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INTERNATIONAL CONFERENCE ON BIOTECHNOLOGY IN THE GLOBAL ECONOMY: SCIENCE AND THE PRECAUTIONARY PRINCIPLE 22-23 SEPTEMBER 2000

The International Conference on Biotechnology in the Global Economy: Science and the Precautionary Principle took place in Cambridge, Massachusetts, USA, from 22-23 September 2000. Organized and hosted by Harvard University's Center for International Development (CID) and the Belfer Center for Science and International Affairs, the conference attracted over 200 participants from governments, industry, non-governmental and intergovernmental organizations, and research and academic institutions. The conference is part of a series of events addressing key policy issues related to biotechnology and globalization, with support from the Rockefeller Foundation. The meeting aimed to explore the policy and practical implications of applying the precautionary principle in the field of biotechnology, specifically with regard to: practical, theoretical, historical and cultural aspects of the principle; previous applications in international environmental and trade law; the various definitions of the principle's use in international discussions and negotiations; and social, economic and political implications of the principle in developed and developing countries.

Participants met in four full sessions to hear keynote speeches and presentations addressing: an overview of the principle; concepts and definitions; scientific and technical foundations; and a recent publication on the potential and hazards of genetically modified (GM) foods. Participants also met in four parallel sessions using case study presentations for discussion in the areas of: national experiences; international experiences; policy and institutional implications; and regulatory implications. A closing plenary reviewed the findings of the conference and discussed priorities for future work.

The outputs of this conference will include a summary outlining next steps and a special journal issue on the topic. This conference material is expected to contribute to current efforts to develop research activities, provide training and promote policy dialogue and awareness on the safe use of biotechnology.

BACKGROUND

The safe use of modern agricultural biotechnology has become one of the most contentiousdebates worldwide. There is general agreement on the need to ensure the safety of biotechnology products through effective risk assessment, management and communication. However, countries differ on how to reflect these measures in public policy and decision-making. Some require that "sound science" be used as a basis for restricting trade in products that pose a threat to the environment and human health. Others, however, argue for "precautionary measures" that allow policy action to be taken in the absence of full scientific certainty.

In 1992, the United Nations Conference on Environment and Development (UNCED) adopted Principle 15, which states that "where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." A version of this principle was recently incorporated into the Cartagena Protocol on Biosafety under the Convention on Biological Diversity, generating significant debate during its negotiation and over its future interpretation. Issues regarding the precise meaning, scope, context and application of the precautionary principle will continue to draw attention and create controversy, especially at the intersection of international trade and environmental management.

REPORT OF THE CONFERENCE

OPENING PLENARY

Sara Sievers, Center for International Development (CID), Harvard University, opened the meeting, noting CID's work in the area of science and technology. She introduced Calestous Juma, CID, as the meeting's Chair. Juma highlighted how this conference builds on a similar meeting held in September 1999 on the general topic of biotechnology and the global economy. He cited significant interest in understanding the relationship between globalization processes and scientific progress, with special attention to biotechnology and its socioeconomic and political implications. He noted that the notion of uncertainty is a central overriding factor encompassing three of the key areas highlighted by the last conference – environmental safety, safety for human health and the safety of socioeconomic systems. Within this context of uncertainty, he stated that no general agreement exists on what the precautionary principle means or how it is applied in different socioeconomic and cultural systems. Juma expressed hope that this meeting could help create a common language and vocabulary, and queried whether the principle serves as a new perspective on uncertainty or whether it complements existing approaches. He further noted that the meeting would address national

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and international experiences with the precautionary principle and its formulation, as well as the ultimate implications for policy, institutional and regulatory systems.

Jeffrey Sachs, CID, stressed the need to integrate scientific and technological issues into global economic development, noting that most proposed economic strategies focus on "globalization" *per se*. He stated that the growing gap between rich and poor countries is due to the increasing divide in technological capacity. In this regard, poor countries generally lack systems promoting domestic innovation and are not adequately adopting and adapting to technologies developed in the industrialized world. He stated that biotechnology is still in its infancy and that it will continue to grow, especially since poor countries will need agro-biotechnology to feed growing populations. Responding to the notion that biotechnology is only for rich countries, he noted the nature of science is to follow the market. He said the potential risks of biotechnology should be assessed individually for developed and developing countries, since developed countries should not determine what are acceptable risks for developing countries. In this regard, he noted the need for capacity building to evaluate these risks.

Sachs stated that the precautionary principle is essentially a risk assessment tool, and that if there are no externalities, then individuals should be able to manage their own risks. He proposed that labeling could be a potentially useful mechanism. He also suggested the need for: delivery assessment to look at biotechnology's net effects; risk evasion frameworks to evaluate whether the loss of a technological application is more painful than its gains; investing in a better understanding of biotechnology; decentralized decision-making; and using independent scientists and peer reviews to evaluate risks. In closing, he suggested that while the political debate over biotechnology may continue in Europe, the furor will subside elsewhere given its general adoption in the US, China, India and increasingly in Latin America. He noted the reluctance to adopt the technology in Africa, mainly due to Europe's influence and donor role, but believed that overall the technology will continue to grow.

John Holdren, Belfer Center for Science and International Affairs, Harvard University, presented relevant comparisons between the theoretical application of the precautionary principle in biotechnology and his experience with comprehensive risk assessment and management of alternative energies. He critiqued the Wingspread formulation of the precautionary principle, which states that when an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically. He noted that it: offers little guidance on the kinds of measures to be taken and the specific costs and risks involved; constitutes a "prescription for paralysis"; and places health and environmental values over economic ones. He noted that difficulties of managing risks in society start with deciding how much and what kinds of caution should be exercised under conditions of uncertainty. Discussing hazard assessment, communication and management, he enumerated relevant components, including, *inter alia*: values of harm, expectation of harm, maximum value of harm, distribution, resistance to remedy, uncertainty and the role of potential victims. Pitfalls in hazard comparisons might include: non-comparable benefits and costs; narrow or inconsistent boundaries of analysis; mixing average and marginal hazards; illusory perceptions; preoccupation with quantification; and hidden values inherent in decisions made by technical experts confusing hazard assessment with hazard management.

Drawing from other sectors' experience, he noted that the proponents of nuclear energy had undermined their own credibility by asserting that no risk existed. In voicing opposition to potentially harmful practices, he encouraged support for establishing alternative methods. He also advocated that extraordinary risks be entertained only in exchange for indispensable benefits, and that a regime of restraint, even if imperfect, is preferable to a complete absence of restraint. He emphasized the need for multiple information sources, maximization of public confidence, reliance upon NGO input, and separate and independent government institutions. He expressed concern over the increasing prevalence of academic and industrial partnerships, which bring into question the role of independent science. He called for cost-benefit analysis of such efforts.

OVERVIEW OF THE PRECAUTIONARY PRINCIPLE

Calestous Juma, CID, facilitated discussion on this session addressing the origins and evolution of the precautionary principle.

Panelists: Konrad von Moltke, International Institute for Sustainable Development, highlighted the importance of "institutions," as distinguished from "organizations." He stated that precaution is an institution of governance and that such institutions are the building blocks of society serving as the "rules of the game" used to make decisions. He emphasized that the scientific basis of all modern environmental policy involves some degree of uncertainty, and that governance procedures to address this uncertainty are essentially the institutions of precaution. He noted that the international debate on the precautionary principle has thus far largely ignored this institutional dimension, and in considering the precautionary principle, he supported efforts to better understand the institutions of precaution through which governments move from science to policy. He stated that such an institutional analysis should account for the public policy differences across countries, highlighting the institutional differences among OECD countries, sub-Saharan countries and international institutions.

Von Moltke pointed out that some developing countries and international institutions must make decisions from a point of ignorance, noting that even with scientific data, governments are still faced with uncertainty. He highlighted several international treaties incorporating some form of precaution (e.g. European Convention on Long Range Transboundary Pollution, fisheries agreements, the Cartagena Protocol), while noting that some had not operationalized the principle. He also noted that Article XX of GATT, which includes environment-related exceptions to GATT rules, was written in the 1940s at a time of scientific uncertainty, and is inadequate for dealing with conflicts coming before the WTO today. He concluded that an institutional approach will help reveal how the precautionary principle or approach is employed in countries actively engaged in developing environmental policies. He noted that recognition of differences in institutional structures can result in different answers to identical questions.

Carolyn Raffensperger, Science and Environmental Health Network, supported application of the precautionary principle and underscored the unprecedented and potentially catastrophic present magnitude of human-induced change on the land. She identified common elements of the principle in international treaties, including threat of harm, lack of scientific certainty and action to prevent harm, while also noting its expression in both active and passive formulations. She cautioned against confusing precautionary action with the precautionary principle. She listed other elements modifying the principle in international agreements, including cost effectiveness, rectification of

environmental damage at the source, the polluter pays principle, cooperation in implementing commitments and inclusion of improvement efforts in management frameworks.

To operationalize the principle, Raffensperger proposed four provisions: people's duty to take anticipatory action; burden of proof on the proponents of a technology; examination of a full range of alternatives; and open, informed and democratic decision-making, including affected parties. She highlighted the principle's use as a belief, regulatory tool, ethical directive and overarching principle, and suggested that the principle be integrated within the formation of research agendas as opposed to at the end of a product's pipeline, which would significantly alter economic implications. Regarding the approval of new technologies, Raffensperger suggested using ongoing monitoring activities, performance bonds and alternatives assessment. She concluded by noting, *inter alia*, that the principle: is not optional in view of the magnitude of potential damage; requires more and different science; employs ethics, as well as science; and is now a public as well as an academic debate.

Discussion: Questions concerning the license to invoke the precautionary principle when the threat of harm is imagined or hypothetical were raised. Von Moltke said it would be helpful to view the precautionary principle as "embedded" in other institutions, noting their inadequacies. Some participants commented on judicial interpretations of the principle, with one noting that some legal systems can interpret the precautionary principle and questionable levels of threat literally, and that in Brazil this has stalled the use of GM crops since 1998. Several participants disagreed with Sachs' comments on the EU's opposition to biotechnology and lack of independent science, asserting that the EU was not trying to prevent free trade or disavow independent scientific study and noting that the EU's concern for health and environment is a cultural characteristic. Some participants requested clarification of the idea that the precautionary principle is new and distinct from the traditional practice of risk assessment. Sachs responded that he viewed the precautionary principle as a regulatory mechanism and noted that risk assessments are undertaken continually in decentralized ways within many institutions.

One participant, emphasizing the difference between risk and alternatives assessments, stated that risk assessment for biotechnology should start with goals and progress through a full range of options rather than limit alternatives to a few bad choices. Sachs concurred that decentralized decision making is essential and noted that many different interpretations of risk assessment exist. Several participants advocated balancing the risks of innovation with those of stagnation. One participant raised ethical concerns about using unproven scientific "facts" and representation of developing country needs by developed countries. Another participant asked how the scientific community could receive more public support, and another suggested increased spending where public support is needed.

BOOK PRESENTATION AND DISCUSSION: PANDORA'S PICNIC BASKET

In an evening dinner session, Alan McHughen, genetic engineer and author of *Pandora's Picnic Basket/Consumers' Guide to GM Foods*, explained the process used to write the book. He noted that it is generally based on questions posed to him by the public. He noted the extremes on both sides of the biotechnology debate, remarking that positions have often hinged on bad science and/or false assumptions. He added that increased public scrutiny of biotechnology is generally a positive development. He stressed the need for a common understanding of the precautionary principle to avoid self-serving, and ultimately conflicting, methods of application. He emphasized the need to look at the current status quo in terms of techniques that biotechnological methods could replace, noting that many conventional activities present greater threats to the environment and human health, yet are not subject to the precautionary principle.

McHughen then compared the Canadian regulatory process for approving a conventionally-bred variety of flax and a genetically modified variety, noting an almost excessive burden of additional information requirements for the GM crop despite a difference only with regard to tolerance of herbicide residues in the soil. He thus argued for specific examination of the variety of biotechnological applications, as opposed to blanket policies, and called for clarification regarding misconceptions around some of the alleged health and environmental effects of GM products. He closed by noting that biotechnology and its products are a fact of life and the market, and that efforts should now focus on how to moderate and minimize their hazards.

Discussion: Responding to a question about the most erroneous assumptions encountered regarding biotechnology, McHughen cited a common misperception that existing cultivars of plants are "natural," noting that most food products are modified in some fashion and little remains that has not been altered by humans. He also highlighted the belief that transferring genes across species was never intended by nature and stated that such gene-flow is a common, natural occurrence. Regarding a comparison of the potential danger of biotechnology to nuclear weapons, McHughen replied that biotechnology is simply a tool that can be used for good or bad and that it may require more stringent guidelines or regulation. Responding to comments about developing a better understanding of biodiversity before promoting biotechnology, he noted that such knowledge will never be complete and that conditioning biotechnology's development on this requirement would effectively kill it. Discussion also highlighted differences between the European and North American scientific communities; the former being more isolated, and as a result besieged by the public, whereas the latter generally maintains more open communication. One participant noted that plants, animals and even humans share many genes in common, and that living organisms have internal means of keeping their genomes intact even in the face of gene transfer.

CONCEPTS AND DEFINITIONS

Kim Waddell, National Research Council, USA, chaired the session outlining key concepts and definitions used in the discourse on the precautionary principle.

Panelists: Marc Saner, Carleton University, Canada, outlined three Western ethical traditions, focusing on: character or attitude, rules to guide actions (formalistic), or goals to guide actions (contextual). In regulatory affairs, character ethics would employ the best people to produce the best possible science. Rules ethics would produce a consistent framework providing a basis for sound science. And goals ethics would mandate flexibility in an otherwise clear framework for sufficiently accurate science. In mapping these traditions onto the precautionary principle: character ethics expresses the view that an attitude of precaution is virtuous; rules ethics implies that we must make our existing rules more stringent; and goals ethics serves as a tool to complement balancing required to select best actions. Applied to stakeholders, those who desire systemic change may focus on character, those who wish to maximize transparency and consistency might choose rules, and "wise" decision-makers would likely focus on goals.

Practical implications of applying these traditions to the precautionary principle would require changes to regulation. This presents the problem of uncertainty, where it becomes difficult to agree on character, action may miss the target, and goals are uninformed. Saner suggested either maintaining a standard approach or developing alternatives that recognize implicit value assumptions and the limited scope of regulatory science. He concluded by: asking whether there are any ethical imperatives and a place for discourse ethics; citing science as a risk assessment of the second order; and advocating a broad conception of the precautionary principle as a call for change in attitude, prescription for formalistic action and a call for contextual action to help conserve its ideal meaning as initially conceived.

Julian Morris, Institute of Economic Affairs, United Kingdom, gave a brief history of "risk," noting that taking risks can be beneficial and that all human activity entails some element of risk. He stated that one should not attempt to eliminate risk, but should instead aim to strike a balance between risks taken, acknowledging that some risk should be avoided (e.g. nuclear war). The question that should be asked is "how do we make decisions on risks that are uncertain?" He stated that most definitions of the precautionary principle fall into two broad classes: strong – take no action unless you are certain that it will do no harm; and weak – lack of full certainty is not a justification for preventing an action that might be harmful. He noted that governments have generally employed the weak version. For example, he said that despite scientific uncertainty, the EC banned hormones used for animal growth promotion on the grounds that "their safety has not been conclusively proven." By contrast, consumers and environmental NGOs have typically employed the strong formulation to justify their demands for restrictions and bans. He quoted Greenpeace's assertion: "Do not admit a substance unless you have proof that it will do no harm to the environment." He criticized this mindset as leading to the damage of GM field trials in the UK, which has discouraged funding of biotechnology research.

He highlighted the following problems with the definition of the precautionary principle in the Rio Declaration (see BACKGROUND): the meaning of "threat" is unclear; "damage" needs to be defined and distinguished from mere "change"; the assumption that all change (and hence all damage) is irreversible; "seriousness" is a subjective concept; and there will always be scientific uncertainty. He suggested that the biotechnology industry needs to promote consumer confidence. In closing, he remarked that "everyone likes progress, but no one wants change," which is a contradiction that must be reconciled.

Anil Gupta, Indian Institute of Management, discussed institutional approaches to the management of risks, their externalities and how the poorest people address such risks. He noted that the poorest people generally live in the highest areas of risk and are often employed in the riskiest types of activities. Households survive by taking risks and coping with their consequences, often while improving their capacity to deal with uncertainties in the future. He stressed that the precautionary principle's application depends on a number of social and other attributes, and that different segments of society require different levels of assurances depending on the type of technology and levels of access. He noted the need to consider whether such risks are reversible, immediate, accumulative, source-identifiable, localized, insulated or recombinant. He called for assessment of such traits in tailoring specific institutional responses, discouraging blanket approaches. He contrasted the public acceptance of GM medicines, such as insulin, with public concern over GM crops.

Gupta also proposed a model to appraise technologies through categories of access, assurances, ability and attitudes, and provided examples within India regarding local application of herbal pesticides and a national effort to address famine through the introduction of hybrid seeds during the green revolution. He also called for a fair chance for competing technologies, voices and visions of the future. He closed by stressing the need to integrate the six-"Es" (ethics, efficiency, excellence, environment, equity and education) into risk assessment and management.

Discussion: One participant asked Saner why risk identification is not a scientific task, and why transparency is more critical to less developed countries than to developed ones. Saner replied that he wanted to separate facts and value, noting scientists are not always qualified to make value judgments regarding the environment and high levels of risk assessment. He said transparency is important for everyone, but he was referring specifically to developing country government officials. Another asked whether institutional frameworks dictate levels of risk, advocating building conflicts of interests into the system to avoid falsely elevating the virtuous aspects of his theory. Saner agreed, saying he wanted to show three independent options, their distinctions and interconnectedness without dictating a hierarchical framework.

Regarding the debate between precaution and innovation, one participant suggested that scientists and economists should collaborate to build models on risks for more effective and objective evaluation. Saner responded that scientists and economists agree that risk management is value-laden and that hidden value assumptions must be under the control of managers, not technicians. When asked about comparisons of alternatives and specific scientific qualities and protocols (peer review, control, transparency) that would improve decision-makers' ability to judge science, Saner responded that this was hard to formalize and often entailed errors and faulty methods.

A participant asked Julian Morris about his comment regarding the shift in debate on genetically modified organisms (GMOs) in Europe. He responded that those who would benefit from GMOs would bring about a change in views. Another cautioned against oversimplifying the debate, noting the real dangers of improper use, the resistance present in farming communities, and the structure of interests that influences public perception. One participant objected to Morris' comments on NGOs, noting that most have been calling for better science and raising valid concerns about gene-flow, transmutation, and unintended consequences. Morris responded that he had wanted to highlight concerns about fundraising, suggesting that some NGOs shifted their focus from environmental to consumer issues to raise public fears and thereby mobilize funds.

SCIENTIFIC AND TECHNICAL FOUNDATIONS

Andrew Spielman, Harvard School of Public Health, facilitated the discussion in this session addressing scientific and technical foundations of precaution as used in risk management.

William Leiss, Royal Society, Canada, discussed "risk controversy," highlighting the following common features: knowledge gaps; distrust of those who perform scientific research, with less trust for industry and increasingly less trust for governments, and more trust in NGOs; difficulty in handling problems of uncertainty; intensive dispute over risk assessment data; spin-doctoring; and poor risk communication, where no one takes responsibility for ensuring that the public is well informed.

He challenged the group to find a way to make risk controversy socially useful, thereby ensuring a transparent process where the public can reach informed decisions.

He illustrated two examples regarding the role of scientists in addressing risks and the precautionary principle: the monarch butterfly study, where many scientists noted flaws in such studies; and the case of pesticides, where some scientists, who previously asserted their safety, later sought their elimination. He noted that this reflected a fundamental question about the credibility of science and its push for GMOs, and wondered whether biotechnology is at the same point where pesticides technology was in the 1950s.

Klaus Ammann, University of Bern, stressed three central themes: people should be able to decide which technology they want to adopt; progress is not always found in new technologies; and corporate and eco-imperialism should be avoided. He noted preference for the term precautionary approach over precautionary principle, as "approach" reflects an iterative planning process adaptable to changing needs and conditions. He noted different kinds of knowledge (factual, deontic, explanatory, instrumental and conceptual), asserting that no single actor has all relevant knowledge.

Ammann then listed four problematic tendencies of the actors involved in the current debate on biotechnology: industry people tend to live in a corporate atmosphere of euphemism and perfection, prefer deontic knowledge and have difficulties understanding external criticism; scientists are often naïve, believing in factual knowledge alone, and manipulate non-scientists by selecting appropriate facts; some NGOs have evolved into powerful protest industries and are not interested in science; and the public often does not know whom to believe and does not understand that criticism and acceptance of biotechnology is a demanding cultural process.

He called for a comparison of biotechnology with organic, integrated and classic farming practices and suggested that biotechnology: evolve towards precise applications, adapted to the local needs of farmers and the environment; eliminate gene-flow where necessary; and attempt to mimic biodiversity's natural processes. He concluded by calling for a focus on the advantages of all farming technologies and their potential integration.

Gary Marchant, Arizona State University College of Law, USA, argued that the precautionary principle is the "wrong" answer to the "right" question of how to prevent harm to human health and the environment before it occurs while recognizing the inherent uncertainty in predicting risks. He stated that the precautionary principle is a reactionary response that neglects judgment of substantive merits and inherently contains many dimensions of risk that should be recognized. He noted that risk assessment has historically dealt with the ambiguities of, *inter alia*, degree and level of risk, data requirements for demonstrating safety, risk trade-offs and type of action required. Until there is agreement on these ambiguities, he stressed that there cannot be consensus on the precautionary principle.

He noted that the intentional ambiguity of the precautionary principle is designed to challenge the status quo of political power, ideology and environment. In asking who decides what a word means, he identified two levels of arbitrariness: to which problems does the precautionary principle apply, and when applied, what does it actually mean? Stating that US courts are guilty of arbitrary and capricious review, he called for determinate binding standards based on criteria defining how clear an agency must be to be understood. Without a limiting principle, he said, results can become absurdly restrictive.

Discussion: One participant criticized those invoking the principle to call for a total ban of DDT, as they fail to appreciate DDT's contributions in controlling malaria. He asserted that the principle is usually invoked by elites in rich countries, which is a form of eco-imperialism. Ammann asserted that factual knowledge of biotechnology alone is not enough. Noting that the public is often misinformed, Ammann proposed concentrating on minimum standards of risk instead of public determination of acceptable risks. Another participant said that the precautionary principle would not work in the US, given its government and policy structure, even though it could work in Germany and perhaps the rest of the international community. It was also suggested that the biotechnology industry was prospering based on the ignorance of the public. Others suggested promoting cultural acceptance of institutions that promote biotechnology and the precautionary principle rather than acceptance of the technology itself.

PARALLEL SESSION: NATIONAL EXPERIENCES

Michael Fisher, Massachusetts Institute for Technology, USA, facilitated this session on the presentation of case studies and national experiences with risk assessment, management and the precautionary principle.

Panelists: Luiz Antonio Barreto de Castro, Brazilian Enterprise of Agricultural Research, illustrated Brazil's complex history of biotechnology and biosafety. He emphasized that new technologies soon will only be limited by those boundaries set by regulators and ethicists. Noting the increase in biosafety regulations, he described a complex web of interactions and consequences that reached beyond biosafety issues to include worldwide agrochemical markets, noting that the global fertilizer market is rising while herbicide use is declining, which affects decisions made about GM crops. The Brazilian biotechnology industry has seen an increase in patents, enactment of patent laws limiting technology, a ban on commercial use of biotechnology since 1998 by the National Technical Biosafety Commission (CTNBio), and acquisition of seed companies by gene companies. The CTNBio is operating its risk assessment and monitoring strategies at an experimental and commercial level, using the precautionary principle in authorizing field releases on transgenics.

He stated that PROGENE, the genome program of the Brazilian environmental agency EMBRAPA, will operate as a network for the identification, characterization, transfer and expression of genes for agriculture. He emphasized that the precautionary principle in Brazil is taken literally by judges, so that no supporting scientific evidence is necessary, and the argument that more testing is necessary is always effective. As judges can always find scientists who disagree, he stressed that the issue is now political. Noting that such criticism of GMOs is so disproportionate, he asked who ultimately benefits from delaying plant biotechnology.

Responding to a question on the problem of distribution, de Castro replied that Brazilian agribusiness must produce more than they actually use on the same amount of arable land in order to meet demands, noting that science will not resolve social problems in general. Another asked whether someone in Brazil could put up a bond in order to temporarily lift the biosafety injunction, as in common law systems. The response was no.

Aarti Gupta, Yale University, USA, presented her field study on precautionary decision-making for biosafety in India. Her main theme was that despite the inclusion of precautionary decision-making in the Cartagena Protocol, the relevance for developing countries of precau-

tionary decision-making for biosafety remains under-examined. Highlighting the Indian Environmental Protection Act (1986), under which LMOs are regulated, she suggested that language on regulation of substances that "may be or tend to be" injurious to the environment could be construed as precautionary. She noted that despite India's stringent biosafety regulations, they have not been fully tested as no LMO for use in agriculture has been commercialized.

She distinguished the status of transgenic crop field-testing between the private sector and the public sector, and gave examples of the status of transgenic crops in contained use. She then elaborated on the institutions of the decision-making process and suggested that decision-making criteria for biosafety are based on "sound science" as well as "socioeconomic considerations." She stated that the information generated in risk assessment is very similar to other national and international models such as in the US, OECD and WHO. She submitted that efforts to draw boundaries around decision-making criteria, such as those contained in the Cartagena Protocol, will have little practical consequences in the Indian context.

She noted that biosafety data is generated by the private sector and provided to public regulators, who are themselves scientists engaged in transgenic research, and that there are still concerns about sharing confidential information and the credibility of data. She also highlighted the crosschecks in the biosafety governance, monitoring and evaluation committee.

John Mugabe, African Centre for Technology Studies, Kenya, gave an overall assessment of biotechnology development in Africa, noting that many African countries do not have the time or choices to reduce scientific uncertainty. He said the debate on perceptions of risk and precaution assumes that society perceives risk in a homogeneous way. He observed that the debate has confused products of biotechnology with the system through which they are distributed, and that addressing food production in most African countries requires technological as well as structural solutions.

He identified various levels of biotechnology development in different countries: low levels of field testing are being done in Ghana and Nigeria; Zambia and others are not investing in biotechnology but are attracting foreign testing; and countries like Tanzania have no investment in biotechnology. South Africa has seen achievements in biosafety, biotechnology risk assessment, and institutions for risk assessment invoking the precautionary principle. Tanzania has passive regulatory measures, while Egypt and South Africa include policies addressing the precautionary principle. He stated that countries investing in biotechnology can move from the precautionary principle to other regulatory policies, and South Africa, Egypt, Kenya and Zimbabwe have science-based risk assessment that includes local inputs. He stressed the point that countries able to invest in GMOs have already developed appropriate risk assessments.

Discussion: Regarding a question on how intellectual property rights (IPR) allow the poor in India to benefit from biotechnology, Gupta responded that the current Indian patent law does not consider life forms and product patents, although there are proposals to amend this law. It was noted that regulatory data for GM crops is not as easily accepted as for pharmaceuticals or agro-chemicals. One participant suggested a correlation between countries that have embraced biotechnology and their institutional capacity to apply precaution and conduct risk assessments. One participant questioned why NGOs have been more successful in blocking GMOs in places like India and Brazil, than in other developing countries. A Brazilian participant suggested that it was because Greenpeace had successfully managed to convince the judiciary of the potential risk. Gupta said that in India the NGOs have not been that successful and this is due to the fact that high-level government officials support biotechnology.

PARALLEL SESSION: INTERNATIONAL EXPERIENCES

Jayashree Watal, CID, facilitated this session on the presentation of case studies and international experiences with risk assessment, management and the precautionary principle.

Panelists: Piet Van der Meer, Ministry of Environment, the Netherlands, highlighted his work with Central and Eastern European (CEE) countries seeking entry into the EU and in the process of adjusting their regulatory frameworks to abide with EU directives on biotechnology. He noted that biosafety frameworks need to include a regulatory framework, an administrative system, decision-making procedures and means for information dissemination. Further, the process of decision-making is key to implementing the precautionary principle and must address three steps: assessment of whether procedural requirements have been met; risk assessment on a scientific basis; and taking a decision, which is a political issue. He stated that risk assessment should address identification, likelihood and consequences of hazards, including worst-case scenarios. He provided examples of how such a model could work for different types of antibiotic resistance markers.

Van der Meer highlighted the need to find a common understanding of the principle's application, recognizing that participants in the debate have been approaching the issue from different domains, levels of generality, stages in the regulatory process and terminologies. He called for assessment of the impacts and conceivable hazards of existing alternatives, as well as further discussion to clarify different conceptions of the principle's purpose and its practical use.

Diego Malpede, Ministry of Foreign Affairs, Argentina, discussed the national context of biotechnology in Argentina, as well as its perspective on international trade and environmental discussions relating to the precautionary principle. He highlighted the national benefits of biotechnology's application as well as Argentina's regulatory structure, including its three invocations of the precautionary principle regarding proposed introductions of varieties of canola, corn and sunflower. He noted a more cautious attitude by the agricultural business sector since the Cartagena Protocol's adoption and the sector's recognition of the need for differentiated agricultural products to satisfy consumer preferences. He added that Argentina has only authorized commercial development of GM varieties already approved by the EU in order to ensure the security of its international markets.

In the area of international policy, Malpede noted common fears that the precautionary principle could be used for protectionist measures, thereby restricting access to foreign markets. He stated that effective capacity-building in developing countries is essential for the Cartagena Protocol's success. He further reviewed the principle's inclusion within the WTO's Agreement on Sanitary and Phytosanitary Standards (SPS) and suggested that precautionary action only take place: where relevant scientific information is insufficient; on the basis of available pertinent information; through efforts to obtain additional information necessary for a more objective risk assessment; and within reasonable timeframes for review. He concluded by noting that regulatory guidelines for the principle should consider: internationally agreed principles; open and transparent functioning; rigorous research, especially by independent

bodies; no more restrictions on trade than necessary; recognition that ignorance is not equivalent to lack of scientific certainty; and reasonable timeframes for decision-making.

Discussion: Participants posed questions on the principle's operationalization. Van der Meer noted that it is basically common sense, and Malpede said that Argentina's decision not to commercialize products not already approved in Europe was an application of the principle in economic terms. Several participants stressed concern with the EU's position, especially as expressed in a recent Communication on the principle claiming that the principle could easily be employed as a non-tariff trade barrier. One participant requested a more explicit definition of the EU's use of the term "sufficient certainty." One participant called for more attention to trade concerns within the debate and suggested a creative competition between trade and environmental goals. Others noted that the European system will simply take more time to work through the process given complexities of internal policy formulation, and that one of the points expressed in its Communication was to avoid the principle's use for trade protectionism. One speaker commended the EU for stating its position in writing and called upon other countries to do the same as a constructive step in the debate.

PARALLEL SESSION: POLICY AND INSTITUTIONAL IMPLICATIONS

Amanda Galvez, Facultad de Quimica, Mexico, facilitated this session on the policy and institutional implications on the evolution of national and international regulatory regimes.

Ed Soule, Georgetown University, USA, spoke about regulatory legitimacy and distinguished between weak and strong versions of the precautionary principle. He defined the weak version as being highly pragmatic, providing regulators with some flexibility in determining relevant factors and deciding on the importance of environmental risks. The strong version is risk averse, limits regulators to consideration of environmental risks and urges prohibition of the commercialization of novel technologies until they are proven safe. He suggested that in the weak version, risk is a valid concern in domestic settings and may necessitate preventing or regulating particular technologies. He also suggested that under this model economic and social considerations are taken into account. However, in the international arena, differences in industrial profiles lead to and invite selfish behavior of domestic industries. If the weak formulation is embraced, it would be a feeble addition to the US regulations concerning genetically modified pest-protected plants. He suggested that the Cartagena Protocol introduced weak precautionary language into an international trade agreement and was concerned that this would encourage production of environmentally risky agrochemicals.

In the case of the strong version, risk is expected to trump all other concerns. It is sometimes argued that uncertainty of risks supports the principle's risk-averse stance. He rejected this proposal, noting the contradiction that one can know enough about GM crops to prevent their commercialization, while not knowing enough to compare their risks to agrochemicals in order to decide which technology is preferable. He suggested that the choice of risks is a political or moral decision and that to preclude either on the grounds of such uncertainty would be very arbitrary.

Professor Philip Bereano, University of Washington, USA, characterized this conference as an expression of the political reality of the precautionary principle. Focusing specifically on the US, he noted that risk assessment, management and communication are political because definitions are not clear or obvious and costs and benefits do not fall equally on everyone. He discussed the historical context of political regimes that have effectively repressed the work of environmental activists, and invoked images of purported democracy masking the struggle for real and transparent processes in past and present administrations. He reminded participants that risks are subjective, and arise not because scientists try to discover them but because the public encounters them. He emphasized that people will react strongly if they believe the risks of GMOs are being imposed upon them without their consent, knowledge or an open and transparent process.

As for the ambiguity of the precautionary principle, he reminded participants that the "reasonable man" standard has been elaborated in the US legal system to accommodate and employ many different interpretations quite effectively. He stated that it is necessary to allow the organic nature of law to define and perfect the meaning of terms like environment and precautionary principle.

One participant saw the political struggle as a battle between industry underestimating risks and NGOs exaggerating risks, wondering which side is currently getting away with the biggest exaggeration. In response, Bereano noted that the NGO community generally addresses possible hazards for further investigation, as opposed to claiming risks.

On ways to achieve transparency, Bereano noted that issues were more salient in Europe partially because of increased tolerance of alternative views in high levels of government, whereas in the US such opinions are dismissed and consumer concerns are marginalized. One participant noted the irony that the US is a participatory democracy, while people in the UK do not generally engage in politics. Another commented that she had served on a recombinant DNA advisory committee and asserted that applications were made public and the process was open. Bereano conceded that the process was open but claimed that it was biased and included an incestuous political struggle.

Parallels were drawn between biotechnology and computer technology within the private sector, regarding the desire for a public regulation process in guiding consumer choice. Bereano responded that values beyond economic efficiency mattered in a democratic process and that the analogy is flawed, as computer technology does not pose a new environmental threat through their ability to reproduce, mutate and migrate.

Gary Comstock, Iowa State University, USA, began by quoting the philosopher, Steven Truman, who said that "rationality is not having a true set of beliefs; it is knowing when to change your mind." He suggested that the principle's formulation in the Rio Declaration implies that new technologies should not be advanced unless there is certainty that it will be safe for humans and the environment. He suggested that this is society's expression of risk aversion and that is why it has been codified into international law and why the EU has invoked the principle to justify its current moratorium on GM crops.

He asserted that a logical analysis of the principle reveals two contradicting propositions: (i) We must not develop GM crops, as some in the EU propose; and (ii) We must develop GM crops. He therefore suggested that the burden of proof is on the principle's defenders to explain why its policy implications are not incoherent. He stated that discussion should not focus on the principle, but rather on the obstacles standing in the way of delivering the potential benefits (e.g. improved nutritional content and decreased environmental and health impacts). He proposed the following questions: if biotechnology advocates want to feed the world's hungry, why aren't they putting more resources into

alternative methods proven to increase production; and what gives biotechnology's opponents the right to take away the choice of using the technology from people in other countries?

Discussion: There was insufficient time for a closing discussion.

PARALLEL SESSION: REGULATORY IMPLICATIONS

William Leiss, Royal Society, Canada, facilitated this parallel session addressing the implications of the precautionary principle for existing regulatory practices.

Panelists: Andrew Apel, *AgBiotech Reporter*, presented his ideas to unify the concepts of substantial equivalence and the precautionary principle. Noting recent criticism of both concepts, he stressed the need to develop a mutual compromise among interested stakeholders. He noted that substantial equivalence generally embodies the idea that existing organisms used as food can provide a comparative basis for assessing the safety of a similar product or variety that is modified or new. He noted that substantial equivalence allows for taking action in the face of uncertainty, whereas the precautionary principle obstructs further action under such conditions. Further, substantial equivalence does not require absolute scientific certainty, a virtual impossibility, to assess and make decisions about potential risks. He noted that conventional food crops produce toxins, carcinogens and other compounds and thereby have their own risks, yet are still publicly accepted. Through the use of substantial equivalence, such conventional crops can serve as the baseline for assessing GM varieties.

Apel did note that substantial equivalence is not equipped to address developments that are so new that they cannot be interpreted in terms of the status quo, at which point the potential risks could be assessed through the precautionary principle. He noted that the principle would thus be subsidiary to substantial equivalence and that this is consistent with the Cartagena Protocol. Finally, he called for an assessment of the risks and dangers of existing non-GM controls to their GM alternatives, suggesting the need for further research on the impacts of herbicide applications on monarchs in addition to work on Bt maize.

Mario Rodriguez, AgroBio Mexico, noted the tendency for the debate to marginalize developing countries, by presuming that they do not have expertise in ethics, applying technologies, or developing regulatory frameworks. He also noted that developing countries should not be treated as a homogenous block, given the diverse range of economic development and interest in biotechnology. He stated that there is no precautionary principle as there is no general consensus on its formulation, and instead supported the use of longstanding principles such as comparative advantage, non-discrimination and most-favored nation status. He stated that technology is an important indicator of a country's ability to derive national benefits and suggested that using the precautionary principle to curtail technological development would leave developing countries disadvantaged in the global economy.

Rodriguez stated that the principle could not be integrated into regulatory frameworks, given the inability to achieve social consensus on development objectives. Alternatively, he proposed concentrating on the role of biotechnology in development, noting that developing countries that want biotechnology generally have the appropriate institutions to regulate it. He expressed concern that the principle's use in the Cartagena Protocol would allow discrimination in trade and lead to the development of trading blocks around those accepting and rejecting biotechnology. He concluded by noting that in the Mexican context, the country needs a regulatory framework matching the US and Canada, given the significant volume of trade with these two countries.

Discussion: Noting disagreement with Rodriguez on the impossibility of integrating the principle into national regulatory frameworks, one participant stressed the sovereign right of countries to address uncertainty in their own manner and suggested strengthening capacity building to assist its integration. Another participant questioned whether irradiated foods and non-dolphin safe tuna would be considered substantially equivalent to their counterparts. He stated that substantial equivalence does not permit consideration of externalities and thereby provides no better ground for decision-making than the precautionary principle. Apel stressed the need to look at differences in products and avoid other externalities. Responding to a question on whether ethics should be factored into such decision-making, Apel replied that such concerns complicate the debate, which should be kept as simple as possible. Rodriguez then questioned whether it would be ethical to take a decision using a principle as recognizably ambiguous as the precautionary principle. Some participants emphasized the need to consider environmental externalities, especially in the case of mega-diverse countries such as Mexico. Finally, one participant called for further examination of the ambiguities and inadequacies within existing risk assessment procedures.

CLOSING SESSION

During the closing session, participants heard summaries of the four parallel sessions and then had a general discussion on the results of the meeting and areas for future work.

Amir Attaran, CID, summarized the session on national experiences, observing that the presentations overlapped constructively to demonstrate that developing countries do have the institutional capacity to regulate biotechnology, which belies rhetoric that they must be protected from it. He highlighted: de Castro's illustration that Brazil's regulatory system has developed enough to have hit a roadblock with non-commercialization; Gupta's point that India recognizes tropical biotechnology as different from non-tropical biotechnology; and Mugabe's outline of the hierarchy of biotechnology development in Africa. Attaran noted that all three speakers expressed the desire to embrace and not retreat from biotechnology.

Jayashree Watal, CID, reviewed the session on international experiences and the presentations, noting that Van der Meer's presentation provided experiences from his work in the CEE countries and his emphasis on developing a common understanding of the precautionary principle. She highlighted Malpede's review of Argentina's national biosafety experiences and perspective on the implications of the Cartagena Protocol and the WTO's SPS Agreement. She noted progress in moving from generalities to a greater level of specificity, while stressing the need for further work in this direction.

Amanda Galvez, Facultad de Quimiqa, Mexico, summarized the session on policy and institutional implications, noting Soule's discussion of strong and weak formulations of the precautionary principle and their implications for assessing the risks of GM and non-GM agricultural practices. She noted that Bereano traced the US history of preventive measures taken from the 1970s to date, and stressed the public's role in asking questions about new technologies. Regarding Comstock's presentation, she highlighted his call for scientists to convey their views to the public and to focus on biotechnology's benefits as well as the problems of traditional agriculture.

William Leiss, Royal Society, Canada, highlighted his session's difficulties in addressing the regulatory implications of the precautionary principle. He noted Apel's presentation on unifying the precau-

tionary principle with substantial equivalence, highlighting Apel's final conclusion that substantial equivalence could generally serve as a replacement for the precautionary principle in dealing with situations of uncertainty. He said that Rodriguez generally disapproved of the precautionary principle, instead preferring that the current debate shift to the use of biotechnology as an economic development tool for developing countries. Leiss suggested that future efforts address the issue in greater detail, perhaps through a comparative analysis of actual cases or a discussion of the implications of a few formulations of the precautionary principle. He concluded by highlighting a question raised by Rodriguez as to whether the precautionary principle's application would result in unfair advantages, particularly between developing and developed countries.

Discussion: Several participants disagreed with Attaran's general reference to "developing countries," calling for different criteria in referring to countries with such diverse bases in biotechnology. Gupta clarified that India does indeed have capacity and regulations, but that the process remains in a state of evolution. Attaran noted that developing poor tropical countries will be relying upon those with biotechnology, and that we cannot rely on the private sector alone but need public funds for poor developing countries. One participant suggested that understanding how externalities impact trade will enable economists to better participate. Another advocated creation of a "toolbox" to come to better terms with the precautionary principle, including a database containing relevant information on crops and biotechnology.

One participant called for comparative assessments of why some developing countries, like Kenya, Brazil and India, do not allow commercialization of GM crops, whereas others like China do. He suggested that democratic structures could be a factor. Another said that globalization is the true context for this debate, as people interact on a profit basis. One participant stated that failure to criticize existing regulatory processes leaves an unbalanced conclusion and that recommendations should ensure data gaps are filled. Another participant concluded that the precautionary approach may condemn the comparative advantages of some developing countries using biotechnology. One participant said that determining what is "insufficient knowledge" would greatly facilitate future discussions. Another said that whether or not the precautionary principle is used, a comparison of advantages and disadvantages requires working across scientific disciplines and in different field settings, rather than in a laboratory.

Closing Remarks: Calestous Juma, CID, then provided some closing remarks and reflections on the meeting and its outcomes. He suggested that there needs to be a co-evolution between technological and institutional change, in order to resolve safety questions. He noted that all are interested in precaution as a guiding principle, but that there are differences in defining it. He stated that if this was solely a domestic discussion it would be easy to resolve, but that domestic actions taken in one country are bound to have implications for others. He anticipated that the Cartagena Protocol's entry into force would generate guidelines on how to apply the precautionary principle. He said that if we do not have common and normative standards, it will be difficult to make sense of the principle and to promote its operationalization. He suggested that such standards will most likely be initially developed at the national level. He noted that despite numerous ecological and human health studies, the international community is still not able to agree on establishing and carrying out domestic assessments of biotechnology. He stressed the need to generate interest in evolutionary biology, noting that ignorance of ecosystem functions increases uncertainty. He emphasized the important role of the public sector.

Juma stated that he would produce a summary reflecting his views of the conference (to be made available at http://www.cid.harvard.edu/cidtech/), and invited all participants to contribute papers for inclusion in a special journal issue. He anticipated organizing further conferences on IPR, ethics and institutional innovations associated with molecular biology.

THINGS TO LOOK FOR

INTERNATIONAL MARINE BIOTECHNOLOGY CONFERENCE: This conference will be held from 29 September – 5 October 2000 in Townsville, Australia. For more information, contact: AIMS; tel: +61-7-4781-6219; fax: +61-7-4781-5822; e-mail: imbc_2000@aims.gov.au; Internet: http://www.aims.gov.au/imbc-2000

SECOND IUCN WORLD CONSERVATION CONGRESS: The second WCC will be held from 4-11 October 2000 in Amman, Jordan. For more information, contact: Usila Hult Bunner, IUCN, Gland, Switzerland; tel: +41-22-9990001; fax: +41-22-9990002; Internet: http://www.iucn.org/amman/index.html

EUROPABIO 2000: FOURTH ANNUAL EUROPEAN BIOTECHNOLOGY CONGRESS: The congress will be held from 9-13 October 2000 in Edinburgh, Scotland. For more information, contact: EUROPABIO Congress Secretariat, EUROPABIO; tel: +32-2-735-0313; fax: +32-2-735-4960; e-mail: mail@europa-bio-be; Internet: http://www.europa-bio.be

FIRST NORTH AMERICAN SYMPOSIUM ON UNDERSTANDING LINKAGES BETWEEN TRADE & ENVIRONMENT: The symposium will be held from 11-12 October 2000 in Washington, DC, USA. For more information, contact: the CEC Secretariat, Montreal, Canada; tel: +1-514-350-4302; fax: +1-514-350-4314; Internet: http://www.cec.org

WORLD TRADE AND ENVIRONMENT: DO WE NEED NEW REGULATIONS AND INSTITUTIONS? Sponsored by Loccum Protestant Academy in collaboration with UNEP, this meeting will be held from 11-13 October 2000 in Hannover, Germany. For more information, contact: Andreas Dally, Evangelische Akademie Loccum, Postfach 21 58, D-31545, Rehburg-Loccum, Germany; tel: +49-5766-81-108; fax: +49-5766-81-128; email: Andreas.Dally@evlka.de; Internet: http://www.loccum.de

RAISING AGRICULTURAL PRODUCTIVITY IN THE TROPICS: BIOPHYSICAL CHALLENGES FOR TECHNOLOGY AND POLICY: This conference, hosted by the Center for International Development, will be held from 16-17 October 2000 at Harvard University in Cambridge, MA, USA. For more information contact: Derya Honca; fax: +1-617-496-8753; e-mail: Derya_Honca@KSG.Harvard.Edu; Internet: http://www.cid.harvard.edu/cidbiotech/homepage.htm

CODEX ALIMENTARIUS: The 33rd Session of the Codex Committee on Food Hygiene will meet from 16-20 October 2000 in Washington, DC, USA. For more information, contact: Alan Randell, FAO, Rome; tel: +39-6-5705-4390; fax: 39-6-5705-4593; Internet: http://www.fao.org/WAICENT/FAOINFO/ECONOMIC/ESN/codex/default.htm

POLICY AGENDAS FOR SUSTAINABLE TECHNOLOGICAL INNOVATION: This international conference will be held from 1-3 December 2000 in London, UK. For more information, contact: Gillian Perkins, University of East London, UK; tel: +44-20-8223-4215; fax: +44-20-8223-7595; Internet: http://www.esst.uio.no/posti/UEL.html