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THE
TASK MANAGER'S REPORT
ON
CHAPTER 16 OF AGENDA 21

Environmentally Sound Management of Biotechnology

MARCH 1995



United Nations Industrial Development Organization

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LIST OF ACRONYMS

BINAS	Biosafety Information Network and and Advisory Service
CSD	Commission on Sustainable Development
DPCSD	Department for Policy Coordination and Sustainable Development
ECA	United Nations Economic Commission for Africa
ECE	United Nations Economic Commission for Europe
ESCAP	United Nations Economic and Social Commission for Asia and the Pacific
ESCWA	United Nations Economic and Social Commission for Western Asia
FAO	Food and Agriculture Organization of the United Nations
IAEA	International Atomic Energy Agency
ICGEB	International Centre for Genetic Engineering and Biotechnology
IFAD	International Fund for Agricultural Development
ILO	International Labour Office
IMO	International Maritime Organization
OECD	Organisation for Economic Co-operation and Development
UNCED	United Nations Conference on the Environment and Development
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNCTAD	United Nations Conference on Trade and Development
UNIDO	United Nations Industrial Development Organization
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WMO	World Meteorological Organization

ENVIRONMENTALLY SOUND MANAGEMENT OF BIOTECHNOLOGY

I. INTRODUCTION

Agenda 21, which is a participatory plan of action jointly formulated and agreed upon by the world community at the Earth Summit in Brazil in June 1992, proposes a number of interrelated programmes and programme actions aimed towards sustainable development. The plan calls for all agencies of the United Nations System to play a key and active role in assisting governments to establish more effective patterns of balanced economic and social development with minimal negative impacts to the environment. Subsequently, the Inter-Agency Committee on Sustainable Development (IACSD) designated a number of organizations as Task Managers for various chapters, issues and programme areas of Agenda 21 with the overall objective of ensuring a collaborative approach in the follow-up to and reporting on the implementation of Agenda 21 by the UN System.

UNIDO has been designated as the Task Manager for Chapter 16 of Agenda 21 which deals with **environmentally sound management of biotechnology**. The subject is a cross-sectoral issue, in conjunction with Chapter 34 (Transfer of Environmentally Sound Technology, Cooperation and Capacity-Building) and Chapter 35 (Science for Sustainable Development), at the Third Session of the Commission for Sustainable Development in April 1995.

The Agenda 21 programme on the environmentally sound management of biotechnology focuses upon the need for (a) increasing the availability of food, feed and renewable raw materials, (b) improving human health, (c) enhancing protection of the environment, (d) enhancing safety and developing international mechanisms for cooperation, and (e) establishing enabling mechanisms for the development and the environmentally sound application of biotechnology.

The five programme areas outlined in Chapter 16 seek to foster internationally agreed upon principles to be applied to ensure the environmentally sound management of biotechnology, to engender public trust and confidence, to promote the development of sustainable applications of biotechnology and to establish appropriate enabling mechanisms to achieve those objectives.

Many of the issues discussed in Chapter 16 are also reflected in other chapters of Agenda 21. Recognized as a cross-sectoral issue, biotechnology is linked particularly to the issues set out in Chapter 6 (Protecting and Promoting Human Health), Chapter 11 (Combating Deforestation), Chapter 14 (Promoting Sustainable Agriculture and Rural Development), Chapter 15 (Conservation of Biological Diversity), Chapter 17 (Protection of the Oceans, All Kinds of Seas, including Enclosed and Semi-Enclosed Seas, and Coastal Areas and the Protection, Rational Use and Development of Their Living Resources), Chapter 18 (Protection of the Quality and Supply of Freshwater Resources: Application of Integrated Approaches to the Development, Management and Use of Fresh Water Resources) and Chapter 21 (Environmentally Sound Management of Solid Wastes and Sewage-Related Issues).

The present Task Manager report reviews the progress achieved, the experiences and lessons learned, and the main policy issues, and it identifies areas for further action for consideration by the Commission on Sustainable Development. In addition, it brings to the attention of the Commission on Sustainable Development certain issues such as biosafety and intellectual property rights with respect to biotechnology that continue to be actively debated in international fora, including the Convention on Biological Diversity and the TRIPS negotiations.

In the preparation of the report, an inter-agency consultation was held to provide a forum for deliberation on strategic issues and to discuss innovative measures to address these issues. An informal inter-sessional consultative group of governments was also briefed on the preparatory process. Significant contributions by the various UN and other international agencies were made prior to, during and, in response to the draft reports, after consultation. In addition, extensive use was made of inputs from national reports as well as reports from intergovernmental bodies, notably the Organisation for Economic Co-operation and Development (OECD), in reviewing developments and trends in biotechnology. Furthermore, special attempts were made to solicit inputs from the private sector, the NGO community and women's organizations in order to include balanced perspectives in the final consolidated report.

The report is intended to be forward-looking and action-oriented. It not only reviews what happened since UNCED, but also what is necessary in terms of action to meet the agreed objectives set out in Chapter 16 of Agenda 21. It served as a reference for the preparation of the Secretary-General's Report.

.1. BIOTECHNOLOGY AND SUSTAINABLE DEVELOPMENT: A GENERAL OVERVIEW

Biotechnology is broadly defined to include any technique that uses living organisms or parts of organisms to make or modify products, to improve plants or animals, or to develop microorganisms for specific use. It ranges from traditional biotechnology to the most advanced modern biotechnology. Commercial biotechnology consists of an expanding range of interrelated techniques, procedures and processes for practical applications in the health care, agricultural and industrial sectors. Commercialization of biotechnology ranges from research to products and services. These are powerful technologies, supported by complementary bioprocess engineering to help translate new discoveries of life sciences into practical products and services. As such, biotechnology should also be seen as an integration of the new techniques emerging from modern biotechnology with the well-established approaches of traditional biotechnology, such as plant breeding, food fermentation and composting.

The concept of sustainable development is based on the conviction that it should be possible to increase the basic standard of living of the world's growing population without unnecessarily depleting our finite natural resources and further degrading the environment in which we live. Emerging biotechnologies, based on new scientific discoveries, offer novel approaches for striking a balance between development needs and environmental conservation. A wider diffusion of the technology is seen as the key to directing its positive impacts onto the world's society as a whole. Biotechnology is continuously and rapidly developing in an increasing number of sectors that improve the effectiveness of the way in which products and services are provided. However, the transfer and development of biotechnology in an environmentally sound manner requires a variety of conditions, including capital inputs that, in the case of many developing countries, are not readily available.

All countries require appropriate infrastructures that permit them to acquire, absorb and develop technology, to manage it properly and systematically, and to build up local scientific and technological competence. The resultant ability of any country and of a developing country, in particular, to discern, choose and adapt an environmentally sound emerging biotechnology can serve as a measurement of sustainable self-reliance that will allow it to participate fully in worldwide efforts to achieve sustainable development. The creation of enabling conditions poses new challenges that must be addressed in order for developing countries to realize the potential benefits of biotechnology and minimize any possibly adverse socio-economic or environmental effects.

III. ASSESSMENT OF PROGRESS ACHIEVED AND EXPERIENCES

Since UNCED, considerable progress has been achieved in raising awareness, particularly among the scientific community, policy makers and, to a lesser extent, the general public, of the potential benefits and risks and the need for environmentally sound management of biotechnology. As a result, it is now widely recognized that biotechnology can play an essential role in fostering the economic and social development of both developed and developing countries, if properly managed. Biotechnology development and applications have continued to grow at a very rapid rate, leading to an expanding range of products and processes across several sectors, that began with pharmaceuticals and health care, was extended to agriculture and, more recently, to the environment. In the area of health, many biotechnological products, such as insulin, diagnostics and vaccines, have already been placed on the market and products such as recombinant-derived hepatitis B vaccine have gained widespread international use. Two new biotechnology-based cholera vaccines have recently been licensed in some countries. Currently, more than 2,000 clinical trials of biotechnology-related products are in progress, mainly in the more biotechnologically advanced countries. In agriculture, products such as diagnostics, biopesticides and bovine growth hormone have been in commercial use. Other products and technologies being developed include improved seeds, new vaccines, novel food ingredients, biotechnology-based techniques for the rapid detection and identification of toxic materials, and several bioprocessing technologies. Developed countries, having increasingly privatized biotechnology research and development, continue to forge rapidly ahead in many sectors. From a global perspective, it has been forecast that major impacts can be expected on health, pharmaceuticals, agriculture, food and the environment within the next 20 years.

Several UN agencies, in cooperation with regional Economic Commissions, have continued to strengthen their biotechnology and related support programmes and to develop new biotechnology initiatives to assist developing countries and countries in transitional economies, with the result that several developing countries now give high priority or increasing attention to biotechnology development. Through these and other multilateral and bilateral programmes, many applications of biotechnology have been made appropriate and accessible to developing countries. The tendency of most developing countries is to acquire biotechnologies aimed at improving agriculture, food and pharmaceutical production and converting low-cost or marginalized raw materials into high value-added products and marginalized lands into more productive areas. Technologies such as biofertilizers, tissue culture, vaccines, and some new diagnostics that can be utilized despite relatively low levels of resources and technological capacity are currently available for immediate transfer and applications to developing countries. In fact, these technologies, especially biofertilizers and bioinsecticides, are gradually being used in several countries around the world to increase crop yield and reduce agrichemical inputs. In addition to the appropriate use of traditional and intermediate biotechnologies, an increasing number of developing countries are seeking to integrate more advanced biotechnologies into national development plans and programmes, either as part of the relevant traditional sectors or as new biotechnology programmes. Some biotechnologies appropriate to and required by developing countries are, however, proprietary in nature. As such, biotechnological solutions in developing countries need to be assessed and selected on the basis of priority and efficacy. New and additional management skills are needed to assist these processes.

With regard to the progress in enhancing safety and developing international mechanisms for cooperation, significant progress in regional consultation and cooperation has been made, building on the previous experience of the UNIDO/UNEP/WHO/FAO Informal Working Group on Biosafety and other more recent international initiatives such as the International Service for National Agricultural Research/International Biotechnology Service (ISNAR/IBS), International Service for the Acquisition of Agri-Biotech Applications (ISAAA) and the Agricultural Biotechnology for Sustainable Productivity (ABSP) project and, in particular, the Biotechnology Advisory Commission of the Stockholm Environment Institute. The Convention on Biological Diversity is in the process of considering the need for and modalities of a possible protocol on biosafety under the Convention. A further important initiative is also underway under the auspices of UNEP to develop further draft international technical guidelines on safety in biotechnology, jointly prepared by the Governments of the United Kingdom and the Netherlands. The recent launching of the Biosafety Information Network and Advisory Service (BINAS) within the UN system, as recommended by the Informal UNIDO/UNEP/WHO/FAO Working Group on Biosafety, encouraged an increasing number of developing countries to participate as national focal points and to cooperate within the regions to establish regional nodes and networks. At the present time, the absence of established biosafety procedures in developing countries constitutes a major constraint to field testing - and, indeed, to product development - by those international public sector designed to facilitate the introduction of biotechnology into developing country agriculture.

A. Country Experiences

1. Developing Countries

With respect to the level of biotechnology development and applications, there is a great variation among developing countries. More technologically advanced developing countries, such as the People's Republic of China, India, Republic of Korea and Singapore in Asia, and Brazil and Cuba in Latin America and the Caribbean, have set biotechnology as a high priority for development. Most of these countries have invested significantly in infrastructure and human resource development and have increasingly encouraged foreign investment. The result has been the establishment of biotechnology-based enterprises, mainly fermentation industry and pharmaceutical products in the regions. Modern biotechnology research programmes have also steadily increased, especially in agricultural sectors such as biofertilizers, biopesticides and virus-free seedlings, including various aspects of tissue cultures. Biotechnology applications in developing countries range from the use of advanced biotechnological techniques, as, for example, in the production of transgenic crops and artificial seeds in China, and in the production of several pharmaceutical products in Cuba and the Republic of Korea, to the use of traditional and intermediate biotechnologies in food fermentation and nitrogen fixation in less advanced countries. Several countries in the Middle East have emphasized the importance of biotechnology in developing stress tolerant agriculture and in bioremediation.

In African countries, the level of sophistication in biotechnology development is extremely variable, ranging from very traditional application such as food fermentation of cassava in least developed countries, to monoclonal antibody and diagnostics research and tissue cultures in other countries. Egypt, Kenya, Nigeria, Zimbabwe and the Republic of South Africa are among the leading countries in this area in the region. In general,

biotechnology research and development in Africa evolves around the various international research and development centres, as, for example, the International Institute for Tropical Agriculture in Nigeria and the International Centre for Insect Physiology and Ecology in Kenya. Egypt and the Republic of South Africa have, in particular, given high priority to biotechnology in the countries' development planning, especially in relation to infrastructural support and human resource development.

The development and applications of biotechnology in developing countries continue to be heavily dependent on investment by the public sector, even though private sector foreign investment in biotechnology has gradually increased. A meeting in 1994 of biotechnology managers from more than 40 developing countries, mostly members of the International Centre for Genetic Engineering and Biotechnology (ICGEB), to explore emerging biotechnologies and industrial opportunities revealed that the understanding and appreciation of local entrepreneurs for the economic potential of the biotechnology industry is still very low. On the other hand, awareness regarding biosafety and the urgent necessity for the environmentally sound management of biotechnology among the biological scientific community is relatively high compared to awareness in the non-biological scientific community. Among the more than 60 countries that have benefited from the UNEP/UNIDO/ICGEB biosafety training workshops, fewer than 20 per cent have developed biosafety guidelines or have established national regulatory mechanisms for addressing the biosafety regulation issue. A number of countries have begun the process of developing a database (national node) on biosafety as well as a national regulatory machinery to ensure the environmentally sound management of emerging biotechnologies. Concerning the issue of intellectual property rights protection, most countries are well aware of the importance of intellectual property rights in general, but have inadequate knowledge and capacity to address effectively the issues relating to life forms and related implications of the TRIPS Agreement concerning intellectual property rights in relation to biotechnology. In this connection, the Government of India, in cooperation with WIPO, hosted an international meeting in 1994 on the role of patents in biotechnological inventions, emphasizing the need to strengthen the information system in this area.

Case studies on biotechnology and sustainable agriculture recently commissioned by the OECD Development Centre for Kenya and Zimbabwe in Africa, India and Thailand in Asia, and Colombia (and Mexico) in Latin America identified common constraints in the diffusion of environmentally sound biotechnologies, especially to small farmers, weak collaboration between the private and the public sectors, and inadequate financial resources as well as mechanisms for the effective exploitation of emerging technologies. A number of major breakthroughs in crop, animal and forestry research and development have been noted. In countries where legal frameworks for biosafety and/or intellectual property protection are in place, the operational aspects need further attention.

Although there is inadequate information on the current state of development and on the immediate economic impact of biotechnology in many other developing countries, mainly because in most of the developing countries biotechnology is integrated in the various traditional sectors, the general trend appears to be positive. It is reasonable to say that the economic impact of biotechnology in a given country is in close correlation to the biotechnology capacity and related investment of that country. In this respect, there is a need

for more effective indicators on progress towards sustainable development through biotechnology is desirable.

2. Developed Countries

Developed countries, particularly the United States of America, Japan and several countries in Europe, have had long experience in the development and applications of biotechnology, including especially the new biotechnology. Numerous studies and reports, prepared by individual countries and by the OECD, in particular, on the various aspects of biotechnology development and management provided a useful background in understanding the evolution and trend of biotechnology development. Improved and innovative institutional, legal and financial arrangements relating to private sector collaboration, university-industry linkage, strategic business alliances and venture capital have been extensively developed to address the emerging issues relating to new biotechnology. Of particular interest is the database on biosafety maintained by OECD. Furthermore, additional mechanisms continue to be developed to address the issues of bioethics public perception and education, including the European Federation for Biotechnology's Task Group on Public Perceptions of Biotechnology, the Gen Suisse Foundation for public information on biotechnology and, in the USA, the Union of Concerned Scientists.

In most developed countries many biotechnological products and services have already been placed on the market and are widely used, especially those in the pharmaceutical sector. Currently more than 1,700 clinical trials and 1,000 field tests are in progress. Successful development and utilization of biotechnologies include, among others, the application of a recombinant rabies vaccine in dealing with the problem of rabies in wild animals and *in situ* bioremediation of contaminated soil. More recent experience, in the USA, involves the shift towards increasing public acceptance of the development and use of biotechnology-based growth hormone for increasing milk yield and the genetically engineered tomato. Similarly, the pressure to decrease dependency on chemical pesticides is expected to drive the growth of biopesticide production and use, estimated to reach US\$ 150 million in the USA alone as compared to the US\$ 6.8 billion for conventional pesticides.

A recent development initiative in Mexico, conceived as a collaborative arrangement between the business sector, a national government, and the UN and international organizations to promote the environmentally sound management of biotechnology, involves an experimental effort to increase the yield of tropical maize. A combination of classical plant biotechnology and advanced genetic engineering techniques involving genes encoding toxins that are lethal to maize insects are being used to produce pest-tolerant tropical maize. The development of appropriate protocols will be part of such an effort that can be expanded to include other crops and products.

3. Transitional Economies

The transitional economies present a case for special attention in their potential role and contribution to the global efforts in the environmentally sound management of biotechnology. Supported by a relatively strong foundation in science and technology and a critical mass of skilled human resources in the field of biological sciences, many countries, especially those in Central and Eastern Europe, can, with the appropriate and timely support

from the international community, move forward rapidly in biotechnology development and its safe applications.

Major constraints being experienced by the countries include, in particular, a drastic decline in financial resources to adequately maintain the various valuable scientific and technological infrastructures and, of increasing concern, the critical reduction in the scientific workforce in bioscience and biotechnology. Current efforts to revitalize biotechnology and foster cooperation include the preparation in Russia of a new State Programme for the Development of Biotechnology During the Period 1994 to 2000, focusing on bioindustrial development and promotion such as microbial biomass protein production for food and pharmaceuticals under a more favourable policy environment. Others include the joint Russian-Hungarian initiative to establish a commercially viable sturgeon (fish) gene bank to support sustainable marine and aquaculture industry and, more recently, the establishment of a regional Task Force of Regulatory Oversight in Biotechnology for Central and Eastern Europe.

B. Experiences of Major Groups and NGOs

NGOs participated actively in the UNCED process. Their role - jointly with United Nations agencies - was critical in raising awareness of the need for safe handling of biotechnology and to conserve biological diversity along with the sustainable use of biological resources. The many meetings, workshops and forums organized by them provided platforms for a better understanding of the issues and linkages between biotechnology and other sectoral and cross-sectoral issues of Agenda 21. Many NGOs emphasize the role of indigenous people and their communities in the uses of biotechnology as well as in its development. National and international scientific organizations dealing with biosciences and biotechnology are particularly active in promoting biotechnology at various levels. Several recent UN and bilateral initiatives to promote biotechnology among farming communities, indigenous people and micro-enterprises have benefited from NGOs' participation in extending their services beyond the traditional government counterpart organizations and in sharing experiences encouraging people's participation in the development efforts.

Biotechnology industrial associations play a key role in promoting biotechnology development and transfer. The Senior Advisory Group on Biotechnology (SAGB) in Europe is concerned with biotechnology-related policy issues, including biosafety and intellectual property rights; it is actively involved in industrial consultation with UNIDO on biotechnology-related matters. The Japan Bioindustry Association (JBA) plays an active role in conducting training courses in bioindustries, an integral part of JBA's technical cooperation support for developing countries. SAGB, JBA and their North American counterparts form an International Biotechnology Forum (IBF) that is active in promoting biotechnology cooperation and development internationally and in their respective regions. These organizations have contributed significantly to presenting the perspectives on biotechnology-related issues at international consultations and meetings.

The role of the NGO community and of citizen groups is increasingly being recognized; with some encouraging results. A joint initiative of the International Organization of Consumers Unions (IOCU) and the Genetic Resources Action International (GRAIN) in producing a Citizens Action Resource Guide on Biotechnology and Third World

Agriculture to provide a constructive foundation for future planning for sustainable development is just one example of this.

The broad range of NGOs, people's organizations and consumer groups can provide a useful and complementary function in the development of environmentally sound applications of biotechnology, by helping to facilitate the diffusion of information about and public acceptance of biotechnology. In this connection, it is noted that biosafety and biotechnology are subjects to be presented by the Once and Future Action Network (OFAN) at the NGO Forum held as part of the Fourth World Conference on Women in Beijing, Republic of China in September 1995; the presentation will focus on women's role in science and biotechnology, linking it simultaneously to people, the environment, and sustainable development

C. Matters Related to Finance

The implementation of the various programmes of Agenda 21 will require the provision of substantial new and additional financial resources to developing countries to supplement financing from those countries' own public and private sectors.

27. The total annual requirement for financial resources from the international community for the period 1993-2000 was estimated by the UNCED Secretariat to be US\$ 197 million for the five programme areas. Needs are greatest in the area of human health, at US\$ 130 million, followed by US\$ 50 million for agricultural improvement. However, the overall total financial cost from all sources was estimated at US\$ 20 billion per year during the same period. The cost estimates for biosafety (programme area D) and endogenous capacity building (programme area E) were much lower, at US\$ 2 million and US\$ 5 million respectively, and based on support to be provided by the international community alone.

Most developing countries are well aware of the potential of biotechnology to foster economic growth and many countries have identified biotechnology as a key area for development. However, basic and applied research activities in biotechnology are primarily confined to the universities and are fragmented. Demand for practical goal-oriented, multidisciplinary research and development is largely beyond the technical and financial resources available to the public-funded scientific sector. With the exception of the more advanced developing countries, finance for meaningful biotechnology research and development comes from external sources, with the private business sector providing only a minimal proportion of the total.

No comprehensive international survey of financial expenditure for biotechnology programmes to address the challenges outlined in Chapter 16 of Agenda 21 is currently available. However, a 1993 survey on international initiatives in agricultural biotechnology conducted by the Intermediary Biotechnology Services indicated that bilateral and multilateral aid agencies, international organizations, private foundations, universities and commercial companies and national governments were all involved in the financing of international biotechnology initiatives for developing countries. It was revealed that since 1985, the contribution in grant funds had amounted to more than US\$ 260 million, as against World Bank loans and credits for national agricultural research and development in developing countries of about US\$ 150 million. It was also clear that compared to biotechnology

research and development in industrialized countries, the amount of finance devoted to international biotechnology initiatives is far from adequate. The survey also provided an interesting profile of financial sources. It indicates the significant contribution made by non-profit organizations (foundations) and bilateral donors and the comparatively small contribution by the private business sector to the development of biotechnology in developing countries.

The active contribution and participation of non-profit organizations in biotechnology development is especially important in view of the social implications of biotechnology and the concerns about equity on the part of developing countries. In addition to the Rockefeller Foundation, which had reportedly contributed more than US\$ 50 million since 1985 to the International Rice Biotechnology Programme alone, biotechnology support activities of other non-profit foundations should also be noted. The Biofocus Foundation in Sweden and the M.S. Swaminathan Foundation in India are examples of social organizations created to help in directing the benefits of biotechnology towards less privileged target groups in developing countries.

Bilateral donors and related bilateral cooperative programmes in biotechnology have been instrumental in strengthening the biotechnological capability and capacity of developing countries. Many developed countries such as Australia, France, Germany, Japan, the Netherlands, the United Kingdom and the United States of America have actively supported biotechnology programmes, including collaborative research and training, and, more recently, commercialization efforts. In addition to the financial contribution through the conventional Official Development Assistance Programme, other channels for funding have also been created. Examples include the fellowship programme of the Japanese Society for the Promotion of Science (JSPS), which has been carrying out special bilateral exchange programmes between universities in Japan and those in several Southeast Asian countries, the joint US-Thailand Company-Directed Research Grants, the Crawford Fund for International Agricultural Research and, of particular interest, IFAD's financial assistance to the least developed countries for agricultural and food development through biotechnology.

Important lessons learned from these assistance/cooperation programmes include:

- (a) Long-term commitment is vital to achieving sustainable capacity building and to enable a country to reach a critical level in self-reliance for further biotechnological development. The Indo-Swiss project initiated since 1974 has led to pilot commercial production of biopesticides in India.
- (b) A networking arrangement among institutions within the country and region is one of the most cost-effective means to maximize limited resources.
- (c) Access to or provision of modern scientific equipment and key biomaterials for research are important components of successful and equitable strategies for collaborative research.
- (d) Most importantly, the financial commitment of developing/recipient country government is critical to successful collaboration. This commitment can include in-kind contributions.

Currently, financial contributions from the private sector for commercial biotechnology development are still relatively low, mainly due to the high business risk involved with modern biotechnology enterprises, but also because of an unfavourable policy environment. Nevertheless, experience from developed countries indicates the importance of the private sector's participation. In view of the relatively high risk associated with biotechnology product development and commercialization, more risk capital needs to be found. Strategic alliances have been particularly successful between USA and European companies and between USA and Japanese firms. Such alliances are also known to have been formed with and within developing countries, and although by no means common in biotechnology development, they are nevertheless being promoted by a number of international programmes and venture capital firms. In the developing countries, one alternative approach being increasingly adopted to promote biotechnology development and commercialization is for the private sector to form partnerships with the governmental enabling institutions, notably science and technology parks. Venture capital funds, such as the Transtech Venture Fund in Singapore, are few as yet but they can nevertheless serve as successful models not only for fund mobilization from banking institutions and industrial subscribers, but also - and more importantly - in terms of the modalities for financing such operations. The Transtech Venture Fund, for example, operates both within and outside the country, placing investments in overseas technology companies providing access to technology as well as related technology and management support.

D. Recent developments and experiences in international cooperation

Since UNCED much work has been done by the UN System organizations in support of Chapter 16: Environmentally Sound Management of Biotechnology of Agenda 21.

1. Programme Area A: Increasing the availability of food, feed and renewable raw materials

Objectives:

- Increase to the optimum possible extent the yield of major crops, livestock, and aquaculture species, by using the combined resources of modern biotechnology.
- Improve the nutritional value of source crops, animals and micro-organisms and reduce food losses using environmentally safe applications of biotechnology.
- Increase the use of integrated pest, disease and crop management techniques to eliminate overdependence on agrochemicals, thereby encouraging environmentally sustainable agricultural practices.
- Evaluate the agricultural potential of marginal lands in comparison with other potential uses and develop, where appropriate, systems allowing for sustainable productivity increases, including situations of emerging environmental stresses.
- Expand the applications of biotechnology in forestry.
- Increase the efficiency of nitrogen fixation and mineral absorption by the symbiosis of higher plants with micro-organisms.
- Improve capabilities in basic and applied sciences and in the management of complex interdisciplinary research projects.

To meet the accelerating demands of a growing worldwide population, the challenge lies not only in increasing food production, but also in significantly improving food distribution systems. Efforts to meet these challenges will be through the successful and environmentally safe application of biotechnology in agriculture. Most of the investment in

biotechnology has been in the industrialized world. International organizations are supporting significant new efforts in biotechnology in the developing world.

FAO is a leading UN agency in promoting the application of agriculture biotechnology among developing countries and is presently assisting more than 30 developing countries in the uses of advanced but relatively conventional biotechnology for increased yield and quality of food and feed crops, cash crops and livestock through the formulation and implementation of specific projects in these areas and through research and information networks. For example, a UNDP/FAO/UNIDO Regional Sub-Programme on Asian Biotechnology and Biodiversity, of the Farmer-Centred Agricultural Resources Management (FARM) Programme in which eight countries, namely China, India, Indonesia, Nepal, Philippines, Sri Lanka, Thailand and Viet Nam are participating, is assessing and pilot-testing appropriate biotechniques and products to enhance crop and livestock productivity through the development and promotion of *in vitro* culture techniques and embryo transfer. A similar FAO-sponsored regional network on plant biotechnology is operational in the Latin American and Caribbean Region. Rice biotechnology, supported by the Rockefeller Foundation, has an extensive network involving several countries in which the ICGEB participates. In the European Region, through the European System of Cooperative Research Networks in Agriculture (ESCORENA), FAO promotes research networks on rice, sunflower and cotton and specific working groups in the application of biotechnology are operational. Biotechnology for improved production of buffaloes, flax and nuts is being pursued. Research is underway on agricultural crops using modern biotechnology techniques. These crops will soon be available in many developing countries. Evidence from different countries indicates that advanced agricultural biotechnologies could be helpful to impoverished farming communities as well as environmentally friendly. They are more adaptable than mechanical innovations and Green Revolution technology, which makes them more accessible to small producers. These biotechnologies can reduce farmers' dependency on environmentally degrading agrichemicals whilst decreasing crop losses.

Important agricultural biotechnology networks have been established to disseminate information to and training within developing countries. Among these are the Plant Biotechnology Network (REDBIO) Cassava Biotechnology Network and the UNDP/FAO/UNIDO programme Farmer-Centred Agricultural Resource Management (FARM), which has a subprogramme on biotechnology and biodiversity, the aims of which is to promote information-sharing and undertake technology assessment on the potential of new biotechnologies to contribute to the characterization of biodiversity. The various international agricultural research institutes have major research programmes to increase the yield of major crops through the study of plant stress resistance, tolerance to herbicides and resistance to some specific pests and toxins, and through the study of lignin biodegradation aimed at the recycling of vegetal wastes as feed stock. Research programmes extend beyond the host countries to many of their cooperating partners/network members.

Tissue culture and artificial seed biotechnologies are contributing significantly to agricultural productivity gains in Asia and, gradually, in Africa, and to the forestation of marginal lands in China. In addition to the World Bank's support to biotechnology in agriculture and health, new initiatives by regional and other financial institutions, such as the Asian Development Bank's support for rice biotechnology, and the Islamic Development Bank's support for biosaline agricultural research, are encouraging. Recent initiatives such

as the ABSP project provide an example of an integrated approach to the transfer of advanced agricultural biotechnology to developing countries in its inclusion of separate components involving research, biosafety, intellectual property and global networking efforts.

The Plant Breeding and Genetics Section of the Joint FAO/IAEA Division of Nuclear Techniques in Food and Agriculture supports the use of biotechnology for plant improvement by promoting tissue and cell culture and molecular techniques through Technical Cooperation Projects (TC) and Coordinated Research Programmes (CRP) on mutation induction. Micropropagation for rapid multiplication of selected mutants as disease-free plants is an important component of several TC/CRP programmes. Anther and microspore culture techniques, to obtain homozygous diploid mutants following irradiation, are frequently used in several mutation breeding projects supported by the Agency. The development of protocols of *in vitro* selection of mutants for disease-resistance and stress-tolerance is a key element in the promotion of sustainable agriculture, and is also supported by the Joint Division. Plant and tissue culture technologies are being used to propagate *in vitro* irradiated plants of banana, plantain, cassava, etc. To encourage environmentally sustainable agricultural practices while moving away from overdependence on agrochemicals, UNEP, in collaboration with FAO, UNESCO and other relevant organizations, supported the regional Microbial Resources Centres (MIRCENs) in Cairo, Nairobi, Dakar, and Porto Alegre in demonstrating on a pilot scale the use of BNF for enhancing soil fertility and increasing legume production at the small farm level. Activities include collection, evaluation, and preservation of *Rhizobium* strains; the establishment of pilot plants for inoculant production; and training of local BNF professionals, technicians and extension workers to popularize the technology.

In the field of animal production, FAO's biotechnology work encompasses three main areas: (i) better disease diagnosis; (ii) better and safer vaccines for disease prevention; and (iii) genetic manipulation of the germ-line of economically important livestock to improve specific disease resistance. Global and regional expert consultations on new and emerging areas of animal biotechnology for the benefit of developing countries are organized on a regular basis.

Several networks on the subject are being developed by FAO that include Reference Laboratories (20 institutions) and Collaborating Centres (internationally recognized centres of expertise covering infectious and parasitic diseases and using modern biotechnology methods), the FAO TC Network on Animal Production and Health Biotechnology for Latin America (8 countries) and South East Asia (7 countries), CANAPS-Computer Assisted Network on Nucleic Acid and Protein Sequencing in Latin America/Caribbean (14 countries), and the FAO Network Programme on Veterinary Biotechnology in Central Eastern Europe (4 countries with economies in transition). The Joint FAO/IAEA Division in Vienna developed with other institutions the ELISA sero-monitoring kit for rinderpest antibodies. The Pan African Network on ELISA Sero-monitoring for Pan African Rinderpest Campaign (PARC) includes over 20 countries. The ELISA Programme for Latin America covers FMD, brucellosis and babesiosis and involves 12 countries.

FAO has also been promoting development of recombinant vaccines against rinderpest that ensures their safety and potency testing. These may supplement in the future the Plowright's Kabeta "O" classical vaccine which is being widely used for ongoing rinderpest

eradication campaigns in Africa (PARC), Middle East/West Asia (WAREC) and South Asia (SAREC). Similarly, successful attempts have been made to increase the Plowright's vaccine shelf life by a modified freeze-drying scheme and the application of stabilisers. A strict, standardized quality control of rinderpest and Contagious Bovine Pleuropneumonia (CBPP) vaccines initiated by the Pan African Veterinary Vaccine Centre (PANVAC) resulted in a significant improvement in quality of the vaccines applied in campaigns against rinderpest. Specific FAO projects in Asia and the Middle East promote the application of fermentation methods for the large-scale production of bacterial aerobic and anaerobic vaccines. At the grass root level, preparations have started in developing a network on orally administered Newcastle disease NDV-4 vaccines that may be extensively applied by women's rural communities to supplement already applied immunization schemes. The Joint FAO/IAEA Division, with multi-country support, has been instrumental in eradicating deadly pests and diseases through the development and use of the Sterile Insect Technique, in particular in the management of the tsetse fly in Africa, a pest that causes trypanosomiasis. Following successful small-scale operation, a collaborative activity between the Joint FAO/IAEA Division and UNIDO is being planned to promote large-scale industrial production through a feasibility study, followed by a demonstration project in Africa.

To promote sustainable agriculture and its diversification while increasing the yield of major crops and livestock and the productivity of marginal lands, UNEP in cooperation with FAO, various UN agencies and with IPGRI and ICARDIA, initiated programmes aiming at the collection, evaluation and conservation of plant, animal and microbial genetic resources, using modern and conventional technologies, and the training of developing countries scientists in relevant technologies. In this respect, ICGEB has made available to member developing countries R and D and training facilities as well as the relevant genetic information through its ICGEBNet service. With respect to sustainable use of raw materials, such as medicinal and aromatic plants, UNIDO and FAO work closely with developing countries to introduce systematic cultivation or harvesting in combination with small-scale processing technologies to increase value-added benefit to local communities. UNESCO has supported, through its Biotechnology Action and in cooperation with the UNESCO/UNEP MIRCEN Network, a variety of activities ranging from training courses, fellowships and research projects to award professorships, establishment of chairs and provision of authenticated laboratory protocols in biotechnologies.

In addition, ICGEB has major research programmes to increase the yield of major crops through the study of plant stress resistance, tolerance to herbicides and resistance to some specific pests and toxins, and through the study of lignin biodegradation aimed at the recycling of vegetal wastes as feed stock. Research programmes extend beyond the Centre to many of its 20 Affiliated Centres in developing countries.

Tropical maize is a very important food staple for the poor in developing countries. Farmers report that their yields are often seriously reduced due to insect pests, but are helpless to prevent the damage. Even if these farmers had the resources to purchase commercial synthetic pesticides (also assuming availability), their usage should be avoided from the standpoint of human health and the environment. Thus, CIMMYT, a CGIAR Institute located in Mexico, has agreed to an experimental effort in which tropical maize will be transformed with genes encoding toxins that are lethal to maize insects but harmless to humans, wildlife and the environment in general. CIMMYT's research has benefited from

assistance from the private sector, while at the same time maintaining its traditional policy of free and open access to its extensive maize germplasm collection. New questions on policy and protocol concerning biosafety, future field testing, and potential problems involving gene flow are arising from this experimental research at CIMMYT. The Mexican Government, CIMMYT and expert consultants from Mexico and elsewhere are working together to resolve these issues. It is hoped that the combination of classical maize breeding and biotechnology will produce pest-tolerant tropical maize that will then be widely tested by farmers and others under appropriate protocols.

WMO provides services to member countries to help them make optimal use of weather information to increase food and agriculture production, to reduce risks, and to reduce crop losses due to various factors including weather hazards, pests and diseases.

Article 10 of the Convention on Biological Diversity (Sustainable Use of Components of Biological Diversity) and the recommendations on the sustainable use of biological diversity of the Open-ended Intergovernmental Meeting of Scientific Experts on Biological Diversity in Mexico City are relevant. Particular emphasis was given in the Convention to human needs for genetic resources from the social, economic and technical point of view and their sustainable use.

The joint United Nations Economic Commission for Europe (ECE)/FAO Working Party on Relations between Agriculture and the Environment periodically reviews governmental economic, regulatory and technological measures for the promotion of sustainable agriculture and production of healthy food. Exchange of information and experience on the effective implementation of these measures are concentrated in particular on organic and integrated agriculture and the uses of biotechnology. Recommendations, guidelines and codes for the promotion of good agricultural practices favourable to integrated pest and crop management are being developed.

The United Nations Economic Commission for Africa (ECA) recently examined the objectives and strategy for the introduction and applications of modern biotechnology to improve agricultural productivity and to increase food production without damaging the environment. A mechanism has been proposed based on building national capability and strengthening or developing regional and international cooperation. It is a holistic approach involving (i) political will from African governments which should accept and commit themselves to develop modern biotechnology as a powerful new tool for agricultural development and food production; (ii) formulation of an appropriate policy for the improvement of agricultural productivity; (iii) identification of priorities and development of relevant national policies for which biotechnology offers a comparative advantage and serves a demonstrated need; and (iv) human resource development by training manpower, and by establishing and equipping national or subregional and regional universities and research institutes for the development and promotion of biotechnology. Through international cooperation and support and encouragement of twinning high education and research institutions, biotechnological centres can be established and maintained, joint advanced training programmes and investigations undertaken, an international biotechnology network established, biotechnology databases and information exchange services developed, and advice in formulating national policies and programmes in biotechnology provided to governments. Regional and international cooperation is needed for developing and applying modern

biotechnology and for reversing the current chronic food situation that leads to malnutrition, hunger, famine, diseases, poverty and death.

The United Nations Regional Commissions have organized conferences aimed at enhancing awareness of the opportunities offered by biotechnology. Strong interest was demonstrated on the part of regional institutions and firms in applying biotechnology to enhance food production capabilities and the quality of agricultural produce. The United Nations Economic and Social Commission for Western Asia (ESCWA) conferences demonstrated the need for a focused approach whereby specific areas in biotechnology may be targeted by regional research and development institutions and confirmed the necessity of establishing stronger links between these institutions and sources of investment and private enterprise. Areas found to merit further concentrated efforts included the development of marine agricultural and industrial biotechnologies and agricultural and agro-industrial applications of genetic engineering and plant cell and tissue culture.

2. Programme Area B: Improving human health

Objectives:

- Programmes to help combat major communicable diseases and to promote preventive health care including vaccine and diagnostic reagents development and production, and new pharmaceutical development using biotechnological approaches.
- Promote good general health.
- Develop and improve programmes to assist in specific treatment of and protection from major non-communicable diseases.
- Develop and strengthen appropriate safety procedures based on programme area D, taking account of ethical considerations.
- Create enhanced capabilities for carrying out basic and applied research and for managing interdisciplinary research.

A critical objective of development is to foster human health. Increasing levels of environmental degradation compounded by poor and inadequate development continue to impact negatively on human populations. International organizations have increasingly important contributions to make in the use of biotechnology to combat major communicable diseases, in promoting good health, in improved programmes for treatment of and protection from major non-communicable diseases, and in developing appropriate safety procedures. Biotechnology products in health care are now fairly widespread.

Although conventional approaches have been highly successful in the development of vaccines against many infectious diseases, they have failed to produce efficient vaccines against some of the most important ones such as malaria, diarrhoeal diseases and HIV. Recrudescence of infectious diseases has also given rise to health care concerns in the developed countries in recent years. DNA technology offers novel approaches towards the design and production of drugs, vaccines and diagnostic tools. To date, even its limited application in these areas has been enormously successful.

WHO is the lead UN agency in this programme area, focusing on efforts to combat major communicable diseases and to promote preventive health care, vaccine and diagnostic reagents development and production, and new pharmacological development using biotechnological approaches. The rapid progress in molecular biology and genetic engineering

provides the basis to simplify immunization, and to improve immunization strategy, which are the research goals of the WHO Programme for Vaccines and Immunization. WHO promotes the improvement of existing vaccines, and the development of new ones, against infectious diseases with the highest mortality or morbidity, including acute respiratory infections, typhoid fever, diarrhoeal diseases, AIDS, tuberculosis, malaria, meningitis and dengue. A WHO meeting on Biotechnology and World Health was held in November 1994 in Geneva, with the participation of researchers, industry, legislative and customer organizations. The meeting recommended further action in the development, testing and use of new vaccines and other medicinal products produced by DNA technology. With respect to biosafety, WHO plays an increasingly active role in cooperation with other UN agencies, especially FAO, based on the Joint FAO/WHO consultation on assessing the safety of foods. WHO's 1993 review of the health aspects of marker genes in genetically modified plants concluded that genes *per se* did not constitute a safety concern. WHO is of the opinion that safety precautions and monitoring procedures should be appropriate to the level of assessed risk in the testing and use of biotechnological products.

A high-level jointly sponsored UNESCO/WHO Technical Meeting in January 1994 covered a wide spectrum of research activities ranging from drug development, vaccine research, vector control, national capacity building and social science research to health education. UNESCO, UNDP and the Government of the Islamic Republic of Iran are collaborating in the use of an antibacterial biocide from *Bacillus thuringiensis* against malaria. In addition, UNDP, UNESCO and UNIDO are jointly supporting a multi-country research project concerning the development of diagnostic kits for leishmaniasis, trypanosomiasis, schistosomiasis and enteric diseases.

As part of the Children's Vaccine Initiative (CVI), UNDP, along with UNICEF, WHO, the World Bank and the Rockefeller Foundation, is establishing an autonomous institute in the Republic of Korea committed to developing, testing and delivering affordable new and improved vaccine for the world's children. It is a partnership of public and private sector institutions, agencies and companies. It will also assist vaccine producers in developing countries to improve vaccine production and quality control systems. The institute will attempt to enhance vaccine research on diseases of particular importance to low income countries. This new initiative addresses a very serious gap in protecting the health of children, especially those living in less developed regions.

ICGEB's research activities relate either to specific diseases, in terms of diagnosis, treatment and/or vaccine production, or to the research of new technologies aimed at the design of innovative drugs, diagnostic kits and vaccines. These are targeted to be less expensive than traditional methods, and to prevent the manipulation of dangerous material. Human Papilloma Virus (a precursor of uterine cervic cancer), Human Immunodeficiency Virus (implicated in AIDS), Hepatitis B, Rotavirus and malaria are among the most important diseases currently being investigated within ICGEB.

The Industry and Technology Sections of ESCWA are providing assistance to the Arab Union of Manufacturers of Pharmaceuticals and Medical Appliances (AUMPMA) in planning a seminar and workshop to be held within 1995, both dedicated to exploring possibilities of utilizing biotechnology in the pharmaceutical industries of the AUMPMA Member States. The seminar will be dedicated to the large-scale manufacture of raw materials for

pharmaceuticals while the workshop will focus on the manufacture of diagnostic reagents and devices.

3. Programme Area C: Enhancing protection of the environment

Objectives:

- The application of biotechnologies for the conservation and sustainable use of biodiversity.
- Prevent, halt and reverse environmental degradation through the appropriate use of biotechnology in conjunction with other technologies, while supporting safety procedures as an integral component of this programme. Specific objectives include the inauguration as soon as possible of specific programmes with specific targets.

The need to prevent, halt and eventually reverse the effects of environmental degradation through the safe uses of biotechnology is urgent. International organizations are promoting production processes that make optimal use of biotechnologies for the rehabilitation of land and water, waste treatment, soil conservation, reforestation and afforestation.

Advances in biotechnology offer powerful tools for the conservation, evaluation and use of genetic resources. New biotechnologies and advances in molecular genetics are essential to the understanding of the genetic structure of species. As the need for genetic stocks increases, important collections will have to receive adequate technology and good financial support. Long-term national and international assistance is essential to conserve, manage and use these resources.

Innovative agreements, in particular the one between Costa Rica's National Biodiversity Institute (INBio), a non-profit organization, and the U.S.-based pharmaceutical firm Merck & Co., Ltd. have shown that biotechnology offers new opportunities for global partnerships in relation to biodiversity utilization, in particular between countries rich in biological resources and the countries that have developed the technological expertise to utilize biological resources sustainably. Although too early to evaluate, this innovative approach to international cooperation deserves to be followed with interest by the international community.

To promote the application of biotechnologies for the conservation and sustainable use of biodiversity and to prevent, halt and reverse environmental degradation, UNEP provides support to a number of regional Microbial Resources Centres (MIRCENs) for the: (i) collection and maintenance of microbial genetic resources in view of the tremendous potential of microbial germplasm for economic development and environmental management and protection; and (ii) training in, research on and pilot application of environmentally sound biotechnologies. Examples include increasing food production and soil fertility through biological nitrogen fixation (BNF), biodegradation of persistent chemicals used in agriculture and industry, bioremediation, biocontrol of insect pests and disease vectors, bioleaching, and bioconversion of agricultural residues and surpluses into useful products.

UNEP supported the establishment of additional regional Microbiological Resources Centres in China, India and Syria. The MIRCEN concept was conceived by UNEP and realized in collaboration with UNESCO, where they act as centres of excellence for training in environmental microbiology and biotechnology, the conservation of microbial genetic

resources of regional relevance, and their pilot application in environmental management. Each MIRCEN is supported by selected institutions in developed countries to increase international cooperation and exchange of expertise in this area.

With UNEP support, Cairo and Nairobi MIRCEN laboratories are active in translating research results in biological pest and vector control into applications as an appropriate approach that offers a sustained long-term environmentally-sound alternative to the continued use of chemical pesticides. The Cairo MIRCEN is designing and testing under field conditions microbial technologies for the biodegradation of key persistent insecticides widely used in agriculture in the region.

The Bangkok and Guatemala MIRCENs focus on agro-industrial wastes of major environmental concerns with support from UNEP. The Bangkok MIRCEN successfully completed a demonstration on a pilot scale for the bioconversion of cassava surplus and the processing of by-products into power alcohol. Pilot demonstration projects for the bioconversion of coffee processing by-products using integrated technologies have been implemented by Guatemala MIRCENs with the full participation of the coffee industries in Guatemala.

UNEP conceived and supported the establishment and use of the international Microbial Strain Data Network (MSDN) as a referral system of information on microbial strains and cell lines and the international Information Resource on the Release of Organisms into the Environment (IRRO). IRRO is a global information network concerned with information on the introduction of genetically modified and novel organisms into the environment. Training programmes were conducted by IPGRI/UNEP on the characterization and conservation of plant genetic resources and gene banks management. As a follow-up to Agenda 21, UNEP initiated a global biodiversity assessment regarding the main aspects of biodiversity including biotechnologies related to its conservation and sustainable use.

Global and regional databanks on animal genetic resources have been established and the first edition of the *World Watch List for Domestic Animal Diversity* was produced in 1993 by FAO/UNEP. Training in relevant biotechnologies is being offered with UNEP support at specialized institutes.

The Convention on Biological Diversity and the reports from the Open-ended Intergovernmental Meeting of Scientific Experts on Biological Diversity and the recommendations to the Conference of the Parties from the second session of the Intergovernmental Committee on the Convention on Biological Diversity recommend the use of biotechnology for:

- (i) ecosystem identification and evaluation (i.e. assessing stability, sustainability and sensitivity of ecosystems, and monitoring micro-organisms including unculturable microbes, etc.);
- (ii) species identification and evaluation (i.e. molecular taxonomy);
- (iii) genetic resources (i.e. evaluation and gene mapping);
- (iv) ecosystem management (i.e. pest management control, impact assessment, and monitoring *in situ* conservation practices);
- (v) species management (i.e. assessing the viability of habitats and small populations of species);

- (vi) management (i.e. collection of micro-organisms);
- (vii) propagation/subculturing technologies (i.e. genetic monitoring in breeding and propagation);
- (viii) germplasm preservation/storage techniques (i.e. *in vitro* conservation, cryogeny, low temperatures, lyophilization, etc.);
- (ix) quality control and genetic integrity (i.e. gene pool sampling, authentication and validation);
- (x) conservation at the subcellular level (i.e. gene storage, DNA banks);
- (xi) development of capacity building and transfer of biotechnology programmes, in particular in areas relevant to the objectives of the Convention; and
- (xii) facilitating access to information on technologies, institutions and experts on biotechnologies relevant to the Convention.

The International Centre for Agricultural Research in the Dry Areas (ICARDA), in Aleppo, Syria, plays a leading role in field studies and research activities on topics related to animal and plant genetics and germplasm preservation concerned with particular crop plants in the ESCWA region. ICARDA and several national centres in the region collect and experiment with wild plant varieties that are related to crop plants. Additionally, ICARDA appears to be the most active institution in the region in the field of germplasm conservation.

A joint ESCWA/FAO study has recently been completed on "Wildlife Conservation for Sustainable Development in Arab Countries" that will be presented to the Ministerial Conference on the Management of Sustainable Development of Drylands in the Arab World in 1995. It is hoped that the recommendations made by the Conference will form an appropriate basis to introduce biotechnologies for the protection and conservation of threatened species.

A project being submitted for funding by the Global Environment Facility on behalf of eight countries is "Biodiversity and Natural Resource Conservation and Management for Sustainable Agricultural Production in the Fertile Crescent". The project, to be executed by ICARDA and the International Plant Genetic Resource Institute (IPGRI), will include agricultural biotechnologies and genetic engineering components.

Combating desertification is a priority area in many Member States in the ESCWA region. It has become the subject of several activities, including meetings, seminars and field projects. Research efforts are underway in university laboratories in Member States, as, for example, in Egypt, Jordan and the UAE with the aim of studying and improving suitable plant varieties to stabilize top soil and stop dune migration. Other efforts are aimed at experimenting with crop varieties resistant to salt water.

The FAO/UNIDO/UNDP Asian Sub-Programme on Biotechnology and Biodiversity has selected pilot sites in different agro-ecological areas in eight Asian countries where biotechniques to characterize and utilize biodiversity may be used. FAO is assisting several developing countries in strengthening their *in vitro* culture and other biological capabilities; this programme includes the training of people for the conservation, characterization and utilization of genetic resources.

FAO is implementing forest tree improvement projects at national and regional levels encompassing a rational blend of conventional tree breeding and biotechnological approaches.

A new OECD project was recently initiated to identify impediments to the diffusion and deployment of bioremediation technologies. Also to be identified are policy options to overcome these impediments. This work builds on an analysis of the scientific basis for bioremediation carried out by OECD's Committee on Scientific and Technology Policy through its work on "Biotechnology for a Clean Environment".

UNIDO has been working in close collaboration with a number of developing countries to develop an institutional capacity in two developing regions of the world, specifically, in Latin America and in Asia, to serve as models and as ICGEB Affiliated Regional Centres for other developing countries. The technological and management capacity and capability of the regions' infrastructural and human resources will thereby be strengthened. Nations will be enabled to systematically catalogue plants and microbial species, basing the work on local needs, and to direct their potential development into commercially viable products. The private sector and NGOs are included in this new initiative.

Recently UNIDO joined UNDP and FAO in launching the Bioinformatics Network on Biotechnology and Biodiversity. It links eight Asian countries, facilitating information dissemination to developing countries and the sharing of information among network members. Within each country, NGOs and the business sector are encouraged to participate in the Network.

Applications of modern biotechnology for bioremediation of contaminated land and water has created increasing global interest and subsequently increased demand by developing countries for technical advice and assistance from UNIDO. Within the UNIDO Programme on Clean Industry, UNIDO has ongoing activities on waste minimization and industrial effluent treatment. Within the UNIDO Programme on Clean Industry, UNIDO has ongoing activities on waste minimization and industrial effluent treatment. A series of regional workshops are being planned and organized aimed at disseminating information on strategies for the development of appropriate technologies and mixtures of technologies, including new biotechnology for the treatment of contaminated soil and water and the treatment of industrial effluents. At a country level, UNIDO is working closely with the Socialist Republic of Viet Nam to develop a programme on microbial remediation of oil pollutants, building on the country's relatively extensive work on petroleum microbiology. In addition, UNIDO has developed programmes for biodegradation of organic pollutants (chlorinated biphenyls) in Jordan and for effluent treatment of industrial fermentation processes in Romania.

The development of environmentally sound alternatives and improvements for environmentally damaging production processes, including the environmentally sound management of wastes, particularly hazardous wastes generated in various sectors of industry and commerce, became a specific component of the recommendations to ECE governments on the five R policies (reduction, replacement, recovery, recycling and reutilization of industrial products, residues or wastes), adopted in 1992. Moreover, the policy recommendations to ECE governments on waste-water management adopted in 1991, called for the development and harmonization at the international level of a code of practice to

provide, *inter alia*, guidance for the control of pollutants in industrial processes, the application of the best available technology for containment and treatment of hazardous substances and the substitution of potentially hazardous substances in industry, trade and service.

Bioremediation of polluted groundwater, technologies for containing pollution, biological methods of treating pollution in the unsaturated zone above groundwaters contaminated by past industrial and military activities, and the treatment of extracted contaminated soil are among the topics of the regional ECE Seminar on the prevention and control of groundwater pollution to be held in September 1995. The seminar will involve policy and decision makers, lawyers, economists and managers who will also address regulations and enforcement, liability and compensation for damage, and assessment and planning techniques.

The Convention on the Protection and Use of Transboundary Watercourses and International Lakes (Helsinki, 1992) contains binding obligations to parties to apply best available technologies for the treatment of industrial waste water containing hazardous substances, to apply at least biological treatment or equivalent processes for treating municipal waste water, and to carry out research on the development of new technologies and environmentally sound disposal practices. These include the use and development of biotechnology, and the setting up of mechanisms to exchange biotechnology between parties for capacity building, particularly in countries in transition.

Currently, a status report is being compiled on the major issues of prevention, control and reduction of water pollution from point sources. Such issues include the upgrading of waste water management systems in accordance with the precautionary principle; the control of pollutants within industrial processes; and recycling of water and recovery of valuable substances. It is expected that this report will be the basis for further measures under the Convention, such as a code of practice to promote the use of environmentally sound technologies in waste water management, including biotechnologies for waste water treatment and sludge disposal.

The International Maritime Organization (IMO) has noted that the appropriate use of biotechnology can prevent, halt and reverse environmental degradation has implications for the future work of IMO since biological agents are finding increasing usage in oil spill remediation and the rehabilitation of hydrocarbon contaminated coastal sites. This can involve both naturally occurring and genetically modified bacteria. Such matters are increasingly the subject of research by Member States of the IMO.

4. Programme Area D: Enhancing safety and developing international mechanisms for cooperation

Objectives:

- Safety in biotechnology development, application, exchange and transfer through international agreement on principles to be applied on risk assessment and management.

This programme area provides a framework for the environmentally sound application of biotechnology as envisaged within Chapter 16 as a whole. As stated in paragraph 16.29:

"There is a need for further development of internationally agreed principles on risk assessment and management of all aspects of biotechnology, which should build upon those developed at the national level. Only when adequate and transparent safety and border control procedures are in place will the community at large be able to derive maximum benefit from, and be in a much better position to accept, the potential benefits and risks of biotechnology." Of integral importance to the issue of ensuring biotechnology safety are the efforts of international organizations for enhancing biosafety and developing international mechanisms for cooperation. In this context, the Informal UNIDO/UNEP/WHO/FAO Working Group on Biosafety needs to be extended to include other appropriate UN organizations such as UNESCO and, in particular, ILO, which is actively engaged in addressing biotechnology safety and risk assessment and management issues in the workplace. The recent United Kingdom/Netherlands initiative on the preparation of international technical guidelines is also of relevance.

The policy issue of biosafety requires rapid and effective resolution. Developing countries and NGOs have expressed concern that clandestine, indiscriminate field testing of genetically modified organisms might be conducted in some developing countries. At the present time, the absence of established biosafety procedures in developing countries constitutes a major constraint to field testing - and indeed to product development - by those public sector initiatives designed to facilitate the introduction of biotechnology in developing country agriculture.

At its first meeting, the Conference of the Parties to the Convention on Biological Diversity decided to establish an open-ended *ad hoc* group of experts on safety in biotechnology nominated by governments and requested the Secretariat to establish a panel of 15 government-nominated experts on safety in biotechnology, with due regard for equitable geographical representation, and in consultation with the bureau of the Conference of the Parties, assisted by UNIDO, UNEP, FAO and WHO, to prepare a background document to be submitted to the open-ended *ad hoc* group of experts. The document should consider the need for and modalities of a protocol for the safe transfer and handling and use of living modified organisms. The expert panel meeting will be held in Cairo, Egypt, from 1 to 5 May 1995, at the invitation of the Government of Egypt, and the meeting of the open-ended *ad hoc* group of experts will be held in Madrid, Spain from 24 to 28 July 1995, at the invitation of the Government of Spain.

Concern over possible safety and environmental risks raised by biotechnology prompted WHO, UNEP and UNIDO to identify and study the various safety issues involved, leading to a UNIDO publication *An International Approach to Biotechnology Safety* in 1990, that proposed roles for UN agencies and ICGEB. As a result, a UNIDO/UNEP/WHO/FAO *Ad Hoc* Working Group was formed to work out practical guidelines through a series of consultations with international experts and scientists from developing countries. A Voluntary Code of Conduct for the Release of Genetically Modified Organisms (GMOs) into the Environment was thus developed in 1991.

Stemming from the joint Informal UNIDO/UNEP/WHO/FAO Working Group's Voluntary Code of Conduct for the Release of Genetically Modified Organisms developed in 1991, and with support from the Norwegian Government, UNIDO further formulated, according to the Code's recommendations, a Biosafety Information Network and Advisory

Service (BINAS). BINAS contains a number of databases that include biotechnology guidelines, regulations and standards for the release of transgenic organisms into the environment. UNIDO works closely with the Organization for Economic Co-operation and Development (OECD) in information and data sharing, thus providing a comprehensive coverage of developing and developed countries. UNIDO recently put its BINAS on-line, making information and advice on biosafety issues more accessible. The establishment of BINAS is thus a major step towards nationalizing environmental concerns and regulatory oversight. Apart from its databases containing information on countries' regulations to control environmental applications of biotechnology, it provides a large repository of Environmental Impact Assessments. BINAS is supplemented and supported by a BINAS Newsletter.

BINAS has been and is being supported by a series of awareness seminars and training workshops organized jointly by UNIDO and ICGEB, most of them in close cooperation with UNEP. A manual on biotechnology safety entitled *Genetically Modified Organisms: A Biosafety Guidebook* has been prepared by the UNIDO Secretariat and ICGEB for the Informal UNIDO/UNEP/WHO/FAO Working Group on Biosafety. The publication is due to be released in early 1995. In line with the Voluntary Code of Conduct for the Release of Organisms into the Environment, developed jointly by UNIDO, UNEP, WHO and FAO, the organizations are assisting in strengthening national human resources and infrastructures to implement biosafety guidelines and procedures. FAO is establishing a "prior informed consent" system and is assisting in building national bio-information systems to assist the countries in elaborating pertinent policies and regulations related to biosafety. ICGEB/UNIDO conduct four training courses each year to assist national and regional regulatory authorities and to provide ongoing technical support on risk assessment methodologies and biotechnology safety. UNEP plays an active role in supporting such training.

The OECD's Environment Policy Committee (EPOC) maintains a work programme on the Environmental Aspects of Biotechnology, which includes linkages to an array of UN and other international bodies. Its cooperative aspects in particular involved work on the development of "Biotrack" (OECD's computerized storage and retrieval system that contains information on introductions into the environment of organisms derived through modern biotechnology). Methods for monitoring organisms in the environment are also being analyzed as a part of this work. Broad international cooperation, particularly through UNIDO's BINAS system, will continue. Two OECD EPOC projects are devoted to developing tools to enhance the harmonization of regulatory oversight, including common methods for generating data used to assess products; methods to encourage the mutual acceptance of data; issues related to the assessment of data; and common approaches and methodologies for the interpretation and evaluation of data. The project on "Industrial Products of Modern Biotechnology intended for Release to the Environment" focuses primarily on organisms intended for use in bioremediation, bioleaching and biomining as well as other similar environmental uses. The project on "Commercialization of Agricultural Products derived through Modern Biotechnology" places primary attention on agricultural crop plants derived through modern biotechnology.

The FAO Commission on Plant Genetic Resources prepared and discussed a draft Code of Conduct on Biotechnology as it affects the Conservation and Utilization of Plant

Genetic Resources at its 5th Session in April 1993. This was the first time that a permanent UN intergovernmental forum had actually discussed a draft Code of Conduct on Biotechnology, encompassing a biosafety module.

In the field of food safety, the Joint FAO/WHO Expert Consultation on Assessment of Biotechnology in Food Production and Processing as Related to Food Safety, held in Geneva in November 1990, recommended that at the international level there was a need to define and establish new procedures to evaluate the safety of foods (including additives and ingredients) that have been produced using biotechnological processes. The use of gene manipulation complicates the final safety review of a product because of all of the new variables introduced, as, for example, the possible presence of viable cells of the transgenic organisms, DNA fragments, or foreign protein. FAO and WHO are striving to standardize and harmonize the procedures for the safety evaluations of foods involving biotechnological manipulation.

Building on experience derived from a series of awareness seminars and training workshops, especially at regional and subregional levels, and with an increasing participation of developing countries in BINAS, considerable progress in regional cooperation in biosafety has been made. Specifically, UNIDO fostered the establishment of a Task Group of Regulation Oversight of Central and Eastern Europe in Biotechnology (ROCEEB). The goal of its activities is harmonization of the regulatory oversight in the region.

Faced with the increasing number of workers who are exposed to biological agents in the workplace, ILO decided to intensify its actions in the evaluation of risk assessment data and the development of preventive measures in the field of biotechnology. In 1993, the International Labour Conference adopted a resolution concerning exposure to and safety in the use of biological agents at work. Based on this Resolution, the Governing Body of the ILO requested the Director General to take fully into account, when drawing up future programme proposals, to take steps to address the question of exposure to and safety in the use of biological agents at work and to consider the need for new international instruments in order to minimize the risks to workers, the public and the environment.

In its 1996-97 programme and budget proposals, the Occupational Safety and Health Branch of the ILO has plans to compile a report on biological hazards and their prevention and on the scope for international instruments in this field. The report is expected to be submitted to a tripartite meeting of experts to be held in Geneva. Cooperation with UNIDO, WHO and UNEP will be sought during the preparation of the meeting. As background work, ILO has prepared a study on the impact of modern technology, including gene technology, on workers' health and the environment. The study identifies potential risks related to the introduction of these new technologies.

The Convention on Biological Diversity is currently discussing the issues surrounding the need for and modalities of a possible protocol on biosafety under the Convention. A number of initiatives are in hand to follow up paragraphs 16.34(a), which calls on governments "organizing one or more regional meetings between countries to identify further practical steps to facilitate international cooperation in biosafety", and "considering the need for a feasibility of internationally agreed guidelines on biotechnology releases, including risk

assessment and risk management, and considering studying the feasibility of guidelines which could facilitate national legislation on liability and competition."

Recent bilateral collaboration between the Governments of the United Kingdom and the Netherlands resulted in the preparation of draft technical guidelines on safety in biotechnology. Following an international meeting of experts in March 1994 in the United Kingdom to provide advice, a larger group of experts from 17 countries from all regions of the world took place in May in the Netherlands. The new guidelines are meant to provide a practical tool in fostering international cooperation. Related regional meetings on international cooperation on safety in biotechnology were held in Harare, Zimbabwe in October 1993 and in Cartagena, Colombia, in June 1994. A workshop is to be held in Thailand in 1995 as a contribution to capacity building.

In 1989, the Senior Advisors to ECE Governments on Science and Technology, one of the principal subsidiary bodies of the United Nations Economic Commission for Europe, assumed responsibility for establishing and maintaining an inventory of existing safety guidelines in biotechnology; it includes existing laws and regulations and, where relevant, any planned measures in order to identify developments and national experiences gained in this field. To date, the secretariat has in its possession national submissions, and in some instances reference material, from 29 governments as well as from UNIDO, the Commission of the European Communities and the Organization for Economic Cooperation and Development (OECD). A compilation of the most recent summaries of national submissions for the inventory in the form of a publication for wider dissemination is in preparation. In a related development concerning protection of water, recommendations to ECE Governments on the prevention of water pollution from hazardous substances adopted in March 1994, requires, *inter alia*, the setting of emission limits based on best available technology from industries that manufacture and process microorganisms and viruses with *in vitro* recombined nucleic acids.

Conferences organized by the United Nations Regional Commissions demonstrated a need for a focused approach whereby specific areas in biotechnology may be targeted by R and D institutions in the region and confirmed the necessity of establishing stronger links between these institutions and sources of investment and private enterprise. Areas found to merit further concentrated efforts include safety considerations in the development of capabilities in biotechnology.

5. Programme Area E: Establishing enabling mechanisms for the development and the environmentally sound application of biotechnology

Objectives:

- Awareness building and public education.
- Strengthening endogenous capacities of developing countries including employment opportunities for women.
- Consolidation of efforts.
- Socio-economic impacts of new biotechnology on conventional production systems.
- The contribution of indigenous peoples and their share in economic and commercial benefits arising from biotechnology.
- Intellectual property rights with respect to biotechnology and bioresources.

- Increase access both to existing information about biotechnology and to facilities based on global databases.
- Helping to create a favourable climate for investments, industrial capacity building and distribution marketing.
- Encouraging the exchange of scientists among all countries.
- Enhancing existing efforts at the national, regional and global levels.
- Providing the necessary support for biotechnology, particularly research and product development, at the national, regional and international levels.

Recognizing that biotechnology is multidisciplinary in nature and that capacity building for its effective environmentally sound management requires new management strategies and approaches, several UN agencies with complementary mandates and programmes have increasingly developed new collaborative initiatives. Programmes dealing with biosafety have expanded beyond the scientific sector to include the concerns of workers exposed to biological agents in the workplace (ILO), farmers (FAO) and the general public, while programmes on marine agricultural and industrial biotechnology call for closer cooperation among FAO, ILO, IMO, UNEP, UNIDO, WHO and WMO. Such efforts extend beyond the UN-wide System to involve the private business sector, financial institutions and NGOs. Regional UN Commissions have taken steps to strengthen in-house capacities with a view to increasing their role in coordinating the several global biotechnology initiatives at the regional level. UNDP has been instrumental in fostering UN System-wide coordination at the national level.

Various UN and other international organizations are engaged in efforts, at the global, regional and national levels, to help countries, particularly developing countries, to take advantage of opportunities offered by rapid advances in biotechnology. Collaborative programmes have been initiated in response to Agenda 21 that enhance training capacity, technical knowledge, research and development facilities, and industrial capacity, and that promote awareness and understanding of the issues surrounding intellectual property rights protection with respect to biotechnology. A broad range of demands, ranging from information to technology on biosafety and biotechnology and from advisory services to financial and management support, experienced through these efforts indicated the need for a more effective integrated approach and closer cooperation in many aspects.

Lessons drawn from development cooperation experiences suggest that the "top-down" approach has shortcomings and that the success of aid programmes and projects depends to a large extent on the participation of developing countries at all levels and phases of design and implementation. They also suggest that if biotechnology is to have a significant impact on developing country agriculture long-term commitments will be required.

Recognizing the high costs of research in biotechnology, several existing agricultural research institutes have strengthened or initiated new biotechnology programmes to address the common elements of research and development as well as the training needs of developing countries in many areas outlined under programme area E, with support from financial institutions, foundations and, to a lesser extent, the private business sector. Intergovernmental technological institutions such as the ICGEB have been instrumental in providing regular training programmes aimed at capacity building of developing countries. Through its network of Affiliated Centres in the various regions, collaborative research projects with national institutions in the developing countries have been encouraged with a view to more effectively addressing regional and national concerns. At the same time,

through its pre-doctoral and post-doctoral fellowship programmes, aimed at training in the best possible environmental and scientific facilities, the Centre ensures the transfer of technology to its member countries.

UNIDO uses its comparative advantage in its close association with the ICGEB as the only operating laboratory in the field of genetic engineering and biotechnology established within the auspices of the United Nations system and an important, recognized resource for developing countries. Collaborative activities are aimed at the global, regional and national levels in an integrated programme approach involving biosafety, technology transfer, investment strategies, and management, including development, acquisition and commercialization of biotechnology products, services and industrial processes.

UNIDO and ICGEB networks include the global bioinformatics network on molecular biotechnology (ICGEBNet), biosafety (BINASNet), lactic acid and food fermentation technology (LABNET) and bioconversion and mushroom technology (MUSHNET). In addition, UNIDO, in cooperation with UNDP and FAO, promotes regional bioinformatics networks in Asia and, with UNDP and UNESCO, a bioinformatics network in Latin America.

In support to the biotechnology networks, UNIDO and ICGEB act as a repository of information by gathering and collating information on research and development activities in Member States; hosting information on commercial products and technologies developed by institutes in Member States; and monitoring matters related to patent laws, release of genetically engineered micro-organisms/products and biosafety legislation.

Benefiting from the Organization's expertise and experience in telecommunication and information technology, as well as extensive computerized information systems that include the Industrial Technology Information Bank (INTIB), UNIDO promotes electronic networking to strengthen technical cooperation among developing countries. Through regional network nodes, it is possible to provide developing countries (network members) with better access to other regional and international databases on biotechnology and related subjects.

Working in collaboration with the Carl Duisberg Gesellschaft-South East Asia Program Office (CDG-SEAPO) in Thailand and the Philippines, UNIDO has seed money to establish Quality Control and Training Centres (QCTCs) in selected developing countries; the QCTCs will focus on training in biotechnologies, on business management skills, on entrepreneurship training, and on increasing opportunities for women to be actively involved in small-scale enterprise development. The QCTCs are expected to be self-sustaining through income generation from the private sector.

A severe lack of information in developing countries on progress in biotechnology and its potentials for commercialization is a major stumbling block preventing policy makers in these nations from venturing into new channels for advancement. Since 1982, UNIDO has directed information to developing countries concerning recent developments and applications of the technology, information on patents and intellectual property rights, and relevant institutional news in its quarterly journal *Genetic Engineering and Biotechnology Monitor*. In tandem with the Monitor, a newsletter specifically concerned with biotechnology in relation to Agenda 21 has been published since the time UNIDO was designated to be Task

Manager for Chapter 16. This newsletter, called *Agenda 21 Biotechnology Watch*, promotes information exchange and stimulates a regular flow of information on the United Nations system-wide implementation of Agenda 21 in the environmentally sound management of biotechnology. Other newsletters entitled *LABNET* and *MUSHNET* are issued to disseminate information to developing countries concerned with improvements in traditional food fermentation technologies and with bioconversion of waste materials for mushroom production, respectively.

In 1984, the former Centre for Science and Technology for Development, the work of which has been taken over by UNCTAD, initiated the Advanced Technology Assessment System (ATAS) as a vehicle for strengthening the scientific capacities of developing countries through technology assessment. The ATAS Bulletin, which is one of the main vehicles of the system, has already devoted two issues to biotechnology. The first one, in 1984, covered one aspect of biotechnology, namely tissue culture. By contrast, the latest and ninth issue, in 1992, focused on food production, but covered a wider spectrum of technologies.

UNEP supports major training programmes in the sustainable use of plant, animal and microbial resources, the application of relevant technologies and in biotechnology safety. The latter courses are conducted in collaboration with sister UN organizations in order to build related professional and institutional capabilities in the assessment and application of environmentally sound biotechnologies for sustainable development. In addition, UNEP continually strengthens and expands the regional MIRCENs network.

Through various national, regional and global level expert consultations and conferences that involve the public and private sectors and NGOs, FAO has been increasing the awareness of the challenges and opportunities of modern biotechnologies at various levels. The regional biotechnology networks sponsored/supported by FAO in different regions are based on the spirit of TCDC and inter-country cooperation and promote exchange of information, expertise and techniques. Regional training courses on biotechnology and joint research on common topics are the main features of these collaborative networks.

The FAO draft Code of Conduct on Biotechnology has an elaborate coverage of the intellectual property rights issue and its impact on information, technique and product sharing. FAO promotes a balanced approach between Plant Breeders' Rights and Farmers' Rights. The implementation of Farmers' Rights is currently being negotiated by FAO member countries through the Commission on Plant Genetic Resources.

Within the framework of the Committee of Experts on Biotechnological Inventions and Industrial Property, the International Bureau of WIPO presented suggested solutions concerning industrial property protection of biotechnological inventions. Its suggested solutions include processes for the creation or modification of living organisms and biological material (process patents) and natural products, living or non-living, which may be the results of biotechnological processes (product patents). There are altogether 16 such suggested solutions.

To address the diversification of the chemical industry to include new biotechnology products and services, a regional networking system concerned with bio-botanical pesticides has been set up in Asia to gather and disseminate information on biopesticides. In addition

to information exchange, a North-South cooperation has been initiated, in cooperation with UNESCO and the International Union of Pure and Applied Chemistry (IUPAC), for training in safety and environmental protection in chemical, pharmaceutical and biotechnological research.

UNESCO has issued a series of documents to encourage the international exchange of ideas on science awareness and technological education, including some relating to biotechnology. In addition, in attempting to disseminate an awareness of the environment and sustainable development with a view to upgrading the quality of environmental education and training, UNESCO has initiated a number of information mechanisms stressing that information by itself is not enough, and that getting people involved is important (the bottom-up approach).

Within the framework of collaboration between UNDP, UNESCO and ICSU in the African Biosciences Network (ABN), support has been provided to encourage research activities and training activities in the biosciences and biotechnologies throughout Africa. The main activities of the African Biosciences Network in the second phase were the conducting of research projects carried out by two, three or more partner countries, and conferences, symposia, training courses and workshops in nine priority areas, which are: forest resources, water resources, insect pests, nutritional problems, endemic diseases, microbiology, medicinal plants, plant breeding and animal breeding.

The International Fund for Agricultural Development (IFAD) increasingly supports, through its Technical Assistance Grants Programme for Agricultural Research and Training, new opportunities offered by biotechnology-based options to increasing the resilience of farming systems to adverse external production constraints, especially under resource-poor conditions in which traditional extensive farming and livestock systems cannot be sustained. IFAD's support for such research aims at the generation of technologies that allow traditional crops/commodities produced by resource-poor farming systems to transcend conventional threshold levels of yield, improve tolerance to environmental stress factors as well as resistance to pests and diseases which currently undermine the productive capacity of poor smallholders. In elaborating the applications of biotechnology, the Fund supports an emphasis that goes beyond one shot increases in yields/productivity to also address issues of stability and sustainability, while carefully considering risks inherent in bio-engineering.

An international meeting on the role of patents in biotechnological inventions, one of the fastest-growing areas of patent applications, was held in November in New Delhi, India, with experts stressing the need to strengthen the information system in this field. The meeting was organized by the World Intellectual Property Organization (WIPO). The topics discussed included the role of intellectual property in promoting technological innovations, aspects of legal protection, microorganism deposit systems and application of patents and special features of licensing.

The United Nations Regional Commissions have organized conferences aimed at enhancing awareness of the opportunities offered by biotechnology. Some conferences were aimed at promoting links between business enterprises and biotechnology R and D institutions, both within the developing country region and between the region and developed countries. These conferences demonstrated the need for a focused approach whereby specific

areas in biotechnology may be targeted by local R and D institutions. They confirmed the necessity of establishing stronger links between these institutions and sources of investment and private enterprise. Areas that merit further concentrated efforts included the development of marine agricultural and industrial biotechnologies and agricultural and agro-industrial applications of genetic engineering and plant cell and tissue culture.

The United Nations Economic Commission for Africa recognizes that biotechnology is rapidly expanding and that an obvious challenge to African countries is to ensure that they participate in the development of biotechnology and make informed decisions to exploit it in various sectors (medical, agriculture, animal production, food processing, etc.). It urges governments to develop explicit policies and strategies which lead to concrete programmes of activities in the development and exploitation of biotechnological resources of relevance to their respective countries. Policy research should be undertaken to identify policy options at the sectoral and national levels and to throw light on the complex issues and issues of intellectual property rights related to biotechnology products and processes. Overall there is urgent need to develop increased awareness amongst the political leadership, the policy makers and the population at large about the potential benefits and opportunities available through biotechnology. Such public education should also bring out the possible shortcomings, i.e. displacement of local food and cash crops, creation of dependency among the local population on the suppliers of new biotechnological products, and questions of sustainability of schemes based on biotechnological inputs.

In addition, the ECA stresses that regional information systems, for example at the African regional Centre for Technology, should be strengthened to exploit data and information residing in global databases on biotechnology for the benefit of their regions. Such strengthened regional information systems will facilitate information exchange with other regional and national information nodes.

Since the main thrust of the activities of the United Nations Economic and Social Commission for Asia and the Pacific (ESCAP) is the promotion of regional cooperation and the coordination of the activities of the organizations of the UN System in the region, its activities primarily deal with regional cooperation. The ESCAP Committee on Environment and Sustainable Development met in Bangkok in October 1994 and deliberated on the document of the ESCAP secretariat entitled "Transfer of Environmentally Sound Technologies, Cooperation and Capacity-building". This document, *inter alia*, covers the issues of transfer of environmental biotechnology, required endogenous capability building in this area, and prospects for regional cooperation in order to formulate a regional cooperative action programme for transfer of environmentally sound technology including environmental biotechnology. For the regular monitoring and coordination of UN industrial and technological activities in the ESCAP region and to ensure complementarity and coordination among strategic goals of technological and industrial development of the relevant UN agencies, an Inter-Agency Committee of Industry and Technology has recently been established in Bangkok with ESCAP serving as its secretariat. Issues to be considered include those related to environmentally sound technology including biotechnology. Furthermore, ESCAP will continue to promote cooperation among national biotechnology institutions in pooling their resources to undertake joint research in areas of biotechnology identified by regional countries during previous ESCAP activities. This activity is expected to be carried

out within a proposed regional network of biotechnology institutions that includes national focal points designated by twelve regional developing countries.

UNDP's recent emphasis on sustainable human development encourages the participatory involvement of local organizations and people in the planning and implementation of scientific endeavour, and seeks to avoid a heavy dependence on the transfer of technology, an approach shared by other UN agencies. Thus, it is hoped that in the future it will be possible for biotechnology to be regarded as one (major) constituent of a broader multi-sector planning approach.

IV. GENERAL LESSONS LEARNED

Enormous scope exists in many countries for productivity gains, for improvement in the quality of food and agricultural products, and for conservation of the environment, using existing technologies which are available but are not being applied. A key issue for developing countries, therefore, should be selectivity in determining whether biotechnology might provide the most effective solution, from both the cost as well as the social point of view. Biotechnology needs not only to be understood but its potential benefits need to be appreciated by policy-makers for it to be fully integrated into national priorities and policies.

The international biotechnology programmes of the United Nations agencies, the OECD Development Centre, and of donor organizations and their bilateral and multilateral aid programmes, demonstrate the extent to which countries can take advantage of new technology. Whether this is through "endogenous" development, international technology transfer or, more often, a combination of the two, will depend on national conditions and policies. External "cooperation" can facilitate technology development and diffusion, but it can only complement - not substitute for - national efforts, capacities and policies.

Past limited experiences by organizations concerned with the successful transfer to and development of biotechnology in developing countries indicated that the successes were based on strategic alliances with institutions in developed countries either at the development stage or at both the research and development stages. Such strategic alliances might involve public institutions or the private industrial sector or both. One common key factor in most cases was the involvement and participation of an intermediary organization, often with financial and/or technical support. The key roles of intermediaries were to identify and assess appropriate technologies and to facilitate negotiation between the two parties in terms of contracts for cooperation, which included licensing agreements and the sharing of benefits. It may be concluded that this technology management (or intermediary) service was a crucial factor. As such, the role of the intermediary organization should be further studied and evaluated as a candidate for future encouragement and promotion.

For biotechnology to be successfully developed, public as well as private support, and support from NGOs, is needed. Financial support to the scientific community alone is not enough. Various new incentive measures, including positive financial, legal and new management mechanisms and approaches for promoting private-public sector collaboration are essential. In most developing countries, public institutions are the main centres in which research is being undertaken on the emerging biotechnologies. The industrial sector and individual entrepreneurs in many of these countries have still to gain confidence in the potential of investing in commercializing results emanating from the research laboratories. In addition, the general public is still inadequately informed about the benefits and risks associated with the development and applications of biotechnology, even though science and technology are seen by many as engines of economic progress. For these and other reasons, constraints such as low levels of public acceptance in certain countries and inadequate support by governments and the private sector continue to exist. Lessons learned from development cooperation experiences over the years suggest that the "top-down" approach has severe shortcomings and that the success of aid programmes and projects depends heavily on the full participation of developing countries at all levels of society and during every phase of design

and implementation. And if biotechnology is to have a truly significant impact, long-term commitments will be required.

V. CONCLUSIONS AND PRIORITY ISSUES FOR FURTHER CONSIDERATION

A. Conclusions

Since UNCED, scientists and policy makers have begun to give high priority to biotechnology development. The more biotechnologically advanced developed countries, having increasingly privatized biotechnology research and development, continue to forge rapidly ahead in several sectors, expanding in particular from the pharmaceutical and health sector (programme area B of Chapter 16) to the agricultural sector (programme area A), with a development trend towards the environmental sector (programme area C). Environmental biotechnology in the future seems increasingly likely to be focused on the conservation, protection and sustainable utilization of the world's scarce natural resources. As a cross-sectoral technology, it ought to be possible to apply biotechnology where appropriate and assist in tackling many of the challenges identified in other chapters and programme areas of Agenda 21, though biotechnology should not be regarded as a magic wand for solving all problems.

Although the "new" biotechnology began to emerge as a science more than two decades ago, Agenda 21 has been instrumental in focusing global attention on the contribution that biotechnology can make in efforts to achieve sustainable development while safeguarding the environment. Biotechnology applications have the potential for making major contributions to the health and welfare of humanity, although biotechnology is still perceived by many to have undesirable and partly unforeseeable ecological, socio-economic, legal and ethical implications.

The issue of biosafety is dealt with in detail in programme areas D and E in Chapter 16, with a strong emphasis on capacity-building and the need for international agreement. A coherent system of controls is not yet in place, despite the intensity of the debate on the issue of safety in biotechnology during and subsequent to the UNCED process. It is widely recognized, however, that it is critical - especially in developing countries - to establish standards for the development, handling and commercialization of biotechnology products to protect human and animal health and to safeguard the environment.

The first steps towards a possible international system of controls were taken at the first meeting of the Conference of the Parties to the Convention on Biological Diversity in Nassau, the Bahamas, in November 1994. The issue of safety in biotechnology extends well beyond the conservation and sustainable use of biological diversity, however. The Commission on Sustainable Development is uniquely placed to set this issue in the context of sustainable development in its widest possible sense.

With the increasingly rapid rate of biotechnology development and increasing privatization of biotechnology, particularly in many industrialized countries, and as biotechnology is a science- and knowledge-intensive field, technological and information gaps between these countries and many developing countries are increasing. There is concern about the ability of these developing countries to acquire and manage new biotechnology without experiencing potential negative impacts. Furthermore, lack of resources constrain those countries from restructuring their science and technology infrastructure, from acquiring new technology management skills, and from adjusting to new standards in biosafety and to

increasing pressures to adopt intellectual property rights protection in relation to biotechnology. The enormous changes in technological capabilities in some developing countries in recent years should also be borne in mind, however, as well as the wide differences among developing countries in their ability to acquire and manage biotechnology.

Responding to the needs and concerns of developing countries, several international and bilateral programmes have strengthened their activities. Many have introduced new initiatives in biotechnology, ranging from capacity building for the improvement of traditional and intermediate biotechnologies, such as food fermentation and tissue culture, to the introduction of new biotechnologies, such as diagnostics and biopesticides, and from information dissemination to advisory services on biosafety and, to a lesser extent, on intellectual property rights protection in relation to biotechnology. Such programmes are also constrained by the inadequacy of available financial resources, specially when compared to private financing in industrialized countries. They have nevertheless already successfully demonstrated in many developing countries the potential of biotechnology applications for improvements in agricultural productivity and in health care, as well as in the diversification of industry, and the conservation of the environment.

The extent to which countries can take advantage of new technologies depends heavily on a range of national priorities and prevailing economic and social conditions, and especially upon the degree of participatory planning among all stakeholders. In a number of developing countries, biotechnology associations comprise mixed membership from both the academic and industrial sectors but are less active in policy-related matters. In many other countries, biotechnology associations' membership is confined to scientists. Where they exist, biotechnology associations provide an effective forum for information exchange as well as a mechanism for private-public sector cooperation.

Although initiatives and efforts in biotechnology have been evenly distributed among the various regions, countries in Asia and Latin America have advanced to more sophisticated levels than those in the other developing regions. Countries in Eastern and Central Europe, with their strong foundation in science, also show strong potential to benefit from biotechnology development. Effective policy formulation and prioritization of resource allocation have helped countries such as Cuba to achieve considerable success in biotechnology development. South-South networking arrangements, such as the Plant Biotechnology Network (REDBIO) in the Latin America and Caribbean regions, and intergovernmental scientific and technological initiatives such as the International Centre for Genetic Engineering and Biotechnology (ICGEB) with bases in Trieste, Italy and New Delhi, India and Affiliated Centres in its several Member States have been effective in diffusing biotechnology among and to developing countries in different regions.

In matters related to financing, the available information indicates a low level of support far below what is required if developing countries are to participate in and benefit from biotechnology development to ensure sustainable development for all mankind. Meeting the many and varied economic and institutional requirements needed to enable Chapter 16 to be fully and effectively implemented with the limited funding currently available from the international community points to the need to focus upon financing high quality biotechnology programmes and initiatives and to giving priority to ensuring the continuity of financial support. Lessons from the still limited investments by regional banks in biotechnology

projects indicate a major potential for expanding the role of financial institutions at various levels in promoting biotechnology programmes.

Intellectual property rights issues with respect to biotechnology have increasingly become the subject of debate in both developed and developing countries, as well as in international fora, notably the TRIPS and, more recently, the Convention on Biological Diversity. Special problems can arise as a result of the gradual extension of patents to new biotechnologies, especially genetic engineering biotechnology, in the absence of clear international minimum standards.

The Green Industry Biotechnology Forum (GIBiP), an industrial association of plant biotechnology-related food and agricultural businesses, has sponsored one much-welcomed initiative in this area by establishing an industry-oriented database on field trials of new biotechnology products. This database contains information complementary to the national country information on biosafety contained in the BINAS and OECD Biotrack databases.

B. Priority Issues

In light of the review and assessment above, a number of priority issues can be identified, as follows:

1. The key role of the private sector - business, industry and the banks - in promoting and applying biotechnology for sustainable development to meet the objectives of Chapter 16.

Some biotechnology business reports on commercial biotechnology predict that the coming decade will see an increasing number of products entering the market place with a tendency for more flexible regulation of biotechnology products. As commercial biotechnology development increases in scope and volume and with the trend towards a globalized economy, the impact of biotechnology itself is likely to become increasingly global in nature. It will be critical, therefore, for efforts to be made to ensure that any expansion in commercial activities of this kind makes a positive contribution to the attainment of global sustainable development. The private sector needs to be actively encouraged to contribute to efforts to work towards sustainable development through the development and use of environmentally sound biotechnologies which balance social, environmental and economic objectives and the dissemination of reliable and accurate information to the public. The banking sector - especially the regional banks - need to be encouraged to participate more actively in the development, and especially, the commercialization of biotechnology - particularly in developing countries.

2. The need to integrate biotechnology concerns into national sustainable development policies for making and building national capacities.

An increasing number of countries have identified biotechnology as a priority area for economic development, especially in science and technology education and research. However, although biotechnology can play an important role in the development of several sectors including agriculture and health, environment, energy, industry, education and trade, biotechnology concerns are not usually sufficiently integrated into wider policy-making at the

national level. There is a need for national development policies and planning to address issues such as the development of management skills for selecting, assessing and prioritizing biotechnologies; the selection of necessary and appropriate standards and regulations for quality and environmental control; legislation and regulation with respect to biosafety issues and intellectual property rights issues with respect to biotechnology; and special economic measures such as tax and legal measures for businesses to foster the successful commercialization of environmentally sound biotechnology applications. Efforts need to be made to mobilize to the fullest possible extent and build upon existing mechanisms, such as BINAS within the UN system, as well as other informal mechanisms such as the Biotechnology Advisory Commission of the Stockholm Environment Institute, the International Service for National Agricultural Research/International Biotechnology Service (ISNAR/IBS), and the Agricultural Biotechnology for Sustainable Productivity (ABSP) project, and to make the most effective use of regional meetings and training supported by those organizations. Moreover, there is a real need for a coherent and comprehensive response from the various UN and other international development organizations. More concerted efforts by the various UN agencies concerned and other international programmes, including in particular private sector initiatives such as the International Service for the Acquisition of Agri-Biotech Applications (ISAAA), will be needed to meet the increasing needs of developing countries in this area.

3. The need to achieve and demonstrate safe and viable results for sustainable development in the application of biotechnology.

There continues to be considerable speculation and debate about the potential risks and benefits associated with biotechnology. The economic returns resulting from those biotechnology applications which have been supported by venture capital have encouraged a steady increase in investment in biotechnology, yet the beneficial results of applications in developing countries and the benefits derived from such applications are not perceived to have extended much beyond the business community. There is a clear case for identifying and disseminating information about examples of "best practice" environmentally sound applications that have demonstrably resulted in meeting the sustainable development objectives of programme areas A, B and C of Chapter 16, especially as they relate to farming or other communities and to small and medium rural enterprises, in particular in developing countries.

4. Safety in biotechnology.

As the question of safety in biotechnology goes beyond the conservation and sustainable utilization of biological diversity, which comprises the main focus of the work on a possible protocol under the Convention on Biological Diversity, there is a need to assess how far the objectives and activities of programme area D, especially paragraphs 16.32 (a), (b) and (c), and of programme area E, are being effectively addressed and implemented in the context of this and any other appropriate ongoing processes, with a view to identifying gaps in existing efforts. Such a review would benefit from regional meetings and consultations organized by the various UN agencies and other international programmes within the framework of Agenda 21. The review could take into account the work on biosafety of other international organizations such as the OECD and include current OECD work designed to facilitate the international harmonization of regulatory oversight in biotechnology. The immediate need for developing countries to develop national regulatory

mechanisms in biosafety issues along with the related capacity for their implementation is an urgent issue to be addressed. Ongoing UN and other international initiatives to follow up Chapter 16, especially in terms of regional consultations and the preparation of international technical guidelines, should be supported.

5. Matters related to intellectual property rights.

Action is urgently needed to facilitate the effective participation of developing countries in the process towards adopting realistic and up-to-date standards for intellectual property rights on biotechnology, taking into consideration new advances in and the understanding of biotechnology, as well as its crucial role in sustainable development, its potential impact on human society, and opportunities for mutually-beneficial collaboration and cooperation.

6. The need to promote greater awareness of biotechnology issues.

Public concern continues to be expressed over the impact of biotechnology, especially as it relates to social, moral and cultural values. At the national level, bioscience and biotechnology need to be appropriately introduced into school curricula. The general public needs to be adequately informed of the potential impacts of the technology on people and society and its concerns addressed in an open and transparent manner. Special efforts need to be made to involve the media with a view to the presentation of an impartial understanding of emerging biotechnology and its impacts. The private sector in both developing and developed countries has a role to play in providing up-to-date, accurate and reliable information in connection with the commercialization of new products and processes.

7. Institutional mechanism for the further development and implementation of international policy on biosafety.

The issue on biosafety has been and is still being debated widely at various levels. In this connection, the CSD may wish to take note of the recent conclusions adopted at the First Conference of the Parties on Biological Diversity, as presented in its Medium-Term Programme of Work of the Conference of the Parties 1995-1997 (UNEP/CBD/COP/1/L.11), in particular the following:

- (a) To establish an open-ended *ad hoc* group of experts nominated by governments to consider the need for and modalities of a protocol on biosafety;
- (b) To establish a panel of 15 experts nominated by governments, assisted by UNIDO, UNEP, FAO and WHO, to prepare a comprehensive background document on biosafety for submission to the above-mentioned open-ended *ad hoc* group of experts.
- (c) To call upon the international community, in particular upon developed countries, to contribute voluntary funds to assist the open-ended *ad hoc* group of experts to discharge its mandate.

It should be pointed out that the issues of biosafety in biotechnology extend far beyond the conservation and sustainable uses of biological diversity. In this respect, coordination between the Convention on Biological Diversity and the Commission on Sustainable Development is crucial. Furthermore, the immediate need for developing countries to

develop national regulatory mechanisms in biosafety issues along with the related capacity for their implementation is an urgent issue to be addressed.

VI. GENERAL RECOMMENDATIONS

1. The Establishment of an Institutional Mechanism for Informal Consultation and Information Sharing on Biotechnology Development Trends and its Impact in Relation to Sustainable Development

The CSD should establish an institutional mechanism for informal consultation and information sharing on biotechnology. Its aim would be to periodically review, examine, assess and report on the current status of the technology, on new trends and emerging issues of concern in biotechnology development and in its applications. Such a mechanism would be important and is necessitated by the extremely rapid rate of biotechnological development. In addition, it can be the focus of a general body of comprehensive and well-balanced information on the ways biotechnology interacts with other factors in achieving the goal of sustainable development.

A small consultative group on biotechnology would appropriately form such an institutional mechanism. The group would be comprised of expert representatives of international organizations that are recognized to be neutral and have long been active in promoting the safe uses of biotechnology. Included, in addition, would be representatives of biotechnology business organizations, NGOs and representatives of other major groups from developed and developing countries. Consultative meetings would be held annually and information gathered could be disseminated to the world community at large.

UNIDO, as Task Manager for biotechnology, could be asked by the CSD to serve as the secretariat of this consultative group on biotechnology. In this capacity UNIDO would hold annual consultative meetings. Current initiatives, as, for example, UNIDO's quarterly *Genetic Engineering and Biotechnology Monitor*, the Netherlands-supported *Biotechnology and Development Monitor*, and the many publications put out by the Organisation for Economic Co-operation and Development (OECD) each year on biotechnology issues can be used as core inputs for such consultations. As proposed, minimal additional financial resources would be needed to support the proposed new initiative, mostly to ensure a balanced participation of developing countries and NGOs.

In establishing this new institutional mechanism, the CSD may wish to especially call upon:

- (a) the donor community to support the participation of developing countries' and NGOs' representatives in the consultation;
- (b) the UN and international organizations dealing with biotechnology initiatives to monitor and document cases that include viable and environmentally sound applications of biotechnology as well as cases that have negative impacts on environment and development;
- (c) the biotechnology business community, through the International Bioindustry Forum, to actively participate in and contribute to the annual international consultation, in providing information on development trends.

2. The Necessity for Additional Action on Biosafety

It is widely recognized that it is critical for developing countries to establish standards for the development, handling and commercialization of biotechnology products. Such standards would make possible the acquisition of new technologies and products, and protect human and animal health and environmental safety. National governments having no administrative regulatory mechanisms or those having outdated ones should be strongly encouraged to seek advice and/or assistance from international agencies experienced in promoting biosafety regulation. These organizations can assist relevant national authorities to formulate and implement biosafety guidelines. In spite of the outcome of the ongoing international debate on an international biosafety protocol, such action must take place to ensure safety in national and in international development in biotechnologies. The scientific community, as public stewards, should take the lead in exercising its ethical responsibility through safe laboratory practices that ensure as well as assure safety. Of increasing importance is the necessity for bioscientists to show greater interest in getting public consent and in actively working to establish the good communications with non-scientists necessary that build public confidence.

There is need for a joint review of all UN agencies' activities relevant to biotechnology applications and biosafety built on the work of the already existing informal UNIDO/UNEP/WHO/FAO working group on biotechnology safety. The joint review should identify overlapping, gaps, strengths and weaknesses and the comparative advantage of each organization, and develop joint programmes, as appropriate. In such a review, consideration should be given to similar non-UN initiatives, including the Biotechnology Advisory Service of the Biotechnology Advisory Commission of the Stockholm Environment Institute and the United Kingdom-Netherlands initiative on biosafety guidelines.

Governments should ensure that steps be taken, if they have not already done so, to collect information and data relating to biotechnology safety in preparation for building up a national database on biosafety information, that would act at the same time as a national focal point for regional and internal exchanges of biosafety information.

In addition, countries are encouraged to establish national biosafety focal points. National focal points will facilitate access to and exchange of biosafety-related information, leading eventually to regional and international coordination on biosafety. When and where feasible, regional cooperation should be fostered and regional capacities in biosafety management be strengthened. Sharing regulatory expertise and technical resources in biotechnology and biosafety risk assessment will benefit regions as a whole.

All UN Regional Commissions could, following the ECCE model, assume responsibility for establishing and maintaining inventories of existing safety guidelines in biotechnology to identify developments and national experiences in each region.

A recent decision was adopted by the Conference of the Parties on the Convention of Biological Diversity in relation to biosafety. It concerns the establishment of an open-ended *ad hoc* group of experts nominated by governments to consider the need for and modalities of a protocol on biosafety. The CSID may wish to consider taking further action in biosafety, beyond the matter of a protocol.

The CSD is requested to note that this open-ended *ad hoc* group of experts is to consider the need for and modalities of a protocol setting out appropriate measures, including, in particular, advance informed agreement, in the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect upon the conservation and sustainable use of biological diversity. The protocol alone, if agreed upon, does not and cannot automatically ensure the safe handling and applications of biotechnology. In developing countries in particular, there is the immediate need for the creation and building up of national biosafety regulatory mechanisms bearing on the environment and on sustainable development that ensure the safe handling and transfer of biotechnology. The capacity to put such regulatory mechanisms in place is of particular importance to developing countries to enable them to sustainably benefit from the emerging biotechnologies poised to be commercially exploited in the very near future.

While the CBD expert group is considering whether or not to establish a biosafety protocol, the CSD may wish to consider taking action with the view to assisting developing countries to build a national capability in preparation for biosafety regulation implementation in a way to facilitate safe biotechnology development and application for development without being detrimental to health or the environment.

Such action could include the formation of a working group on biosafety to coordinate with the Secretariat of the Convention on Biological Diversity on further development of the work of the CBD open-ended expert group on biosafety and to develop a work plan aimed at capacity building in biosafety for developing countries. The work plan should include activities to ensure effective coordination of ongoing efforts by international and bilateral biosafety promotion programmes and a means for resource mobilization for implementation of the activities to be recommended.

In this connection, the CSD may wish to consider the role of the Informal UNIDO/UNEP/WHO/FAO Working Group on Biosafety to serve as the core of such a working group, taking into consideration the work and recognition for the role of the Informal UNIDO/UNEP/WHO/FAO Working Group by governments and the private sector. Expansion of the working group to include ILO and UNESCO would be desirable.

Finances for a CSD working group on biosafety can come from a mechanism to be set up in the form of an international biosafety trust fund with voluntary contributions from financial institutions, foundations, private donors.

3. An Advisory Service for Developing Countries on Intellectual Property Rights Issues with respect to Biotechnology

It is proposed that the CSD undertake a new international initiative to promote understanding of intellectual property rights protection issues with respect to biotechnology and with respect to genetic resource issues. A policy issue of concern in international biotechnology initiatives, both for donors and for developing countries, is that of intellectual property rights. The legal arrangements made thus far in the cases where proprietary technology has been used suggest that proprietary technology need not necessarily imply high costs, nor constitute an insurmountable obstacle for developing countries in gaining access to a particular technology. The role of the "honest broker" may be important, particularly

where neither the foreign partner nor the developing country concerned has expert legal knowledge of the rapidly-changing developments in intellectual property rights issues with respect to biotechnology.

Scientists, researchers and biotechnology managers in most developing countries are not always informed of changes in the patent law field with respect to biotechnology as they occur, and thus they miss out in utilizing opportunities that can be to their benefit. New international agreements such as TRIPS can equally work to the advantage of developing countries if the subject is well understood by all parties concerned.

Special problems have arisen as a result of the gradual extension of patents to new technologies, in particular to genetic engineering technology, without the emergence of clear international minimum standards. International reviews and debates on this subject are taking place. A recent study by UNCTAD of TRIPS agreements (September 1994) treated the subject of intellectual property rights protection under non-traditional subject matters; it indicated that microbiological advances routinely affect changes in the higher plant and animal world, with the result that legal distinctions between inventions said to be macrobiological processes or microbiological process in nature have not always been implemented with consistent or persuasive results. Nor has a firm consensus emerged concerning the application of patent law mechanisms in this field. Intellectual property regimes relating to genetic material is an important issue being discussed by the Convention on Biological Diversity, yet the matter extends into many sectors that impact sustainable development and would appropriately be addressed by the CSD.

The CSD may wish to request UN agencies charged with promoting these activities, WIPO, UNCTAD, and the new WTO, to expand their efforts and resources to meet the needs of developing countries so they can effectively participate in trade and technology transfer negotiations in matters related to biotechnology. An international effort could be launched by these agencies to provide up-to-date information and advisory services to developing countries on the subject of intellectual property rights protection, especially with respect to non-traditional technologies such as genetic engineering and biotechnology. Resources to fund such an initiative can be sought from developed countries and from the international business community.

4. Accelerated Efforts for Capacity Building

The CSD is urged to encourage national governments to undertake and strengthen activities focused toward the acquisition and advancement of biotechnologies with potential to positively contribute to sustainable development. National efforts are crucial in achieving the global partnerships envisaged in Agenda 21 aimed at reconciling the principle of healthy economic development with the principle of a high-quality environment. Endogenous capacity is recognized to be the most important component and prerequisite for sustainable development. International institutions should be called upon to support such national capacity building efforts.

The CSD can encourage governments to effectively enhance efforts in national capacity building in biotechnologies, giving serious consideration not only to the science- and

knowledge-based nature of the technology but also to the fact that biotechnology closely interacts with living things and living ecosystems that differ widely in different places in the world. It will be important in national planning efforts for attention to be given to the role of all major players - the government, the UN organizations and the international community, major groups, indigenous people, women and men, and NGOs - to permit a balance in opportunities for all concerned to participate and contribute. National governments should be encouraged to consider ways to strengthen local initiatives in:

- Enhancing public awareness and promoting an accurate understanding of biotechnology

Enhancing public awareness and promoting an accurate understanding of biotechnology are critical prerequisites for the successful wide-scale applications of biotechnology that will be required to achieve sustainable development and to preserve the environment. Although the new biotechnology began to emerge as a science more than two decades ago, the general public is still inadequately informed. Not well understood are the benefits and risks associated with the development and applications of biotechnology. As a result, constraints that include low levels of public acceptance and inadequate support continue to be encountered. Intensive efforts should be mobilized by all concerned to increase awareness building at all levels. At the national level, bioscience and biotechnology should be appropriately introduced in school curricula. The general public should be adequately informed of potential impacts of the technology on people and society. Special efforts must be made to involve the media in helping to increase awareness strengthened by an accurate understanding of emerging biotechnologies and an understanding of their impacts. The private sector in both developed and developing countries must be made accountable to the public in being required to provide proper information to consumers in connection with the commercialization of new biotechnology products and processes.

- Cross-fertilization of ideas between and among major groups

Even if the necessary information is available, decision making on biotechnologies within countries is a very complex issue. Information exchange between the groups involved is usually very limited; decision making on biotechnology in many countries is reduced to an *ad hoc* process depending on the suggestions of those close to decision makers. Two factors help explain this phenomenon. First the results of research carried out in different scientific fields are not systematically integrated and made accessible to decision makers. Second, the different organizations and social groups involved - scientists, experts, consultants, donor organizations, policy makers, farmers, producers, consumers, business people and groups, indigenous peoples - often have different perceptions of the problems to be solved and of their appropriate solutions.

To help countries in their decision-making process, it will be necessary to pay more and systematic attention to identifying problems to be solved, to the interests of those with economic and political power, to the different groups involved, and to the appropriateness, feasibility and sustainability of perceived biotechnological solutions. Public fora can be important in helping to orient the biotechnology R and D agenda to be more people-oriented and sustainable development-sensitive.

A strategy for linking different groups, known as the interactive bottom-up approach, has been successfully used, e.g. in Zimbabwe, to meet this criteria. It seeks to avoid technology-push and to identify biotechnologies that are real, practical, and demand-oriented, and to include the opinions of scientists, the people affected by the technology, and the organizations that represent or work with them. Three phases in this strategy can be distinguished: the preparatory phase in which an interdisciplinary research team is brought together to study the situation, to support the development of relevant, innovative and new ideas, and to identify relevant groups; the interaction phase in which the output of the first stage is openly discussed in public debate in order to gain support, to anticipate negative side effects, and possibly to lead to rejection of some of the ideas, or to a change of priorities and adaptation of the proposals; and the final phase in which decisions are made in different organizations on the basis of the momentum created on their involvement in a local capability building programme

Developed countries can be asked by the CSD to share their experiences in using this interactive approach. UN organizations and other international organizations with such experience, as for example the Intermediary Biotechnology Service (IBS) of the International Service for National Agricultural Research (ISNAR), can be asked by the CSD to take the initiative in facilitating the follow-up on activities that ensure that appropriate projects, programmes and institutions are created.

- The role of national governments with respect to the effective integration of biotechnologies into economic and environmentally sustainable development

The CSD may wish to call upon the international community to assist developing country governments in building biotechnology capability by funding case studies of successful examples of government-supported initiatives in biotechnology. Important new initiatives could be developed from these as model cases; they should be focused and demand-oriented, and identified by the developing countries themselves in a participatory planning process. They would be funded and undertaken along with the full commitment of developing country governments in terms of allocating resources and putting in place favourable and necessary economic and environmental conditions.

5. Establishment of an International Venture Capital Fund for Biotechnology

The rapid rate of biotechnology development, the increasingly widening economic and technological gap between developed and developing countries, and the major role of the private sector in commercial biotechnology development are causes for concern about equity in biotechnology transfer agreements among countries. Developing countries are genuinely concerned that developed countries will be able to use new proprietary biological tools in producing high-value products that displace materials currently produced by developing countries, negatively affecting the already weak position of most developing countries in the highly competitive and increasingly globalized markets. At the same time, developing countries are concerned about their weak capacity, technological and financial, to access new, effective biotechnologies developed by the private sector in developed countries that provide new opportunities for improvement and diversification in agricultural and industrial production.

Lessons learned from various biotechnology venture funds indicate that these are the most effective means to rapidly transfer commercial biotechnologies. Venture capital funds can be used to facilitate transfer of biotechnologies specifically serving common needs of developing countries and at the same time facilitating the process of capacity building in biotechnological development. Examples include biotechnologies for new vaccine development for major communicable diseases, biotechnologies for marginal lands and biotechnologies for pollution abatement (bioremediation).

The International Venture Capital Fund could be initiated by multilateral or regional development finance institutions and implemented by the International Finance Corporation. Part of the Fund could be used to conduct feasibility studies on potential commercial biotechnology projects in order to promote joint ventures and attract additional funding sources.

6. Financial Support from the International Community for Biotechnology-Related Local Initiatives in Developing Countries

In view of the increase in biotechnology-related initiatives being undertaken by developing countries, the CSD should encourage the international community to provide additional financial support to facilitate the integration of strategic biotechnologies that enhance biotechnological solutions to local problems, especially those having potential benefits for other developing countries. Examples of appropriate problem-oriented biotechnology-related initiatives include a Petroleum Microbiology (Bioremediation) Project in Viet Nam, a Sustainable Development Training Centre Project in China, a Traditional Medicine for AIDS Project in Thailand, and a Biosaline Agricultural Centre in the United Arab Emirates. Financial support from the international community can be used to effectively mobilize international experts and access appropriate biotechnologies that augment national efforts. Such financial support strategies allow not only maximum cost effectiveness of the limited resources provided by the international community but also opportunities for a more active participation of developing countries in implementing the Agenda 21 work plan. The sharing of developing countries' financial resources and the valuable indigenous knowledge are some of the positive contributions that can also be highlighted.

7. Expanding the Role of the Business Sector

The CSD may wish to call upon the biotechnology business sector, through the International Bioindustry Forum (IBF), to contribute more actively to biotechnology development for sustainable development through one or more of the following activities:

- Human resource development in biotechnology, especially in management aspects, directly through training and/or indirectly through the provision of fellowships to appropriate institutions to supplement existing efforts by governments and international organizations.
- Active participation and contribution to international consultations on biotechnology development trends and impact assessment, aimed at providing the world community with the impartial and well-balanced information required for policy and decision making.

- **Support for independent research and educational institutions in conducting case studies on viable and environmentally sound applications for biotechnology, especially in developing countries, that are contributing to sustainable development.**
- **Support for the establishment of biotechnology associations in developing countries to promote cooperation among the biotechnology-related industries and between the private and public biotechnology sectors.**

VII. SPECIFIC RECOMMENDATIONS TO THE COMMISSION ON SUSTAINABLE DEVELOPMENT

In the light of the priority issues identified action on the following matters may be considered:

1. **Enhancing the contribution of the private sector to sustainable development, in which governments seek to involve business, industrial and banking interests more actively in safely applying and promoting biotechnology to meet the sustainable development objectives of Chapter 16, with particular reference to:**
 - **participation in and contribution to national, regional and international consultations on biotechnology development trends and impact assessment;**
 - **support for independent research and educational institutions in conducting case studies on "best practice" environmentally sound and viable applications for biotechnology, especially in developing countries;**
 - **support for the establishment of biotechnology associations in developing countries to facilitate the commercialization and application of biotechnology products and processes, including human resource development in biotechnology management; and**
 - **other appropriate, innovative and environmentally sound approaches, especially with regard to financing international, regional and national biotechnology programmes.**

2. **Integrating biotechnology concerns into national-level development policy making and building national capacities, in which governments, supported by UN and other appropriate intergovernmental bodies, act to:**
 - **ensure the participation and contribution of all major groups in the integration process;**
 - **enhance public awareness through promoting and disseminating an accurate understanding of biotechnology that includes the issues associated with progressive trends in its development;**
 - **support cross-fertilization of ideas between and among major groups to enable decision makers to identify problems to be solved and to recognize the appropriateness, feasibility and sustainability of perceived biotechnological solutions;**
 - **strengthen environmentally and economically sustainable capabilities in the sound management of biotechnology, including matters relating to intellectual property rights.**

- establish national databases on information relating to biosafety in biotechnology; and
 - assess the need for advice and assistance in promoting appropriate biotechnology and biosafety regulations where these do not already exist or need to be strengthened, with a view to designing effective programmes, building wherever possible on existing capabilities.
3. Promoting "best environmentally sound and viable practices", in which governments, with maximum support from UN and other organizations as well as the private sector, cooperate to identify and exchange information, especially at the regional level, about examples of "best practice" viable and environmentally sound applications that have demonstrably resulted in meeting the sustainable development objectives of programme areas A, B and C of Chapter 16.
 4. Encouraging the environmentally sound application of biotechnology for sustainable development, by:
 - taking note of the decision of the first meeting of the Conference of the Parties to the Convention on Biological Diversity to establish a process for determining the possible need for and modalities of a protocol on biosafety;
 - assessing how far the objectives and activities of programme areas D and E are being effectively implemented at the national, regional and global levels; and making recommendations on possible further steps needed to address the wider issue of safety in biotechnology; and
 - the encouragement by governments of the scientific communities in their countries, as public stewards, to take the lead in exercising an ethical responsibility through safe laboratory practices and good communications with the public at large.
 5. Considering the steps required for the possible development of strategies for meeting the sustainable development objectives of Agenda 21, including the need for:
 - initiating a procedure for periodic reviews of biotechnology development trends to ensure the effective integration of the new biotechnology into global sustainable development efforts;
 - close cooperation between the CSD and UN agencies with the Convention on Biological Diversity with a view to following developments on the process for determining the possible need for and modalities of a protocol on biosafety and to ensure coordination, especially in identifying gaps and initiating follow-up action; and
 - advice from an *ad hoc* group of experts on such steps.

ANNEX I

FINANCING BIOTECHNOLOGY FOR SUSTAINABLE DEVELOPMENT

I. Introduction

The concept of sustainable development is based on the conviction that it should be possible to increase the basic standard of living of the world's population without unnecessarily depleting our finite natural resources and further degrading the environment in which we live. Technology can be the key to a more effective utilization of the world's limited resources that help at the same time to achieve sustainable development. The rapid global changes in technology are significant factors in setting the pattern and rate of industrial and subsequently the rate of economic growth; thus they significantly affect the development of society as a whole.

Agenda 21, a participatory plan of action jointly formulated and agreed upon by the world community at the Earth Summit in Brazil in June 1992, addresses many pressing problems of the world, including the concept of sustainable development, and focuses on addressing the challenges of the next century. Agenda 21 proposes a number of interrelated programmes and programme actions for implementation that are to be carried out by various key players according to the different capacities, situations and priorities of countries, taking into account all the principles contained in the Rio Declaration on Environment and Development.

Among the several proposed programmes of Agenda 21 are the transfer of environmentally sound technology (Chapter 34) and the environmentally sound management of biotechnology (Chapter 16), which reflects the necessity to properly manage technological and environmental changes resulting from new, rapidly advancing and sophisticated biotechnologies, in particular the changes brought about by the applications of genetic engineering.

All countries require appropriate infrastructures that permit them to acquire, absorb and develop technology, to manage it properly and systematically, and to build up local scientific and technological competence. The resultant ability of any country and of a developing country, in particular, to discern, choose and adapt an environmentally sound technology can serve as a measurement of sustainable self-reliance that will allow it to fully participate in worldwide efforts to achieve sustainable development.

Biotechnology, especially the modern version being developed on the basis of modern scientific research, is widely regarded to be a new technological tool because of its perceived potential impact on economies and on society. It is applied at increasing levels of sophistication in more and more sectors, improving the effectiveness of the way in which products and services are provided. However, the effective transfer and development of biotechnology in an environmentally sound manner requires a variety of conditions, the most important of which are capital inputs that, in the case of many developing countries, are not readily available. The financing of biotechnology poses new challenges that must be addressed to enable developing countries to realize its potential benefits, to minimize any

possibly adverse socio-economic effects, and for the donor community to properly plan and mobilize its funding in support of developing countries.

This paper attempts to provide a broad overview of the rationale and justification for new and additional sources of financial support, the financing currently available, the requirements for future funding, and a discussion of some future financial policy options that include an increase in active participation by developing countries in the development and applications of biotechnology focused toward sustainable development.

II. Assessment of Biotechnology Development: A General Overview

It is now widely recognized that biotechnology can play an essential role in fostering the economic and social progress in developed and in developing countries as well, if properly managed. In the industrialized world, biotechnology research, development and applications are growing at a very rapid rate, leading to an expanding range of products and processes across several sectors, a range that began with pharmaceuticals and health care, and extended into agriculture and, more recently, into the environmental sector. At present, more than 2,000 clinical trials of biotechnology-related products are in progress, primarily in more advanced countries. Other new products and technologies include improved seeds, new vaccines, novel food ingredients, biotechnology-based techniques for the rapid detection and identification of toxic materials and several bioprocessing technologies. The tendency of most developing countries is to acquire biotechnologies aimed at improving agriculture, food and pharmaceutical production, and in converting low-cost or marginalized raw materials into high value-added products and marginalized lands into more productive areas.

In addition to traditional technologies, many kinds of biotechnology are appropriate and accessible to developing countries. Tissue culture and some new diagnostics that demand a relatively low level of resources and technological capacity are currently available for immediate transfer to developing countries. However, many biotechnologies appropriate to and required by developing countries are proprietary in nature. Therefore, biotechnological solutions to problems in developing countries must be assessed and selected on the basis of priority and effectiveness. New and additional management skills are urgently needed. Along with the continued use of conventional technologies as appropriate, developing countries can seek to integrate more advanced biotechnologies into national development plans and programmes.

III. Economic Impact of Biotechnology

Economic analysts agree in predicting that biotechnology will have significant impacts on health care, on agriculture and on environmental management. Biotechnology in its broad sense ranges from traditional biotechnology to the most advanced modern biotechnology. Commercial biotechnology consists of a growing range of interrelated techniques, procedures and processes that apply in practical ways to the health care, agricultural and industrial sectors. The effective commercialization of biotechnology links basic research to concrete products and services.

Because there has been a very rapid rate in biotechnological research as well as a wide technological gap between developed and developing countries, advanced genetic engineering

techniques are more widely used in industrialized countries. Moreover, the current popular public understanding of biotechnology's impact tends to be confined mainly to the impact of modern biotechnology products and services. In this connection, data concerning the USA biotechnology industry show that worldwide annual sales of biotechnology-derived products have grown from zero in 1980 to US\$ 5.9 billion in 1992; these sales are projected to reach US\$ 50 billion by the year 2000 in the United States alone (Ernst and Young: *Biotechnology Series*). The 1994 report in the series indicates that the biotechnology industry as a whole continued to grow steadily. The total annual revenue of the industry increased in this period to US\$ 10 billion. More than US\$ 5.7 billion was spent on research and development by the private sector alone; more than US\$ 4 billion was spent by the public sector.

As commercial biotechnology applications gradually increase in scope, from pharmaceutical and health care to agriculture and environment, their economic impact will undoubtedly increase throughout the world, especially in response to an increasingly globalized economy. Pressure to decrease dependency on chemical pesticides, for instance, is expected to drive the growth of biopesticide sales worldwide. As an indication of this growth, sales in the USA for this newly emerging biopesticide industry are expected to reach over US\$ 150 million by 1997, as compared to US\$ 6.8 billion in sales of conventional pesticides.

Several reports on the United States commercial biotechnology industry have predicted that the coming decade will see a stabilizing of biotechnology activities, especially in the private sector, on the basis of an increasing number of products entering the market and a global tendency for more flexible government regulation of biotechnology products.

A similar trend in Europe, Japan and Canada has been reported. A 1994 report commissioned by the Senior Advisory Group on Biotechnology analyzes the macroeconomic potential of biotechnology; on the basis of the current data, it estimates a market value of US\$ 50 billion. Revenues are expected to double by the year 2000. Of special interest is information concerning the number of jobs directly related to biotechnology, estimated to be 184,000. With respect to investment in biotechnology, US\$ 1.2 billion a year was reported.

In contrast to industrialized countries, most developing countries have very little, if any, modern industrial biotechnology. Programmes in biotechnology deal mainly with traditional and with intermediate biotechnology, some exceptions being in a few of the more advanced Asian and Latin American developing countries. Nevertheless, an increasing number of developing countries have steadily invested, at a very low but significant level, in a broad version of biotechnology development. However, comparable figures on investment and sales are not readily available for developing countries. Nevertheless, there appears to be a positive trend in biotechnology development and in its impact. In the Republic of Korea, three major biotechnology-related companies in the pharmaceutical sector have a share of about 20 per cent of the total market. Moreover, the research investment in the area of biotechnology is growing at about 40 per cent. It has been estimated that the Republic of Korea will eventually produce about 2 per cent of the world's biotechnology-related pharmaceutical products. Major projections for the Taiwan Province of China are US\$ 600 million in sales in the field of the more conventional tissue culture biotechnology and about US\$ 60 million in sales of vaccines in 1996. An economic impact of similar intermediate biotechnologies in other biotechnology-advancing developing countries is also being noted.

With respect to investments in biotechnology, a decision was recently made by the Islamic Development Bank to support the establishment of a Biosaline Agriculture Centre. The Centre will rely on accessing biotechnologies from other centres of excellence in order to make use of marginal lands and sea water irrigation. A feasibility study on the project estimates a minimum benefit and cost ratio at close to 2 and up to 5.

In spite of scanty information about the immediate economic impact of biotechnology in developing countries, the trend for development in developed and advanced developing countries, in particular in Asia, indicates a similar positive trend. It is reasonable to say that the economic impact of biotechnology in a given country is in correlation with the biotechnology capacity and related investment.

IV. Economic and Institutional Environment of Biotechnology Development

A brief overview of the economic and organizational nature of biotechnology development may be useful as a basis for funding considerations. This is especially important because the international community faces increasing difficulty in mobilizing funds for development assistance to developing countries. Key prerequisites for successful biotechnology development include:

(a) *A strong scientific and multidisciplinary base.* Undeniably the rapid evolution of molecular scientific knowledge in the last two decades is and will be the critical foundation for successful commercial biotechnology development. In developing countries, the role of universities and research institutions in building the necessary infrastructure for generic research into new biotechnologies has been widely recognized.

(b) *Public and private sector cooperation.* This cooperation ranges from the university-industry cooperation in various forms, including science parks, to public financing of the private sector's research and development, to joint ventures. It is a key and critical requirement.

(c) *Active private sector participation.* Bringing scientific knowledge and basic research to development and from there to the market requires high resource inputs, especially in terms of investment, supporting engineering services, and management. The active participation of the private sector is crucial for success.

(d) *Enabling policy environment.* In addition, it is widely recognized that a positive policy environment is a critical prerequisite for the successful commercial development of biotechnology. Because of the scientific, social and economic implications of biotechnology, it is vital that an enabling policy environment be created through effective formulation, integration and coordination. The creation of science and technology policy based on biotechnology alone and in isolation is not enough. Of particular importance is the issue related to biosafety regulation that is currently under discussion at various fora and levels, most actively within the Convention on Biological Diversity.

Lessons learned from successful industrialized countries and from developing countries that enjoy a more advanced level of biotechnology development indicate that economic and

institutional structures play very important roles in fostering biotechnology industrial development.

V. Financing and Financial Sources for Biotechnology in Developing Countries

Most, if not all, developing countries are well aware of the potential of biotechnology to foster economic growth. Many countries have identified biotechnology as a key area for development. However, the basic and applied research activities are conducted primarily in the universities and are fragmented. A demand for practical goal-oriented research and development is largely beyond the technical and financial resources available to the scientific sector. With the exception of more advanced developing countries, funds for meaningful biotechnology R and D come from external sources. Financing for biotechnology is rarely supplied by the private business sector.

There have been no direct or comprehensive international surveys of financial expenditures concerning biotechnology programmes that address the challenges outlined in Chapter 16 of Agenda 21. However, a 1993 survey concerning international initiatives in agricultural biotechnology was conducted by Intermediary Biotechnology Services. It indicated that bilateral and multilateral aid agencies, international organizations, private foundations, universities, commercial companies and national governments are all involved in the financing of international biotechnology initiatives for developing countries.

Since 1985, the contribution in grant funds for biotechnology programmes in developing countries was over US\$ 260 million, in comparison with World Bank loans and credits for national agricultural research and development at a level of about US\$ 150 million. Compared to biotechnology research and development in industrialized countries, the total financial efforts devoted to international biotechnology initiatives are far from adequate.

The IBS survey provides an interesting profile of financial sources, as follows:

Foundations	40.9 per cent
Bilateral donors	31.6 per cent
Multilateral donors	16.5 per cent
National institutions (matching funds)	4.6 per cent
Miscellaneous research grants	3.9 per cent
Private commercial	2.3 per cent

These data indicate: (a) a significant participation by non-profit organizations (foundations) in biotechnology development; (b) a similarly significant role of bilateral donors; and (c) weak participation by the private business sector in contributing financially to the development of biotechnology in developing countries.

The active contribution and participation of non-profit organizations in biotechnology development is of particular importance in view of the social implications of biotechnology and the concern on the part of developing countries about equity. In addition to the Rockefeller Foundation, that reportedly has contributed since 1985 more than US\$ 50 million to the International Rice Biotechnology Programme alone, there are biotechnology support

activities of other non-profit foundations. The Biofocus Foundation in Sweden and the M.S. Swaminathan Foundation in India are examples of social organizations created to help direct the benefits of biotechnology towards less privileged target groups in developing countries.

Bilateral donors and related bilateral cooperative programmes in biotechnology have been instrumental in strengthening the biotechnological capability and capacity of developing countries. Many developed countries such as Japan, France, the United States of America, Australia and the Netherlands have actively supported biotechnology programmes, including collaborative research and training. In addition to the financial contribution through the conventional Official Development Assistance Programme, other channelling of funds have also been created. Examples include the Japanese Society for the Promotion of Science (JSPS) which has been carrying out special bilateral exchange programmes in biotechnology with several Southeast Asian countries, and Australia's Crawford Fund for International Agricultural Research.

Important lessons learned from these assistance/cooperation programmes include the following:

- (a) Long-term commitment is vital to achieving sustainable capacity building and to enable a country to reach a critical level in self-reliance for further biotechnological development. The Indo-Swiss project initiated in 1974 has led to pilot commercial production of biopesticides.
- (b) A networking arrangement among institutions within the country and region is one of the most cost-effective means to maximize limited resources.
- (c) Access to or provision of modern scientific equipment and key biomaterials for research are important components for successful and equitable strategies for collaborative research.
- (d) Most importantly, the financial commitment of a developing/recipient country government is critical to successful collaboration. This commitment can include in-kind contributions.

The Asian Development Bank, in cooperation with the German Government, is funding the Asian Rice Biotechnology Network. The network is a new major initiative of the International Rice Research Institute (IRRI). The programme aims to transfer advanced biotechnology in rice to national agricultural research systems (NARS). The fund will provide for joint NARS-IRRI biotechnology programme, a biotechnology training laboratory at IRRI and equipment and supplies for NARS laboratories, leading to biotechnology products to be shared with NARS in Asia. The newly launched UNDP/FAO/UNIDO Farmer-Centred Agricultural Resources Management project (FARM) has an important biotechnology component; it actively involves NGOs.

As part of the Children's Vaccine Initiative (CVI), UNDP, along with UNICEF, WHO, the World Bank and the Rockefeller Foundation, is establishing an autonomous institute in the Republic of Korea. The institute is to be committed to developing, testing and delivering affordable new and improved vaccines for the world's children. It is a partnership

of public and private sector institutions, agencies and companies. It will assist vaccine producers in developing countries to improve vaccine production and quality control systems. The institute will attempt to enhance vaccine research on diseases of particular importance to low income countries. This new initiative addresses a very serious gap in protecting the health of children, especially those living in less developed countries.

The World Bank and the United Nations agencies that include UNDP, FAO, UNEP, UNIDO and WHO have been and continue to be a significant, although relatively small, source of funding and/or technical assistance for biotechnology development in the developing countries, due mainly to the continuity and coverage, technological and geographical. Examples include support to various international agricultural resource centres (IARCs) and, more recently, to the International Centre for Genetic Engineering and Biotechnology (ICGEB). Approximately 10 per cent of the total core budget of IARCs (US\$ 23.6 million of the total US\$ 236 million in 1993) is spent on biotechnology.

The ICGEB, established by UNIDO, spends approximately US\$ 15 million annually to support its biotechnology programme for developing countries. Currently, ICGEB receives its funding mainly from its host countries, i.e. Italy and India, and voluntary contributions from its Member States.

Within developing countries, the government's financial support for biotechnology is in general far below what is normally required to provide the adequate scientific and technical infrastructure necessary for meaningful biotechnology development. However, the trend is encouraging. This is indicated, for example, by the plan in Viet Nam to seek US\$ 30 million to re-equip the country's biotechnology-related research and development facilities, and by the significant increase from less than US\$ 1 million in 1985 to US\$ 18 million in 1995 for biotechnology programmes in Thailand.

Bio-based micro-enterprises and small bioindustries in developing countries play a significant role in income generation for rural populations in providing markets for agricultural produce and providing employment. They benefit from improved biotechnology and related support technologies if given opportunities along with technical and management assistance. The small industries and enterprises involved in traditional biotechnologies is also a subject of bilateral assistance. The technical assistance project, Training and Technology Transfer Project on Application for Small Bioindustries Development, funded by the Carl Duisberg Gesellschaft-South East Asia Program, is a classic illustration of support leading to benefits derived from biotechnology applied in a holistic and sustainable manner. The project uses a fund of less than DM 3 million to provide technical and management training, support services, an information database and a networking arrangement between South-South institutions and with South-North cooperation. The project is largely built upon existing resources and the potential for capacity building in the developing countries themselves. As a result, mechanisms are being developed that apply to a number of small bioindustries and can serve as models for other small bioindustries and in other developing countries. The project evolves around strengthening local technology institutions, R and D capability, and on technology transfer. It includes resource mobilization through networking arrangement. The biotechnology promotion model is based on the institutionalization of a vital quality control and training programme for bio-based small-scale industries that include biofertilizers, food fermentations and mushroom cultivation.

Currently, financing contributions from the private sector for commercial biotechnology development is still low, mainly due to the high business risk involved with modern biotechnology enterprises and partly due to unfavourable policy environments. Experience from developed countries indicates the importance of the private sector's participation. Limited but successful experiences in developing countries such as the Republic of Korea and Singapore could lead to an increase in the next decade in the private sector's financing in biotechnology, especially in Asia where the economy has been continuously growing at a significant rate.

In developing countries, the formation of partnerships between the private sector and government enabling institutions, notably science and technology parks, is an approach being increasingly adopted for promoting biotechnology development and commercialization. Venture capital funds, such as the Transtech Venture Fund in Singapore, are few but they can serve as successful models for fund mobilization from banking institutions and industrial subscribers, and also - and more importantly - in the fund's financing operation. The Transtech Venture Fund operates both within and outside the country, and includes investments in overseas technology companies that provide access to technologies and to management support.

In view of the relatively high risk associated with biotechnology product development and commercialization, more risk capital must be found. Cross-country strategic alliances have been particularly successful between USA and European companies and between USA and Japanese firms. Strategic alliances with and in developing countries, although not common in biotechnology development, have been known and are being promoted by a number of international programmes and venture capital firms. The role of such enabling mechanisms and institutions should be encouraged to foster biotechnology development.

VI. Assessment of Financial Resource Requirements for Biotechnology under Agenda 21

The implementation of the various programmes as set out in the Agenda 21 will undoubtedly require the provision of substantial new and additional financial resources to developing countries. These new and additional financial resources are needed to supplement financing from a country's own public and private sectors. In principle, industrialized countries reaffirm, through Agenda 21, commitments to reach the United Nations target of 0.7 per cent of the Gross National Product (GNP) for official development assistance.

Chapter 16 of the Agenda 21: The Environmentally Sound Management of Biotechnology identifies five programme areas for action. These are:

- A. Increasing the availability of food, feed and renewable raw materials;
- B. Improving human health;
- C. Enhancing protection of the environment;
- D. Enhancing safety and developing international mechanisms for cooperation;
- E. Establishing enabling mechanisms for the development and the environmentally sound application of biotechnology.

For each of the programme areas, objectives are established and a number of activities are proposed for implementation. Cost estimates are also given to indicate the financial resource requirements, during the period 1993-2000, necessary for achieving the agreed-upon objectives. These are briefly outlined below:

<u>Programme Area</u>	<u>Objectives</u>	<u>Annual Cost Estimate</u> <u>US\$</u>
A. Agriculture	<ul style="list-style-type: none"> • Increase productivity and nutritional and keeping quality • Eliminate overdependence on agrochemicals • Evaluate potential of marginal lands 	5 billion (50 million from international community)
B. Human health	<ul style="list-style-type: none"> • Combat major communicable diseases • Create enhanced R&D capabilities • Promote good health 	14 billion (130 million from international community)
C. Environmental protection	<ul style="list-style-type: none"> • To adopt environment-friendly production production processes • To promote bioremediation 	1 billion (10 million from international community)
D. Biosafety and international cooperation	<ul style="list-style-type: none"> • To ensure safety in biotechnology through international agreement on risk assessment and management 	2 million from international community
E. Endogenous capacity building	<ul style="list-style-type: none"> • To promote biotechnology development and application • To identify and develop effective strategies • To establish mechanisms for risk assessment 	5 million from international community

The total annual requirement for financial resources from the international community for the period 1993-2000 is estimated to be US\$ 197 million for the five programme areas. Needs are highest in the area of human health, at US\$ 130 million, followed by US\$ 50 million for agricultural improvement. However, the overall total financial cost estimate from all sources is US\$ 20 billion per year during the same period. The cost estimates for biosafety (Programme Area D) and endogenous capacity building (Programme Area E) are much lower, at US\$ 2 million and US\$ 5 million respectively, and are based on support to be provided by the international community alone.

VII. Key Implications for Policy and Plans

- In view of the different economic and institutional requirements for the environmentally sound management of biotechnology and the limited amount of funds expected to be mobilized from the international community, emphasis must be given to ensure "quality" financing of biotechnology programmes and initiatives. Moreover, it is essential

to ensure a continuity in financial support in achieving clearly defined objectives and practical biotechnological solutions.

- Biotechnology is considered to be a cross-sectoral issue; biotechnological solutions can be found for many problems addressed in other programmes of Agenda 21. New and additional resources/facilities within the framework of Agenda 21 should be structured with sufficient flexibility that expands their scope and coverage, where appropriate and feasible, and accommodates the integration of the relevant biotechnological components.
- Successful lessons from the still limited investments by regional banks in biotechnology projects indicate a large potential for expanding the role of financial institutions at various levels in promoting biotechnology programmes. Regional banks should be encouraged to participate more actively, directly or indirectly, in the development and, especially, in the commercialization of biotechnology in developing countries.

VIII. Financing Arrangements for Consideration

1. New Financial Resources and Mechanisms

1.1. Establishment of an International Biosafety Trust Fund

Of urgency is a rapid solution to the controversy surrounding the biosafety issue. Concerted efforts must be applied ensuring that biosafety will not become a constraint against the development, transfer and applications of biotechnology in the global drive to achieve sustainable development.

An International Biosafety Trust Fund would provide funds to strengthen capacity building in biosafety regulation in developing countries and to facilitate the effective participation of developing countries in a participatory process on biosafety. The objective of this process would be to bring into agreement a set of internationally agreed-upon principles facilitating the development and transfer of biotechnology that benefits the world community.

In this connection, the International Bioindustry Forum has called for the establishment of a Task Force to examine common principles and practical approaches to biosafety issues. It has further suggested that UNIDO, as Task Manager and lead UN agency for biotechnology and Chapter 16 of Agenda 21, be asked to bring such a Task Force together and to provide its Secretariat. The suggestion is particularly appropriate in view of the fact that UNIDO is cooperating closely with the Interim Secretariat of the Convention on Biological Diversity on the issue of biosafety in biotechnology in matters related to scientific and technological issues.

The proposed International Biosafety Trust Fund could be executed by UNIDO, on behalf of the UNIDO/UNEP/FAO/WHO Informal Working Group on Biosafety, in cooperation with other UN agencies that have programmes in biosafety, including the Interim Secretariat of the Convention on Biological Diversity.

The biotechnology business community should be encouraged to contribute to the Fund.

1.2. Establishment of an International Venture Capital Fund for Biotechnology

The rapid rate of biotechnology development, the increasingly widening economic and technological gap between developed and developing countries, and the major role of the private sector in commercial biotechnology development are causes for concern about equity in biotechnology transfer agreements among countries. Developing countries are genuinely concerned that developed countries will be able to use new proprietary biological tools in producing high-value products that displace materials currently produced by developing countries, negatively affecting the already weak position of most developing countries in the highly competitive and increasingly globalized markets. At the same time, developing countries are concerned about their weak technological and financial capacity, to access the new, effective biotechnologies developed by the private sector in developed countries that provide new opportunities for improvement and diversification in agricultural and industrial production.

Lessons learned from various biotechnology venture funds indicate that these are the most effective means to rapidly transfer commercial biotechnologies. Venture capital funds can be used to facilitate transfer of biotechnologies specifically serving common needs of developing countries and at the same time facilitating the process of capacity building in biotechnological development. Examples include biotechnologies for new vaccine development for major communicable diseases, biotechnologies for marginal lands and biotechnologies for pollution abatement (bioremediation).

The International Venture Capital Fund could be initiated by the World Bank/International Monetary Fund and implemented by the International Finance Corporation. Part of the Fund could be used to conduct feasibility studies on potential commercial biotechnology projects in order to promote joint ventures and attract additional funding sources.

In parallel to the operation of the Venture Capital Fund for Biotechnology, it would be worthwhile to consider the establishment of a programme for an Expert Volunteer Corps in Biotechnology, based on the model of the successful programme of the (Business) Executive Volunteer Corps. Under such a programme, retired biotechnology experts' service would be made available to developing countries to augment the limited biotechnology management expertise available within the developing countries.

1.3. Increase in Official Development Assistance (ODA) for Biotechnology

Within the framework of the general commitment by governments to increase the ODA to the level of 0.7 per cent of GNP by the year 2000, governments supporting biotechnology development in developing countries should be encouraged to expand and/or extend their financial assistance to more developing countries. Similarly, governments that have no ODA programme in biotechnology are encouraged to consider including biotechnology for future ODA financial assistance. Contributing to the newly proposed International Biosafety Trust Fund is a response to the commitment to increase ODA funding.

Such contributions to the International Biosafety Trust Fund would create a significant window for broader and coordinated participation in implementing the action plan of Chapter 16 of Agenda 21: the Environmentally Sound Management of Biotechnology.

2. New Improved Financing Strategies

2.1. Financial Support from the International Community for Biotechnology-Related Local Initiatives in Developing Countries

In view of the increase in biotechnology-related initiatives being undertaken by developing countries, additional financial support from the international community should be encouraged to facilitate the integration of strategic biotechnologies that enhance biotechnological solutions to local problems, especially those having potential benefits for other developing countries. Examples of appropriate problem-oriented biotechnology-related initiatives include a Petroleum Microbiology (Bioremediation) Project in Viet Nam, a Sustainable Development Training Centre Project in China, a Traditional Medicine for AIDS Project in Thailand, and a Biosaline Agricultural Centre in the United Arab Emirates. Financial support from the international community can be used to effectively mobilize international experts and access appropriate biotechnologies that augment national efforts. Such financial support strategies allow maximum cost effectiveness of the limited resources provided by the international community and also provide opportunities for a more active participation of developing countries in implementing the Agenda 21 work plan. The sharing of developing countries' financial resources and of their valuable indigenous knowledge are positive contributions that can be highlighted.

2.2. Third-Country Financing in Cooperation with New Small Donor Countries

Despite the declining official development assistance from traditional donors for developing countries, there is an encouraging sign of emergence and increasing participation of small new donors in the international community. These donors are advancing developing nations seeking gradually to increase their role in the international community. Many of these countries give high priority to biotechnology development and seek to further advance their biotechnological capacity. On the other hand, they are in a position to provide training and resources that promote the "intermediate" biotechnologies often required by less developing countries.

Third-country financing through tripartite cooperation should be actively encouraged and promoted in order to consolidate and maximize limited resources and to actively pursue commonly shared objectives and goals. These cooperative activities will help to ensure that efforts to implement Agenda 21 are globally integrated among countries.

IX. Conclusion

Because biotechnology is a key and rapidly evolving technology and can be widely applied in efforts to achieve globally sustainable development, innovative mechanisms should be adopted to ensure that developing countries participate as full partners in global and integrated efforts to implement the various programmes set out in Agenda 21. To meet this

challenge, three new financial resource mechanisms are suggested for consideration by the international community. These include:

- The establishment of an International Biosafety Trust Fund
- The establishment of an International Venture Capital Fund for Biotechnology
- An increase in Official Development Assistance for biotechnology

In addition, new and improved financing strategies suggested for consideration include:

- Financial support from the international community for biotechnology-related local initiatives in developing countries
- Third-country financing in cooperation with new small donor countries.

ANNEX II

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