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EDUCATION, SCIENCE, TRANSFER OF ENVIRONMENTALLY SOUND TECHNOLOGIES, COOPERATION AND CAPACITY-BUILDING

Environmentally sound management of biotechnology

Report of the Secretary-General

SUMMARY

An overview of the progress made, the problems encountered and the lessons learned, and priority issues for further consideration, with respect to chapter 16 of Agenda 21, 1/ are discussed in the present report.

Chapter 16 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.

This report is based on a thorough analysis of information obtained from a wide range of sources, including Governments, the United Nations and other intergovernmental organizations, non-governmental organizations, the scientific and academic communities, the business community, donors, and others.

This report presents several proposals on which the Commission on Sustainable Development is invited to take action in order to support and initiate activities at the national level and promote international cooperation. The proposals emphasize the key role of the private sector in contributing to sustainable development, and the need for close cooperation with the Convention on Biological Diversity 2/ on the issue of biosafety.

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INTRODUCTION

1. Agenda 21 1/ addresses many pressing issues, including the concept of sustainable development, and focuses on addressing the challenges of the next century. It calls for a number of interrelated programmes to be carried out by various key players according to the different capacities, situations and priorities of countries and taking into account the principles contained in the Rio Declaration on Environment and Development. 3/

2. Chapter 16 of Agenda 21, 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. These five programme areas 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.

3. 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 water resources) and chapter 21 (Environmentally sound management of solid wastes and sewage-related issues).

4. Agenda 21 calls upon all organizations 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. The United Nations Industrial Development Organization (UNIDO), designated by the Inter-Agency Committee on Sustainable Development as the task manager for chapter 16, is responsible for the preparation of the present consolidated report on the implementation of the programme on the environmentally sound management of biotechnology.

5. In the preparation of this 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 United Nations and other international bodies 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

Cooperation and Development (OECD), in reviewing developments and trends in biotechnology. Furthermore, special attempts were made to solicit inputs from the private sector, the non-governmental organization community and women's organizations in order to include balanced perspectives in the final consolidated report.

I. BIOTECHNOLOGY AND SUSTAINABLE DEVELOPMENT: A GENERAL OVERVIEW

6. 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 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. The technologies concerned are powerful ones, supported by complementary bioprocess engineering to help translate new discoveries of the 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.

7. 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 such technology is seen as the key to directing its positive impacts towards world society as a whole. Biotechnology is developing continuously and rapidly 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 which, in the case of many developing countries, are not readily available.

8. 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 adopt an environmentally sound emerging biotechnology can serve as a measurement of sustainable self-reliance that will allow it to participate fully in world-wide 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 possible adverse socio-economic or environmental effects.

II. ASSESSMENT OF PROGRESS ACHIEVED AND EXPERIENCES

9. Since the United Nations Conference on Environment and Development, 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 across several sectors of products and processes that began with pharmaceuticals and health care, and 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 ahead rapidly 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.

10. Several United Nations organizations, in cooperation with the regional 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 are now giving 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, and 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 bio-insecticides, are gradually being used in several countries around the world to increase crop yield and reduce agrochemical 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.

11. 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/United Nations Environment Programme (UNEP)/World Health Organization (WHO)/Food and Agriculture Organization of the United Nations (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), the 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 2/ 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 under way 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 of Great Britain and Northern Ireland and the Netherlands. The recent launching of the Biosafety Information Network and Advisory Service (BINAS) within the United Nations system, as recommended by the UNIDO/UNEP/WHO/FAO Informal 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 initiatives designed to facilitate the introduction of biotechnology into developing-country agriculture.

A. Country experiences

1. Developing countries

12. 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 China, India, the 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.

13. In African countries, the level of sophistication in biotechnology development is extremely variable, ranging from very traditional applications 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 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 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.

14. 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 with regard to the economic potential of the biotechnology industry are still very low. On the other hand, awareness regarding biosafety and the urgent necessity for the environmentally sound management of biotechnology among the biology-related scientific community is relatively high compared with awareness in the non-biology-related 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 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 trade-related aspects of intellectual property rights (TRIPS) Agreement concerning intellectual property rights in relation to biotechnology. In this connection, the Government of India, in cooperation with the World Intellectual Property Organization (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.

15. 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.

16. 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 into 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 with 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.

2. Developed countries

17. 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, especially the new biotechnology. Numerous studies and reports, prepared by individual countries and by 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 public perception and education with respect to bioethics, 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 United States, the Union of Concerned Scientists.

18. 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, inter alia, 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 United States, 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 United States alone as compared with the US$ 6.8 billion for conventional pesticides.

19. A recent development initiative in Mexico, conceived as a collaborative arrangement between the business sector, a national Government, and the United Nations 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 gene-encoding toxins that are lethal to maize insects is being used to produce pest-tolerant tropical maize. The development of appropriate protocols will be part of such an effort, which can be expanded to include other crops and products.

3. Transitional economies

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

21. 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 the Russian Federation of a new State Programme for the Development of Biotechnology During the Period 1994-2000, focusing on bio-industrial development and promotion such as through 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 a 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 non-governmental organizations

22. Non-governmental organizations participated actively in the United Nations Conference on Environment and Development process. Their role - jointly with United Nations bodies - was critical in raising awareness of the need for safe handling of biotechnology and the conservation of 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 non-governmental organizations 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 United Nations and bilateral initiatives to promote biotechnology among farming communities, indigenous people and micro-enterprises have benefited from non-governmental organizations' participation in extending their services beyond the traditional government counterpart organizations and in sharing experiences encouraging people's participation in the development efforts.

23. Biotechnology-related 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 bio-industries, 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.

24. The role of the non-governmental organization 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.

25. The broad range of non-governmental organizations, 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 to be held as part of the Fourth World Conference on Women in Beijing, 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

26. 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 United Nations Conference on Environment and Development 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.

28. 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 confined primarily 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.

29. 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 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 with 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 indicated 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.

30. 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.

31. 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 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 South-East Asian countries, the joint United States-Thailand Company-Directed Research Grants, the Crawford Fund for International Agricultural Research and, of particular interest, financial assistance of the International Fund for Agricultural Development (IFAD) to the least developed countries for agricultural and food development through biotechnology.

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

(a) Long-term commitment is vital to achieving sustainable capacity-building and to enabling a country to reach a critical level in self-reliance for further biotechnological development. The Indo-Swiss project in operation since its initiation in 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 important, the financial commitment of the developing/recipient country Government is critical to successful collaboration. This commitment can include in-kind contributions.

33. Currently, financial contributions from the private sector for commercial biotechnology development are still relatively low, owing mainly 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 United States and European companies and between United States 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 that where the private sector forms 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 operates, for example, 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

34. Since the United Nations Conference on Environment and Development much work has been done by United Nations system organizations in support of chapter 16: Environmentally sound management of biotechnology of Agenda 21. A comprehensive review of these activities is given in annex I.

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

35. The challenge of meeting the accelerating demands of a growing global population lies not only in increasing food production and increasing the nutritional content of the food produced, but also in significantly improving food distribution systems. Efforts to meet this challenge will increasingly be through the successful and environmentally safe applications of biotechnology in agriculture. Most of the investment in biotechnology has been in the industrialized world, yet international organizations are supporting significant new efforts to introduce modern biotechnology and apply it so as to improve agricultural productivity and increase food production without damaging the environment. FAO, the leading United Nations body in agricultural biotechnology, along with the Joint International Atomic Energy Agency (IAEA)/FAO Division of Nuclear Techniques in Food and Agriculture and other United Nations and international agricultural organizations, is promoting the applications of biotechnology in agriculture and presently assisting 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 and through research and information networks. Research is under way 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 environment-friendly. That they are more adaptable than mechanical innovations and green revolution technology makes them more accessible to small producers. These biotechnologies can reduce farmers' dependency on environmentally degrading agrochemicals while decreasing crop losses.

36. 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 Farmer-Centred Agricultural Resource Management (FARM) programme, which has a subprogramme on biotechnology and biodiversity, the aims of which are 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.

37. 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.

2. Programme area B: Improving human health

38. 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 the promoting of good health, in improved programmes for treatment of and protection from major non-communicable diseases, and in the developing of appropriate safety procedures. Biotechnology products in health care are now fairly widespread.

39. 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 human immunodeficiency virus (HIV). The recrudescence of infectious diseases has also given rise to health-care concerns in the developed countries in recent years. Deoxyribonucleic acid (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.

40. WHO is the lead United Nations 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 for simplifying immunization, and for improving 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, acquired immunodeficiency syndrome (AIDS), tuberculosis, malaria, meningitis and dengue. A WHO conference on biotechnology and world health was held in November 1994 in Geneva to assess the risks and benefits of DNA technology as a means of producing medical products. The overwhelming consensus was that the great

benefits of DNA technology far outweigh the potential problems associated with its use. The conference recommended a framework with which to facilitate the safe and effective implementation of DNA technology for the health-related benefit of people throughout the world. Many products produced by biotechnology are now among the best characterized and purest biological medicines in clinical use today. The meeting recommended further action in the development, testing and use of new vaccines and other medicinal products produced by DNA technology.

41. As part of the Children's Vaccine Initiative (CVI), UNDP, along with the United Nations Children's Fund (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 vaccines 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.

42. ICGEB's research activities relate either to specific diseases, in terms of diagnosis, treatment and/or vaccine production, or to the researching of new technologies aimed at the design of innovative drugs, diagnostic kits and vaccines. These are targeted at being less expensive than traditional methods, and at preventing the manipulation of dangerous material. Human papilloma virus (a precursor of cancer of the uterine cervix), HIV (implicated in AIDS), hepatitis B, rotavirus and malaria are among the most important diseases currently being investigated within ICGEB.

3. Programme area C: Enhancing protection of the environment

43. 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.

44. 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.

45. Innovative agreements, in particular the one between Costa Rica's National Biodiversity Institute (INBio), a non-profit organization, and the United States-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 it is too early to evaluate this

innovative approach to international cooperation, it deserves to be followed with interest by the international community.

46. 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 (a) 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 (b) 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.

47. The application of modern biotechnology for the bioremediation of contaminated land and water has created increasing global interest and increased demand from 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. 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.

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

48. 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 UNIDO/UNEP/WHO/FAO Informal Working Group on Biosafety needs to be extended to include other appropriate United Nations organizations such as the United Nations Educational, Scientific and Cultural Organization (UNESCO) and, in particular, the International Labour Organization (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.

49. The policy issue of biosafety requires rapid and effective resolution. Developing countries and non-governmental organizations 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.

50. 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. It was determined that the document should consider the need for and the 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.

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

51. Recognizing that biotechnology is multidisciplinary in nature and that capacity-building for its effective environmentally sound management requires new management strategies and approaches, several United Nations organizations 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, the International Maritime Organization (IMO), UNEP, UNIDO, WHO and the World Meteorological Organization (WMO). Such efforts extend beyond the United Nations system to involve the private business sector, financial institutions and non-governmental organizations. The regional 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 United Nations system-wide coordination at the national level.

52. Various United Nations 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.

53. 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.

54. 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 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.

55. The regional commissions have organized conferences aimed at enhancing awareness of the opportunities offered by biotechnology. Some conferences have been aimed at promoting links between business enterprises and biotechnology research and development institutions, both within the developing country region and between the region and developed countries. The conferences have demonstrated the need for a focused approach to enable specific areas in biotechnology to be targeted by local research and development institutions. They have confirmed the need to establish stronger links between these institutions and sources of investment and private enterprise. Areas meriting further concentrated efforts include the development of marine agricultural and industrial biotechnologies and agricultural and agro-industrial applications of genetic engineering and plant cell and tissue culture.

56. UNDP’s recent emphasis on sustainable human development (an approach shared by other United Nations bodies) 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. Thus, it is hoped that in the future it will be possible for biotechnology to be regarded as one (major) constituent of a broader multisector planning approach.

III. GENERAL LESSONS LEARNED

57. 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 that are available

but not being applied. A key issue for developing countries, therefore, should be selectivity in determining whether biotechnology might provide the most effective solution, from the cost as well as the social point of view. For biotechnology to be fully integrated into national priorities and policies, not only does it need to be understood but its potential benefits need to be appreciated by policy makers.

58. The international biotechnology programmes of the United Nations organizations, the OECD Development Centre, and 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.

59. 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, as a candidate for future encouragement and promotion, should be further studied and evaluated.

60. For biotechnology to be successfully developed, public as well as private support, and support from non-governmental organizations, are 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. Furthermore, if biotechnology is to have a truly significant impact, long-term commitments will be required.

IV. CONCLUSIONS AND PRIORITY ISSUES FOR FURTHER CONSIDERATION

A. Conclusions

61. Since the United Nations Conference on Environment and Development, 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 ahead rapidly 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.

62. 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.

63. 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 United Nations Conference on Environment and Development 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.

64. 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 within the context of sustainable development in its widest possible sense.

65. With the increasingly rapid rate of biotechnology development and the increasing privatization of biotechnology, particularly in many industrialized

countries, and in so far 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, those countries are constrained by lack of resources 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.

66. Several international and bilateral programmes, responding to the needs and concerns of developing countries, 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 with 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.

67. 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 association membership is mixed and is drawn from both the academic and the industrial sector, but these associations are less active in policy-related matters. In many other countries, biotechnology association 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.

68. 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 the Caribbean region, 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.

69. In matters related to financing, the available information indicates a 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.

70. 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 forums, 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-cut international minimum standards.

71. 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

72. 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

73. 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 that

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

74. 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 ones so that businesses may 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 United Nations 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 United Nations and other international development organizations. More concerted efforts by the various United Nations organizations 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

75. 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 that 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 the examples of "best practice" environmentally sound applications that have resulted in a demonstrable meeting of 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-sized rural enterprises, in particular in developing countries.

4. Safety in biotechnology

76. 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 areas D, especially paragraphs 16.32 (a), (b) and (c), and E, are being effectively addressed and implemented within 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 United Nations organizations and other international programmes within the framework of Agenda 21. The immediate need for developing countries to develop national regulatory mechanisms in biosafety issues along with the related capacity for their implementation is an issue to be urgently addressed. Ongoing United Nations 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

77. Action is urgently needed to facilitate the effective participation of developing countries in the process directed 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

78. 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.

V. PROPOSALS FOR ACTION

79. In the light of the priority issues identified, the Commission on Sustainable Development may wish to take action on the following matters:

(a) Enhancing the contribution of the private sector to sustainable development, by urging Governments 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:

(i) Participation in and contribution to national, regional and international consultations on biotechnology development trends and impact assessment;

(ii) 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;

(iii) 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;

(iv) Other appropriate, innovative and environmentally sound approaches, especially with regard to financing international, regional and national biotechnology programmes;

(b) Integrating biotechnology concerns into national-level development-policy making and building of national capacities, by requesting Governments, supported by United Nations and other appropriate intergovernmental bodies, to:

(i) Ensure the participation and contribution of all major groups in the integration process;

(ii) Enhance public awareness through promoting and disseminating an accurate understanding of biotechnology that includes the issues associated with progressive trends in its development;

(iii) 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;

(iv) Strengthen environmentally and economically sustainable capabilities in the sound management of biotechnology, including matters relating to intellectual property rights;

(v) Establish national databases on information relating to biosafety in biotechnology;

(vi) 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;

(c) Promoting "best environmentally sound and viable practices", by calling on Governments, with maximum support from United Nations and other organizations as well as the private sector, to identify and exchange information, especially at the regional level, about examples of "best practice" viable and environmentally sound applications that have resulted demonstrably in meeting the sustainable development objectives of programme areas A, B and C of chapter 16;

(d) Encouraging the environmentally sound application of biotechnology for sustainable development, by:

(i) 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;

(ii) 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;

(iii) Urging Governments to encourage 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;

(e) Considering the steps required for the possible development of strategies for meeting the sustainable development objectives of Agenda 21, including the need to:

(i) Initiate a procedure for periodic reviews of biotechnology development trends to ensure the effective integration of the new biotechnology into global sustainable development efforts;

(ii) Cooperate closely 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;

(iii) Seek advice from an ad hoc group of experts on such steps.

Notes

1/ United Nations Conference on Environment and Development, Rio de Janeiro, 3-14 June 1992, vol. I, Resolutions Adopted by the Conference (United Nations publication, Sales No. E.93.I.8 and corrigendum), resolution 1, annex II.

2/ See United Nations Environment Programme, Convention on Biological Diversity (Environmental Law and Institution Programme Activity Centre), June 1992.

3/ United Nations Conference on Environment and Development, Rio de Janeiro, 3-14 June 1992, vol. I, Resolutions Adopted by the Conference (United Nations publication, Sales No. E.93.I.8 and corrigendum), resolution 1, annex I.

Annex I

UNITED NATIONS SYSTEM AND INTERNATIONAL ORGANIZATION ACTIVITIES IN SUPPORT OF CHAPTER 16 OF AGENDA 21: ENVIRONMENTALLY SOUND MANAGEMENT OF BIOTECHNOLOGY

1. Since the United Nations Conference on Environment and Development (UNCED) much work has been done by the United Nations system and international 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:

(a) Increase to the optimum possible extent the yield of major crops, livestock, and aquaculture species, by using the combined resources of modern biotechnology;

(b) Improve the nutritional value of source crops, animals and micro-organisms and reduce food losses using environmentally safe applications of biotechnology;

(c) Increase the use of integrated pest, disease and crop management techniques to eliminate overdependence on agrochemicals, thereby encouraging environmentally sustainable agricultural practices;

(d) 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;

(e) Expand the applications of biotechnology in forestry;

(f) Increase the efficiency of nitrogen fixation and mineral absorption by the symbiosis of higher plants with micro-organisms;

(g) Improve capabilities in basic and applied sciences and in the management of complex interdisciplinary research projects.

2. FAO is a leading United Nations organization 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. For example, a UNDP/FAO/UNIDO Regional Subprogramme on Asian Biotechnology and Biodiversity, of the Farmer-Centred Agricultural Resources Management (FARM) programme, in which eight countries, namely China, India, Indonesia, Nepal, the 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 America and the Caribbean region. Rice biotechnology, supported by the Rockefeller Foundation, has an extensive network involving several countries in which 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 buffalo, flax and nuts is being pursued.

3. The Plant Breeding and Genetics Section of the Joint FAO/IAEA Division, International Atomic Energy Agency, 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, and so forth. 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 biological nitrogen fixation (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: (a) better disease diagnosis; (b) better and safer vaccines for disease prevention; and (c) genetic manipulation of the germline 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.

4. 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), the Computer Assisted Network on Nucleic Acid and Protein Sequencing (CANAPS) in Latin America/Caribbean (14 countries), and the FAO Network Programme on Veterinary Biotechnology in Central and 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 the Pan African Rinderpest Campaign (PARC) includes over 20 countries. The ELISA Programme for Latin America covers foot-and-mouth disease, brucellosis and babesiosis and involves 12 countries.

5. FAO has also been promoting such development of recombinant vaccines against rinderpest as 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 stabilizers. 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 the 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-roots 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 FAO/IAEA Joint 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 in Africa of the tsetse fly, a pest that causes trypanosomiasis.

6. 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 United Nations bodies and with the International Plant Genetic Resources Institute (IPGRI) and the International Centre for Agricultural Research in Dry Areas (ICARDA), 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-country scientists in relevant technologies. In this respect, ICGEB has made available to member developing countries research and development 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 both of plant stress resistance, tolerance to herbicides and resistance to some specific pests and toxins, and 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.

7. 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.

8. The joint 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 is 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.

2. Programme area B: Improving human health

Objectives:

(a) Develop 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;

(b) Promote good general health;

(c) Develop and improve programmes to assist in specific treatment of and protection from major non-communicable diseases;

(d) Develop and strengthen appropriate safety procedures based on programme area D, taking account of ethical considerations;

(e) Create enhanced capabilities for carrying out basic and applied research and for managing interdisciplinary research.

9. WHO is the lead United Nations organizations 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 developments using biotechnological approaches. The rapid progress in molecular biology and genetic engineering provides the basis for simplifying immunization, and for improving 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 United Nations bodies, in particular 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.

10. 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.

11. 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 vaccines 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.

12. 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 at being less expensive than traditional methods, and at preventing the manipulation of dangerous material. Human papilloma virus (a precursor of cancer of the uterine cervix), HIV (implicated in AIDS), hepatitis B, rotavirus and malaria are among the most important diseases currently being investigated within ICGEB.

13. The Industry and Technology sections of the Economic and Social Commission for Western Asia (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:

(a) Apply biotechnologies for the conservation and sustainable use of biodiversity;

(b) 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.

14. 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 (a) 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 (b) 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. The MIRCEN concept was conceived by UNEP and realized in collaboration with UNESCO; the Centres 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.

15. 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.

16. 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.

17. 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 the International Centre for Agricultural Research in the Dry Areas (ICARDA) in the ESCWA region and the International Plant Genetic Resource Institute (IPGRI), will include agricultural biotechnologies and genetic engineering components.

18. The FAO/UNIDO/UNDP Asian Subprogramme 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. 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, non-governmental organizations and the business sector are encouraged to participate in the Network.

19. 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".

20. 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. 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 Viet Nam to develop a programme on microbial remediation of oil pollutants, building on the country's relatively extensive work on petroleum microbiology.

21. 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.

22. 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.

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

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

23. 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 Organisation for Economic Cooperation 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.

24. 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.

25. 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.

26. 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.

27. 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 ILO requested the Director General to take fully into account, when drawing up future programme proposals, the taking of steps to address the question of exposure to and safety in the use of biological agents at work and consideration of the need for new international instruments in order to minimize the risks to workers, the public and the environment.

28. In its 1996-1997 programme and budget proposals, the Occupational Safety and Health Branch of 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.

29. The OECD's Environment Policy Committee (EPOC) maintains a work programme on the Environmental Aspects of Biotechnology, which includes linkages to an array of United Nations 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 analysed 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.

30. 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 fifth session in April 1993. This was the first time that a permanent United Nations intergovernmental forum had actually discussed a draft Code of Conduct on Biotechnology, encompassing a biosafety module.

31. 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 paragraph 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 to consider "the need for a feasibility of internationally agreed guidelines on biotechnology releases, including risk assessment and risk management", and for "studying the feasibility of guidelines which could facilitate national legislation on liability and competition".

32. 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 meeting of a 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 scheduled to be held in Thailand in March 1995 as a contribution to capacity-building.

33. The Senior Advisers to ECE Governments on Science and Technology, one of the principal subsidiary bodies of the United Nations Economic Commission for Europe, have established and are 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 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.

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

Objectives:

(a) Awareness-building and public education;

(b) Strengthening endogenous capacities of developing countries including employment opportunities for women;

(c) Consolidation of efforts;

(d) Socio-economic impacts of new biotechnology on conventional production systems;

(e) Contribution of indigenous peoples and their share in economic and commercial benefits arising from biotechnology;

(f) Intellectual property rights with respect to biotechnology and bioresources;

(g) Increase access both to existing information about biotechnology and to facilities based on global databases;

(h) Helping to create a favourable climate for investments, industrial capacity-building and distribution marketing;

(i) Encouraging the exchange of scientists among all countries;

(j) Enhancing existing efforts at the national, regional and global levels;

(k) Providing the necessary support for biotechnology, particularly research and product development, at the national, regional and international levels.

34. Through its network of affiliated centres, ICGEB is in a position to guarantee to developing countries an assistance following the "bottom-up" approach, financing collaborative research projects submitted by national institutions in the developing country itself. 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. Trainees are expected to return to their country of origin and from there to provide a research channel that continues to operate between ICGEB and the trainee's own country through collaborative research projects. The training activities of ICGEB include a short-term programme that allows scientists from all member countries to participate in short courses, seminars and symposia on very advanced and specific scientific topics in biotechnology.

35. 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.

36. 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.

37. 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.

38. 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.

39. 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. To help countries overcome the barrier, UNIDO directs 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.

40. As part of UNCTAD's work on the Advanced Technology Assessment System (ATAS), the 1992 issue of the ATAS Bulletin covered tissue culture, among a wider spectrum of technologies, in focusing on food production in assessing the scientific capacities of developing countries.

41. 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 United Nations 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 non-governmental organizations, 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.

42. 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.

43. 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.

44. 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.

45. 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.

46. 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 that 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.

47. 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, micro-organism deposit systems and application of patents and special features of licensing.

48. Finally, 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 transfer of technology. This emphasis is shared by other United Nations organizations. Thus, in general, it is likely that in the future, biotechnology will be part of a broader multisector initiative rather than a "stand-alone" project.

Annex II

ADDITIONAL SOURCES OF INFORMATION

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