first outline of the present Draft Guidelines was presented during the Expert Panel Access and Benefit Sharing held in San José, Costa Rica, October 1999. The Draft Guidelines have been drawn up with the active collaboration of the partners that were already involved in the above-mentioned survey. They are intended to serve as a starting point in the discussion on access to genetic resources and benefit sharing.

The present Draft Guidelines can be described as follows:

- Their primary function is to serve as a point of reference for all stakeholders involved in access to genetic resources and their utilisation, and in the fair equitable sharing of benefits arising from their utilisation.
- They aim at (1) promoting the appropriate access to genetic resources, and (2) to fair and equitable sharing of benefits arising from the utilisation of these resources.
- They are based on the sovereignty of States over their genetic resources.
- They set standards and contain principles that should be observed by those stakeholders which adhere to it.
- They are of voluntary nature.
- Due to their voluntary nature, the Draft Guidelines can be applied not only by States, but also by all other stakeholders involved in access to genetic resources and the sharing of the benefits arising from their utilisation.
- They are based on an approach which differentiates the various steps involved in access to genetic resources and the sharing of the benefits arising from their utilisation, that is, they differentiate all steps from the collection of genetic resources to the commercialisation of the findings of scientific research and development. The present Draft guidelines thus follow a process-based approach and list the responsibilities of all stakeholders involved in access to genetic resources and benefit sharing.

Dr. Andreas Drews, German Agency for Technical Cooperation (GTZ):

“REGULATING ACCESS TO GENETIC RESOURCES – THE ASEAN APPROACH”

Possessing ecosystems being considered as among the most diverse in the world member states of the Association of South East Asian Nations (ASEAN) consider conservation of nature and natural resources as an essential means to protect the environment and to promote sustainable development. Realizing the potential value of biological and genetic resources in the development and commercialization of products that have medicinal, industrial, and agricultural applications and acknowledging the need to ensure uniformity and consistency of access regulations in the ASEAN region by setting minimum requirements for national implementation 1998 ASEAN Senior Officials on the Environment (ASOEN) have initiated a process to draft the „ASEAN Framework Agreement on Access to Genetic Resources“.

In February 2000 members and technical experts of the ASEAN Working Group on Nature Conservation and Biodiversity (AWGNCB) met in Singapore to discuss the inputs made by public and private organizations, groups and institutions on the 1st draft of the agreement and to come up with a 2nd draft document to be raised to the ASOEN in summer 2000.

The framework agreement respects the sovereignty of each member state over its biological and genetic resources and notes the need to comply to the three objectives of the CBD: promote conservation and sustainable use of these resources as well as the fair and equitable sharing of benefits arising from their utilization. As a fundamental principle, prior informed consent (PIC) of the member state and its indigenous peoples and local communities embodying traditional lifestyles has to be secured before access can take place. The member states shall recognize, respect, preserve and maintain the knowledge, innovations and practices of indigenous peoples and local communities embodying traditional lifestyles to their natural resources, including genetic resources. Biological and genetic resources are regarded as sacred heritage for all humankind and the application of the patent system thereon is rejected. The importance to enhance food security in the region and to exchange and utilize food crop germplasm, which is already widely dispersed and utilized, is recognized.

The Framework Agreement covers all biological and genetic resources including the traditional knowledge associated therein. *Ex-situ* materials originating from the ASEAN region collected prior to the adoption of CBD are considered as held in trust for the benefit of humankind where the application of intellectual property rights is not allowed as well as prospecting and application of intellectual property rights on genetic materials of human origin.

The implementation of the Framework Agreement will be facilitated by a regional clearing house, whose functions initially will be performed by the ASEAN Regional Centre for Biodiversity Conservation (ARCBC) in the Philippines until a permanent body will have been designated by ASEAN.

Dr. M. Broggio, Istituto Agronomico Oltremare (Ministry of Foreign Affairs), Florence Italy:

THE MULTI-STAKE-HOLDER APPROACH AND THE DELIQUESCENCE OF AFRICAN STATES

For a multi-laterally agreed bi-lateral system of Access and Benefit Sharing (ABS) to be functional, the principles of equity and operability should constitute the base of any further technical consideration.

According to the first principle of *equity*, either provider and potential user of genetic resources should possess a comparable record of capacity, access to information, transparency and responsibility (liability) prior to the negotiation on the terms of ABS.

For the second principle of *operability*, either potential partners should be embedded in a national framework system of rules, legislation and policies concerning the implementation of the CBD as well as other international obligations, managed by an effective administrative engine which is at work for the enforcement of those rules.

Unfortunately the conditions for the respect of such fair principles are not in place, as far as Developing Countries (DCs) as a whole are concerned, particularly the African countries, with some outstanding exceptions.

In the case of many sub-Saharan African countries, the situation has been depicted as that of “deliquescence” (*Le Monde Diplomatique*, February 2000), and it could be characterised, *inter alia*, by the evanescence of the public administration, which is in some instance even virtually dissolved since the salaries are really miserable if they get disbursed at all, also due to the cuts in public budgets.

In such conditions, where the enforceability and implementation of any though balanced and equitable rule and agreement is hard to be expected, we see a serious contradiction of the bi-lateral approach foreseen by the CBD: the resources of interest might be in such instances obtained in a manner that does not meet the CBD’s principles and objectives, or they can simply smuggled out of the country, or on the contrary the access could be object of unacceptable claims beyond any reasonable level.

How can this unfair reality be approached for the sake of the CBD’s objectives, including the recognition of the legitimate expectations of the local populations and indigenous peoples?

In our view, a possible solution might be explored in the implementation of the Multi-stakeholder approach at the supra-national level, by envisaging the establishment of a flexible and transparent regional or sub-regional body representing the national governments and major stakeholders, including the respective NFPs and CNAs, which would be charged of the specific Clearing-house system, where all applications, negotiations and transactions, as well as model transactions, best practices models and so for, should be dealt with and disclosed to the international public.

An aggregated multi-national body might foster and facilitate the build up of expertise, also by channelling and concentrating the efforts of the financial mechanism of the Convention; it might possibly enhance the reciprocal confidence between provider and user partners, which is key to the success of ABS negotiations. It might finally also address the potential competition among neighbouring countries from one side, and would contribute to foster fair competition between large and corporated companies and SMEs for the access to genetic resources.

It should be politically correct that the Developed Countries and the private sector stake-holders interested in the access to genetic resources support the set up of such regional “ABS CHM”.

Prof. Dr. Michael Wink, Heidelberg University, Institute for Pharmaceutical Biology:

GUIDELINES OF CBD THREATEN NON-COMMERCIAL BASIC ACADEMIC RESEARCH

Several areas of basic, non-commercial research depend on an easy access to plants and animals living on our planet. Such areas of organismal research are:

- systematics and taxonomy
- ecology
- biodiversity
- molecular phylogeny & evolution
- chemical ecology
- molecular phylogeography

Most of these areas are important for an inventory and for the conservation of nature, especially in tropical areas whose environments are highly endangered. Many of these studies enlarge our knowledge and provide the means for planning & sustainable development.

Typical research in these areas requires that samples which have to be taken in the field are later analysed in a museum or academic laboratory. In most projects samples are not only taken in a single locality or on a single species, but usually many species living at several localities are involved. These localities are usually not known beforehand but need to be discovered during expeditions. In many instances, field work is not only restricted to a single country but comprises several countries, often on different continents. For a study in systematics or molecular evolution we usually require samples from all living species in a certain group, often showing a wide geographic distribution.

In general, such research is carried out in collaboration with scientists from national universities, which take part in the sampling and publishing of the results. It is common practice that students from these university come to my University to obtain a training in modern fields of biology (which is also a form a reciprocal help).

Guidelines presented by the Asian, Andean and African countries render such basic research almost impossible. These guidelines might apply to commercial projects, where industries are only interested to obtain, say 1000 extracts, from a given area. Since basic research in the fields mentioned above usually comprises several localities and countries, the paper work, bureaucracy and costs will effectively prevent any future basic research, which cannot be the ail of the CBD.

Therefore, we need a much simpler regulation for basic, non-commercial research. In order to ensure a fair access and benefit sharing it would be sufficient to

- obtain a written consent from a national university or research organisation in respective countries to carry out defined non-commercial basic research projects

It cannot be ruled out that a biotechnological and commercial product could unexpectedly emerge from a basic research project, although these instances will be very rare (about 1 in 20,000 cases). Scientists are bound to strict ethical rules, which are signed by all universities in Germany. Behaviour not in accord with these rules will have severe consequences, e.g. the loss of an academic position. Because of these strict rules, it would be sufficient to add a clause, such as the following:

„If a commercial utilisation of an organism or any parts of it (or of indigenous intellectual property) which is part of CBD, is taking place, then it is the task of the scientist involved, to ensure that benefits are shared with the country or indigenous people, where the species was collected“.

Dan Leskien (as Memeber of the Crucible Group), Friends of the Earth International:

This Abstract has been excerpted from the Introduction of the Crucible Group's publication:

**SEEDING SOLUTIONS: THE STRUGGLE FOR GENETIC RESOURCES,
INTERNATIONAL POLICY ISSUES, INTRODUCTION**

The Current Challenge

The intersection between intellectual property and biodiversity, and the policy debate over its wider implications for society, is a subject of conflict and uncertainty at the dawn of the 21st century. The challenge is formidable because science, technology, and social and legal thought that relate to biodiversity and intellectual property are evolving rapidly. Policymakers are faced with active, complex debates relating to IP and biodiversity in multiple intergovernmental fora. Advances in science and technology have changed the way society uses and values biological diversity. The scope of a growing number of countries' intellectual property laws is being expanded, under prescribed circumstances, to include a variety of biological materials and processes (e.g., those that can be said to be novel, useful and non-obvious if they are inventions; distinct uniform and stable, and in some cases, discovered, if they are plant varieties). In most cases, these expansions of scope are being undertaken in compliance with minimum standards established in international trade agreements such as TRIPs and NAFTA. Consequently, policy makers are being faced with the daunting task of drawing a line in the sand between those biological materials and processes which can be made subject to intellectual property protections, and those which should not.

The debate surrounding control and ownership of intellectual property in biological resources spans local communities, national governments and intergovernmental organizations. At all levels, there are enormously diverse actors and stakeholders, and, not infrequently, intense conflicts between them. There are differences of opinion regarding how the benefits of biodiversity should be shared, and whether or not (and to what extent) biological materials should be subject to IP claims. For some governments, policymakers, scientists, private sector representatives, and civil society organizations (CSOs), the subject is perceived primarily as a finance and trade issue; for others it is a topic relating to agriculture, food security, and human rights; for still others it is debated in the context of the environment and development.

Balancing immediate obligations with long-term commitments

Timing is critical, not only because national governments are faced with immediate legal obligations under international trade and environment treaties, but also because the loss of biological diversity, and particularly that of farmers' varieties, is accelerating. Despite heightened appreciation and awareness of biodiversity, and the crafting of international treaties designed to conserve it, the loss of biological diversity continues. We are losing the options we need to strengthen food security and survive global climate change.

Nearly two decades of debate surrounding agricultural biodiversity have firmly established that all nations of the world are genetically interdependent in terms of access to genetic resources. Whether agricultural genetic diversity is found in farmers' fields, in private collections, or in high-tech gene banks no country is self-sufficient in plant or animal genetic resources. Even the most genetically abundant nations of the world look beyond their own borders for at least half of the germplasm required for their staple foods. This reality underscores the need for international cooperation.

In 1996 the world community adopted Leipzig's Global Plan of Action, a blueprint for sustainable management and use of plant genetic resources. The Global Plan has not been fully implemented. Ultimately, a coherent global policy for conserving and utilizing genetic resources is not possible without commitment from the international community.

The Convention on Biological Diversity establishes that biological diversity is subject to national sovereignty, but rules governing access to biodiversity and benefit-sharing are still being negotiated. To what extent will there be an internationally agreed regime? Will access be determined by a multilateral system, bilateral agreements, or both?

Encouraging Scientific Innovation and Promoting the Public Good

The issues of intellectual property and biodiversity are influenced by the larger trends of globalization and privatization. Increasingly, the development and use of knowledge is proprietary. The roles of

public and private sector agricultural research have shifted dramatically. The past decade saw dramatic consolidation in the life sciences industry, with market shares of bio-industrial products related to commercial agriculture, food and health tightly concentrated in the hands of (change) giant but a few transnational enterprises. Should we not strengthen and protect the international public good associated with the optimal flow of germplasm? What are the most appropriate mechanisms for encouraging scientific innovation?

Amid the process of globalization, new rules and new actors are changing governance structures. Multilateral rulemaking in a global marketplace is influencing (some would say eroding) the role of the nation state. Will the role of civil society organizations and national sovereignty be restricted or enhanced by these developments? How do we insure a genuinely "level playing field" for all governments with respect to access to information, and equitable participation in relevant negotiating fora related to biodiversity? The 1994 agreements between the international gene banks of the Consultative Group on International Agricultural Research (CGIAR) and the Food and Agriculture Organization of the United Nations (FAO) provide legal recognition that the world's most important collection of genetic resources for food and agriculture are held in trust for the world community. In an era (change) of rapidly evolving IP regimes, proprietary science when an increasingly large proportion of global research and development is subject to intellectual property rights, and the CG's research budgets are in decline, can the FAO/CGIAR Trust Agreement protect these genetic resources and insure that they remain in the public domain? Today, knowledge is perhaps the most important factor determining a nation's standard of living – more than land, than tools, or labor. In some cases, the growing knowledge gap between North and South is exacerbated by the privatization of the knowledge enterprise. Eighty percent of the world's commercial R&D and a similar share of its scientific publications come from the more industrialized nations. World Bank vice-president Ismail Serageldin warns of an "emerging scientific apartheid."

The strengthening of intellectual property regimes and their extension to biological materials creates both opportunities and concerns for developing countries. The World Bank's 1999 World Development Report observes that stronger IPRs are a "permanent feature of the new global economy."⁹ While IP is widely accepted as an important tool for stimulating domestic R&D, the report also notes that there is limited empirical evidence that stronger IP regimes lead to increased investments in R&D, even in industrialized countries.

The World Development Report points out that stronger IP regimes, often covering fundamental research tools as well as marketable products, may lead to a higher cost of acquiring knowledge, and could erect barriers to the participation of new firms and researchers in the developing world. There is a concern that stronger IP may actually slow the overall pace of innovation, and increase

the knowledge gap between industrial and developing countries. Once again, there is limited empirical evidence to confirm this, just as there is very little on the positive impact of IP on increased R&D.¹² Some believe that the knowledge gap can only be narrowed by promoting transfer to developing countries from technology owners in the industrialized world, and that a firm IP framework is an essential pre-condition for this to happen. “A desirable IPR regime, concludes the World Development Report, “is one that balances the concerns of all parties affected by strengthened IPRs.”

Balancing rights and responsibilities

There is growing recognition that the innovation of farmers and indigenous peoples is of utmost importance in understanding, utilizing and conserving biological diversity. This principle is a prominent feature of the Convention on Biological Diversity (CBD) and of Farmer’s Rights as enshrined in FAO’s International Undertaking on Plant Genetic Resources. The Draft Declaration on the Rights of Indigenous Peoples also recognizes the rights of indigenous peoples over their cultural and genetic resources.

The World Trade Organization’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) brings intellectual property to center stage in international trade negotiations, and obliges member nations to implement national IP laws for plant varieties and other biological materials. However, existing IP regimes do not recognize or protect the rights of informal innovators over their genetic resources and knowledge. Some people believe that existing IP regimes appropriate the genetic resources and knowledge of farmers and indigenous people. Recent IP claims on plants and human genetic material, for instance, have inflamed charges of “biopiracy” in many regions of the world. Others insist that claims of biopiracy are based on ignorance or a misunderstanding of the principles and application of IP. Can national governments meet their obligations to international trade agreements while fulfilling their responsibility to recognize, protect and promote the knowledge and resources of farmers and indigenous peoples? Is a regime for the protection of community knowledge compatible with existing IP regimes?

The development of new genetic technologies, stimulated, in part, by intellectual property protection, has led to the commercial introduction of biotechnological products for agriculture and human health. However, international IP laws covering new seed technology increasingly allow for national laws to restrict the right of farmers to save and re-use proprietary seed. Similarly, scientists are developing genetically engineered plants that are designed to yield sterile seeds. Genetic seed sterilization, if commercialized, could potentially restrict the ability of farmers to save and re-use seed from their harvest. Do these laws and technologies threaten biological diversity, global food security and the innovative capacity of farmers? Or will they have a positive impact on biological diversity?

The Struggle for Genetic Resources: International Policy Issues

The Crucible Group re-convened in 1998 because of the urgency of wrestling with these complex and controversial issues. In the following pages we offer a summary of the facts, the fights and fora relevant to genetic resources and intellectual property. We review some of the major socio-political developments that influence and inform the biopolicy debate, as well as the technologies that are transforming our ability to decipher, use and engineer the genomes of all living organisms. Ultimately, the objectives of this report are to distill information for decision-makers, to promote a level playing field for all, and to move the policy debate forward.

The Crucible Group deliberated long and hard about how to present most effectively the inter-related topics covered in this volume. Should major scientific developments be introduced before

legal and policy trends were considered, or vice versa? In reality, scientific developments have very direct political implications. Conversely, many scientific and technological trends are spurred by institutional or political developments. In the end, one could easily argue for a different ordering of the chapters, or a different presentation of the topics within chapters. As this document illustrates, science and politics are inextricably linked, more so than ever before.