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HARVARD INTERNATIONAL CONFERENCE ON BIOTECHNOLOGY IN THE GLOBAL ECONOMY

INTERNATIONAL CONFERENCE ON BIOTECHNOLOGY IN THE GLOBAL ECONOMY 2-3 SEPTEMBER 1999

The International Conference on Biotechnology in the Global Economy took place in Cambridge, Massachusetts, USA, from 2-3 September 1999. Organized and hosted by the Center for International Development (CID) and the Belfer Center for Science and International Affairs, Harvard University, the conference attracted over 200 participants from academic institutions, civil society, industry, government departments and international organizations, including the UN Commission on Science and Technology for Development, UN Conference on Trade and Development (UNCTAD), UN Food and Agriculture Organization (FAO), the World Bank and the Global Environment Facility Secretariat(GEF). The conference aimed to broaden the debate on biotechnology beyond the narrow confines of the biosafety question and to foster dialogue between researchers, entrepreneurs, political leaders, policy makers and practitioners.

Participants met in four plenary sessions to hear keynote speeches on science and economy in the new millennium; science, technology and international development; biotechnology in the global economy; and the way ahead. They also met in nine break-out sessions to discuss: the evolution of the biotechnology industry; biotechnology in international trade; intellectual property rights (IPRs) in biotechnology; biotechnology and international relations; bioprospecting; biotechnology in developing countries; environmental aspects of biotechnology; biotechnology and human health; and ethics, social values and biotechnology.

The output of the conference will be a brief summary of the discussions which Calestous Juma will prepare, focusing on solutions rather than on concerns. This conference material is expected to feed into research agendas, policy discussions, and training and educational material on biotechnology and public policy. The Harvard CID will set up a task force to keep open the emerging dialogue among participants on the continually evolving issues in the biotechnology field.

BACKGROUND

Although humans have cross-pollinated plants and cross-bred animals for centuries to suit their own needs, recent technological advances that permit manipulation to extend to the genetic level have provoked differing reactions from different sectors of the society, ranging from optimism to cautiousness to moral outrage. While Europe has witnessed a strong public outcry against genetically modified foods, elsewhere in the developed world concern has been centered on the possible trade restrictions on agricultural exports and consequent loss of profits. While some have focused on the possible negative health, safety and socio-economic repercussions of biotechnology, others have stressed its enormous potential to feed the burgeoning populations of the developing world with pest-free and nutrient-enriched food.

Consensus on this controversial issue has thus far eluded policy makers, resulting in conflict and dissension in the various international fora that are currently considering differing aspects of biotechnology – the Organization for Economic Cooperation and Development (OECD), the FAO Commission on Access to Genetic Resources, Codex Alimentarius, the World Trade Organization (WTO) and the Convention on Biological Diversity (CBD). Earlier this year an Extraordinary Meeting of the CBD Conference of the Parties failed to reach agreement on the biosafety protocol as scheduled, and informal consultations of the CBD's *Ad Hoc* Working Group on Biosafety to resume the extraordinary meeting of the COP are scheduled for mid-September. It is against this background of controversy that Harvard's International Conference on Biotechnology is set.

REPORT OF THE CONFERENCE

OPENING SESSION: SCIENCE AND ECONOMY IN THE NEW MILLENIUM

Jeffrey Sachs, CID, opened the conference, noting intense controversy over biotechnology in the last few months. He contrasted the remarkable potential of biotechnology in areas such as health and agriculture with the great challenge of making it safe and publicly acceptable.

David Sandalow, White House Council on Environmental Quality/ National Security Council, highlighted seven questions the Conference should aim to address:

- What are the potential benefits of biotechnology?
- What are the risks of biotechnology?
- What processes and principles should national governments use to regulate this technology?
- How can national governments better understand this technology?
- What international mechanisms can best help manage this technology?
- How should we balance private and public sector roles?
- How can we improve public discourse on this topic? How can the public be better informed on this issue?

Peter Raven, Missouri Botanical Garden, began his presentation by discussing the global transformations within which biotechnology has emerged in this century, notably: the advent of crop and animal domestication; agricultural expansion into wilderness areas; increasing

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human population densities; rising disparities in wealth and consumption patterns; global climate change; and the rapid loss of stratospheric ozone and biodiversity. He asserted that the CBD ought to focus on biodiversity conservation, biospheric sustainability and wealth sharing rather than on trade battles over genetically modified crops. He stated that sustainability implies living on the earth's interest rather than its capital and that biodiversity, as an intrinsically regional and national good, requires local actions and initiatives.

On the organization of the biotechnology industry, Raven emphasized the importance of scientific knowledge networks. He traced the history of research on DNA and genetic transfers, contending that 1990s "hype" regarding genetic modification and transgenics has not recognized that genetically modified crops are biologically similar to other kinds of crops. However, Raven expressed support for: sustainable agriculture; the labeling of bio-engineered foods; and the examination of their properties and potential environmental impacts through publicly trusted institutions. He recommended making the 21st Century an "age of biology", with more transparent and frequent consultations between the stakeholders involved in biotechnology, and establishing new socially-oriented institutions able to handle the rapid advances and impacts of biotechnology.

DINNER ADDRESS: SCIENCE, TECHNOLOGY AND INTERNATIONAL DEVELOPMENT

In his dinner address, Mohamed Hassan, Third World Academy of Sciences, highlighted growing disparities in scientific development between developed and developing nations as one of the major challenges currently being faced by the global scientific community. He said that while 90% of research on science and technology is based in developed countries, only a few developing countries have experienced significant scientific or technological progress in recent years. He asserted that efforts by international organizations to overcome these disparities have not been successful and emphasized the importance of scientific knowledge and research and development (R&D) as a means to bridge the gap between developed and developing countries. Hassan underscored the need to enhance developing countries' research capacities in areas of concern to them, including information technology and biotechnology. He called for the creation of centers of excellence in developing countries and establishment of information-sharing networks on the internet that link scientists, academies, centers of excellence and R&D institutions throughout the world.

KEYNOTE ADDRESSES: BIOTECHNOLOGY IN THE GLOBAL ECONOMY

Jeffrey Sachs, CID, asked participants to consider how biotechnology and global science might be mobilized for economic development in poor countries and whether institutions that reflect the health and food system needs of developing countries can be established which also reflect global market realities.

In describing the "ecology of economic development," Sachs suggested that two ecological gradients determine the geographic distribution of poverty and wealth: latitudinal climate and access to sea navigability. Sachs also claimed that economic models of convergence, which assume that open trade flows and markets narrow the gap between rich and poor, operate within rather than across regional ecological zones. Hence, biotechnology sciences are both ecologically specific and driven by market forces. Sachs recommended:

- establishment of contingent funds for scientific R&D pertinent to developing countries, such as a contingent fund for the malaria vaccine;
- long-term nutrition cohort studies in developing countries;
- expansion of the private sector-university nexus through centers of scientific excellence in the tropics for biotechology R&D;
- incentives to expatriate developing country scientists to pursue biotechnology-related work in their own countries;
- university networks between developed and developing countries with joint training centers and degrees in tropical food and health systems;
- roundtables on biotechnology to enable communication between political and business leaders; and
- a task force on biotechnology as an outcome of this conference.

Stefan Moraveck, United Nations Commission on Science and Technology for Development, described the Commission as an advisory body to the United Nations Economic and Social Council (ECOSOC) which examines and makes recommendations to the UN regarding science and technological matters. He expressed the Commission's interest in interacting with academia, the private sector and R&D institutions.

Moraveck noted frequent political friction within the Commission on the relationship between R&D and market forces. He stated that the Commission had recently concluded that partnerships and networks are a means to achieve national and regional capacity-building for biotechnology. He said the Commission had also addressed critical issues on biotechnology for food production not currently addressed in other fora. He recommended:

- improvements in the dissemination of balanced information on biotechnology;
- further research on intellectual property rights in developing countries;
- support for networks between public and private sectors
- capacity-building in developing countries for biotechnology R&D; and
- identification of areas for the establishment of centers of excellence and investments by the private sector in these countries.

EVOLUTION OF THE BIOTECHNOLOGY INDUSTRY

Fernando Quezada, Biotechnology Center of Excellence Corporation, facilitated this session that traced the evolution and structure of the biotechnology industry in relation to national competitiveness and globalization. Quezada proposed that a distinction be made between the geographic distribution of biotechnology companies and their numbers, as well as between cyclical changes and changes that present completely novel and hence risky transformations. He asserted that globalization has led to the establishment of a few, large global biotechnology companies that maintain entry thresholds too high for smaller, later arriving competitors. Quezada recommended consideration of how to balance public and private sector involvement and better understand recent reconfigurations of relationships between government, industry, academic and public actors.

Panelists*:* Richard Lewontin, Museum of Comparative Zoology, Harvard University, focused on the key problems and gradual evolutionary changes in the agro-biotechnology industry. He emphasized the dominance of rich country innovations and their increasing protection and control through intellectual property rights. He highlighted the shift from hybrid crops, identifiable through gene markers for the purpose of detecting replanting of seeds without contractual permission, to the new terminator technology, which produces plants with infertile seeds, that he considered useless to farmers and consumers.

Lewontin further highlighted recent agribusiness activities, particularly the genetic domestication of tropical specialty crop traits (caffeine and palmytic oils) into temperate crops such as soy beans and rape, which may harm unique agro-ecological systems and export economies in the developing world. He encouraged reflection on the implications of public sector involvement in the creation of terminator technology and its protection through property rights, referring specifically to contributions by the United States Department of Agriculture.

Lynn Mytelka, UNCTAD, discussed a number of ruptures associated with the evolution of the biotechnology and life sciences industry, which she said was not restricted to agrotechnology and pharmaceuti-

cals. She particularly highlighted the roles of new genetic technology, market saturation, patent expiration and ecological impacts as driving the changes in this dynamic industry, characterized by inter-firm alliances, mergers and acquisitions and rapid R&D investments. She said that new dedicated biotechnology oligopolies are increasingly knowledge-based, global and dependent on patents and licensing.

Michael Malinowski, Center for the Study of Law, Science and Technology, Arizona State University, highlighted US accomplishments in promoting biotechnology applications, especially new pharmaceuticals. He noted the rapid transformation of life science research platforms into biotechnology tools and commercial products since 1988. He attributed this "success story" of drug discovery to: the recognition of industry-academic alliances; regulatory responsiveness regarding the patentability of living matter; the US product- rather than process-oriented approach; the creation of incentives for small business; state agency reform; and the initiation of the Human Genome Project. Malinowski also pointed to emerging needs, including standards of care, funding for clinical research, and the harmonization and removal of impediments to global market access.

Discussion: In ensuing discussion, numerous participants questioned whether and how to balance public and private sector involvement in biotechnology R&D. One participant suggested that the private-public boundary has become blurred. Another participant asked if the emergence of knowledge-based oligopolies was different from international biotechnology research networks such as the Consultative Group on International Agricultural Research (CGIAR) system.

Lewontin argued that public investments in science ultimately serve to subsidize private interests and outcomes. Mytelka stressed that the public and private sectors are distinct, adding that oligopolies are closed structures motivated to acquire private gain and exclude others. Although the CGIAR system, like earlier public sector biotechnology, was not designed to be a closed system, its need for economic survival makes patents and closer collaboration with industry increasingly attractive.

Malinowski said that increasing the number and diversity of biotechnology transfer agreements would be beneficial, as would centralizing standardized reporting through technology transfer institutions open to public scrutiny and full disclosure. During remaining deliberations, panelists and participants offered a number of possible solutions to current dilemmas, such as:

- increased public debate on biotechnology;
- the creation of systematic channels for regional information exchange on competition policies;
- the establishment of mechanisms to regulate and monitor bio-industry oligopolies; and
- the promotion of responsible linkages between public and private sector biotechnology R&D through measures such as joint research between universities, co-patenting between companies and researchers, and technology transfer agreements.

BIOTECHNOLOGY IN INTERNATIONAL TRADE

Scott Stern, Sloan School of Management, Massachusetts Institute of Technology, facilitated debate on the linkages between the health and environmental risks of biotechnology and international trade relations between nations and economic blocs.

Panelists: Per Pinstrup-Andersen, International Food Policy Research Institute, Washington D.C., predicted biotechnology would be an important aspect of the next trade round at the WTO, particularly on labeling and the precautionary principle. He added that the Codex Alimentarius Committee would likely be drawn into the WTO.

Pinstrup-Andersen attributed opposition to GMOs in Europe to the fact that Europeans generally do not perceive a need for GMOs. He highlighted the issue of trade restrictions on seed, referring to India's recent ban on terminator technology. He stressed the significance of biotechnology to developing countries, stating that developing countries, slated to double their net import of grain by 2020, will have difficulty reducing their imports without increasing food productivity through GMOs.

Les Levidow, Center for Technology Strategy, Open University, posed a series of strategic questions: How can the dichotomy between science and politics created by terms such as "science-based regulation" be breached? What is the relevance of market stage precautions and criteria, such as those associated with the WTO-Sanitary and Phyto-Sanitary agreement, to potential trade barriers and disputes?

Since the precautionary approach involves taking political responsibility for scientific and normative uncertainties regarding possible undesirable effects of biotechnology, how can it be refined in practice on a case-by-case basis? How might international trade be linked to precautionary practices devised by regulators to ensure the safe use of genetically-modified crops with respect to their non-genetically-modified counterparts?

Peter Pauker, Canadian Department of Foreign Affairs and International Trade, categorized concerns about GMOs as related to socio-ethical and religious factors, safety, and environmental damage. He said that socio-ethical and religious concerns were driving the debate and needed to be addressed. In identifying the reasons for vehement opposition to GMOs, he said that GMOs had become a lightening rod for past and present regulatory failures. Pauker called for the establishment of credible, balanced and transparent processes to deal with the issues raised by biotechnology. He stressed that the WTO, Codex Alimentarius and CBD should each focus on their respective areas of competence. He highlighted the need for the WTO to determine whether existing trade provisions apply to biotechnology and whether new provisions are required. Parker recommended public engagement in a dialogue to enable people to determine the real risks and benefits of biotechnology.

Discussion: The ensuing discussion focused on the precautionary principle, the role the WTO with respect to biotechnology, and the anatomy of current public opposition to GMOs. One participant, identifying reasons for such opposition to GMOs in the UK, said GMOs are believed to be unnatural, unnecessary and without benefit. Another participant responded that all agricultural modifications are unnatural, and today agricultural innovations are tested with unprecedented levels of precision, predictability and safety. While one participant said that people make irrational choices and need more information on biotechnology, another said that the public today is more scientifically literate than ever before and stressed the need to examine why the public is opposed to the idea of GMOs.

Several participants highlighted the important role of improving dissemination of biotechnology-related information to the public. Noting that food security problems in Africa were not due to production shortfalls but, rather, to mismanagement and corruption, one participant questioned the use of biotechnology to solve hunger and food production problems. He critiqued the discussion of the biotechnology issue in the WTO, which is perceived by developing countries to be lacking in transparency. Pinstrup-Andersen responded that since the genetically modified nature of a product can be used to create a non-tariff barrier to trade this issue belongs within the WTO forum. He claimed that biotechnology does not belong within Codex Alimentarius discussions or ongoing negotiations of the CBD.

One participant underscored the role of risk assessment and management in determining the dimensions of doubt. He said the debate on biotechnology is not an ideological one but one on the strategic use of doubt. Stern concluded the session by identifying one area requiring further discussion: the diffusion patterns of biotechnology products.

INTELLECTUAL PROPERTY RIGHTS IN BIOTECHNOLOGY

Deborah Hurley, Harvard Information Infrastructure Project, facilitated the session on Intellectual Property Rights (IPRs). She introduced the members of the panel and said they would present perspectives on IPR regulation in the US, Europe and other countries.

Panelists: Terry Fisher, Harvard Law School, outlined the intellectual property protection system in the US and referred to the requirements for patent protection under it. In comparing US patent requirements to those established in international agreements such as the Trade Related Intellectual Property Rights (TRIPs) agreement and European directives, he described patent protection in the US as being "generous" in allowing patents on genetically altered microorganisms, multicellular plants, animals and certain types of single genes. He pointed to disadvantages of patent protection, including: rent dissipation; impediment of secondary innovations; concentration of ownership of genetic information in developed countries; and exacerbation of inequalities in wealth distribution. Among advantages he noted incentives for innovation and acceleration of the pace of biotechnology applications. Fisher recommended requiring stricter construction of patent claims, allowing compulsory licenses, permitting price discrimination and regulating the uses of "patent substitutes" such as contracts and technological protections, as possible ways of retaining the advantages while mitigating the disadvantages of patent protection.

John Barton, School of Law, Stanford University, referred to the pharmaceutical sector in the US as the "child" of patent protection. He noted that technological innovations in the pharmaceutical sector can be easily replicated, and without adequate patent protection companies would be unwilling to invest in R&D. He indicated that in recent years disputes over patent rights have driven pharmaceutical companies to merge instead of litigating against each other. He expressed concern that, as a consequence of this, control of the world's pharmaceutical markets is in the hands of 5 or 6 multinational companies. He predicted the continuation of this trend thanks to the TRIPs agreement extending IPR protection to the rest of the world. He said that within five years 75% of the pharmaceutical companies in the world will be owned by bigger companies from developed nations. Barton therefore suggested balancing patent protection regulations with new laws and regulations on anti-trust and competition.

Johnson Ekpere, Scientific, Technical and Research Commission, of the Organization of African Unity, called for enhanced scientific knowledge tailored to the specific circumstances of African countries. He noted that while biotechnology has been promoted as a panacea for African food security, the skill and capacity related to this new technology resides in industrialized nations. Ekpere drew attention to the potential risks posed by biotechnology and recommended capacity-building in the areas of assessment, management and monitoring of risks before biotechnology is commercially introduced into Africa.

Discussion: Several participants referred to the differences between patent protection laws and regulations in the US and other parts of the world. One participant noted that in many countries plant and animal varieties are not subject to patents. Another participant indicated the EU requirement to disclose patents within a certain period of time to make them part of the public domain is not present in US patent law. Other participants highlighted their lack of understanding on how patents would act as an incentive for inventions and development of technological innovations in developing countries. Some participants referred to the benefits associated with investment by multinational companies in developing countries. Others argued that investment by multinational companies is not necessarily geared towards creating benefits for developing countries. One participant cautioned that biotechnology might be used to create food supply monopolies. Several participants questioned the relationship between the CBD and the TRIPs agreement, particularly with respect to the protection of traditional knowledge through *sui generis* systems. Another participant cautioned against the potential creation of monopolies in food supplies through the use of biotechnology.

BIOTECHNOLOGY AND INTERNATIONAL RELATIONS

Cristián Samper, Chair of the CBD Subsidiary Body for Scientific, Technical and Technological Advice (SBSTTA), facilitated the session on biotechnology in international relations. He spoke of the links between biological research and international processes such as FAO and the CBD and noted the increasing tension between environmental regimes and the international trade system. He invited panelists and participants to think about the impact of biotechnology on international relations and *vice versa*.

Panelists: Patrice Laget, European Commission, outlined the complex institutional scheme for R&D for biotechnology development in Europe. He explained the role of the European Commission within the European Union. He noted a recent increase in resources allocated to R&D in the life sciences, including research on food, nutrition health and the environment. He stressed the Commission's interest in seeking the involvement of scientists from developing countries through, *inter alia*, fellowship programmes.

Michael Oborne, OECD, highlighted the contributions of the OECD to the harmonization of international regulations on biotechnology, including the elaboration of common scientific concepts, principles and data requirements to underpin regulation. He gave a brief overview of the work of the OECD Group on Harmonization and Regulatory Oversight, the Committee for Scientific Work on recombinant DNA Safety and the Group of National Experts on Biotechnology and GMOs. He recalled the recent G-8 (Group of Seven highly industrialized nations plus Russia) mandate on the need to undertake further research on the implications of biotechnology for food safety.

Edward Hammond, Consultant in Genetic Resources, presented a brief overview of how indigenous peoples' rights are being addressed in international fora, including the CBD, World Intellectual Property Organisation (WIPO) and the FAO Commission on Genetic Resources. He expressed concern over the lack of an international system to protect communities' traditional knowledge and said that IPRs pose an additional threat. He stated that IPRs prey on traditional knowledge and said that attempts to protect traditional knowledge through *sui generis* systems would improve indigenous peoples' situation. He recalled WIPO's work in this regard but noted that it has come under increasing pressure from the WTO. He said that the FAO Commission on Genetic Resources work on farmers' rights over seeds used in their own land is a ray of hope against the use of "terminator technology" which renders seeds sterile.

Discussion: On terminator technology, one participant questioned why society would want to deprive companies of the necessary incentives to develop new technologies through R&D that may benefit many people. Hammonds responded that sufficient incentives exist for profit generation and added that terminator technology does not render agronomic nor socio-economic benefits.

Another participant suggested broadening the scope of the discussion and called for consideration of how technology is affecting international relations and why people are reacting so strongly to biotechnology. On the first question, one participant noted the difficulties countries face in trying to adapt to provisions under international agreements. On the second question, many participants referred to the uneasiness caused by the uncertainties inherent in the use of biotechnology and stressed the need for scientific, social, cultural and ethical input. Others countered that scientific knowledge is the only way to resolve uncertainties and reach consensus.

Samper concluded the session by drawing attention to the fragmented state of the debate and suggested that increased transparency, dissemination of information and participation in decision-making processes would be useful for bridging differences of opinion among peoples, countries and sectors regarding biotechnology and its use.

BIOPROSPECTING

This session was facilitated by Theadore Panayotou, Environment and Natural Resources, CID. Panayotou opened the discussion by emphasizing that while bioprospecting represents a direct link between biodiversity and technology, benefit sharing is not a simple exchange of technology for biological resources between developed and developing countries. He highlighted the North's patented technology and capacity to produce chemical synthetics in contradistinction to the unprotected status of Southern and tropical biodiversity. He added that fair benefit sharing depends on how biodiversity is valued and what is being valued - an entire ecosystem habitat, a protected area or species, genetic material or associated patented properties or products.

Panelists: Timothy Swanson, School of Public Policy, University College, London, spoke on estimating the informational and use value of genetic resources. He emphasized that such biological resources are not without economic value and described three approaches to economic valuation of biodiversity: the factorial approach that allocates shares of total revenues at the end of pharmaceutical production to numerous factors such as royalties for biological specimens and the value of land allocated for plant collection and screening; the search approach to valuation that estimates the marginal value of probability of genetic resources providing a medical solution; and the production function approach that enables measurement of the contribution of genetic resources to the production of final outputs in agricultural contexts.

Anil Gupta, Indian Institute of Management, spoke on biopiracy, bio-partnership and bio-grassroots ventures. He said that the burden of fairness should not only be placed on biotechnology producers but also on all pertinent social institutions, and that sustainable extraction should not be isolated from *in situ* biodiversity conservation. He noted that: two-thirds of plant-derived human drugs are used for the same purposes for which native peoples discovered and used them; innovation, investment and enterprise need to be linked in bioprospecting and such linkages cannot emerge from the state alone; indigenous peoples and their knowledge systems and experts cannot be simply seen as "traditional" or "communal"; and bioprospecting can be pursued by local as well as global industries. In conclusion he called for:

- •global disclosure by corporations of their sources of genetic materials;
- •a global registry of biodiversity-derived innovations;
- •prior informed consent and fair practices in accessing and exploiting biodiversity;
- •monetary and non-monetary incentives to learn about and implement sustainable use and restoration of biodiversity in multi-species ecosystems;
- •implementation of creative benefit sharing models; and
- •the development of methods to inspire younger generations to learn about biodiversity.

Katy Moran, Healing Forest Conservancy, spoke about sharing benefits arising from plant-based drug discovery and commercialization. She described her institution's strategy and experience in returning long-term benefits to all countries and culture groups that choose to contribute plants and knowledge to Shaman Pharmaceuticals. No matter where a plant sample or knowledge originates, she emphasized that benefit sharing requires: diverse models; different time frames; prior informed consent; the recognition of local knowledge and experimentation; long-term profit; and risk sharing. Benefit-sharing activities supported by Healing Forest Conservancy include: community development projects such as water irrigation and airfield construction during drug development; training in plant collection and the preparation of herbaria specimens; and, in the case of drug commercialization, trust funds and legal constitutions for allocating financial resources equitably for the purposes of integrated rural development and traditional medicine.

Discussion: In ensuing discussion, facilitator Panayotou asked participants to reflect upon shifting biodiversity values and the interdependence that may exist between biotechnology, patents and biodiversity knowledge. Many participants noted the challenge of developing national policies for access to genetic resources to ensure biodiversity conservation and the partitioning of benefits.

One participant noted that pharmaceutical companies place economic value on phytochemical extracts rather than on genetic or living material, adding that attaching dollar values to a hectare of forest may ignore the existence values not captured by quantifying genetic material. Another participant questioned the distinction being made between contemporary and traditional knowledge, while yet another noted that biodiversity is treated economically as an open access resource but legally as patentable private property. A few participants highlighted the issue of academic, research or botanical institutions acting as intermediary spokespersons for diverse local communities and disadvantaged groups, while other participants called for increasing collaboration with commercial actors. Also mentioned was the need to obtain prior informed consent, recognize the heterogeneity of local communities, and bring together diverse stakeholders to discuss ways to resolve bioprospecting conflicts and devise alternative strategies.

BIOTECHNOLOGY IN DEVELOPING COUNTRIES

As facilitator, Sudha Nair, M.S. Swaminathan Research Foundation, requested participants to examine the institutional factors affecting the ability of developing countries to use biotechnology to meet their needs, and to focus on devising strategies to optimize the benefits of the biotechnology revolution.

Panelists: Manfred Kern, Biological Research, AgroEvo GmbH, Germany, characterized biotechnology as a tool to deal with food insecurity in sub-Saharan Africa which is due, *inter alia*, to: poor marketing and processing systems; low investment capacity; poor administration; lack of funding for research; and poor management of natural resources. He stressed the need for developing countries to draw up a catalogue of unsolved technical problems for presentation to big companies. He affirmed that although AgroEvo GmbH would not expect to make a profit when approached by developing countries for assistance, it would not expect to lose money in the endeavor. In addition to biotechnology, Kern identified several potential measures for feeding the world, including: facilitating access to developed country technology; cooperation/partnerships/pilot projects in R&D; enhancing R&D on neglected crops; support for safety research; promotion of private local seed companies; and promotion of patents in developing countries.

Hans Herren, International Center of Insect Physiology and Ecology, Kenya, asked whether developing country farmers needed GMOs. He said biotechnology could do little to address the problems of soil infertility, difficult credit and market access, lack of storage facilities and inadequate infrastructure that plague developing country agriculture. Herren highlighted issues such as gene flow and genetic pollution risks in the deployment of new GM varieties. He recommended training to enable people to understand what happens when GMOs are deployed. He cautioned that GMOs are not a "silver bullet" solution and concluded that there is a need for a comprehensive strategy to address food insecurity in the developing world.

Robert Herdt, Rockefeller Foundation, said that solving Africa's food problems necessitates addressing food productivity. He stressed the need for better education for women, well-functioning markets and higher farm productivity. He said higher farm productivity would

depend on broader use of currently available improved technology, the importation of well-adapted technology and local adaptive research. He identified a potential role for biotechnology but cautioned that because farmers reuse seed the market is very small. On the situation of developing countries vis-à-vis biotechnology, Herren stressed that multinational seed companies are not focused on their needs; the CBD and TRIPs are forcing the pace of change; and there is little biotechnology that merits IPR protection. He said developing countries get very little help from the US to address their needs in agriculture. Major companies focus on profitable hybrid maizes and hybrid cottons rather than on the rice, yam and cassava that are staple foods in the developing world. He called for strategies to harness biotechnology to improve living conditions in the developing world.

Discussion: Several participants expressed concern for the recent decrease in agricultural development assistance. Some identified a need for political will at the national and international level. One participant asked how to initiate a dialogue with political leaders in developing countries to get them to take the lead. Another participant stressed that the focus be on helping developing countries develop local capacity to address their problems.

Herren cautioned those seeking a "quick fix" that the potential of biotechnology should be used "in harmony" with other social, cultural, economic and ethical aspects. One participant highlighted the need for institutions and processes to include women's views, considering women's significant involvement in farming. One participant queried the value added by biotechnology. In response, Kern said biotechnology could contribute higher yields and lower pesticide use.

ENVIRONMENTAL ASPECTS OF BIOTECHNOLOGY

Facilitator Victor Buxton, Environment Canada, introduced the topic by saying that countries now face the challenging prospect of developing institutional arrangements to identify and manage the risks associated with biotechnology. He queried whether biotechnology is likely to offer the next generation of environmental remediation technology.

Panelists: William Clark, Belfer Center for Science and International Affairs, Harvard University, identified structural questions to help provide a framework for analysis:

- What is the biotechnology issue and who gets to say?
- How do the risks and benefits of biotechnology compare to their alternatives?
- Who bears the risks and who reaps the benefits of biotechnology?
- How should the inconclusiveness of risk assessments be handled?

He proposed that: the imbalance of benefit takers and risk takers be addressed, especially for the developing world; collaborative networks for research, monitoring and assessment be developed; adaptive management strategies with provision for outside evaluation be designed; and precautionary values be taken seriously.

René von Schomberg, European Commission, sought to focus discussions on three questions:

- Is the precautionary principle designed to restrict trade?
- Does the precautionary principle conflict with risk assessment?
- Does the precautionary principle lead to more restrictive environmental measures?

He asserted that the precautionary principle is neither designed to restrict trade nor to conflict with risk assessment. He referred to the European Directive 90/220/EC concerning the deliberate release of GMOs into the environment. This Directive translates the precautionary principle into precautionary regulation that incorporates flexible regulatory standards and proportionate regulatory requirements.

Luther Val Giddings, Biotechnology Industry Organization, said that biotechnology applied to agriculture is critical to meet the challenges of food production. He added that many aspects of biotechnology are fundamentally "green" in their application. He stressed that biotechnology could alleviate pressures on wild lands and biodiversity and suggested applying the standard of "relative risk" rather than absolute risk to biotechnology. He stressed that transgenic food crops have been subjected to more safety reviews and *a priori* scrutiny than any other crop in history. He lamented the fact that biotechnology had become a lightening rod for many issues with the ironic consequence of delaying the influx of more environmentally safe technologies. On information dissemination, Giddings said that while there were several facts that would be "nice to know," there are only some facts that regulators "need to know."

Discussion: One participant termed the efforts to justify biotechnology on grounds of food insecurity as "disingenuous", since current efforts at biotechnology have not been targeted towards the South, and recommended examination of the consumption patterns of the North. Val Giddings responded that biotechnology is not the sole solution to food insecurity in the developing world, but pointed out that a few companies have targeted research and technology towards developing countries.

BIOTECHNOLOGY AND HUMAN HEALTH

The session on biotechnology and human health was facilitated by Alexander Golikov, Inter-Agency Commission on Genetic Engineering Activity, Russian Academy of Sciences.

Panelists: Sheldon Krimsky, Department of Urban and Environmental Policy, Tufts University, said there had never been such a global debate over an issue about which so little is known. He noted that there were no standard tests for health hazards in crops as there are for chemicals. He said there are two prevalent views on testing for health risks associated with genetically modified food. According to the first, food is considered to be safe when it does not cause or contribute to disease. The second view is broader and more complex because it involves the nutritional components of food to determine food safety. He noted the US Food and Drug Administration's voluntary consultative process to test transgenic food products for safety.

Elettra Ronchi, OECD, referred to her institution's contribution to science-based approaches to risk regulation, referring to the "Blue Book" of principles and guidelines developed in 1982 by a group of OECD national experts. Work on food safety was later undertaken and the principle of "substantial equivalence" was developed. The science-based approach to risk regulation refers to the fact that guidelines, rules and regulations are to be based on the best available scientific knowledge and should be sufficiently flexible to adapt to new technology. According to the principle of "substantial equivalence," the most practical approach to the determination of safety is to consider whether food components from organisms developed by the application of modern biotechnology are substantially equivalent to analogous conventional food.

Julian Kinderlerer, Department of Molecular Biology and Biotechnology, Sheffield University, elaborated on the effects of information on public opinion and consumer behavior. He recounted that until 1991 the only genetically modified food on the market in the UK was a certain brand of tomato paste. Once the highest-selling brand in the market, it was ultimately removed from counters due to adverse publicity about genetically modified foods. He noted, however, that in many instances public opinions are shaped by misconceptions due to inadequate information, citing reports that the vast majority of Europeans believe only transgenic foods contain genes.

Discussion: Referring to the impact of GMOs on human health, one participant questioned why public perception of genetically modified crops as an alternative to use of hazardous pesticides has recently shifted to a view that they represent a threat. Krimsky pointed to the role played by NGOs and other segments of civil society regarding biotechnology. One participant noted that sometimes activism discredits

the veracity of scientifically-based facts. Other participants argued that NGOs play an important role in asserting the right of consumers to know whether they are purchasing a genetically modified good or not. Most participants agreed that better public understanding of GMOs is important and called for better communication strategies and dissemination of information about genetically modified organisms, goods and products by the companies or institutions that research and produce them.

ETHICS, SOCIAL VALUES AND BIOTECHNOLOGY

Facilitator Timothy Weiskel, Environmental Ethics and Public Policy Program, Harvard University, introduced the session on the ethical dimensions and social values attached to biotechnology.

Panelists: Sheila Jasanoff, Belfer Center for Science and International Affairs, Harvard University, began by noting how a sense of crisis permeates many presentations. She suggested seeing such perspectives as an outcome of the success of reason and values of the 18th Century Enlightenment, particularly: the wide diffusion and accessibility of technical knowledge; the institutionalization of complex governance structures; and the enhanced capacities of people to be reflective and critical about the technologies we produce.

Jasanoff proposed that biotechnology debates take into consideration three well-established critiques of technology: the notion that technologies lead to unintended consequences; an understanding of technology systems as political, rather than value-free, channels for reaffirming inequalities and structural problems out of which technologies emerge; and, finally, recognition that rationality and progress must be seen differently by different social and cultural actors. She concluded by asking whether biotechnology rests on competing visions of progress and what institutional mechanisms can assist in resolving and negotiating around these differences.

Harriet Strimpel, Bromberg and Sunstein Attorneys at Law, discussed the role of patents in biotechnology. She said that the value of a patent depends on the "terrain of patentability," that is, the actual use of patents, the national jurisdiction and legal infrastructure within which they are legalized, and whether mechanisms for effective exclusion of others exist. She pointed out differences between the US, where no moral legal provision exists in the patent system, and Europe, where moral concerns for not disrupting *l'ordre public* (the public order) can justify non-patentability. She concluded by asking participants to reflect upon whether there is a distinction to be made between real property and intellectual property or between human organs and plant materials.

Tony La Viña, Biological Resources Programme, World Resources Institute, linked the issues of ethics and social values to the current paralysis of negotiations associated with the CBD and its pending biosafety protocol. He portended a crisis of failure given the ease with which ethical and social issues are recognized but not seriously addressed. He noted three factors that make current biotechnology especially difficult to grapple with: its rapid pace of development; its pervasiveness; and its profound implications for equity and the basic human concerns of life, food security, livelihoods, and human and ecosystem health.

La Viña called for adoption of a precautionary approach to the potential unintended consequences of the terminator technology and other biotechnologies; participatory social and ethical debates on the issue; risk assessments and implementation of labeling schemes; and adherence to the principle of prior informed consent.

Discussion*:* As facilitator, Weiskel questioned: how scientific agendas are being set in relation to social agendas; whether ethics concerned with the "oughtness of things" and self-restraint are related to the power relations involved in politics; and whether ethical concerns need to go beyond generational human matters to include interspecies, ecosystemic and intergenerational ethical concerns. Given that genetic material is both a real sequence and informational, he noted the challenges posed by making a distinction between real versus intellectual property. He also noted that urgent issues, such as biosafety, may not yet be the most important ones for current policy-making.

Participants debated whether the wealth of a society and disadvantaged groups afford different ethical sensibilities; what constitutes precaution if risks are not clear in the case of new biotechnologies; and to what extent social values, ethics and institutions get transferred with particular technological systems.

Participants generally agreed that cultural and social structures cannot be separated from technical and scientific developments. La Viña objected to the idea of terminator technology given the risks associated with farmer inability to plant future crops and potential impacts on the environment.

One participant wondered if new biotechnologies are exporting Western ethics like no other technology before them, particularly the ethics of exclusive ownership and control of nature through patents and acceptability of recombinant DNA practices. Another participant said that if the manipulative nature of biotechnology was the main concern it should have been raised 10,000 years ago when the first crops and animals were domesticated.

CLOSING SESSION

In his concluding remarks, Calestous Juma, provided an initial outline of his forthcoming summary, which will include a section on the background to the biotechnology debates, an insight into key issues and suggestions on ways to move forward. He said he will avoid focusing on concerns in order to shift focus onto plausible solutions. Juma drew attention to the tensions between globalization and biotechnology, and to linkages between discussions on biotechnology and discussions on trade. He highlighted the differing uses of the term "biotechnology," ranging from clusters of techniques to products resulting from the application of such techniques or, in some cases, even the biotechnology industry itself. He asserted that the question of what national governments should regulate would depend on cultural values.

Juma elaborated on possible next steps. On research, he said various theoretical issues needed to be sorted out such as the precautionary principle and substantial equivalences between organisms. He recommended training policy makers and fostering consultation between people with different views. He advocated more communication with the public regarding governance systems and questions of transparency. On conference follow-up, he said a biotechnology task force would be set up by the CID, in consultation with conference participants and other interested parties in order to address issues such as institutions, research and training pertinent to biotechnology and the global economy.

Jeffrey Sachs closed the conference at 5 p.m. on September 3.

THINGS TO LOOK FOR

BIOTECHNOLOGY 2000-11TH INTERNATIONAL BIOTECHNOLOGY SYMPOSIUM: 3-8 September 1999, Berlin, Germany. Contact: USDA; Internet: http://www.agnic.org/mtg/2000.html.

3RD TRONDHEIM CONFERENCE ON THE ECOSYSTEM APPROACH: 6–10 September 1999 Trondheim, Norway. Contact: NINA NIKU, Odd Terja Sansdlund; Tel: +47-73-80-15-48; Fax: +47-73-80-14-01; E-mail: odd.t.sanslund@ninatrd.ninaniku.no; Internet: http://www.ninaniku.no.

GLOBAL CHANGE AND PROTECTED AREAS: 8-16 September 1999, L'Aquila, Italy. Contact: Guido Visconti, Dipartimento di Fisica, Universita degli Studi di L'Aquila, Via Vetoio, Coppito, 67010 L'Aguila, Italy; E-mail: guido.visconti@aquila.infn.it; Internet:http://www.aquila.infn.it/glbch

SUSTAINABLE DEVELOPMENTS

DISPLACEMENT, FORCED SETTLEMENT AND CONSERVATION: 9-11 September 1999, Oxford, UK. Contact: Dominique Attala, Refugee Studies Programme, Queen Elizabeth House, 21 St Giles, Oxford, OX1 3LA, UK; Tel: +44-1865-270-722; Fax: +44-1865-270-721; Email: rspedu@ermine.ox.ac.uk.

INFORMAL CONSULTATION ON THE PROCESS TO RESUME THE EXTRAORDINARY MEETING OF THE COP TO ADOPT THE PROTOCOL ON BIOSAFETY: 15-19 September 1999, Vienna, Austria. Contact: CBD Secretariat; World Trade Center, 393 St. Jacques Street, Suite 300, Montréal, Québec, Canada H2Y 1N9; Tel: +1-514-288-2220; Fax: +1-514-288-6588; E-mail: chm@biodiv.org; Internet: http://www.biodiv.org.

COLLOQUIUM ON THE RISKS AND REGULATIONS ON GMO FOOD PRODUCTS: 1-2 October 1999, New York University School of Law, New York, NY, USA. Contact: Bobbie Glover, NY School of Law; Tel: 1-212-998-6415, 998-6417; Fax: 1-212-995-4037.

REGIONAL SESSION OF THE GLOBAL BIODIVERSITY FORUM (SOUTH AND SOUTHEAST ASIA): 24-26 October 1999, Colombo, Sir Lanka. Contact: P. Balakrishna, IUCN - The World Conservation Union, 48, Vajira Road, Colombo 5, Sri Lanka; Tel: + 94-74-510-517; Fax: +94-1-580-202; E-mail: pbala@sltnet.lk.

CGIAR INTERNATIONAL CENTERS WEEK 1999: 25-29 October 1999, Washington, DC. Contact: CGIAR Secretariat; Tel: +1-202-473-8951; Fax: +1-202-473-8110.

WORLD INTELLECTUAL PROPERTY ORGANIZATION MEETING ON BIODIVERSITY AND THE CONVENTION ON BIOLOGICAL DIVERSITY: 8-10 November 1999, Geneva, Switzerland. Contact: Internet: http://www.wipo.org.

3RD ANNUAL EUROPEAN BIOTECHNOLOGY BUSINESS CONGRESS-BIOTECHNOLOGY FOR ECONOMIC GROWTH AND IMPROVED QUALITY OF LIFE: 16-19 November 1999, Munich, Germany. Contact: EuropaBio '99; Tel: +32-2-735-0313; Fax: +32-2-735-4960; E-mail: mail@europa-bio.be; Internet: http://www.europa-bio.be.

RECOMBINANT GENE PRODUCTS: EXPRESSION TECHNOLOGIES: New Delhi, India, 22 November-3 December 1999. Contact: ICGEB; Tel: +91-11-616-7356; Fax: +91-11-616-2316; E-mail:chatterj@icgeb.res.in.

FIFTH MEETING OF THE CBD COP: 15-26 May 2000, Nairobi, Kenya. Contact: CBD Secretariat; World Trade Center, 393 St. Jacques Street, Suite 300, Montréal, Québec, Canada H2Y 1N9; Tel: +1-514-288-2220; Fax: +1-514-288-6588; E-mail: chm@biodiv.org; Internet: http://www.biodiv.org.