

Biotechnology and the State of Global Negotiations

Centre for Global Studies
University of Victoria

Ms. Aimee Zweig

Introduction

Kofi Annan's We the Peoples: The Role of the United Nations in the 21st Century announces the UN's intention to convene a global policy network on biotechnology¹. This confirms the global importance of biotechnology as one of the most pressing issues of the next decade. Biotechnology is an issue that will deeply impact global policy negotiation. The scope and potential impact of biotechnology is so extensive that policy makers at the national and international level will be forced to work together to develop a global approach to regulating this burgeoning field. The urgency for this collaboration was evident at the recent Biosafety Protocol talks in Montreal (January 2000). Fuelling this urgency for policy makers is the increasing media coverage and polarized debate that has surfaced over the past 12 months. As well, the rising power of civil society and the importance of the private sector make a biotechnology network an important tool in addressing global issues related to biotechnology.

Given this context, the purpose of this paper is to provide a survey of the issues so that policy makers, financial backers and eventual participants of a global policy network may gain an understanding of the breadth of the issues related to biotechnology. The array of policy considerations related to biotechnology is so vast that not only the public, but policy makers too, can become overwhelmed. This paper seeks to bring some order to the complex world of biotechnology policy. It does not seek to be definitive in any one area, and nor is it written for those already "expert" in this area.

The first section of the paper will set out the governance structures and agreements that currently regulate biotechnology on a global scale. The next section details each of the global policy issues related to biotechnology including: ethics, environment, health, risk assessment, economic development, and public perception. The paper attempts to take a balanced approach by putting forth arguments made by both the pro and anti-biotechnology sides. Four emerging issues are then identified with some comment on how they will play out over the next few years. The paper then considers a global policy network for biotechnology and identifies potential stakeholders and funders. The paper concludes with a discussion of the role of the United Nations in a prospective global policy network for biotechnology and identifies the potential products of this network.

A. UN Convention on Biodiversity

The Convention on Biodiversity (CBD) was signed at the UN Conference on Environment and Development in June 1992. There are currently 176 participating countries including Canada and the United States (although the latter has not ratified the agreement).²

The CBD provides an international legal framework to achieve the following objectives: "the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources"³. The CBD is the first global agreement to address all aspects of biological diversity: genetic resources, species, and ecosystems. The agreement recognizes that the conservation of biological diversity is a common concern of the global community and a key part of the development process. To achieve its objectives, the Convention, in accordance with Agenda 21, promotes a renewed partnership among countries.

Given these objectives the CBD has four main areas of application:

- Parties are to develop national strategies, plans and programmes for the sustainable use and conservation of biodiversity and to integrate them into general development plans.
- Parties are to identify, monitor and maintain data on components of biodiversity.
- Parties are to introduce appropriate procedures requiring environmental Impact assessments for projects likely to have significant adverse effects on biological diversity.
- Parties are to submit reports on measures they have taken for the implementation of the Convention at intervals (the first reports were submitted in January 1998)⁴.

i. Mechanisms for Implementation

The Conference of the Parties (COP) is the governing body for the implementation of the CBD. Through consensus, the COP agrees upon and adopts procedural rules, sets meetings and decides upon budgets for the period between meetings. The COP establishes policy and guidelines for eligibility for financial resources administered by the Global Environment Facility. In addition, the COP establishes subsidiary bodies to provide advice particularly on scientific and technical issues⁵.

The Global Environment Facility (GEF) is the institutional structure that administers the financial aspects of the CBD. The GEF is directly accountable to the COP and provides reports at each regular meeting of the COP⁶. Article 20 of the CBD describes how participating countries are divided into two categories, developed and developing countries. Those countries that are deemed to be developed are required to contribute additional resources to enable developing countries to fulfil the objectives of the CBD⁷

A secretariat was established under Article 24 of the CBD to perform administrative functions to support the COP. The secretariat is located in Montreal, where it prepares reports and co-ordinates the implementation of the CBD⁸.

B. The Cartagena Protocol on Biosafety

i. Background

The Parties to the CBD established an open ended Ad Hoc Working Group on Biosafety in November 1995. The group was asked to develop a protocol on biosafety that addressed transboundary movement of any living modified organism (LMO) resulting from modern biotechnology that might have adverse effects on the conservation and sustainable use of biological diversity. LMO's are organisms capable of reproducing or replicating genetic material such as seeds, saplings or fish.

Six meetings of the Working Group were held during the period from July 1996 to February 1999. The Parties formed five negotiating groups at the February 1999 meeting: the *Like Minded Group*: most developing countries; the *European Union Group*; the *Miami Group*: Canada, USA, Australia, Argentina, Chile, and Uruguay (all major agricultural exporters); the *Compromise Group*: Switzerland, Norway, Japan, Korea, Mexico, Singapore and New Zealand; and the *Central and Eastern European Group*. As no consensus was reached in the last meeting in Cartagena (February 1999), informal consultations continued and the Extraordinary Conference of the Parties to the CBD was held in Montreal (January 2000). The Parties finally reached an agreement at 6:00 a.m. on January 29 in Montreal⁹.

ii. Highlights of the Protocol

The Scope of the Cartagena Protocol is limited to transboundary movement, transit, handling and the use of all living modified organisms that may have adverse effects on biological diversity, including risks to human health. Food safety is not addressed in this Protocol and only some provisions of the Protocol apply to LMOs in transit or in "contained use". In addition, pharmaceuticals for humans that are covered under other international agreements or organizations are exempted¹⁰.

Advanced Informed Agreement (AIA) procedures apply prior to the first transboundary movement of LMOs for intentional release into the environment. Decisions by importing countries are to be made based on risk assessments and pursuant to specified procedures and time frames. Failure to communicate consent does not imply consent to import¹¹.

Information Sharing on Domestic Approvals of LMOs destined for food, feed and processing (bulk commodities) is required within 15 days of granting such approvals. This information will be made available in a Biosafety Clearing House. Providing this advanced information will allow potential importers to advise what regulatory requirements would apply to the first import of such LMOs. Existing domestic regimes will apply to all imports. Those countries without domestic regulations may make first import decisions based on risk assessment procedures outlined in Annex II of the Protocol within 270 days¹².

Identification of LMOs is required for shipments intended for food, feed or processing (bulk commodities) with the phrase "*may contain*" (LMOs not intended for introduction into

Section 2: Global Governance Structures and Agreements

the environment)¹³. Negotiations on a more detailed labelling regime are to be completed within two years of the Protocol taking effect.

Trade with Non-Parties must be consistent with the objective of the Protocol. This is important for countries such as the USA which cannot ratify the Protocol until they have ratified the CBD¹⁴.

Socio-Economic Considerations (i.e. the value of biodiversity to indigenous and local communities) can be taken into account, consistent with the Parties' international obligations in risk management but not risk assessment¹⁵.

Relationships with Other International Agreements are to be mutually supportive with a view to achieving sustainable development. This does not imply a change in the rights and obligations under existing international agreements nor does it subordinate the Protocol to other agreements. Although the Protocol incorporates the CBD's dispute settlement provisions, Parties have preserved their right to have trade disputes resolved in the World Trade Organization.

The Precautionary Principle states that lack of scientific certainty due to insufficient information of potential adverse effects (including risks to human health) shall not prevent a Party from making a decision on the import of an LMO, however, the principle is understood to be linked to a science-based process for taking import decisions.

C. The World Trade Organization (WTO)

The WTO administers two agreements that have a bearing on international trade in biotechnology or products derived from biotechnology. Both agreements exist within the Final Act that helped establish the WTO in 1995. Any trade disputes related to these two agreements are settled by the WTO dispute settlement system.

i. The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)

The SPS Agreement sets out the rules governing trade to protect food safety and animal and plant health. The SPS Agreement, while maintaining the sovereign right of governments to regulate the level of health protection it deems necessary, also ensures these rights are not used for protectionist purposes that could result in trade barriers. The Agreement reduces possible arbitrariness of decisions by ensuring that trade decisions are based on scientific data related solely to ensuring food safety and animal and plant health. In addition, the Agreement encourages the use of international standards where appropriate to ensure consistent regulation is applied to protect food safety and animal and plant health. A special committee has been established within the WTO to facilitate the implementation of all aspects (including compliance) of the SPS Agreement. In addition, participating governments are required to notify other countries of any new or amended SPS requirements which impact trade, and to set up offices (called "Enquiry Points") to respond to requests for more information on new or existing measures¹⁶.

ii. The Agreement on the Technical Barriers to Trade (TBT Agreement)

The TBT Agreement is set out to ensure that regulations or standards do not create unnecessary barriers to trade. The TBT Agreement differs from the SPS Agreement in that it covers all technical regulations, voluntary standards and the procedures to ensure these are met (except those falling under the SPS Agreement). For example, the TBT Agreement would cover labelling requirements of food and pharmaceutical restrictions. The Agreement encourages countries to use international standards where appropriate, but does not require them to change their levels of protection as a result. In addition, countries may introduce TBT regulations when necessary to meet objectives such as national security¹⁷.

D. Organization for Economic Cooperation and Development (OECD)

The OECD with twenty-nine member countries has developed various working groups on biotechnology including an internal coordination group to facilitate the different agendas. The Working Group on the Harmonization of Regulatory Oversight in Biotechnology works to "...ensure that environmental health and safety aspects are properly evaluated, while avoiding non-tariff trade barriers to products of the technology."¹⁸ The main work of the group is to produce consensus documents on specific issues related to biotechnology and maintain a database (Biotrack Online) on LMO approvals and field trials. In addition, the group develops standardized definitions and guidelines for biotechnology and products. Currently, the various working groups are preparing reports in response to the request from the heads of state of the G8 to "...undertake a study of the implications of biotechnology and other aspects of food safety."¹⁹ This program of work includes five elements:

- A report on the safety of novel foods
- A report on related environmental issues
- A compendium describing national and international food safety systems
- The results of the OECD consultations with NGOs
- A report on the OECD Conference on *GM Food Safety: Facts, Uncertainties and Assessment*

E. The Food and Agriculture Organization (FAO) of the UN

The FAO is involved in administering two international agreements related to biotechnology. The first agreement related to food and food processing, the Codex Alimentarius, is co-administered with the World Health Organization. The second agreement, the International Plant Protection Convention (IPPC), is focused on protecting plants from the spread of harmful pests.

i. The Codex Alimentarius

The FAO along with the WHO developed the Codex Alimentarius (the Codex) in the 1960's in order to harmonize widely divergent food standards and to ensure their implementation. The Codex provides a forum for the development of codes governing hygienic processing practices and makes recommendations relating to compliance with those standards. The main objective of the Codex is to protect the health of consumers and ensure fair practices in the food trade²⁰. The WTO's SPS and TBT Agreements both recommend the use of the Codex as the preferred international standard for trade in food.

ii. International Plant Protection Convention (IPPC)

The second agreement, the IPPC, seeks to "...secure common and effective action to prevent the spread and introduction of pests of plants and plant products and to promote measures for their control."²¹ The IPPC is the source for international standards for the phytosanitary measures affecting trade (as cited in the WTO's SPS Agreement).

F. United Nations Conference on Trade and Development (UNCTAD) & the United Nations Environment Program (UNEP)

In February 2000, UNCTAD and UNEP jointly launched a task force to build an international consensus on trade and environment issues so that policies are mutually supportive of sustainable development. The task force is to focus on building capacity in developing countries and countries with economies in transition to integrate policies on trade, environment and sustainable development²².

A. Ethical Considerations

Ethical considerations underlie each of the policy issues related to biotechnology. Although one cannot separate values from important decisions regarding biotechnology, products and uses, one can explicitly address differing value frameworks and strive to reconcile these differences. The following discussion outlines three areas of ethical consideration related to biotechnology.

i. Intellectual Property Rights

Intellectual Property Rights (IPR) concern patents, designs, trademarks, plant breeders' rights, copyright and trade secrets. In the evolving field of biotechnology it is patents that create the most disagreement. Patents are of national origin and are only enforceable in the country which grants the permit for a period of up to 20 years²³. IPR are "...the legal instruments which confer protection on processes or products of research and development efforts and formally assure the allocation of benefits to the innovator in return for full disclosure to society."²⁴ Two recent agreements have sought to build on an older agreement, the International Union for the Protection of New Varieties of Plants (UPOV), to harmonize regulations in an international forum: the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) which entered into force in 1995, and the Convention on Biological Diversity (CBD) which entered into force in December 1993.

a. The Agreements

UPOV, created in 1961, provided protection by giving plant breeders rights to particular varieties, but allowed an exemption for farmers to save seed for their own use (farmers privilege). A 1991 amendment to UPOV extended plant breeders rights to all plants and species that satisfy the criteria of distinctiveness, utility and stability. In addition, exclusive rights are given to the breeder covering all harvested material and the collection of royalties from the sale of seeds²⁵. The 1991 amendment gives patent like protection for plant varieties.

The TRIPS Agreement (Article 27.3b) stipulates that member states must protect plant varieties by patents or by an effective "sui generis" (or unique) system. More specifically, member countries must, "...make patents available for any inventions, whether products or processes, in all fields of technology without discrimination, subject to the normal tests of novelty, inventiveness and industrial applicability."²⁶ The agreement does provide for the patents exclusion where an invention's exploitation should be prevented to protect morality²⁷

The CBD has the stated objectives of conserving biological diversity and the equitable sharing of the benefits of biological diversity. These objectives can be seen to be in direct conflict with the TRIPS and UPOV agreements, as monopolies may encourage the spread of monocultures, which could inhibit biodiversity. In addition, the sharing of benefits and transfer of technology may be inhibited by the TRIPS and UPOV agreements.

b. The Issues

The objective of IPR, as stated in TRIPS, is to contribute to the promotion of *technological innovation* and to the *transfer of technology*²⁸. These two objectives provide a context for the controversial issues pertaining to IPR.

The promotion of *technological innovation* is based on incentives. Developing a new transgenic plant for commercial use can cost over \$150 million (US)²⁹. Some argue that without patent protection the investment in research and development could never be recovered and therefore innovation would be stifled. Others argue however, that farmers, especially in the developing world, must have the ability to practice traditional methods, such as saving seeds. In addition, excessive protection can minimize consumption and maintain high prices.

The *transfer of technology* and the sharing of benefits is a multi-faceted issue. With no legal model or paradigm in place the transfer of technology proceeds on an ad hoc basis³⁰. As a high concentration of patents rest with very few multinationals, there is a danger that a monopoly situation could raise prices so that the new technologies are inaccessible to developing countries. Access to these technologies may be dictated or limited by the willingness of the patent holders to license the new technologies.

Biopiracy or theft of resources is currently an issue particularly in some developing countries where biodiversity is rich. In some cases, it has been alleged that companies are stealing genetic resources and traditional knowledge from local populations, patenting, then selling these resources³¹. This is not consistent with IPR, however, as patents should only be extended to new inventions that are not obvious (traditional knowledge can be viewed as “obvious”). In addition, the CBD has provisions (Articles 15, 16 and 19) that stipulate prior informed consent and a contractual agreement for access to genetic resources within a nation's sovereign territory³².

Some developing countries, such as India, are developing a “sui generis” system that would help protect indigenous knowledge, ensure equitable benefit sharing and facilitate the access to and transfer of technology. This type of system builds on the spirit of the CBD by recognizing the sovereign right of states to regulate access to their resources³³. Some argue, however, the construction of biodiversity as a global resource that can be integrated into international markets through the use of IPR may undermine local regimes of biodiversity and inhibit the development of indigenous people³⁴.

ii. The Human Genome Project and Moral Limits

The Human Genome Project (HGP) is a \$3 billion project funded by the US and British government. The goals of the project are to: identify all the approximate 100,000 genes in human DNA, determine the sequences of the 3 billion chemical bases, store this information in searchable databases for analysis and address the ethical, legal and social issues that may arise from the project³⁵. With this major project and other projects in the private sector, the mapping of human DNA sequences is expected to be complete by 2003. The ethical ramifications of this new body of knowledge are extensive.

Some of the ethical problem areas identified by the project staff are:

- Fairness in the use of genetic information;
- Privacy and confidentiality of genetic information;
- Psychological impact and stigmatization due to an individual's genetic differences;
- Genetic testing of an individual for a specific condition due to family history;
- Reproductive issues;
- Gene therapy;
- Genetic enhancement;
- Fairness in the use of genetic technologies;
- Clinical issues;
- Commercialization of products;
- Conceptual and philosophical implications in relation to human responsibility, free will versus genetic determinism, and concepts of disease and health³⁶.

These types of ethical dilemmas lead to the debate around the "*moral limits*" of biotechnology. This debate revolves around not whether one can manipulate nature but whether one should. Differing cultural and religious perceptions of what limits or regulations should be placed on biotechnology are difficult to reconcile. These perceptions make up an entire continuum of responses to biotechnology: from limits based solely on scientific risk analysis to moral repugnance to any form of human intervention in nature. An effort must be made to assess the level of moral support so that global policy may better reflect public perception³⁷.

iii. Liability

The debate on liability revolves around whether to create a liability and redress mechanism and what form it would take. A liability mechanism would allow for financial responsibility to be assigned to the exporter (or the insuring agent) if damage resulted from the import of a biotechnology product (or LMO)³⁸. Environmental groups would argue for a strong liability mechanism given the potentially detrimental effects of LMOs and the irreversible effects once released into the environment. Others argue that there have been no negative environmental or health effects to date, therefore there is no need for a liability mechanism.

Currently, under the recently negotiated Cartagena Protocol on Biosafety (January 2000), a four year time frame within which negotiators will develop rules and procedures on

liability was agreed. Although the issue of liability was postponed, there was a general consensus that rules are necessary and a commitment was undertaken by the parties to develop those rules within the timeframe allotted³⁹.

B. Environmental Considerations

There are four main environmental areas that may be impacted by the widespread use of biotechnology: pesticide/ herbicide use, genetic pollution, climate change and biodiversity. In each of these areas there is some disagreement on the impacts biotechnology will have on the environment. The following will provide a survey of the issues and includes dissenting opinions.

i. Pesticide/ Herbicide Use

There are two main traits that are genetically engineered into crops that may impact the level of pesticide or herbicide use: *herbicide tolerance*, and *insect resistance*. Herbicide tolerant (HT) crops are varieties on which herbicides can be used to kill weeds, without killing the crop itself⁴⁰. The suppliers of herbicide tolerant seeds would argue that herbicide use on these crops is less detrimental and more effective than extensive pesticide use. Their opponents argue that herbicides pollute groundwater and HT crops ignore other more sustainable methods of controlling weeds such as intercropping and mulching. Some researchers have found that uncommon weeds emerged with the use of HT crops, thus requiring additional herbicides⁴¹. In addition, the multinational corporations such as Monsanto, Novartis and Dupont are the largest providers of both HT crop seeds and the necessary herbicides, creating a conflict of interest⁴².

The most controversial of these genetically engineered traits are insect resistant crops. Most notable are crops that produce toxins called Bt which kill some insect pests. Because these crops produce their own insecticide, they drastically reduce the need for chemical pesticides. Opponents to Bt crops argue that these crops increase the resistance of pests to both insecticides and the crop itself. Proponents of Bt, in order to avoid this, have set aside refugia (land where non-Bt crops are planted), as a haven for the pests. In this way, the pests that survive the Bt crop will breed with the non Bt insects from the refugia, so that widespread resistance will not develop⁴³. Studies on the effects of Bt crops on beneficial insects such as bees and butterflies have produced conflicting or inconclusive results⁴⁴. This will be discussed further in the section below on genetic pollution.

ii. Genetic Pollution

Genetic pollution refers to the movement of engineered genes (or transgenes) into non-target species. This pollution can be manifested in everything from bugs, to weeds, to wild fish stocks. "Transfer of certain genes, such as resistance to insects, fungi and viruses could increase fitness (ability to reproduce) of any resulting hybrids, possibly forming aggressive weeds or plants that swamp wild populations."⁴⁵ Very little research and no long term studies on the impact of gene flow has however, been done to assess the impacts.

Another related type of genetic pollution, as noted above, is the impact of genetically modified crops or species on non-target species such as butterflies and wild fish stocks. As these non-target species interact with genetically modified crops or species, unknown effects may occur. Research has provided conflicting results on the impact of this interaction.

iii. Biodiversity

There are three main avenues of risk to biodiversity resulting from biotechnology and its products. Some feel that biodiversity may be lost, as a result of the displacement of traditional crops, by a small number of genetically modified cultivars⁴⁶. This may result in widespread monocultures. The potential for gene flow may negatively impact biodiversity by creating superbreds that destroy either plants or entire ecosystems. The third area of risk is the potential for natural or "in situ" ecosystems to be destroyed, therefore limiting research on gene pools of native ecosystems. Without this research and the resulting knowledge, it would be difficult to protect the biological diversity of the given ecosystem⁴⁷.

Proponents of biotechnology feel that research methods and new biotechnologies will assist in the conservation of biological diversity. For example, marker assisted selection and DNA fingerprinting may assist in the conservation and characterization of biodiversity⁴⁸.

iv. Climate Change & Clean Technologies

Biotechnology has great potential to impact positively climate change and to develop clean technologies. Biotechnology and its products may provide a clean alternative to using environment damaging fossil fuels. For example, genetically engineering switch grass whose by-product ethanol can be produced economically could put an end to our reliance on oil. As well, other crop plants are being used to produce lower cost oils, lubricants and plastics. Some feel that "industrial farmers" in the U.S.A will be able to grow enough fuels and chemicals to almost eliminate the American dependence on foreign oil within 25 years⁴⁹. Biotechnology applications provide a clear opportunity to respond to climate change issues and the Kyoto Protocol.

A multitude of 'clean technologies' that utilize biotechnology to reduce, remove or prevent pollution are being actively developed. Examples of this are: biological gas cleaning utilizing biofiltration and bioscrubbers to reduce pollutants and bioremediation and phytoremediation which utilizes biotechnology applications to efficiently restore and rehabilitate contaminated sites⁵⁰.

C. Health Considerations

Biotechnology may impact health in three main areas: pharmaceuticals, genetically modified foods, and the global food supply. On the surface biotechnology may seem to have a positive impact on each of these areas of health. There are dissenting opinions,

however, on the potential for negative health consequences of pharmaceuticals and foods that are the products of biotechnology.

i. Pharmaceuticals

Medical biotechnology holds great promise. Biotechnology already provides for the development of better, safer drugs and vaccines⁵¹. The burgeoning field of pharmacogenomics (the development of new drugs through the application of knowledge of DNA) will provide new medications that will be individually tailored to meet medical needs. This new field can move medicine from being strictly reactive to the modification of disease in a proactive way. Regenerative medicine, or therapeutic engineering, will provide new techniques to repair or re-grow injured or diseased cells⁵².

The other side of the evolution of pharmaceuticals is the potential risks the new technology could create. There are growing national security implications in the context of biowarfare and bioterrorism. In addition, the potential for discrimination in employment, education or insurance, based on genetic information, is a real concern⁵³.

ii. Genetically Modified Foods

Currently, there is no evidence to suggest that the process of genetic modification (GM) is harmful to human health⁵⁴. At a recent OECD conference, Biotechnology and Food Safety, there was consensus that no harmful effects on human health have been detected⁵⁵. It is widely recognized, however, that without any longitudinal data, the possibility of negative effects of GM foods cannot be summarily rejected⁵⁶. In fact, a report commissioned by the United Kingdom recommended instituting a system for population health surveillance to detect any adverse health effects over time⁵⁷. Some more radical anti-biotechnology groups feel a moratorium on GM foods should be implemented until more longitudinal data is collected.

A potentially positive health effect of GM foods is the development of nutritionally enhanced staples such as rice. Some Swiss scientists have developed a GM rice with higher levels of vitamin A and iron. It is estimated that nearly 2 billion people are iron deficient⁵⁸ and millions of children suffer from blindness resulting from vitamin A deficiency. As rice is the staple for approximately 2.4 billion people, this application of biotechnology could significantly positively impact human health⁵⁹.

There are two other notable health risks of GM foods. Some GM foods contain marker genes for antibiotic resistance which are inserted to aid selection of genetically-engineered strains. These antibiotic resistance genes have no agronomic or nutritional value, but could contribute to the further build up of bacteria resistant to antibiotics⁶⁰. The second potential health risk is the possibility of GM foods containing toxins, carcinogens or allergens that are not traditionally found in the given food⁶¹. Others argue toxins, carcinogens or allergens are equally as likely to occur in non-GM foods⁶².

iii. Global Food Supply

Biotechnology has the potential to increase the global food supply so that the health needs of the global community can be met without further degrading the environment⁶³. Norman Borlaug estimates that to meet projected food demands by 2025, the average cereal yield will need to increase by 80% over the 1990 average⁶⁴. Building on the successes of the "Green Revolution", some feel the "Doubly Green Revolution", which utilizes biotechnology to increase yields while being environmentally sustainable, will be required to meet the expanding population in the next 20 years⁶⁵.

Others put forth that global production of food is sufficient to meet the demands of the world population, despite the fact that 840 million people suffer from malnourishment, the problem being one of maldistribution⁶⁶. In addition, some feel that because biotechnology is being driven by the private sector, innovations are mainly being realized in the developed world with little transfer of technology to the developing world⁶⁷.

D. Risk Assessment/Management

All new technologies require appropriate risk assessment and management. In terms of the necessary regulatory frameworks and standards, there are two contentious policy issues: risk assessment methods, specifically the notion of "substantial equivalence", and labelling GM foods and other products of biotechnology. In order to manage the risk related to biotechnology and its products, global policy makers have recognized the need to build the regulatory capacity in developing countries. The third fractious issue related to risk assessment and management is information sharing and technology transfer, so that regulatory bodies can make decisions based on the most current information.

i. Regulatory Frameworks and Standards

The main products of biotechnology, food and agricultural products, are regulated under national regimes as well as international regimes such as the Codex Alimentarius (FAO/WHO), the UN Convention on Biological Diversity and the resulting Cartagena Protocol on Biosafety. More recently (March 2000) an international task force has been established by the Codex Alimentarius Commission to develop standards and guidelines for foods derived from biotechnology to supplement the CBD⁶⁸.

a) Substantial Equivalence

The main item of contention related to risk assessment guidelines is the idea of substantial equivalence. The concept of substantial equivalence involves comparing the characteristics, including the levels of key nutrients and other components, of GM food to traditionally produced food⁶⁹. In 1993 the OECD established the principle of substantial equivalence⁷⁰, after which time it became the national and international standard for assessing the risk of GM foods. Currently, in Canada, if a product meets the test for substantial equivalence, then the producer considers the nature of the modification (process) and runs further tests such as animal feed trials⁷¹.

Supporters of the substantial equivalence method argue that it is appropriate to assess the characteristics of the product such as allergenicity rather than the method by which the product was created⁷². The main assumption that underlies this position is that food safety considerations are generally of the same nature for both GM and non-GM foods⁷³. Others, including a scientists group, argue that this is an unscientific method of assessment. More specifically, the group argues that there is a difference between GM and non-GM foods because the insertion of a foreign gene may cause unpredictable metabolic changes which are not currently tested. Generally, this group feels that more rigorous and long-term testing is required to assess these potentially hazardous substances⁷⁴.

b) Labelling

The recent Cartagena Protocol requires the labelling of shipments of bulk commodities such as GM foods and feed with the phrase "may contain". Further details on labelling LMOs will be negotiated over the next two years under this protocol⁷⁵. It is the labelling of retail GM products, however, that is the most controversial. Different nations have different labelling regimes. For example, Japan, Australia, Brazil and the European Union (EU) all have blanket mandatory labelling, although the minimum level of GM ingredients that trigger labelling requirements differ⁷⁶. Although it appears from opinion polls that the Canadian public is in favour of labelling GM foods, there is no consensus on whether this should be mandatory or voluntary labelling⁷⁷.

Those in favour of labelling GM foods feel it is their right as a consumer to have the choice of whether to purchase GM foods or not. As choice and honesty are fundamental values for consumers, many feel that they should have the ability to choose to buy GM food, and thus the ability to avoid them for religious, cultural, other personal or ethical reasons⁷⁸. In addition, public mistrust of government and large corporations to protect the best interests of the consumer fuels these demands for labelling.

Opponents of labelling feel that if a GM food meets the test of substantial equivalence and do not present any risk, there is no scientific basis for labelling that food. As genetic modification is a process, labelling food based on the process used to create it, instead of the actual content of the food, is akin to labelling a car with a sign saying 'wrenches used'⁷⁹. In addition, many feel that the demands for labelling are driven by anti-biotechnology activists who feel labelling will stigmatize GM foods so that sales will be stunted. Finally, opponents feel that any labelling regime will impose excessive costs on GM food producers, as it would force the segregation of biotech and non-biotech crops⁸⁰.

The logistics of both mandatory and voluntary labelling of GM foods are problematic. For example, there is no consensus to date on what constitutes a GM food and it is nearly impossible to measure GM DNA or protein molecules in most foods made from the current generation of GM crops. In addition, the definition of biotech foods is not standardized so that some regulatory regimes ignore mutagenesis (gene changes caused by deliberate exposure to nuclear radiation)⁸¹. There is also concern that labelling would only provide a warning instead of providing any useful information for the consumer. With all of these

potential difficulties in mind, policy makers will have to decide on one of the three following models: "Genetically Modified" labelling; "GMO-free" labelling; or alternative information sources (ie. 1-800 numbers, databases or point-of-purchase information)⁸².

ii. Capacity Building in Developing Countries

Effective risk assessment and management requires regulatory infrastructure, strong political and government support, as well as the human resources to carry out the work. Other issues such as access to information and technology will play an important role in risk assessment and management. The environmental and health risks associated with biotechnology have the potential for a global impact. For this reason it is essential that all countries, not just the main producers of biotechnology products, have the internal capacity to assess the risks associated with this new technology.

Regulation is an inherently political process that will be subject to the conflicting interests of both the public and private sector. In addition, there are those that feel because the market for biotechnology products is controlled by a limited number of multinational corporations, they will inhibit the ability of developing nations to regulate their products. Developing regulatory frameworks that are transparent and based on scientific principles will prove difficult in such a highly politicized environment⁸³.

Various international organizations and recent conventions have, however, begun to address these concerns. Specifically, the OECD has participated in developing two databases (BioTrack Online and Binas Online) that track regulatory issues related to biotechnology in both their member countries and other countries⁸⁴. The Biosafety Information Network and Advisory Service (Binas) is an initiative of United Nations Industrial Development Organization (UNIDO) which, in conjunction with the OECD, developed Binas Online to help facilitate information sharing and technology transfer to support regulatory regimes⁸⁵. The recently signed Cartagena Protocol sets out global risk assessment guidelines that may help to build the capacity of developing countries to undertake their own regulatory regime⁸⁶. In addition, this protocol proposes the development of a clearing house mechanism, as did the Convention on Biological Diversity, to amass a database of information on both biosafety and biodiversity⁸⁷. Other organizations such as the World Bank are developing partnerships through funding arrangements that build capacity in developing countries to regulate the products of biotechnology⁸⁸.

E. Economic Development

The economics of biotechnology and its products are staggering. In 1998 the global market for biotechnology products surpassed US\$13 billion, with most of the products medically related⁸⁹. Given the size and potential for the biotechnology market, its development is almost certain. The global imperative for sustainable development and emerging trade issues has, however, the potential to either impede or foster this growth.

i. Economic Growth

Economic growth related to biotechnology is intrinsically linked to how well the international community deals with the various policy issues including health, environment, risk assessment, ethics and public perception. For example, the rapid advancements in the world of human genomics hold great economic promise for the pharmaceutical industry. Without equitable and strong IPR laws, however, the private sector may not take on the costly research and development that is required to produce the economic benefit expected from their discoveries.

Another issue complicating the economic growth of the biotechnology sector is the fact that currently most of the work is taking place in the private sector. With widespread public distrust of multinational corporations, government must find a balance between regulating these companies for the “public good” and partnering with them to develop further the economic potential of biotechnology⁹⁰.

ii. Sustainable Development

In this era of globalization, economic development cannot be mutually exclusive of sustainability. Monsanto's development of the terminator seed is a good example of why it is essential for the private sector to embrace the concept of sustainability in order to realize sought after profits⁹¹. Biotechnology has the potential to reinforce sustainable development principles with its land-saving crops, more effective pharmaceuticals and enriched foods. As reviews of the earlier Green Revolution have revealed, however, sustainable economic development will depend not on the actual technology but how national infrastructures are developed to implement the technology⁹².

Sustainable development involves addressing environmental, health and social concerns so that development is liveable in the broadest sense of the word. As discussed earlier, capacity building, particularly in developing countries, will be an essential part of the successful integration of biotechnology and development in a sustainable and economically beneficial manner. Some see capacity building simply as a matter of training and the development of human resources. Others argue for a more broadly based approach including the development of procedures, management, organizational structures and/or strategy formulation⁹³. Whatever the prescription, it is clear that economic development must be based on sustainable development principles that build national capacities.

iii. Trade Issues

Trade in the products of biotechnology is a very complex and highly contested issue partially because of the huge economic and safety impacts it could have. As noted previously the WTO is the main governance structure for issues in trade, however, because biotechnology risks and benefits span various different governance areas, there is a great deal of uncertainty. The two main policy issues related to trade in biotechnology

products are: the relationship of the WTO to other international agreements, and the somewhat related issue of trade protectionism.

The WTO administers the SPS, TBT and TRIPS Agreements which seek to regulate potential trade restrictions that are designed to safeguard health, the environment or other national interests. It is the potential conflict between international environmental agreements that have trade related regimes, and the WTO's Agreements, that is causing so much uncertainty. Most recently the Cartagena Protocol on Biosafety has delved into the world of WTO regulation. The text of the Cartagena Protocol is sufficiently vague so that it is not immediately evident how a conflict between the two bodies would be resolved. The Protocol in its Preamble, states that the rights and obligations of parties under existing international agreements shall not change. The preamble also states, however, that the Protocol is not subordinate to other international agreements⁹⁴.

The second related issue, trade protectionism, is a function of the relationship between the Cartagena Protocol and the WTO's regime. The Protocol, under Article 11, stipulates a precautionary principle that would allow Parties to ban the import of products of biotechnology based on a relatively small amount of scientific evidence. The exporter could have recourse with an appeal to the WTO as this type of trade barrier could breach WTO regulations. The Miami Group of countries (including Canada and the US) feel that the precautionary principle may be used as a trade barrier to protect internal markets contrary to the spirit of trade liberalization⁹⁵.

F. Public Perception

As civil society gains a more powerful voice in public policy-making a public perception of issues becomes increasingly important. In the heated debate over biotechnology, its safety and potential benefits, public perception has strikingly polarized into two adversarial positions. This polarization of public opinion is driven, in part, by two factors: issues of trust and conflicting information.

i. Trust Issues

Public perception of biotechnology products in many cases is driven by a lack of trust. Multinational corporations have driven much of the development of biotechnology, and as such have drawn the suspicion of the public. As profit-seeking entities, multinational corporations such as Monsanto have not demonstrated that the "public good" will take precedence over the profit motive⁹⁶. Augmenting this mistrust is the fact that most testing of new biotechnology products is done by the producing companies themselves and not government regulators. In addition, the first wave of biotechnology products has not provided much evident benefit to the consumer, as distinct from the producer, and this has further entrenched an environment of mistrust.

Public trust in government regulatory systems is also a factor in the public perception of biotechnology. In Europe, for example, public confidence has plummeted after various food scandals, including the infamous "Mad Cow" debacle⁹⁷. Some have suggested that

public confidence, even in countries like Canada that have not had major problems with food safety, is eroded by the lack of opportunity for the public to participate in the policy and regulatory process⁹⁸.

ii. Conflicting Information

The media, government, NGOs, industry, scientists and academics all contribute to the dissemination of biotechnology information to the public. The media, however, as the main vehicle for this dissemination plays a critical role in how information is portrayed. In a 1998 Canadian opinion poll, the public ranked the media last on a relative scale of credibility on biotechnology issues⁹⁹. This poll is a good indication of the public's mistrust of the information they are receiving. Headlines such as "Food Fright"¹⁰⁰ and "Frankenfoods"¹⁰¹ only serve to sensationalize the debate on biotechnology.

Fuelling the media's enthusiastic treatment are the accusations and sometimes misleading science of both the pro- and anti-biotechnology lobbies. The anti-biotechnology lobby has, over the past few years, waged an intense public relations campaign to disparage biotechnology, including undertaking radical actions such as destroying crops and laboratories. The scientific community and industry has slowly stepped up their campaigns publishing petitions, studies and writing articles in support of biotechnology. More recently a coalition of large biotechnology companies, including Monsanto and Novartis, launched a \$50 million campaign to promote their biotechnology products¹⁰².

The often conflicting information distributed by the two sides only serves to further polarize the public perception of biotechnology. Governments and international organizations have recognized this destructive trend and are moving to set up objective, expert panels to assess biotechnology. Currently Canada has sponsored an expert panel on the future of biotechnology¹⁰³. The OECD has proposed an international panel to assess objectively biotechnology research, so that both governments and the public will have access to a reliable source of information¹⁰⁴.

A. Intellectual Property Rights

Intellectual Property Rights are influenced by a variety of ethical, social, and economic factors that make any discussion of their emergence very complex. Adding to this complexity is the speed of technological change that is outpacing the regulatory capacity of nearly every government on the planet. Despite this complexity one can speculate, based on the two issues discussed previously, technological innovation and the transfer of technology, on the emergence of IPR. In addition, a brief discussion of the emerging trends with respect to IPR considerations regarding the Human Genome Project is appropriate during this time of genetic mapping.

IPR will continue over the next few years to be strengthened in accordance with the TRIPS agreement. The TRIPS agreement regulations, with the implementation assistance of WIPO, ensure that developing country members are to have implemented IPR regimes by January 2000 and the least-developed countries to have done so by January 2006¹⁰⁵. This continued implementation of IPR regimes will help to foster the technological innovation that biotechnology promises. The struggle to balance the rights and obligations under TRIPS with the obligations of the CBD will continue to be an issue for international policy makers. These issues will next be discussed at the WTO's meeting in June 2000 of the Council for Trade Related Aspects of Intellectual Property Rights where the CBD Secretariat has been granted observer status¹⁰⁶. Given the strong momentum toward implementing TRIPS, it does not seem likely that IPRs will be weakened. Instead, one can forecast IPR regimes that are mutually supportive of both conservation and privatization, and that are reflective of each country's regional and indigenous nature.

The transfer of technology and benefit sharing will continue to be a major factor in the formulation of IPR regimes. Strong IPR regimes can serve to enhance the potential for benefit sharing. As the parties of the CBD have committed themselves to the principle of equitable benefit sharing, there is a critical mass of international policy players that will put forth strong regulations on benefit sharing. The COP5 meeting of the CBD in May 2000 will serve as a forum to flesh out the details of regulations to ensure technology transfer and benefit sharing occur. Some of the regulations that will be discussed are: prior informed consent for bioprospectors; the continuation of the traditional use of genetic resources; collaboration in education, training, research and development (with the providing country)¹⁰⁷. By implementing such regulations a shift toward a more equitable sharing of benefits and transfer of technology will occur in the near future.

The Human Genome Project and parallel private efforts to map the human genome are fuelling the heated debate on the patenting of genetic sequences. It seems unlikely that raw genetic sequences will be patentable in the future given the public declarations of Prime Minister Blair and President Clinton in support of public access to this information. Unless a researcher knows what a genetic sequence does and what its uses are, patents will be hard to come by for these raw sequences. There appears to be fairly widespread support for raising the bar on patents so that a balance may be found between the protection of R&D investments and not discouraging research by scientists who may not be able to afford licensing fees¹⁰⁸.

B. Liability

The Cartagena Protocol stipulates a four year time frame within which negotiators are to develop rules and procedures for a liability mechanism. It is not clear in the text of the Protocol however, whether this means that the rules themselves will be in place at the end of the four years (2004) or just a process for elaborating the rules¹⁰⁹. One could speculate on the basis of the time required, six years, to negotiate a liability regime for the Basel Convention on Hazardous Wastes, that a similar amount of time will be required for a liability regime on biotechnology to be negotiated¹¹⁰. Even the European Union (EU), which has been at the forefront of the precautionary approach to biotechnology, recently voted down an amendment that would introduce environmental and health liability for biotechnology producers¹¹¹. Instead, the EU will take some time to develop a comprehensive horizontal liability regime that should be introduced before the end of 2001¹¹².

The international liability regime will likely mirror many of the elements of the Basel Convention. The negotiated liability regime may contain separate rules on each phase of transboundary movement, from the production phase through international transit to the final use stage. It is likely that the new liability regime will include strong statements on prevention, capacity building and compliance as well.

C. Relationship Between International Agreements

One of the more contentious issues that will be emerging over the next few years is the relationship between international agreements, specifically the Cartagena Protocol on Biosafety, and the WTO's SPS and/or TBT Agreements. It is the use of the precautionary principle in the Protocol that may conflict with WTO rules which lean toward protecting commercial interests from trade protection.

The relationship between these two agreements will evolve over the next few years by being tested in an international appellate body, probably at the WTO. One can speculate, however, that the Cartagena Protocol has now established the "Precautionary Principle" or approach (as contained in the Rio Declaration), as a principle of environmental law. This new status is bolstered by a previous WTO Dispute Panel decision in the US-EU Beef Hormone case that concluded that the precautionary has been incorporated into the SPS Agreement.

The Protocol serves to explicitly define how and when the precautionary principle can be exercised. The Protocol's detailed rules help to fill some holes in the SPS Agreement by operationalizing the precautionary principle. For example, the Protocol, in Annex II, gives explicit details on what a risk assessment entails while the SPS does not. As well, the SPS does not mention risk management, but the Protocol makes it clear that risk management is a necessary process. In this way the two agreements can be seen to be mutually supportive.

The common practice of looking to non-WTO law to help rule on appeals of WTO law¹¹³ upholds the proposition that the two agreements can be mutually supportive. It seems, then, that the Protocol and more specifically the "Precautionary Principle", will serve as a guide within which trade in biotechnology products will be regulated in the WTO¹¹⁴.

D. Capacity Building in Developing Countries

In order for the benefits of biotechnology to be felt globally, capacity building in developing countries will have to occur in IPR, risk assessment/management and technology development. The borderless nature of biotechnology, along with the potential risks and benefits, provide a strong impetus for the international community to ensure all countries have the internal capacity to benefit from biotechnology. The UN has taken up this challenge by taking a leadership role in establishing capacity building initiatives so that the benefits of biotechnology can be shared equally.

Agenda 21 has set the world stage for UN initiatives to strengthen human resource and institutional capabilities for environmentally sound management of biotechnology (chapter 16)¹¹⁵. The political will is there to build the institutional and technical capabilities in developing countries, particularly to offset the overwhelming power of the multinational corporations which are involved in the biotechnology sector. It is this political will, with leadership from the UN, that will forge the necessary partnerships in the future to level the playing field for developing countries. Various initiatives are already underway such as the UN Conference on Trade and Development's Biotrade Initiative launched in 1996 which "...seeks to enhance the capability of developing countries to produce value-added products and services from biodiversity for both domestic and international markets"¹¹⁶. Other UN initiatives, such as the World Intellectual Property Organization's initiative to build IPR regimes, will continue to create the necessary infrastructure for developing countries to realize the benefits of biotechnology.

Although capacity building in developing countries will continue to be an important issue on the world policy stage, the groundwork has been laid for progress in this area. The challenge ahead will lie in building the necessary partnerships with the private sector, NGOs, governments and civil society to successfully implement capacity building initiatives.

A. The Rationale for a Global Policy Network

Global policy networks are usually trisectoral alliances of government agencies, non-governmental agencies (NGO's) and corporations. These networks bring together experts from government, international aid organizations, industry, and academia to help policy makers meet the challenges of policy making in a highly interconnected world. The three areas where policy networks can make particularly powerful impacts on the global policy stage are: "managing knowledge, overcoming market and intergovernmental failures, and broadening participation."¹¹⁷.

The multi-disciplinary, geographically diverse and controversial nature of biotechnology along with its immense promise makes a biotechnology policy network an excellent tool for improving the global governance of this expanding field. The potential benefits and risks inherent in biotechnology and its borderless nature make a network of experts almost essential to sort through the complex flow of information. A biotechnology policy network has the potential to create an environment where building consensus, and implementing and monitoring regulatory standards and agreements are achievable.

B. The United Nations as Network Facilitator

As civil society and non-governmental actors gain prominence on the global policy stage, it has become increasingly important to include the two groups in policy discussions. The UN is well placed as an international policy forum to facilitate a biotechnology policy network. Kofi Annan; Secretary General of the UN in his *We the Peoples* report states, "I intend to convene a high-level global public policy network to address these and related controversies concerning the risks and opportunities associated with the increased use of biotechnology and bioengineering."¹¹⁸

In *Critical Choices*, a report on global policy networks, Reinicke and Deng put forth the notion that the UN is directly linked to the future of global policy networks.

By working with global public policy networks and facilitating their emergence, the United Nations can help strengthen the capacities of state and nonstate actors to participate in the development of global public policy, while increasing its own effectiveness and credibility. In many ways, the future of global public policy networks is the future of the United Nations, and vice versa¹¹⁹.

It would seem then, that the UN is poised to take on the role of network facilitator for a global public policy network on biotechnology. What remains to be seen is whether the UN can implement a strategic approach to network facilitation.

C. Illustrative Potential Funders and Participants

i. Government

One representative from each of the five negotiating groups at the Cartagena Protocol Negotiations (Like Minded, European Union, Miami, Compromise, and Central and Eastern European Groups)

ii. Industry

Monsanto, International Bioindustry Forum and International Federation of Pharmaceutical Manufacturers

iii. Academics

Jennifer Thompson (Capetown), Doug Powell (Guelph), Calestous Juma (Harvard), Carlos Correa (Argentina), and Carliene Brenner (OECD Development Centre)

iv. Special Interest Groups

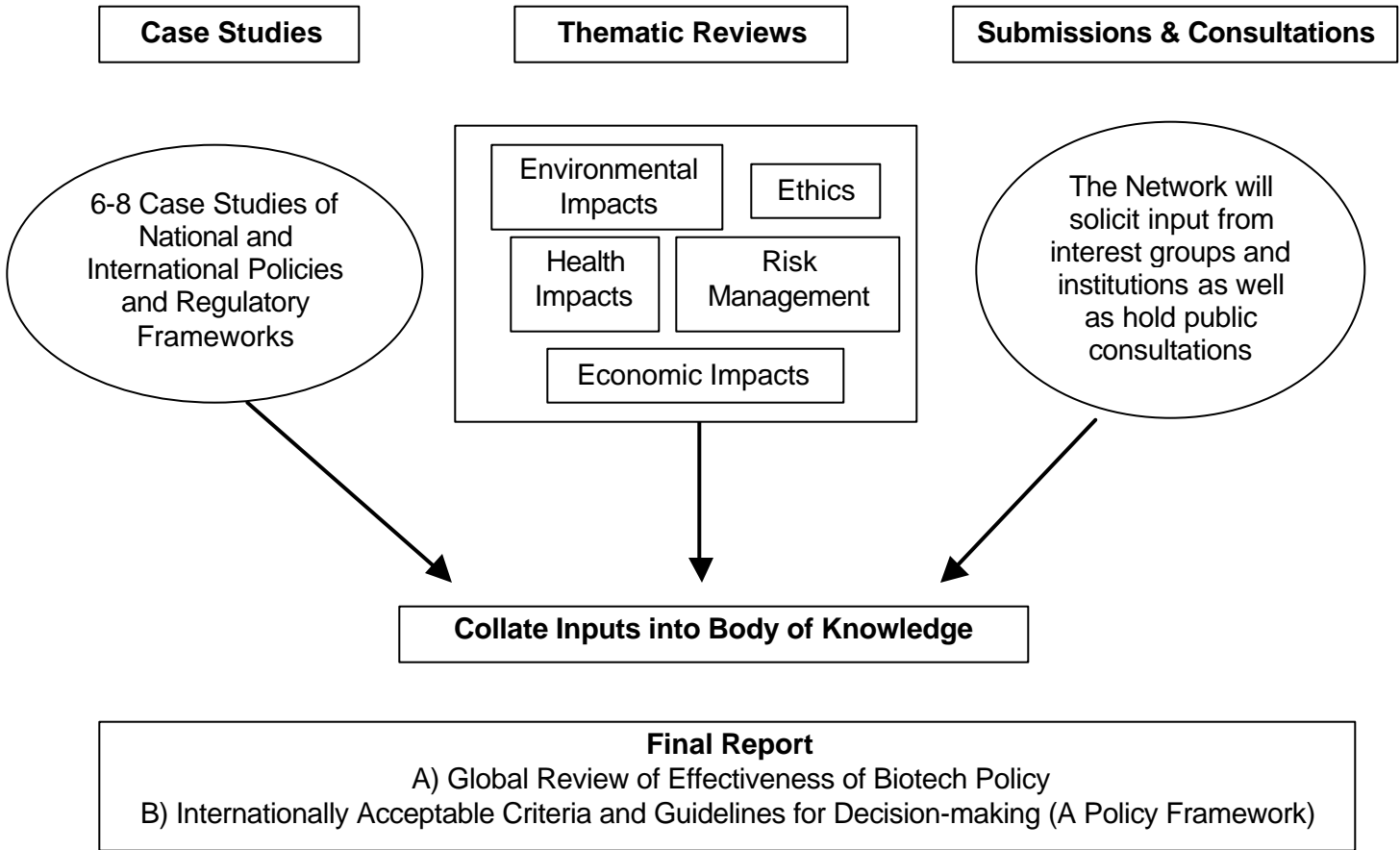
Greenpeace, International Food Policy Research Institute (Per Pinstrup-Andersen) and CGIAR (Ismail Serageldin), Third World Network (Martin Khor)
Other contacts include International Service for the Acquisition of Agro-Biotech Applications (Anatole Krattiger) and the Intermediate Biotechnology Service of ISNAR in CG system (Netherlands - Joel Cohen)

v. Potential Funding Sources

Monsanto, Novartis, Rockefeller Foundation, Eli Lilly Foundation

D. A Graphic Display of Policy Network Outputs

Program Outputs for a Two-Year Period



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