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GENETICALLY MODIFIED ORGANISMS AND THE CARTAGENA PROTOCOL ON BIOSAFETY: WHAT IS AT STAKE FOR COMMUNITIES?

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Executive Summary

This working paper provides an overview of the Cartagena Protocol on Biosafety, an international agreement expected to come into force by the end of 2003, with an emphasis on its implications and significance for poor communities worldwide. Because of its subject matter – the regulation of the transboundary movement (export and import) of genetically modified organisms (GMOs) from one country to another, the Protocol could have an enormous impact on the food, livelihood and environmental security of communities in both developed and developing countries. This working paper analyzes the key challenges raised by modern biotechnology, the benefits and risks the technology poses to communities, and the opportunities for maximizing benefits and minimizing risks that are provided by the Cartagena Protocol on Biosafety.

The Cartagena Protocol on Biosafety was designed to respond to the challenge of modern biotechnology, which promises substantial benefits to societies but, at the same time, poses significant environmental, health, social and economic risks. For poor communities, potential benefits include more productive and better crops, as well as solutions to pervasive hunger and malnutrition. But this technology also brings risks to these same communities: to their health; to their biological and other environmental assets; and, to their livelihoods and traditional knowledge, among other socio-economic risks. Parts I and II of this working paper identify and assess these benefits and risks.

The Cartagena Protocol on Biosafety does not address all concerns related to modern biotechnology. Its objective and scope are limited, being principally intended to guide governments in making decisions on exporting and importing genetically modified organisms. The Protocol, however, can be a compelling instrument to deal with the risks posed by modern

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biotechnology. As explained in Part III, communities can use the Protocol to promote and protect their interests by invoking such concepts as the *precautionary principle*, *public participation* and *liability and compensation*. As well, the communities can utilize mechanisms created by the Protocol, including the *Advance Informed Agreement* procedure and the *Biosafety Clearing House*. Part III of the paper elaborates how communities can use these concepts and mechanisms to their advantage. It also identifies the areas that funders could support to enhance the engagement of communities in biosafety processes.

The Cartagena Protocol is a first step that must be taken advantage of in dealing with modern biotechnology. Investing in building the capacity of communities to engage proactively in the Protocol's implementation is imperative if the challenges posed by modern biotechnology are to be overcome.

Outline of the Working Paper

I. **Introduction:** This section briefly introduces the Cartagena Protocol on Biosafety: its nature as an international agreement; its legal status; and, its principal objective.

II. **The Challenge of Modern Biotechnology:** This section describes modern biotechnology and distinguishes it from previous forms of biotechnology such as conventional selective breeding. Its impact on food and agriculture is highlighted and potential benefits to communities are identified.

III. **Modern Biotechnology and the Risks to Communities:** The environmental, health and socio-economic risks of modern biotechnology, with a particular emphasis on impacts on poor communities, are identified and assessed.

IV. **The Cartagena Protocol on Biosafety:** Implications to Communities. Strategies on how communities could maximize the opportunities provided by the Protocol to promote and protect their interests are identified and elaborated. Priorities for funders are suggested and identified.

V. **Conclusion:** The author concludes by underscoring the importance of supporting community engagement in implementing the Protocol as a first, small step to overcome the challenge of modern biotechnology.

I. INTRODUCTION

After five years of difficult negotiations, the Cartagena Protocol on Biosafety was adopted by governments in Montreal, Canada in February 2000. It is an international legal agreement adopted by Parties to the Convention on Biological Diversity (CBD). Although the Protocol is not yet legally in force, it will likely take effect by the end of 2003, if not earlier. As of March 7, 2003, 45 countries (out of the 50 required) have ratified or acceded to the agreement.[1] Although it actively participated in the negotiations, the United States, which is not a party to the CBD, will not be able to ratify the Protocol. It can, however, enter into bilateral agreements (which must be consistent with the rules established by the Protocol) with Parties, allowing it to export and import GMOs with such countries.

The Cartagena Protocol was negotiated and adopted to respond to the challenges that societies are facing with the advent of modern biotechnology: The technology promises important economic and environmental benefits to society while also presenting serious environmental, health, and socio-economic risks. According to a prominent expert: "*The potentials for genetic engineering are almost endless. But alongside the benefits are risks, some real, some imagined*." (Conway, 2000) The Protocol was designed to meet this challenge by imposing legally binding rules on governments as they make decisions on exporting and importing genetically modified organisms.

II. THE CHALLENGE OF MODERN BIOTECHNOLOGY TO COMMUNITIES

For local communities – farmers and indigenous peoples in particular – the challenges presented by modern biotechnology are no different from those faced by governments and society in general: how to maximize the benefits of the technology and how to find effective measures and mechanisms to avoid or minimize the risks posed. Modern biotechnology and its products promise benefits to poor communities, such as better crops (resistant to insects, diseases, and even to natural calamities such as droughts), solutions to the threat of hunger (by helping to increase food production) and malnutrition (i.e. by creating rice that contains both beta-carotene – which the body converts to Vitamin A - and iron) and making agriculture more environmentally sustainable (i.e. through pest resistant crops that reduce the need for chemical pesticides). At the same time, this technology presents a genuine risk to communities.

Like other sectors of society, local communities have to deal with the risks to human health that GMOs, particularly those used in food, bring. Indeed, because their choices are more limited than those with higher incomes, the world's poor could disproportionately bear the health risks posed by GMOs in food *(See Box 1: The Controversy over Gene-Modified Food Aid)*. In addition to the health risks, the potential environmental impacts of the release of GMOs could have serious consequences for the biological diversity that many communities rely on for their food, livelihoods and cultural survival. Additionally, because modern biotechnology, as it has developed in recent years, is essentially a tool for industrial and corporate agriculture, this technology may have serious socio-economic impacts on many communities.

[1] See http://www.biodiv.org/biosafety/signinglist.asp?sts=rtf&ord=dt for the list of countries and regional groups that have ratified the Protocol.

Box 1: The Controversy over Gene-Modified Food Aid

The ongoing controversy over the appropriateness of including genetically modified food as food aid to countries faced with famine and hunger is a powerful illustration of the difficult challenges modern biotechnology poses to governments and the international community. Should countries facing a serious and immediate threat of famine and hunger accept gene-modified food aid? Who is more irresponsible? The food donor who insists on the acceptance of such aid? Or those governments refusing aid on the grounds that genetically modified food poses serious environmental and health risks to their people?

These are not theoretical questions for the more than 14 million people in six countries in southern Africa who, in 2002, confronted hunger resulting from natural (such as droughts and floods) and man-made (bad policies) disasters. Should the governments of the affected countries accept genetically modified maize, donated mostly by the United States? Swaziland and Lesotho accepted the GM maize. Mozambique, Malawi and Zimbabwe insisted that it had to be milled into flour so that farmers can not plant the seed. But Zambia, with almost 3 million hungry, rejected the maize in any form. (1) In September 2002, Zambian President Levy Mwanawasa made it clear why it could not accept such food aid: "We have rejected GM-food. It is not a slight on donors. There is no conclusive evidence that it is safe. We wish not to use our people as guinea pigs in this experiment." (2)

More recently, India was also reported to have rejected a large shipment of food aid from the United States because it contained genetically modified food. The shipment of maize and soya - part of the US government's annual $100m in food aid to parts of India that suffer from chronic malnutrition - was thought to have contained bio-engineered content. An Indian official was quoted saying "We are not against GM foods per se. But if there is reason to believe that there may be damage to human health, we have the right to reject any import." (3)

These decisions to reject international food aid containing GMOs have been severely criticized by groups, led by the United States government. Critics have blamed the groups campaigning against GM food aid in affected countries for sowing disinformation at the expense of peoples' lives. One US official was even reported to have accused such groups for committing "the highest crimes against humanity". (4)

Sources:
(1) Rory Carroll, *Zambians starve as food aid lies rejected*, The Guardian, October 17, 2002, at http://www.guardian.co.uk/gmdebate/Story/0,2763,813220,00.html;
(2) Manoah Esipisu, *Zambia says rejection of GM food aid is final*, which can be downloaded at http://www.ncrlc.com/GM_statement03.html (September 2003);
(3) Edward Luce, India rejects gene-modified food aid, Financial Times, 3 January 2003 at http://www.truthabouttrade.org/1071/wrapper.jsp?PID=1071-22&CID=1071-010303A;
(4) *US calls food aid refusal a crime against humanity*, Reuters, Dec 9, 2002, posted at http://www.gene.ch/genet/2002/Dec/msg00037.html

What is Modern Biotechnology?

Biotechnology is an application of biological science that uses biological systems, living organisms, or genetic material from living organisms, to make or modify products or processes for agricultural, industrial and medical use. For many centuries, societies and communities have used this technology to alter plants and animals to achieve such results as better food and improved production. Through selective cross-breeding, for example, farmers have modified, enhanced or added desired characteristics to plant crops resulting in superior products or increased production volumes. In recent years, however, new scientific and technological developments have revolutionized biotechnology.

The science of genetics, from which modern biotechnology has emerged, has enabled society to identify, isolate, transfer and use the specific genes that control individual traits in an organism. In agriculture, this improved ability to modify and control the genetic endowment of crops, trees, livestock, fish and microbes continues the practice of genetic improvement farmers have carried out over the centuries by crossing and selecting better plants and animals. (Persley, 1999) Through genetic engineering, it is now possible to transfer selected individual genes across unrelated species (and kingdoms). Thus with modern biotechnology, as distinguished from conventional breeding processes, the genetic material of one species can be inserted into another, crossing natural barriers that were previously impassable. *(See Box 2: Distinction between Genetic Modification and Conventional Selective Breeding)*

Box 2: Distinction between Genetic Modification and Conventional Selective Breeding

- **Selective breeding** uses combinations of genes from within the natural pool of genetic variation in the crops or animals concerned and, therefore, enables selection and breeding of traits that may be influenced by several (or many) separate genes, as well as traits under the control of single genes. Breeding normally takes place between individuals of the same species, or in some cases, between closely related species and, if necessary, may apply techniques to overcome some barriers to breeding between the individuals concerned. No modifications are made to the genetic material of the individuals concerned.

- In **genetic modification**, scientists isolate single genes that control particular characteristics, copy them with modifications and splice them with other control elements from genes to form a 'gene construct' so that they work well within the target organism. The scientists then insert the constructs/genes, usually in a random position, within the organism. The techniques used for gene modification involve steps that take place *in vitro*, that is, they take place outside of any organism. The use of genetic modification techniques allows for very large evolutionary barriers to be crossed and for the movement of one or a few genes between organisms, including organisms that have not been known to have genetic contact.

Source: R. Mackenzie et. al., An Explanatory Guide to the Cartagena Protocol on Biosafety, published by IUCN and Field in cooperation with WRI (Forthcoming 2003). See Introduction.

Modern biotechnology's impact has been felt most in the fields of medicine and agriculture. Natural sources of biologically active chemicals, such as plants, insects, marine invertebrates, fungi and bacteria are, once again, important sources of new pharmaceuticals. Meanwhile, in agriculture, modern biotechnology is seen by the private sector as the technology of the future – influencing everything from the development of seeds to the prevention and control of animal diseases. Industrial applications of this technology have also emerged, such as producing motor oils and specialty chemicals from plant-based material.

Modern Biotechnology in Food and Agriculture

The biggest debate over modern biotechnology is in its application to food and agriculture. There are three reasons for this:

- Hunger is a real problem in the world today and is only expected to worsen in the coming years.
- Food and agriculture are at the center of the economies of many societies and communities. The livelihood of hundreds of millions of people in numerous countries relies on this sector.
- The environmental, health, and social risks this technology brings are most obvious and critical in food and agriculture.

The global area where GM crops are being planted has been steadily increasing worldwide. In a recent report *Global Status of Commercialized Transgenic Crops: 2002* (James, 2002) it was reported that:

- The estimated global area of transgenic or GM crops for 2002 is 58.7 million hectares (ha) or 145 million acres, grown by between 5.5 and 6.0 million farmers in sixteen countries - up from 5 million farmers and thirteen countries in 2001.
- The increase in area between 2001 and 2002 is 12%, equivalent to 6.1 million ha. or 15 million acres. A sustained rate of annual growth of more than 10% per year has been achieved every year for the last six years, since their introduction in 1996.
- During the seven-year period 1996 to 2002, global area of transgenic crops increased 35-fold, from 1.7 million ha. in 1996 to 58.7 million ha. in 2002. This ranks as one of the highest adoption rates for crop technologies.
- Globally, the principal GM crop was GM soybean occupying 36.5 million ha. in 2001 (62% of global area), followed by GM corn at 12.4 million ha. (21%), transgenic cotton at 6.8 million ha. (12%) and GM canola at 3 million ha. (5%).
- In 2002, for the first time, more than half of the world's population lived in countries where GM crops are approved and grown.

Potential Benefits to Communities

If applied properly, biotechnology "will be essential if yield ceilings are to be raised, excessive pesticide use reduced, the nutrient value of basic foods increased, and farmers on less favored lands provided with varieties better able to tolerate drought, salinity and lack of soil nutrients." (Conway, 2000) In fact, there are new, already available, genetic traits that could help food production in the poorest countries if transferred into their crops. These include (Flavell, 1999):

- Beta carotene enrichment to correct vitamin A deficiency;
- More nutritious oils, starches and amino acids;
- Better fatty acid profiles;
- Better digestibility for livestock;
- Delayed over-ripening of fruits and vegetables;
- Bacterial and fungal disease resistance;
- Insect resistance;
- Virus resistance;
- Salt tolerance; and,
- Aluminum and manganese tolerance.

Because of this potential to improve the productivity of agriculture, it has been argued by experts that poor farmers cannot afford to say no to the opportunities offered by modern biotechnology. They believe that modern biotechnology, applied together with appropriate policies, infrastructure and traditional research methods, can help poor farmers around the world by developing crop varieties that "increase productivity and lower risks, reduce unit costs in production and thus lead to lower food prices, improve the nutrient content of food, and convert nitrogen in the air to plant nutrients." To them, while modern biotechnology is not a 'silver bullet' or a 'catch-all' answer to the problems of poor farmers, "it is a partial solution to their problems, and they should not be denied access to it." (Pinstrup-Andersen and Cohen, 2000)

III. MODERN BIOTECHNOLOGY AND THE RISKS TO COMMUNITIES

There are three types of risks that have been associated with modern biotechnology and genetically modified products: environmental (particularly on biological and genetic diversity); health-related; and, socio-economic[2]. Risks to health are generally similar across countries and continents but environmental and socio-economic risks are frequently place-based, resource-sensitive and community-specific, thus they differ from country to country.

[2] For a critical view of the benefits of modern biotechnology and an analysis of the risks it poses, see Miguel A. Altieri and Peter Rosset, "Ten Reasons Why Biotechnology Will Not Ensure Food Security, Protect The Environment, And Reduce Poverty In The Developing World," University of California, Berkeley & Food First/Institute for Food and Development Policy, 1999, which can be downloaded at http://www.agbioforum.org/v2n34/v2n34a03-altieri.htm

Environmental Risks

The United Nations Development Programme describes the potential negative impacts of GMOs on the environment as follows[3]: (UNDP, 2001)

- Transformed organisms could displace existing species and change the ecosystem. The introduction of European rabbits in Australia in the 1850s, resulting in the destruction of habitats and native flora and fauna, is the best example of how ecosystems can be destabilized and biodiversity reduced by introducing new species.
- Gene flow among plants could transfer the novel genes into related species, leading, for example, to "super weeds."
- The novel genes could have unintended harmful effects on non-target-species. The well-publicized study showing that the pollen of Bt corn, designed for pest control against stem borers, can also kill monarch butterflies illustrates this danger.

Identified as the most serious environmental risk posed by the release of GMOs into the environment is the possibility that they could contaminate other crops, particularly wild relatives important for biodiversity, or that they could escape and contaminate organic varieties on nearby farms. Genes from commercial and cultivated crops can and do pass to organic crops – and vice versa – and genes from both transfer to wild relatives. (Conway, 2000) If this "genetic contamination" happens in a large scale way, as many fear, not only will centuries of innovation and traditional knowledge be lost, but the economic and cultural basis of many communities will be undermined, if not irreversibly ruined. *(See Box 4: GMO Contamination of Maize in Mexico)*

[3] See UNDP Human Development Report 2001, posted at http://www.undp.org/hdr2001/

Box 4: GMO Contamination of Maize in Mexico

Mexico is the center of origin, and home to the greatest diversity, of maize – one of the world's most vital food crops. In 2001, it became the focal point – ground zero – of the debate over GM food when genes from genetically modified maize were reportedly found in Mexican landraces, despite a moratorium on planting GM maize in Mexico imposed in 1998. Because Mexico imports large quantities of maize grain from the United States for food, it is quite possible that some of the GM maize imported into Mexico was planted intentionally or accidentally.

Landraces of maize, developed and maintained by small-scale farmers and indigenous peoples over many centuries, are important because they possess unique traits carried and exchanged through their genes. Mexico's land races represent one of the world's most valuable reservoirs of genetic material for plant breeding, essential for food security. Mexico is also the host of the International Center for Maize and Wheat Improvement (CIMMYT), which houses the world's most important collection of endangered maize seeds. (1)

The controversy erupted when an article in *Nature* (authored by David Quist and Ignacio Chapela) reported that farmers' traditional maize varieties in two remote Mexican states, Oaxaca and Puebla, had been contaminated with DNA from GM maize. (2) Expectedly, there was a reaction from supporters of modern biotechnology who disagreed, on methodological grounds, with the findings of the authors. In April 2002, *Nature* published the exchange between the authors and their critics with an editorial note concluding that, in hindsight, the original paper's publication was unjustified but leaving it to the readers to judge the science. The authors of the article, however, refused to back down. (3) Subsequently, the Mexican government confirmed that its own studies found high levels of contamination in its native maize populations. According to Jorge Sober, Secretary of Mexico's National Biodiversity Commission, "This is the world's worst case of contamination by genetically modified material because it happened in the place of origin of a major crop. It is confirmed. There is no doubt about it." (4)

These reports of genetic pollution in Mexican maize landraces have caused people, Mexicans and foreigners alike, to fear that a resource of major ecological, economic, practical and cultural value has been seriously endangered and degraded. This was particularly distressing for many indigenous and traditional farming communities in Mexico. In the words on one Oaxaca farmer: "Native seeds are for us a very important element of our culture. The (Mayan) pyramids could be destroyed, but a fistful of corn is the legacy that we can pass on to our children and grandchildren, and today we are being denied that possibility."(5)

Sources:

(1) For an overview of the importance of maize to the world and to food security, see the website of CIMMYT, http://www.cimmyt.org, where its reactions to this controversy have also been posted.
(2) David Quist & Ignacio Chapela, *Transgenic crops: Tell-tale markers in traditional maize*, Nature 414, 541-543 (29 November 2001), http://www.nature.com/nature/links/011129/011129-4.html
(3) Peter Aldhous, *Agribiotech: More heat than light*, Nature, 26 December 2002, posted at http://www.nature.com/cgi-taf/DynaPage.taf?file=/nature/journal/v420/n6917/full/420730a_fs.html
(4) ETC Group, *Genetic Pollution in Mexico's Center of Maize Diversity*, Backgrounder, Spring 2002, Food First: Institute for Food and Development Policy, Volume 8, no. 2, posted at http://www.foodfirst.org/pubs/backgrdrs/2002/sp02v8n2.html#notes. See also ETC Group, *GM Fall-out from Mexico to Zambia: The Great Containment*, 25 October 2002, http://www.rafi.org/article.asp?newsid=366
(5) *El maz nativo, recurso de autogobierno*, Ojarasca, La Jornada, February 2002, quoted in Carmelo Ruiz-Marrero, *Genetic Pollution: Biotech Corn Invades Mexico*, Special to CorpWatch, March 20, 2002, http://www.corpwatch.org/issues/PID.jsp?articleid=2088

Health Risks

While the Cartagena Protocol is principally an environmental (not a health) agreement, it acknowledges the risks to human health posed by modern biotechnology. Thus, in implementing the Protocol and in making decisions about whether to allow the importation of GMOs, governments are also urged to take into account the risks to human health.

Two events in 2002 illustrate the importance of dealing with health risks:

- It was discovered that StarLink, a GMO corn hybrid that was approved by the U.S. Environmental Protection Agency for livestock use only, had found its way into food for human consumption both in the United States and abroad. Recall of food products had to be implemented to minimize the risks to the health of consumers.[4]

- ProdiGene Inc., a biotechnology company, paid a $250,000 fine plus an estimated $2.8 million to buy and destroy contaminated soybeans in order to settle federal allegations that it tainted crops in Nebraska and Iowa with an experimental corn plant engineered to produce medicine. ProdiGene's experimental bio-corn, which is grown to produce trypsin for diabetes and another compound to treat diarrhea, has not been approved for human or livestock food[5].

The World Health Organization (WHO) identifies three main public health issues that GM food poses. These are (WHO, 2002):

- *Allergenicity.* As a matter of principle, the transfer of genes from commonly allergenic foods is discouraged unless it can be demonstrated that the protein product of the transferred gene is not allergenic. While traditionally developed foods are not generally tested for allergenicity, protocols for tests for GM foods have been evaluated by the Food and Agriculture Organization of the United Nations (FAO) and WHO. No allergic effects have been found relative to GM foods currently on the market.

- *Gene transfer.* Gene transfer from GM foods to cells of the body or to bacteria in the gastrointestinal tract would cause concern if the transferred genetic material adversely affects human health. This would be particularly relevant if antibiotic resistance genes, used in creating GMOs, were to be transferred. Although the probability of transfer is low, the use of biotechnology without antibiotic resistance genes has been encouraged by a recent FAO/WHO expert panel.

- *Outcrossing.* The movement of genes from GM plants into conventional crops or related species in the wild (referred to as "outcrossing"), as well as the mixing of crops derived from conventional seeds with those grown using GM crops, may have an indirect effect on food safety and food security. This risk is real, as was shown when traces of a maize type that was

[4]For a comprehensive account of this controversy, see the website of Agroecology/Sustainable Agriculture Program at the University of Illinois at www.aces.uiuc.edu/~asap/expanded/gmo/starlink.html.

[5] See the website of Planet Ark at http://www.planetark.org/dailynewsstory.cfm/newsid/18935/newsDate/9-Dec-2002/story.htm for details on the ProdiGene contamination,

only approved for feed use appeared in maize products for human consumption in the United States. Several countries have adopted strategies to reduce mixing, including a clear separation of the fields within which GM crops and conventional crops are grown.

Are GM foods safe then? The WHO answer is not unequivocal. Because each GM organism includes different genes, inserted in different ways, individual GM foods and their safety should be assessed on a case-by-case basis. Therefore, it is not possible to make general statements on the safety of all GM foods. The continuous use of risk assessments and, where appropriate, post market monitoring, are necessary to evaluate the safety of GM foods. (WHO, 2002)

Socio-economic Risks

The advent of modern biotechnology and its application, especially to food and agriculture, brings with it socio-economic implications (both benefits and risks) that vary from country to country. Food production, incomes, livelihoods and agricultural imports and exports could be enhanced or diminished (even completely destroyed) as modern biotechnology becomes more prevalent in food and agriculture. Depending on the country – its capacity to conduct biotechnology, the role of agriculture in its economy, the crops it needs for its domestic food supply and what it exports for foreign exchange, etc. – the socio-economic impacts of agricultural biotechnology will be different for each country (De Casas, 2000). Thus, in light of such differentiation, the most relevant socioeconomic effects of biotechnology on agriculture in developing countries have been classified as follows (Commandeur and von Roozendaal, 1993 in Leisinger, 1995):

- Countries that are net agricultural exporters but with weak biotechnology research sectors will not be able to benefit as much from plant biotechnology as those who have research capacity. Therefore, to the extent that GM products may be more competitive than conventional crops, these countries will be affected more adversely.

- Countries that have weak technological potential but are net importers of food could profit short-term from lower prices on the world market. However, in the long term, competitive pressures brought about by the emergence of GM crop substitutes could adversely affect food production and increase food insecurity in such countries.

- Countries with strong technological potential (and strong intellectual property rights over technology) and high food imports could benefit most from biotechnology, since it could help them to orient their economies towards self-sufficiency.

- Countries with strong technological potential and high food exports could benefit from biotechnology by using it to diversify their exports.

In sum, a country's vulnerability to new biotechnologies is greater where a low technological potential coincides with net exports of potentially substitutable agricultural products. This is the case of many countries in Sub-Saharan Africa and the Caribbean.

Many of the socio-economic risks posed by modern biotechnology, particularly to poor farmers in both developed and developing countries, results from the fact that innovations in agricultural biotechnology have largely been profit-driven rather than need-driven. The engine behind the biotechnology revolution is the private sector which has invested billions in research and development and in organizing the delivery and marketing vehicles for its products. While acknowledging the potential of this technology to contribute to solving many of the problems of the world's poor, the companies that are leading this revolution are driven principally by the accountability to their shareholders. As a result, almost all of the biotechnology-based products currently on the market have been developed for markets in developed countries. It is in these countries where companies can expect the returns on the substantial investments they have made. This also explains why the commercial biotechnology sector has not been inclined to invest in biotechnological applications relevant to the problems of poor communities.

It is not a coincidence that pharmaceutical, food, environmental, and agricultural biotechnology activities have been concentrated in developed countries, which have the capital and industrial infrastructure needed to make biotechnology research, development, and commercialization profitable. The high capital costs associated with biotechnology innovation have meant that only a small number of transnational corporations (mainly agro-chemical and pharmaceutical corporations) play a dominant role in agricultural biotechnology development. The globalization of the biotechnology industry, however, means that changes in both the national and international regulation of biotechnology activities will greatly affect how the industry does business and maximizes profits. This has given the biotechnology industry the impetus to seek to influence government regulatory decision-making to create a favorable regulatory climate at home and abroad. The industry is concerned about the impact of regulation on the trade of GMO products. They are particularly concerned that environmental agreements, such as the Cartagena Protocol, or regional rules, such as those imposed by the European Union, become an undue restraint on international trade.

For this reason, the United States, citing concerns over the controversy on gene-modified aid *(See Box 1)*, recently signaled that it is likely to bring suit in the World Trade Organization against the European Union for its refusal to accept and approve genetically modified food. For the United States, which is echoing industry arguments, the European restrictions on GMOs are not based on legitimate scientific concerns but are a response to unreasonable public fears. U.S. Trade Representative Robert Zoellick has been reported to have said that he was deeply concerned that European resistance to biotechnology might be influencing the trade policies of other nations, including the decisions made by some African countries to refuse gene-modified food aid. Zoellick said: *"I don't see things getting improved. Instead, I see something extremely disturbing: the European anti-scientific view spreading to other parts of the world – not letting Africans eat food you and I eat, and instead letting people starve."* (Gillis and Blustein, 2003)

Socio-Economic Impacts Specific to Poor Communities

The impact of modern biotechnology on trade is not purely a concern of the private sector. Farmers, whether from developing or developed countries, face enormous risks that their products will not gain consumer acceptance in key markets or receive regulatory approval from governments. For example, producers of fruits and vegetables in South or Central America who

export their products to Europe could face significant regulatory and trade obstacles given the stringent rules the European Union has imposed on GM products. The same is true for those who might want to export GM agricultural products (e.g. soy bean, rice) to countries like Japan, China and Thailand. These producers share the risks with food manufacturing and distribution companies, whether from developed or developing countries. Workers, many of them poor women, who are dependent on these sectors for their livelihoods also bear the risks.

Equally threatening to poor farmers is the very real possibility that a shift to transgenic crops from GM seeds produced by private biotechnology companies could lead to the loss of control of their traditional farming systems, as well as to further dependence on outside sources of seeds and crop inputs. This includes, in exchange for varieties that might be more productive in the short run, losing local crop varieties more suited to the ecological conditions of the locality and even social and cultural dislocation. Because of stringent intellectual property right rules regulating the use of GM seeds, farmers would have to approach the companies supplying them the seeds annually (or planting season after planting season). The traditional practice of saving seeds does not have a place under such an industrial regime of agriculture. This risk applies not only to food products but also to non-food agriculture such as cotton.

Finally, another socio-economic risk that the emergence of modern biotechnology poses to communities is its significant impact on the flow of already scarce financial, technological and human resources that support sustainable agriculture. The public sector, both domestically (in key developing countries like India and China) and internationally (mainly through the Consultative Group on International Agricultural Research or CGIAR) has substantially increased its investments in developing and applying modern biotechnology for food and agriculture. Critics have pointed out that these investments should have been used to expand support for ecologically based agriculture. To them, “Failure to promote such people-centered agricultural research and development due to the diversion of funds and expertise towards biotechnology will forego an historical opportunity to raise agricultural productivity in economically viable, environmentally benign, and socially uplifting ways.” (Altieri and Rosset, 1999)

Those who see the potential of modern biotechnology to help poor farmers recognize that biotechnological research for agriculture and food is currently focused on the agricultural sectors of industrialized nations where private companies can expect a reasonable return on their research investment. However, they are concerned that poor farmers do not have access to the new crop varieties being developed because they do not present an interesting market for these companies. To them, public sector investments in modern biotechnological research are imperative and the small percentage of the public international agricultural research dedicated to this is far too inadequate to develop the appropriate technology needed by small farmers in developing countries. (Pinstrup-Andersen and Cohen, 2000)

IV. THE CARTAGENA PROTOCOL ON BIOSAFETY: IMPLICATIONS TO COMMUNITIES

As an environmental agreement, the Cartagena Protocol on Biosafety deals principally with environmental concerns. As a protocol to the Convention on Biological Diversity (*See Box 5: History of the Cartagena Protocol on Biosafety*), its principal focus is the potential adverse impacts of modern biotechnology on the conservation and sustainable use of biological diversity. In this sense, the Protocol fails to address an important issue crucial for poor communities: how to promote and facilitate the transfer of modern biotechnology that would be of significant benefit to such communities. Other mechanisms, including public-private investments and partnerships that would focus efforts and resources on making the technology relevant to the poor, would have to be designed and implemented to meet this particular challenge. Otherwise, the technology would continue to be a tool only for transnational companies and would benefit only producers and consumers from developed countries.

The Protocol, if implemented effectively, is a powerful instrument to deal with the risks posed by modern biotechnology to communities. Strategies on how to maximize the opportunities provided by the Protocol include:

- Invoking the general principles contained in the Protocol, particularly those on the precautionary approach, the importance given to biological and genetic diversity and the non-subordination by trade rules of environmental concerns;
- Using the Protocol, though limited in objective and scope, to guide the development of domestic rules and regulations;
- Effectively implementing the advance informed agreement procedure;
- Applying the precautionary principle and the article on socio-economic considerations in decisions on GMOs;
- Creatively utilizing the Biosafety Clearing-House;
- Holding governments accountable to their obligations on public participation;
- Participating in capacity building; and,
- Intervening in the negotiations on liability and compensation.

These are also the priority areas which require the support of funders who want communities to be able to respond creatively to the challenge of modern biotechnology.

Box 5: History of the Cartagena Protocol on Biosafety

Rio de Janeiro 1992: The Protocol is a direct result of provisions from the Convention on Biological Diversity (CBD) adopted by governments in 1992 during the Earth Summit in Rio de Janeiro, Brazil. In particular, two provisions of the CBD provided the legal basis for a biosafety agreement:

- Article 8 (g) requires Parties, at the national level, "to establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health."

- Article 19 (3) calls on governments, at the international level, to consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

Jakarta 1995: During its second meeting, held in Jakarta in November 1995, the Conference of the Parties (COP) of the CBD agreed to launch negotiations to develop a draft protocol on biosafety, specifically focusing on transboundary movement of any living modified organism resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity. The COP established an "Open-ended Ad Hoc Working Group" composed of representatives, including scientific and legal experts, nominated by Governments and regional economic integration organizations, which was urged to complete its work by 1998.

Aarhus 1996: The working group assigned to negotiate a biosafety protocol first convened in Aarhus, Denmark. No substantive decisions were made at this meeting. Instead, Parties exchanged views on what they considered essential elements of a protocol on biosafety.

Montreal 1997-1998: The working group accelerated its work during these years – meeting four times in Montreal, Canada. While the negotiations were difficult and contentious, slowly a draft of a biosafety protocol emerged from the talks in Montreal. Positions were clarified and options were identified during these meetings in the spirit of brainstorming. But given the complexity of the subject matter and the economic (particularly trade) implications of an agreement, it became clear that extraordinary good will and effort were necessary to bring the negotiations to a successful completion.

Cartagena 1999: Meeting in an extraordinary session in Cartagena, Columbia, the COP was unable to agree on the adoption of the Protocol. Issues related to trade (the impact of a biosafety protocol on the free flow of products containing GMOs) and to liability and compensation (in case of adverse impacts of GMOs) were the critical subjects that prevented agreement. In this stalemate, European countries, joined by a "like-minded" group of developing countries, insisted on strict rules while a mixed group of developed (including the United States and Canada) and developing (such as Argentina) countries collectively known as the Miami Group, wanted an agreement that would not be a hindrance to trade. Governments agreed to suspend the session and to meet again to try to resolve their differences.

Montreal 2000: Following a series of informal meetings, including a ground-breaking session in Vienna, Austria, the COP resumed its extraordinary meeting in Montreal and adopted the Cartagena Protocol on Biosafety.

Source: Bail, Falkner & Marquard, 2002

General Principles

The preamble of the Cartagena Protocol articulates fundamental principles which can be utilized by communities to ensure that the application of modern biotechnology is not harmful to their environmental, health and economic interests. These principles include:

- *The reaffirmation of the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development.* This means that lack of scientific certainty about the risks in applying a technology should not be used as a reason by governments for inaction to prevent such risks from occurring. The adoption of a precautionary approach to modern biotechnology can be used by communities to insist on a 'go slow' approach where the risks – environmental, health or socio-economic – are unknown or are uncertain.

- *The belief that that modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health.* There is an appreciation of the potential benefits that the technology brings, as long as the risks are well-managed. Communities can demand that adequate safety measures must be put into place first before indiscriminately adopting modern biotechnological approaches.

- *An appreciation of the crucial importance to humankind of centres of origin and centres of genetic diversity.* Governments are specifically concerned about the impact of modern biotechnology on these centres of origin. Many of these centres of origin and diversity, as in the case of Mexican maize *(See Box 4)*, have been nurtured and conserved by communities throughout many generations and centuries. Communities can insist that extra precaution be taken where these centres are threatened with genetic contamination or pollution.

- *The recognition that trade and environment agreements should be mutually supportive with a view to achieving sustainable development.* The potential trade implications of the Protocol are recognized with governments adopting a view that conflicts between trade and environment concerns should be reconciled in the best way possible. It should be noted that this principle does not subordinate environmental agreements (i.e. the Cartagena Protocol) to trade considerations. Community interests, especially in protecting their biological and genetic resources, and their traditional knowledge, do not have to be sacrificed in the name of trade and commerce.

Objective and Scope of the Protocol

Following the precautionary approach, the objective of the Cartagena Protocol on Biosafety is *"to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements."* (Article 1) While the Protocol is explicitly an environmental agreement, it also requires governments to take into account concerns related to human health. Its focus is on the transboundary movement of GMOs – i.e. the transfer, intended or unintended, of GMOs from

one country to another, including the transit, handling and use of such organisms in the course of the movement or transfer. By express provision, the Protocol does not apply to the transboundary movement of living modified organisms that are pharmaceuticals for humans, which are addressed by other relevant international agreements or organizations, or those that are in transit or intended for contained use (i.e. those GMOs imported purely for research purposes)[6].

Because of its limited scope, the Protocol is useful to countries and communities only with respect to the export and import of GMOs intended for release into the environment. It does not apply to purely domestic activities which must be regulated under national law. Communities and their civil society allies must work separately to make sure that national rules and regulations are put in place to address the risks from such activities. However, the Protocol, and the precedent it sets, is a useful guide in developing national policies and measures. Many of the rules of the Protocol, elaborated below, are applicable to purely domestic activities and can easily be adapted towards this end.

Advance Informed Agreement

The heart of the Protocol is the establishment of a procedure called Advanced Informed Agreement (AIA), which requires governments to give consent before GMOs can be imported into a country. The AIA procedure is a mechanism through which importing countries are notified of impending imports of GMOs to their territory. Under the AIA system, notification (which must be written and submitted prior to importation) triggers risk assessment, risk management and decision making procedures – all of which are geared towards a final action by the importing government as to whether or not it will allow or refuse the importation. The AIA applies to GMOs intended for intentional introduction into the environment, such as seeds to be planted for agriculture or genetically modified animals, such as fish[7].

A modified procedure is allowed for GMOs intended for direct use as food or feed (e.g., grain for animal feed), or for processing (e.g., ingredients for manufacturing food). In this case, the notification is posted on the Biosafety Clearing-House *(see below)* and the importation is allowed to proceed unless the importing government decides that a risk assessment process is necessary before permitting the trans-boundary movement in question.

Communities, through their organizations and civil society partners, should monitor how their respective governments implement this AIA requirement. Because the Protocol requires governments to ensure public participation in implementing the Protocol, they have the right to insist that the procedure is implemented properly. Among the highest priorities are constant monitoring of notifications received by governments and demanding the highest standards for risk assessment and management

[6] Articles 4, 5, & 6 of the Protocol, collectively, lay down the scope of the agreement and to which GMOs and activities it applies.
[7] See Articles 7-13 of the Protocol.

Precautionary Principle

The Cartagena Protocol contains one of the strongest articulations of the precautionary principle in an environmental agreement. It states:

> *"Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question . . . in order to avoid or minimize such potential adverse effects."* (Article 10)

Communities can utilize this principle to insist that decisions allowing the importation of GMOs are made consistent with this principle. Lack of or inadequate information regarding environmental, health-related and socio-economic risks is not an excuse for inaction or, even worse, an affirmative decision by governments to accept the importation of specific GMOs.

Socio-Economic Considerations

In adopting the Cartagena Protocol on Biosafety, governments recognized the socio-economic implications of modern biotechnology. Under Article 26, in reaching a decision on allowing or refusing import, governments can take into account socio-economic considerations arising from the impact of genetically modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities. In taking into account such considerations parties must act consistently with their international obligations (the obvious reference here is to impacts on trade). Article 26 also encourages Parties to the Protocol to cooperate on research and information exchange of any socio-economic impacts of living modified organisms, especially on indigenous and local communities.

Socio-economic considerations that governments may take into account include the impact that decisions on imports may have on[8]:

- The continued existence and range of diversity of the biological resources in the areas inhabited or used by indigenous or local communities;
- The loss of access to genetic and other natural resources, as a result of biodiversity loss, previously available to indigenous or local communities in their territories; or,
- The loss of cultural traditions, knowledge and practices in a particular indigenous or local community as a result of the loss of biological diversity in the community's territory.

Communities should consider the effective implementation of Article 26 as a priority. For example, they should insist on the inclusion of procedures for assessing and addressing socio-economic impacts in risk assessment and management and on subjecting decisions on import of GMOs to prior public comment, review and social acceptability processes. This is particularly

[8] See *An Explanatory Guide to the Cartagena Protocol*, Commentary on Article 26.

important for communities that will be directly affected by the import decision – i.e., the local community in which the GMO is destined for field trial or use, or which may be affected by any potential adverse impacts of the GMO on biodiversity.[9]

Information Sharing and the Biosafety Clearing-House

A Biosafety Clearing-House is established to facilitate the exchange of scientific, technical, environmental and legal information on GMOs and to assist Parties to implement the Protocol (Article 20)[10]. The Biosafety Clearing-House shall provide access to information made available by the Parties relevant to the implementation of the Protocol. It shall also provide access to other international biosafety information exchange mechanisms. Examples of the information governments must provide to the Biosafety Clearing-House are:

- Existing laws, regulations and guidelines for implementation of the Protocol, as well as information required by the Parties for the advance informed agreement procedure;
- Bilateral, regional and multilateral agreements and arrangements;
- Summaries of risk assessments or environmental reviews of living modified organisms generated by regulatory processes; and,
- Final decisions regarding the importation or release of living modified organisms.

Communities and their civil society allies should develop the capacity to monitor this Biosafety Clearing House and build the capacity to respond in a timely manner when information relevant to their concerns and interests is posted. This is of particular importance for GMOs that are imported not for release into the environment, but for direct use as food or feed, or for processing, which, as noted earlier, is where a modified notification procedure is required.

Capacity Building

In negotiating the Protocol, governments acknowledged the limited capabilities of many countries, particularly developing countries, to cope with the nature and scale of known and potential risks associated with GMOs. Thus, governments have the obligation to cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety for the effective implementation of the Protocol (Article 22). Particular emphasis is given on the capacity of developing country governments, in particular the least developed and small island developing states among them, and those with economies in transition. This is to be done through existing global, regional, subregional and national institutions and organizations and, when appropriate, through facilitating private sector involvement.
Through the Protocol, governments recognized that capacity building in regulating GMOs is a priority in dealing with the challenges of modern biotechnology. These include obligations to provide resources and funding for building country capacity in biosafety and biotechnology. Communities and their allies in civil society should be aware of this and advocate for the inclusion of their organizations in such programs.

[9] Id.
[10] For more information on the Biosafety Clearing-House, see http://www.biodiv.org/bch/

Liability and Redress

During the negotiations, governments were not able to reach an agreement on the question of liability and compensation, i.e., who would pay for damages resulting from the release of GMOs that adversely affect the environment or human health. This question has been postponed to the first meeting of the Parties to the Protocol which *"shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analyzing and taking due account of the ongoing processes in international law on these matters..."* (Article 27) Governments are urged to complete this process within four years.

Communities have a huge stake in following and intervening in these continuing negotiations on liability and compensation. If in fact damage results from transboundary movements of GMOs, it is likely that poor communities – their biological assets and traditional knowledge – will be the likely victims. The damage can be far-reaching and irreversible. Developing the mechanisms to compensate such losses – including identifying who should be liable – is, therefore, a priority for community engagement.

Public Awareness and Participation

The Cartagena Protocol contains obligations related to public awareness and participation (Article 23). With respect to public awareness, for example, governments are urged to:

- Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking into account risks to human health.
- Endeavor to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with the Protocol that may be imported.

In accordance with their respective laws and regulations, governments must also consult the public in decision-making processes regarding GMOs and should make the results of such decisions available to the public, while respecting confidential information.

The public participation obligation imposed by the Protocol is an application, in the field of biosafety, of Principle 10 of the Rio Declaration. *(See Box 6: Principle 10 of the Rio Declaration)* Principle 10, recently reaffirmed by governments during the World Summit on Sustainable Development, articulates three "pillars" of public participation. These are: (1) the right of citizens to information; (2) their right to participate in environmental decisions which affect them; and (3) their access to mechanisms of redress and justice when their rights are violated.

Box 6: Principle 10 of the Rio Declaration

"Environmental issues are best handled with the participation of all concerned citizens, at the relevant level. At the national level, each individual shall have appropriate access to information concerning the environment that is held by public authorities, including information on hazardous materials and activities in their communities, and the opportunity to participate in decision-making processes. States shall facilitate and encourage public awareness and participation by making information widely available. Effective access to judicial and administrative proceedings, including redress and remedy, shall be provided."

Source: *The Rio Declaration on Environment and Development* (1992)

Under Article 23, communities and civil society organizations should be able to participate in implementing the Protocol. Funders should support communities and civil society organizations so they can intervene effectively in priority areas such as: the development and adoption of domestic regulatory measures; effective implementation of advance informed agreement procedures; participation in risk assessment and risk management; monitoring the implementation of the precautionary principle; the application of Article 26 on socio-economic considerations; and, participation in developing national positions on the continuing biosafety negotiations, especially on liability and compensation.

Domestic Regulatory Measures: Legislation and rules are necessary to implement the Protocol effectively. Many governments worldwide are now in the process of developing the appropriate regulatory measures and communities should be supported so they are able to articulate their interests before these domestic measures are adopted. Priority areas include identifying the "national competent authority" (the government agency that will be mandated to give consent to the importation of GMOs), the GMOs and the activities that will be covered, the criteria for approval and denial of consent, and the rules for public participation when decisions are made.

Advance Informed Agreement: As noted earlier, communities and civil society organizations should monitor applications for AIA received by their respective governments and should intervene in cases where specific GMOs may affect adversely the environment, health or socio-economic interests of specific communities. For example, they could, through the competent national authority, request for additional information from the exporter in cases where the risks are unclear or they file an opposition to the granting of consent for importation if warranted by the risks.

Risk Assessment and Management: Communities and civil society organizations should demand the highest standards for risk assessment and management from their governments. They should lobby for their active involvement and participation in both risk assessment and management activities.

The Precautionary Principle: Effectively implementing the Precautionary Principle, as specifically established in the Protocol, is fundamental to its successful implementation. By monitoring how governments interpret and utilize this principle and by insisting on the highest standards in its implementation, communities and civil society organizations can play a critical role in implementing the Protocol.

Socio-Economic Considerations: Public participation is essential if communities are to benefit from the article in the Protocol on socio-economic considerations (Article 26). Communities need to understand the economic, social and cultural consequences of GMO decisions. They would have to identify their specific interests in these decisions, articulate them to decision-makers, and invoke Article 26, if applicable, so that their socio-economic interests are considered by their governments when making importation decisions.

International Negotiations: Important issues are still being negotiated even as the Protocol is about to take effect. These include how the Protocol will address liability and compensation as well as the labeling of GMO products. Communities and civil society organizations should seek to actively influence their respective national delegations in these negotiations.

V. CONCLUSION

The Cartagena Protocol on Biosafety is not an all-encompassing solution to the challenges posed by modern biotechnology for poor communities worldwide. Its scope (the trans-boundary movement of GMOs) and its objective (principally environmental) are far too limited to address all the concerns emerging from the new technology. But while the Protocol is only a small, first step in dealing with modern biotechnology; it is an important development that must be taken advantage of. Investing in building the capacity of communities and their organizations, as well as their civil society allies, to engage proactively in its implementation is essential if the challenges posed by modern biotechnology are to be overcome.

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