



# Biosafety Policy Brief

## African Regional Coverage Project

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### EXECUTIVE SUMMARY

This policy brief aims to evaluate the challenges ahead for African negotiators on areas related to biotechnology and biosafety during the year 2007. It reviews the framework documents adopted in the region in order to harmonize approaches to biotechnology and biosafety, including: Africa's Science and Technology Consolidated Plan of Action adopted by the New Partnership for Africa's Development and the African Union; the report of the High-Level African Panel on Modern Biotechnology; the African Position on the Issue of Genetically Modified Organisms and Agriculture, adopted by the Conference of Agricultural Ministers of the African Union; and the draft African strategy on biosafety presented by the African Union's Directorate of Human Resources, Science and Technology.

Three core policy objectives are derived from these documents in order to guide the analysis, namely to: promote research and development in biotechnology to eradicate poverty and achieve sustainable development; build Africa's capacities to develop and safely apply biotechnology in agriculture, health, mining, industry and other areas like biofuels; and ensure policies are science-based and promote food security and economic growth. Based on these core guiding principles for policy-making agreed at the regional level, this brief presents proposals and ideas to apply them in biotechnology-related multilateral negotiations on environmental issues, specifically negotiations on liability and redress in the context of the Cartagena Protocol on Biosafety, access and benefit-sharing under the Convention on Biological Diversity, and funding for biosafety in the framework of the Global Environment Facility.

With regard to liability and redress in the context of the Cartagena Protocol on Biosafety, it is suggested that African negotiators adopt a pragmatic approach focusing on: measures to allow for compensation of harm in a proportionate measure to risks, to ensure that research and development opportunities are not hampered; channeling liability to the private sector, to ensure the liability regime also applies to entities operating from non-Parties to the Protocol; and possibly establishing exceptions to strict liability for research activities or for some points in the production chain where due diligence is important and risks are lower (i.e. transport), to ensure that research and development is not hampered and that there are incentives for the private sector to exercise due diligence in the management of living modified organisms.

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Regarding the international regime on access to genetic resources and benefit-sharing negotiated in the framework of the Convention on Biological Diversity (CBD), it proposes that Africa aim for a strong regime to address misappropriation cases, including: a requirement for disclosure of origin of genetic resources and associated traditional knowledge in patent applications; and a formalized system of sharing of benefits deriving from the commercialization of such genetic resources or their derivatives towards the holders of the genetic resources and traditional knowledge. However, Africa should also consider including in the regime facilitated access to genetic resources, in order to promote research and development in biotechnology and foster local biotechnological innovation.

Regarding the Global Environment Facility (GEF), it is proposed that Africa play a more active role in the decision-making process, presenting proposals that represent a strategic approach to biosafety funding for the region. The presentation of a coherent biosafety-project portfolio for the fourth GEF replenishment is key for Africa to increase local capacity for risk management and benefit from biotechnology products, while ensuring health and environmental safety. Africa should also follow closely indicators on global benefits for the biodiversity focal area, to ensure they reflect Africa's strategic approach to biotechnology.

The policy brief concludes that international negotiations within the CBD, Cartagena Protocol and GEF present opportunities to promote biotechnology research and development in the region and overcome the existing gap with developed countries, and such opportunities should not be lost. Biotechnology and biosafety issues are best addressed with a clear picture of priorities and constraints for the region, through a proactive approach, rather than a purely defensive one, and focusing on pragmatic solutions that enhance Africa's capacity for applying biosafety and obtaining benefits from the use of its genetic resources in order to support sustainable development and poverty eradication efforts.

## INTRODUCTION TO BIOSAFETY AND BIOTECHNOLOGY POLICY ISSUES IN AFRICA

AFRICA, a continent rich in genetic resources and biotechnology potential, is working to establish common approaches to biotechnology regulation throughout the region, to enhance its capacity to benefit from progress in this field and use it as a tool to promote poverty eradication and sustainable development. Following the adoption of Africa's Science and Technology Consolidated Plan of Action<sup>1</sup> in August 2005 by the African Ministerial Council on Science and Technology, and the African Union (AU), a High-Level African Panel on Modern Biotechnology was established to facilitate regional dialogues on policies for biotechnology. The High-Level Panel presented its conclusions in July 2006.<sup>2</sup>

In November 2006, the Extraordinary Conference of the African Ministerial Council on Science and Technology (AMCOST), held in Cairo, Egypt, considered the report of the High-Level Panel, as well as a draft strategy on biosafety

<sup>1</sup> AU/NEPAD, 2005.

<sup>2</sup> AU/NEPAD, 2006.

### **Box 1: Key Policy Objectives**

#### ***Science and Technology Consolidated Plan of Action***

- *Enable* Africa to harness and apply science, technology and related innovations to eradicate poverty and achieve sustainable development;
- *Ensure* that Africa contributes to the global pool of scientific knowledge and technological innovations;
- *Build* Africa's capacities to develop and safely apply biotechnology in agriculture, health, mining, industry and other areas;
- *Establish* informed policies and strategies to respond to developments associated with biotechnology, rather than react to agendas set by other regions of the world; and
- *Build* common consensus and strategies on how best to ensure that they maximize benefits from the technology while at the same time addressing potential environmental, health, ethical and economic risks or concerns emerging with rapid advances of the technology.

#### ***African High-Level Panel on Modern Biotechnology***

- *Recognize* African ownership and responsibility for the continent's development;
- *Promote and advance* democracy, human rights, good governance and accountable leadership;
- *Promote* self-reliant development to reduce dependency on aid;
- *Build* capacity in African institutions;
- *Promote* intra-Africa trade and investment; accelerating regional economic integration;
- *Promote* the advancing of women;
- *Strengthen* Africa's voice in international forums;
- *Forge partnerships* with African civil society, the private sector, other African countries and the international community.

Source: AU/NEPAD, 2005; AU/NEPAD, 2006.

presented by the AU's Directorate of Human Resources, Science and Technology (HRST); and adopted the Cairo Declaration,<sup>3</sup> endorsing the report of the High-Level Panel and committing to working together to develop a 20-year African biotechnology strategy. This Strategy would include specific regional technology goals to be implemented through regional groupings, and would aim to develop and harmonize national and regional regulations that promote the application and safe use of modern biotechnology.

This policy brief will seek to translate the key policy objectives identified in Africa's Science and Technology Consolidated Plan of Action and in the High-Level Panel Report (Box 1), into concrete proposals for a coherent African position in ongoing multilateral environmental negotiations on biotechnology-related issues, namely, on biosafety and genetic resources.

Africa's Science and Technology Consolidated Plan of Action establishes a common vision, objectives and principles to guide research and development programmes on several issues,

<sup>3</sup> AMCOST, 2006.

## **Box 2: Key Policy Measures**

### ***Draft African Strategy on Biosafety***

- Proposed measures regarding international negotiations include:
- Capacity-building efforts relevant to individual countries as well as the entire African region;
- Collaborative partnerships between public and private research initiatives, and participatory decision-making and regulatory mechanisms to minimize risks while maximizing benefits; and
- Coordination among African negotiators, and support to negotiators by the AU, before any major international meeting.

### ***Agricultural Ministers' position on genetically modified organisms and agriculture***

- Proposed measures to guide AU activities include:
- Mechanisms to raise public awareness;
- Elaborating an adequate African strategy on biosafety (reinforcing capacities and work groups);
- Creating adequate conditions for the application of biotechnology by encouraging the dialogue among different ministries and all stakeholders;
- Necessary mechanisms to facilitate the harmonization of regulatory and control systems; and
- Reinforcing the African capacities for effective participation in international negotiations.

Source: AU, 2006a; AU, 2006b.

including the safe development and application of biotechnology (Programme 1.2), and building a common African strategy for biotechnology (Programme 5.4).

The AU/New Partnership for Africa's Development (NEPAD) High-Level African Panel on Modern Biotechnology (APB) worked on the idea of promoting "regional innovation communities" across Africa operating within the framework of designated Regional Economic Communities (RECs). The APB report highlights the role of modern biotechnology in regional economic integration and trade; outlines priority areas of relevance to African development; identifies critical capabilities needed for the development and safe use of modern biotechnology; specifies harmonized regulatory measures needed for advancing research and commercialization, safe use and trade; and proposes strategic options for creating and building regional biotechnology innovation communities and local innovation areas in Africa.

As a conclusion, the APB states that African countries must integrate policies on biotechnology into overall national development policy frameworks while reducing resistance to its adoption, diffusion, and integration within economically-important sectors. For example, it proposes that Africa should develop an industrial biotechnology research and development (R&D) agenda for the development of biofuels, and develop scientific capacity to assess biotechnology-related risks through regional and/or continental institutions or mechanisms, so that

"all biotechnology policy is informed by science and not fear or skepticism." In particular, it notes that the continent, through its RECs, needs to adopt an evolutionary approach where regulatory systems develop hand in hand with technological opportunities and applications.

Two other documents have been presented to the AU and are relevant for the understanding of current discussions within Africa and the development of the proposed 20-year African biotechnology strategy: the first is the draft "African Strategy on Biosafety,"<sup>4</sup> presented to AMCOST by the AU's HRST, and the second is the "African Position on the Issue of Genetically Modified Organisms and Agriculture" adopted by the Conference of Agricultural Ministers of the AU in December 2006.<sup>5</sup> Both documents have common issues of concern, but approach the topic with different perspectives.

The draft African Strategy on Biosafety (ASB) reviews the existing divergent opinions on benefits and risks of genetically modified organisms and then addresses the participation of African countries in capacity-building activities, such as those financed by the Global Environment Facility (GEF), as well as in sub-regional initiatives within RECs, concluding with a proposal for an African regional strategy on biosafety. The draft strategy proposes that the AU put in place capacity-building initiatives and projects to help member countries generate the required institutional and human capacities for African countries to apply modern biotechnology for maximum benefits, "while avoiding all the possible risks;" as well as to further endeavor to ensure that African delegates to international meetings and negotiations are adequately prepared for maximum effectiveness in negotiations. The draft strategy is based on the following pillars:

- Establishment and strengthening of institutional frameworks;
- Awareness raising and biosafety information exchange;
- Capacity building and preparedness for negotiations;
- Policy and legal frameworks;
- International cooperation; and
- A sustainability mechanism.

Agricultural Ministers expressed the need for the AU to elaborate a common approach to biotechnology and biosafety in the face of competing, and sometimes biased views, that are polarizing the political discourse. Building on decision EX.CL/Dec.26 (III) that requires a common position on biotechnology, they propose that biotechnology be used to aid countries to increase and improve agricultural production, while ensuring biosafety. They suggested core issues that should be taken into account when evaluating or developing new biotech products, including that:

- Most African agricultural producers are smallholder farmers;
- New technologies should target problems in Africa from an African perspective, and should not be imposed from abroad;
- Biotechnologies should support and complete traditional agricultural production knowledge and technologies and be adapted to the local environment;
- Biotechnologies should develop native African crops and not only commercial crops like cotton or corn;
- It is imperative to conserve and protect local or indigenous genetic resources;

<sup>4</sup> AU, 2006a.

<sup>5</sup> AU, 2006b.



- Biotechnology products' costs must be considered to ensure that a comparative advantage in the relevant sector exists and merits their use; and
- Governments and RECs must dedicate sufficient resources to this process.

A common issue that comes up in the policy papers described is the need for greater coherence among African negotiators within multilateral processes related to biotechnology. A common problem faced by all regions is that a multiplicity of agencies participate in different negotiating processes, leading in many cases to incoherent guidance at the international level.

Biotechnology and biosafety are regulated at the global level through different multilateral instruments and processes, from binding rules to flexible guidelines and financing. Main processes address the following aspects: transnational movement of living modified organisms (the Cartagena Protocol on Biosafety); access to genetic resources and sharing of benefits arising from their utilization (the Convention on Biological Diversity); finance for biosafety capacity-building activities (the GEF); access to plant genetic resources for food and agriculture (the FAO International Treaty on plant genetic resources for food and agriculture); trade in biotech products including agricultural commodities (the World Trade Organization (WTO) including its agreements on the application of sanitary and phytosanitary measures and on technical barriers to trade; standard-setting organizations related to international trade of plants, animals and food (International Plant Protection Convention, the World Organization for Animal Health and CODEX *Alimentarius*); and intellectual property rights over biotech products (the WTO Agreement on trade-related aspects of intellectual property rights (TRIPs) and the World Intellectual Property Organization (WIPO)).

Based on the policy guidance adopted by the AU, AMCOST and NEPAD in the papers reviewed, this brief will look at current multilateral negotiations on biotechnology through the perspective of the following three core policy objectives, which seek to condense some of the main principles agreed within the AU:

- Promote R&D in biotechnology to eradicate poverty and achieve sustainable development;
- Build Africa's capacities to develop and safely apply biotechnology in agriculture, health, mining, industry and other areas like biofuels; and
- Ensure policies are science-based and promote food security and economic growth.

This brief will review major issues to be discussed in global multilateral processes related to biotechnology during 2007, which merit the development of an informed common position by Africa. It will focus on negotiations taking place within the Convention on Biological Diversity and its Cartagena Protocol, and within the Global Environment Facility. Specific topics to be addressed include: liability and redress for the transboundary movement of living modified organisms; access to genetic resources and benefit-sharing; and funding for biosafety. For each of these processes, main policy debates, tensions and challenges will be noted, and proposals and ideas to transform the former policy principles into concrete African positions will be presented, with the objective of increasing Africa's say and influence at the level of general policy approaches and on specific substantive issues during 2007.

## CARTAGENA PROTOCOL ON BIOSAFETY: NEGOTIATIONS ON LIABILITY AND REDRESS

The Cartagena Protocol on Biosafety regulates the transboundary movement of living modified organisms (LMOs) resulting from modern biotechnology to ensure their safe transfer, handling and use. It thus establishes rules and procedures for allowing the import of LMOs and requirements on documentation for LMO exports. Different import procedures and identification and handling requirements are established according to LMOs prospective uses, whether it be for planting (release into the environment), for human or animal consumption (food, feed or processing), or for research and development (contained use).

The Protocol was negotiated within the Convention on Biological Diversity (CBD), but as a separate legal instrument it requires ratification by CBD Parties. As of December 2006, the Protocol has been ratified by 138 Parties, including 39 African countries.<sup>6</sup> One of its major shortcomings, however, is that the main producers and exporters of GM crops, namely, the US, Canada, Argentina and Australia, have not ratified it (the US is not a Party to the CBD, therefore it can not participate in the Protocol). This is a consideration that must be borne in mind during negotiations as it places additional challenges on Parties of import and may limit the effectiveness of some international regulations.

Since its entry into force in 2002, Parties to the Protocol have advanced in: the regulation of handling, packaging, transport and identification of LMOs; the promotion of capacity building for risk assessment and risk management; and the provision of guidance to the GEF on funding for biosafety-related activities. The next meeting of the Parties to the Cartagena Protocol (COP/MOP-4) will be held, back-to-back with the CBD Conference of the Parties, from 12-16 May 2008 in Bonn, Germany. The meeting will provide an opportunity for African countries to evaluate the first five years of the Protocol's implementation, and present their needs and demands for capacity building on the basis of such an assessment (Box 3).

During 2007, the main issue that will be addressed by negotiators within the Cartagena Protocol is a regime on liability and redress for the harm caused by LMOs. An *Ad Hoc* Working Group on Liability and Redress in the context of Protocol has been established according to Article 27 of the Protocol, which states that Parties shall establish 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, and shall endeavor to complete this process within four years. The group will meet in Montreal, Canada, twice during 2007, on 19-23 February and on 22-26 October.<sup>7</sup> Co-chairs for the meetings are Jimena Nieto (Colombia) and René Lefeber (the Netherlands).

<sup>6</sup> African countries Parties to the Cartagena Protocol on Biosafety are: Algeria, Benin, Botswana, Burkina Faso, Cameroon, Cape Verde, Chad, Congo, Democratic Republic of the Congo, Djibouti, Egypt, Eritrea, Ethiopia, Gambia, Ghana, Kenya, Lesotho, Liberia, Libyan Arab Jamahiriya, Madagascar, Mali, Mauritania, Mauritius, Mozambique, Namibia, Niger, Nigeria, Rwanda, Senegal, Seychelles, South Africa, Sudan, Swaziland, Togo, Tunisia, Uganda, United Republic of Tanzania, Zambia, Zimbabwe.  
<sup>7</sup> Documents for the meeting, including a compilation of country submissions, can be found at: <http://www.biodiv.org/doc/meeting.aspx?mtg=BSWGLR-03>

## **POLICY DEBATES, TENSIONS AND CHALLENGES**

Even though negotiations on a liability Protocol are still nascent, a broad spectrum of opinions across the board is clear. On one end of the spectrum, countries which are or expect to be large biotechnology exporters and their traditional allies, such as the US, Canada, Australia, Argentina and New Zealand, do not favor a tough liability instrument, and question its usefulness or need within the Biosafety Protocol's context, cautioning on the effects of such a regime on agricultural exports and biotech

### **Box 3: Input by Parties required prior to the next Cartagena Protocol meeting in 2008:**

#### **Handling, transport, packaging and identification of LMOs:**

Parties are requested to submit:

- Information on experience gained with the use of existing documents (decision BS-III/8, paragraph 1);
- Views and information on the adequacy of existing rules and standards for identification, handling, packaging and transport of goods and substances to address concerns relating to the transboundary movement of LMOs, and on gaps that may exist and that may justify a need to develop new rules and standards or to adjust existing ones (decision BS-III/9, paragraph 1);
- Information on experience gained with the use of LMO sampling and detection techniques and on the need for and modalities of developing criteria for acceptability of, and harmonizing, sampling and detection techniques (decision BS-III/10, paragraph 11).

#### **Risk assessment and risk management**

- A regional workshop for Africa on risk assessment and risk management will be held, subject to securing relevant funding (decision BS-III/11, section B, paragraph 10).

#### **Monitoring and reporting**

- Parties are requested to submit their first national report, covering the period since the entry into force of the Protocol, by 11 September 2007 (decision BS-III/14, paragraph 7).

#### **Assessment and review**

Parties are invited to submit their views on the:

- effectiveness of the Protocol; and
- procedures and annexes under the Protocol, with a view to identifying difficulties arising from implementation as well as suggestions for appropriate indicators and/or criteria for evaluating effectiveness and ideas on the modalities of the evaluation (decision BS-III/15).

#### **Socio-economic considerations**

- Parties are requested to provide their views and case studies, where available, concerning socio-economic impacts of LMOs (decision BS-II/12, paragraph 5).

Source CBD, November 2006.

research. During past meetings of the Liability Working Group for example, New Zealand proposed to include certain effectiveness criteria within the liability negotiations to determine whether liability rules will work in the Cartagena Protocol's context. Other countries agreed to consider these, including that the scope of the regime and damage definitions, as well as individuals or entities to which rules apply, be clearly defined, and that rules are meaningful, easy to apply and provide incentives for the exercise of precaution.

On the middle spectrum of opinions, EU countries and others that see themselves as both importers and possible exporters of biotech products, propose instruments that enable the compensation and redress for harm caused by transboundary movements of LMOs, while not impacting excessively on this industry or generating State liability.<sup>8</sup>

Finally on the other end, African countries have placed themselves as net importers of biotech products, requesting the strictest biosafety liability rules, including the responsibility of exporting States and a broad consideration of damages.<sup>9</sup>

### **GENERAL APPLICATION OF PRINCIPLES**

The following remarks address the likelihood of liability discussions within the Cartagena Protocol to affect the three key policy objectives identified:

- 1. Promote R&D in biotechnology to eradicate poverty and achieve sustainable development:** The establishment of a harmonized regime for liability through the Cartagena Protocol is useful and may be more convenient than establishing different regimes in each country, which may disincentive biotechnology development. In this sense, the relevant APB's recommendation that Africa should "adopt an evolutionary approach where regulatory systems develop hand in hand with technological opportunities and applications" should guide the way. In order to promote R&D of African biotech products, considering the restricted application of such research and relatively low risk, stronger liability requirements could be restricted to products approved for commercial application only. For example, liability for harm caused by LMOs used for research and development could be limited to cases where there is fault, i.e. when appropriate safety measures, for example to contain field tests, were not followed.
- 2. Build Africa's capacities to develop and safely apply biotechnology in agriculture, health, mining, industry and other areas like biofuels:** The consideration of liability rules that provide incentives for adequate risk assessment and management by the private sector and do not place undue restrictions or burdens on research and development of biotech products, such as crops for biofuels, is key to turn the policy principles into practice. An efficient liability regime could generate the incentives to ensure that government regulatory agencies, generally lacking adequate capacities and resources to implement "command and control" approaches to regulation of biotechnology products, are able to adequately control and minimize risks.

<sup>8</sup> CBD 2006b; EU Proposal.

<sup>9</sup> CBD 2006b; Ethiopia Proposal. Please note that within the CBD context, Ethiopia generally represents the views of the African Group.

### 3. Ensure policies are science-based and promote food security and economic growth:

A liability regime may create incentives for the correct assessment of risks prior to a product's approval, and the disclosure of all relevant information to authorities allowing them to take informed decisions when authorizing a product's import or commercialization. In this regard, African countries would benefit from a regime that imposes different levels of liability according to the performance of an adequate risk assessment and compliance with risk management measures; favoring those companies or entities that have taken all appropriate measures, and penalizing those that did not provide relevant information or assess or manage relevant risks, and caused damages as a result.

**Policy Consideration:** Ensure effective achievement of African biotech objectives through a pragmatic approach that focuses on: measures to allow compensation of harm in a proportionate measure to risks, and a process that institutes measures that may be implemented in the short-term where capacity for risk management is likely to be weaker. A strategy to build Africa's risk assessment and risk management, as well as monitoring, capacity is further needed to ensure implementation of any liability regime.

#### SPECIFIC POLICY ISSUES

The following issues within the liability regime discussions merit efforts within Africa to arrive at a common position, as they are likely to be those most relevant during 2007 negotiations of the Liability Working Group: the type of regime and procedures to be implemented (whether binding, voluntary or mixed); the scope of damages to be addressed; how such damages will be linked to the liable entities (individuals, firms, multinationals, States); what limitations or exclusions for liability will be incorporated; and which financial instruments will secure that adequate compensation or redress is available. Countries have been requested to present their views and text proposals in preparation for the next meeting of the Liability Working Group. It is interesting to note that the only African country presenting its views was Ethiopia, which submitted a complete text for a liability protocol.<sup>10</sup>

#### OPTIONS FOR THE LIABILITY REGIME

**ARCHITECTURE:** Parties must decide whether liability and redress will be addressed by a separate international legal instrument, or through other voluntary procedures. A key aspect of such a decision must be related to the lack of participation by main exporting countries in the Protocol, which requires a rethinking of most effective alternatives to harness entities potentially liable for harm. Up to now, discussions have reflected this question on the issue of the nature of the liability instrument; and whether it should be binding, non-binding or a mix of both.

**Binding instrument/s:** A binding instrument establishing an international liability regime for damage caused by LMOs is favored by many developing countries, including African countries, which fear that damages caused by the use of LMOs in productive activities, may cause harm to biodiversity (or even livelihoods) that otherwise would not be compensated. A binding

regime is, in theory, the most effective way to channel liability and redress between Parties, or to execute claims against foreign firms or individuals, while ensuring a coherent and harmonic approach to this issue at the international level. In practice, however, this approach lies on the assumption that all relevant stakeholders participate in the regime. Furthermore, due to the need for additional ratification procedures, it also entails the most lengthy and cumbersome process. Considering that main exporters have not ratified the Biosafety Protocol, it is unlikely that they would ratify a liability instrument, therefore such an instrument, albeit binding on Parties, may not be useful at this stage, to target firms located or exporting from non-Parties. A prior example of such an instrument negotiated within a multilateral environmental agreement, that did not succeed in harnessing the needed ratifications and has yet to enter into force, is the Basel Protocol on Liability and Compensation for Damage Resulting from Transboundary Movements of Hazardous Wastes and their Disposal.

**Non-binding instruments:** A non-binding regime is favored by some developed country Parties and exporters (like the US, Australia, New Zealand, and Argentina), which question the need for a regime pointing to the fact that a strong liability regime would disincentive exporters from ratifying the Protocol and suggesting that voluntary mechanisms, such as the adoption of model laws and guidelines, may be most effective in achieving the harmonization of liability regimes. An example of a non-binding instrument promoting the harmonization of regional legislation on biosafety is the African Model Law on Safety in Biotechnology.<sup>11</sup> Benefits of voluntary guidelines or codes of conduct include the more rapid negotiation and adoption processes, although it is important to consider that unless they are accompanied by binding mechanisms for the recognition of international sentences, they do not serve to impose liability to foreign companies without presence in import countries.

**Mixed approach:** Many EU countries and developing countries support a mixed approach that minimizes conflict while achieving the compensation for harm. For example, the EU proposes a two-staged approach, starting with a non-binding decision recommending all Parties to the Protocol to implement a common liability regime, and following with an assessment on its effectiveness, prior to considering other alternatives, such as a binding Protocol. Other related proposals include recommendations on administrative measures to implement civil liability regimes at the national level, guidelines to be included both in national legislations and import/export contracts, such as to resort all biosafety liability claims to an international arbitration tribunal, or to require specific insurance or guarantees when authorizing LMOs for liberation into the environment.<sup>12</sup>

**Policy Consideration:** When negotiating, keep efficiency considerations in mind, such as how to channel liability to firms operating from abroad. An effective strategy should focus on proposals and clauses that may be most effective under the different options for an international instrument, notwithstanding the lack of participation of key exporting countries in the system.

<sup>11</sup> AU, 2001.

<sup>12</sup> Colombia, for example, proposes a mandatory financial security requisite. Country and regional views presented can be consulted at: <http://www.biodiv.org/doc/meetings/bs/bswglr-03/information/bswglr-03-inf-01-en.pdf>

<sup>10</sup> Country and regional views presented can be consulted at: <http://www.biodiv.org/doc/meetings/bs/bswglr-03/information/bswglr-03-inf-01-en.pdf>



### OPTIONS FOR THE SCOPE OF DAMAGE TO BE

**ADDRESSED:** Parties must decide the scope and type of damages which will be addressed by the regime; for example, whether it will include: damage by unintentional transboundary movements of LMOs or just intentional ones; damage caused by the transboundary movement itself or by the subsequent use of the LMOs; and damages to biodiversity only, or also to the environment, human health or livelihoods.

**Broad consideration of damages:** Most importing countries, including African countries, favor a broad definition of damages, that would cover harm to biodiversity and other environmental components caused by LMOs (such as harm caused by the crossing of an LMO with natural crop varieties) and possibly including socioeconomic damages (for example if a community's livelihood selling organic produce is lost due to crops contamination with LMOs) and the cost of response measures.

**Consideration of damages proportional to risks:** Other countries, like Colombia, propose that the types of damages covered be adjusted according to the levels of risk of specific types of LMOs.

**Restricted consideration of damages:** Exporting countries favor a restricted consideration of damages that relate to harm caused within a particular transboundary movement, i.e. leaving out those caused by their "use" once a shipment has been legally imported.

**Policy Consideration:** At this stage, most proposals refer to damages in general without making a difference according to the use of LMOs or levels of risk. Negotiators may consider establishing a criterion of proportionality between degree of risks and damages covered to ensure that livelihoods and biodiversity in Africa are preserved, while improving farmer's income and food security, and promoting research and development opportunities.

### OPTIONS TO ESTABLISH CAUSATION AND

**DETERMINE WHO WILL BE LIABLE:** Considering that most exporters are not Parties to the Protocol, the options to channel liability will focus mostly on the private sector (producers, exporters and importers of LMOs) with alternatives including whether to establish strict or fault-based liability.

**Strict Liability:** Most importing countries including the EU favor strict liability, whereby liability would be established upon the occurrence of harm caused by LMOs, irrespective of fault or negligence.

**Fault-based liability:** Exporters in general favor a fault-based approach where private entities respond for their fault or negligence in controlling risks, but not for damages caused by the product's inherent risk notwithstanding good management practices.

**Channeling to the private sector:** Most countries, including exporters, prefer channeling liability to the private entities that are in the best position to control risks posed by these products, such as producers, transporters, and exporters and importers. Importers also favor this option, as it may enable the liability regime to be applicable to entities selling their products from countries that are not Parties to the Protocol. Some African countries, like Ethiopia, however, propose the inclusion of residual State liability for Parties where the LMO shipment originated.

**Policy Consideration:** Channeling liability to the private sector, and possibly establishing exceptions to strict liability for research activities or for some points in the production chain where due diligence is important and risks are lower (i.e. transport), may be an effective means to both ensure that research and development opportunities are not hampered and that there are incentives for the private sector to exercise due diligence in the management of LMOs.

### BIODIVERSITY CONVENTION: NEGOTIATIONS ON AN INTERNATIONAL REGIME ON ACCESS TO GENETIC RESOURCES AND BENEFIT-SHARING

The Convention on Biological Diversity currently has 190 Parties, including 52 African countries.<sup>13</sup> It enjoys almost universal membership, with the US being the most notable non-Party. Negotiations on an international regime on access to genetic resources and benefit-sharing (ABS) began as a result of the call by the World Summit on Sustainable Development (WSSD) to negotiate, within the framework of the CBD, an international regime to promote the fair and equitable sharing of benefits arising out of the utilization of genetic resources. In 2006, Parties to the CBD mandated the *Ad hoc* Open-ended Working Group on Access and Benefit-sharing to negotiate an international regime on access and benefit-sharing and requested to complete its work at the earliest possible time before the tenth Conference of the Parties to the CBD (COP-10) to be held in 2010.<sup>14</sup>

The next CBD COP will be held from 19-30 May 2008, in Bonn, Germany; with two meetings of the ABS Working Group planned for 10-14 September 2007 and 21-25 January 2008, and

#### **Box 4: Access to genetic resources and Benefit-Sharing in the CBD**

One of the three CBD objectives, is the "fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding" (CBD Article 1).

CBD Article 15 presents a framework for the implementation of its objectives on access to genetic resources and benefit-sharing. In addition, CBD Article 8(j) encourages the equitable sharing of the benefits arising from the utilization of knowledge, innovations and practices of indigenous and local communities.

These provisions are linked to a number of other provisions, including on: access to, and transfer of technology (CBD Article 16), technical and scientific cooperation (CBD Article 18), and handling of biotechnology and distribution of its benefits (CBD Article 19, para. 1 & 2).

Source: CBD

<sup>13</sup> All African countries except Somalia are Parties to the CBD.

<sup>14</sup> CBD Decision VIII/4; <http://www.biodiv.org/decisions/default.aspx?m=COP-08&id=11016&lg=0>



### **Box 5: Input required from Parties prior to the next meeting of the ABS Working Group**

#### ***International regime:***

Parties are requested to submit:

- information regarding the inputs on an analysis of existing legal and other instruments at national, regional and international levels relating to access and benefit-sharing (Decision VIII/4, part A, para 3);
- further information relevant to the gap analysis (Decision VIII/4, part A, para 8);
- information on the legal status of genetic resources in their national law, including their property law where applicable (Decision VIII/4, part A, para 10).

#### ***Bonn Guidelines:***

- Parties are invited to submit reports on their experiences in developing and implementing Article 15 of the Convention at the national level, including obstacles encountered and lessons learned (Decision VIII/4, part B, para 2).

#### ***International certificate:***

- Parties are invited to undertake further work, including through research and submission of views, on the possible options for the form, intent and functioning of an international certificate of origin/source/legal provenance and on its practicality, feasibility, costs and benefits, including consideration of certificate models as an input for the work of the Expert Group (Decision VIII/4, part C, para 5).

#### ***ABS indicators:***

- Parties are invited to submit their views and information to the Executive Secretary on the need and possible options for indicators for access to genetic resources and in particular for the fair and equitable sharing of benefits arising from the utilization of genetic resources and associated traditional knowledge (Decision VIII/4, part E, para 2 and recommendation 3/5 of the ABS Working Group, paras 1 and 2).

Source: CBD Decision VIII/4.

a meeting of technical experts on an internationally recognized certificate of origin/source/legal provenance from 22-25 January 2007. Tim Hodges (Canada) and Fernando Casas (Colombia) are designated as Co-Chairs of the ABS Working Group. In addition, the regime is expected to come into consideration at the next meeting of the *Ad hoc* Open-ended Working Group on Article 8(j) and related provisions, to be held from 17-21 September 2007.

### ***POLICY DEBATES, TENSIONS AND CHALLENGES***

Debates on ABS indicate the divergence of opinions between the G-77/China, including developing countries which are countries of origin/providers of genetic resources, and developed countries which consider themselves as mainly users. Developing countries, including the African group, support the development of a strong, legally-binding instrument, with focus on benefit-

sharing, to stop misappropriation of genetic resources and traditional knowledge. Mainly providers of genetic resources, they wish to gain from biodiversity use.

Holding middle ground, Mexico, Norway, the EU and Switzerland are, for different reasons each, open to the development of a relatively strong regime. Mexico, a biodiverse country with rapidly developing research sector, probably sees itself as both a provider and a user of genetic resources. Norway and Switzerland, with strong research capacities, want to ensure uninterrupted and legal access, as well as the legality of patents, while Norway has introduced mandatory disclosure requirements in its national legislation. The EU has not formed its definitive view yet, apparently divided between provider countries of the South (i.e. Spain) and countries with a strong biotech industry (i.e. France).

At the other end, other developed countries seeing themselves as users, such as the US, Canada, Australia and Japan, seem reluctant to negotiate an international regime, point to the possibilities offered by national legislations and do not wish any alteration to the current framework of protection of intellectual property rights.

### ***GENERAL APPLICATION OF PRINCIPLES***

The following remarks address the likelihood of CBD ABS negotiations to affect the three key policy objectives identified:

- 1. Promote R&D in biotechnology to eradicate poverty and achieve sustainable development:** A harmonized international regime would assist in achieving this objective by facilitating access to genetic resources to foster research and development; respecting the rights of both national governments and local communities; and establishing a formalized system of sharing of benefits, monetary or not, to ensure flow of benefits to the holders of the genetic resources and traditional knowledge.
- 2. Build Africa's capacities to develop and safely apply biotechnology in agriculture, health, mining, industry and other areas like biofuels:** Capacity building and technology transfer are generally considered as non-monetary benefits and it can be expected that such issues will be addressed as part of the regime. Africa should seek to formalize such provisions, to develop its own capacities to use its genetic resources.
- 3. Ensure policies are science-based and promote food security and economic growth:** An international system of facilitated access and formalized sharing of benefits would foster agricultural research and development in Africa and enhance its capacities to achieve food security and economic growth.

### ***SPECIFIC POLICY ISSUES***

There are several key policy issues to be decided in the context of an international regime on access and benefit-sharing, including the type of instrument, its scope, the mechanism to ensure sharing of benefits, and issues related to enforcement and compliance.

**a) Type of instrument/instruments:** Parties must decide whether the regime under negotiation will be legally binding or not, and whether it will consist of a new instrument with, or without, a combination of existing ones.



**1. Legally binding instrument:** Countries rich in biodiversity like those in the G-77/China and other countries of origin such as Mexico, as well as part of the EU, see a legally binding international instrument as the most effective way to address the unauthorized appropriation of genetic resources and traditional knowledge, and ill-granted patents over products incorporating genetic resources and associated traditional knowledge. However, negotiating such an instrument may take a long time, and is likely to consume a great deal of resources.

**2. Combination of binding and non-binding elements:** Some EU countries, Norway and Switzerland suggest that the regime could be a combination of both binding and non-binding elements or instruments. Binding elements/instruments could address, for instance, a certificate of origin/source/legal provenance or measures in user-countries, while non-binding elements could include the Bonn Guidelines or address controversial issues unlikely to be resolved through a binding instrument.

**3. Non-binding instrument:** Some countries who use genetic resources and are content with the *status quo*, prefer a non-binding instrument arguing it could be easier to negotiate and adopt, and could then be implemented in national legislations. However, national legislations, even if properly enforced, would not be able to target patents granted internationally and may excessively limit access to genetic resources, an indispensable condition for research and development. The view has not yet been expressed in the negotiations, although it is expected to gain the support of most developed countries: until now, Canada has stated that the issue of the type of instrument should be considered later on in the negotiation process, while Australia, New Zealand and Japan question the need for an international instrument highlighting the role of national legislation.

**Policy Consideration:** Taking into consideration that Africa is home to a rich biodiversity of great potential value, policy makers could consider how to ensure a strong regime to address misappropriation cases. This could be achieved by either a binding instrument or an appropriate combination of binding and non-binding elements. A strategy identifying a limited number of priorities, including defining the “misappropriation” term in the African context, and ensuring adequate terms for sharing of benefits, would be most useful in the negotiating table, considering the time and resources that will be needed in the long run, and that the type of instrument issue may be resolved towards the end of negotiations.

#### **b) Facilitating or restricting access to genetic resources?**

Parties must decide whether the regime would aim not only to ensure fair and equitable benefit-sharing but also to facilitate access. The G-77/China opposes including facilitated access in the scope of the regime, arguing that access to genetic resources should be regulated rather than facilitated, and noting that the current framework –or lack thereof– allows access but no benefit-sharing. The EU and JUSCANZ prefer to include facilitated

access in the regime, so that research and development of products based on genetic resources can be continued without obstacles.

**Policy Consideration:** Africa may consider whether to place itself within the negotiations as solely a provider of genetic resources, or also as a user. In the second case, it would be possible to develop its R&D in biotechnology and foster local biotechnological innovation. This would entail addressing and regulating effectively facilitated access in the regime, as a prerequisite for fostering research and development.

#### **Box 6: WTO TRIPS Negotiations on Biological Resources**

**The Issue:** A review of TRIPS Article 27.3(b), which allows the patentability of micro-organisms and plant varieties began in 1999 and was broadened in 2001 to include the relationship between the TRIPS Agreement and the CBD, and the protection of traditional knowledge and folklore, pursuant to the Doha Declaration (para 19). The 2005 Hong Kong Declaration requested the Director-General to intensify his consultative process, noting that the General Council shall review progress and take any appropriate action no later than 31 July 2006. However, disagreement among Members remains.

**The Debate:** A group of developing countries, represented by India and Brazil and supported by the African group, submitted a number of proposals on the need to amend the TRIPS Agreement to bring it in line with the CBD: according to these proposals, patent applicants would be required to disclose the country of origin of genetic resources and associated traditional knowledge, along with evidence of prior informed consent and benefit-sharing. Failure to satisfy this requirement would entail legal consequences, including revocation of patents.

The EU supports a mandatory disclosure requirement, but with legal consequences lying outside the scope of patent law.

Switzerland has proposed an amendment to the regulations of WIPO’s Patent Cooperation Treaty so that domestic laws may ask inventors to disclose the source of genetic resources and traditional knowledge when they apply for patents. Failure to meet the requirement could stop a patent or, when done with fraudulent intent, could entail a granted patent being invalidated.

The US and other developed countries oppose a multilateral disclosure requirement, and have argued that the CBD provisions on access to genetic resources and on benefit-sharing could best be achieved through national legislation and contractual arrangements based on such legislation, which could include disclosure requirements.



**c) Including derivatives?** Parties must decide whether the scope of any international regime will include derivatives of genetic resources. This is expected to be one of the most difficult questions to be addressed in the negotiations, as derivatives (i.e. extracts of genetic resources or chemical compounds derived from them) are the substances most often used in commercial products based on genetic resources. The G-77/China therefore wants to make sure that derivatives are included in the regime to enable the sharing of benefits arising from the commercialization of derivatives; while most developed countries don't want to include derivatives in the scope of the regime.

**Policy Consideration:** Africa should consider prioritizing inclusion of derivatives in the regime, as they are the products most likely to generate economic benefits, and to prevent ill-granted patents and ensure sharing of benefits from products currently in the pipeline.

**d) Disclosing the origin of genetic resources in patent applications?** The issue of disclosure requirements in patent applications is currently under consideration in the CBD, WIPO and the TRIPS Council (Box 6). Developing countries, as the Group of 77 and China (G-77/China), propose to address the issue in the regime and support a mandatory requirement for disclosure of origin, prior informed consent and benefit-sharing in patent applications when the subject matter incorporates genetic resources and/or traditional knowledge. Developing countries are also active to that regard in the WIPO and WTO negotiations. With regard to developed countries, Mexico, Norway, the EU and Switzerland want/are open to address the issue with various preferences with regard to fora; while the US, Canada, Australia, New Zealand and Japan don't want any changes in the current intellectual property framework.

**Policy Consideration:** To prevent misappropriation of its genetic resources, Africa should consider developing a coherent position in all relevant fora, such as WIPO, TRIPs, the International Plant Protection Convention, and the FAO Treaty on Plant Genetic Resources for Food and Agriculture. Including a disclosure requirement in the regime and recognizing the role and rights of local communities would be central in that regard.

## THE GEF COUNCIL NEGOTIATIONS ON FUNDING FOR BIOSAFETY

The GEF is an independent financial organization administered by the World Bank group that provides grants to developing countries for projects that benefit the global environment and promote sustainable livelihoods in local communities. It functions as the financial mechanism for the Convention on Biodiversity and its Cartagena Protocol on Biosafety, thus being the largest global provider of funding for biosafety. Fifty-one African countries are members of GEF. They participate in the GEF Council according to regional constituencies, with one representative each.<sup>15</sup>

<sup>15</sup> Current representation at the GEF Council (December 2006) is as follows:

*Constituency 1: Botswana, Lesotho, Malawi, Mozambique, Namibia, South Africa, Swaziland, Zambia, Zimbabwe.* Representative: Raphael Peter Kabwaza (Malawi);

The GEF Council takes main policy decisions within GEF. The December 2006 Council Meeting adopted a series of reforms that will impact on the project pipeline portfolio.<sup>16</sup> GEF's new CEO, Monique Barbut proposed to invigorate GEF through proposals to: shift from a project-driven to a programmatic approach by focusing strategies on a clear set of priority issues for the global environment; reduce the current project pipeline in half; and redesign the project approval cycle to reduce it from 66 to 22 months.<sup>17</sup> Since reducing the project pipeline will require the cancellation of many project proposals, decisions were adopted on objective criteria for project selection, pipeline management and cancellation.

A Biosafety Strategy was also adopted, and is focused on enhancing the cost-effectiveness of capacity-building efforts to implement the Cartagena Protocol, by requiring all new projects to perform a stock-taking assessment and determine clearly defined targets. It also promotes a mix of regional and sub-regional full-sized projects and of medium-sized country projects or multi-country thematic projects, according to the sharing of resources' cost-effectiveness and the possibilities for coordination between biosafety frameworks.

The next meeting of the GEF Council will be held on 4-8 June 2007, in Washington DC, where a biodiversity strategy for the next four years period will be approved. Other relevant issues that will be addressed include: a review of proposals regarding the review and revision, as necessary, of the six focal areas strategies; operational guidelines for the application of the incremental cost principle; and steps for project cycle streamlining.

### POLICY DEBATES, TENSIONS AND CHALLENGES

Policy debates within GEF center on the implications of the application of its new Resource Allocation Framework (RAF) (see Box.7). During 2006, GEF conducted a series of sub-regional workshops on the RAF, which showed that African countries resented the presentation of RAF as a "fait accompli" and questioned GEF's decision-making structure, whereby donors have larger weight.<sup>18</sup> Although the RAF has already been approved by the Council, better intra-regional coordination with GEF regional representatives is key to enhance Africa's participation in the process for the RAF's mid-term review that will commence in 2008. During 2007, the new project cycle and indicators for the determination of RAF will continue to be discussed, as well as focal area strategies for the next four

*Constituency 2: Algeria, Egypt, Morocco, Tunisia.* Representative: Najeh Dali (Tunisia);

*Constituency 3: Burkina Faso, Cape Verde, Chad, Guinea-Bissau, Mali, Mauritania, Niger, Senegal, the Gambia.* Representative: Carlos Alberto de Sousa Monteiro (Cape Verde);

*Constituency 4: Comoros, Djibouti, Eritrea, Ethiopia, Kenya, Madagascar, Mauritius, Rwanda, Seychelles, Sudan, Tanzania, Uganda.* Representative: Aboubaker Doualé Waiss (Djibouti);

*Constituency 5: Benin, Cote d'Ivoire, Ghana, Guinea, Liberia, Nigeria, Sierra Leone, Togo.* Representative: Mr. Theophile Chabi Worou (Benin);

*Constituency 6: Burundi, Cameroon, Central African Republic, Congo, Congo DR, Equatorial Guinea, Gabon and Sao Tome and Principe.* Representative: Gustave Doungoube (Central African Republic);

<sup>16</sup> GEF 2006d.

<sup>17</sup> GEF 2006e.

<sup>18</sup> GEF/UNDP 2006a; GEF/UNDP 2006b; GEF/UNDP 2006c.

years (countries were invited to comment on draft strategies by 15 January 2007), therefore countries may elaborate on RAF's benefits and shortcomings and present a common position.

### GENERAL APPLICATION OF PRINCIPLES

The following remarks address the likelihood of discussions within the GEF Council to affect the three key policy objectives identified:

- 1. Promote R&D in biotechnology to eradicate poverty and achieve sustainable development:** The current criteria used for GEF to allocate funds for biodiversity and biosafety privileges biodiversity conservation. However, the biodiversity focal strategy is still under discussion, therefore a focus on biotechnology as a tool for poverty eradication or sustainable development may be enhanced.
- 2. Build Africa's capacities to develop and safely apply biotechnology in agriculture, health, mining, industry and other areas like biofuels:** GEF is the main source of international funding for building capacity on biosafety; therefore, the presentation of a coherent biosafety-project portfolio for GEF-4 is key for Africa to ensure that all allocations are utilized by the end of the period and render expected results.
- 3. Ensure policies are science-based and promote food security and economic growth:** The adopted Biosafety Strategy includes capacity building for the implementation of the Cartagena Protocol, and the performance of risk assessments and use of the Biosafety Clearing-house. Projects to strengthen approval mechanisms for biotech products improving institutional capacities for risk management and risk assessment, may therefore receive funding, as long as they are included within each countries priorities.

**Policy Consideration:** Follow substantive developments on indicators on Global Environment Benefits for the biodiversity focal area within RAF to ensure that African priorities and special characteristics are reflected; also, contribute to indicators for progress in the biodiversity strategy to ensure they reflect African priorities on biotechnology and biosafety.

### SPECIFIC POLICY ISSUES

Current biosafety-related discussions within the GEF Council focus on the impact of GEF's new RAF on funding available for Biosafety, on the cancellation of projects within the project pipeline, and on the approval of a biodiversity strategy for 2007-2010. Biosafety is part of the wider Biodiversity Focal Area that has been allocated US\$ 1 billion for the four year period, of which around US\$ 200 million may be allocated to African countries.

**FUNDS AVAILABLE FOR BIOSAFETY:** Pursuant to the RAF, individual countries must decide how to distribute the funds available to them for the biodiversity cluster according to their own priorities. Such individual priority-setting exercise will determine overall funds available for biosafety; however, GEF's funding estimation for Biosafety during the next four years is US\$ 90 million.<sup>19</sup>

It is interesting to note that in the past four-year period, as a result of the entry into force of the Cartagena Protocol, funds for Biosafety have amounted to US\$ 56,4 million divided into

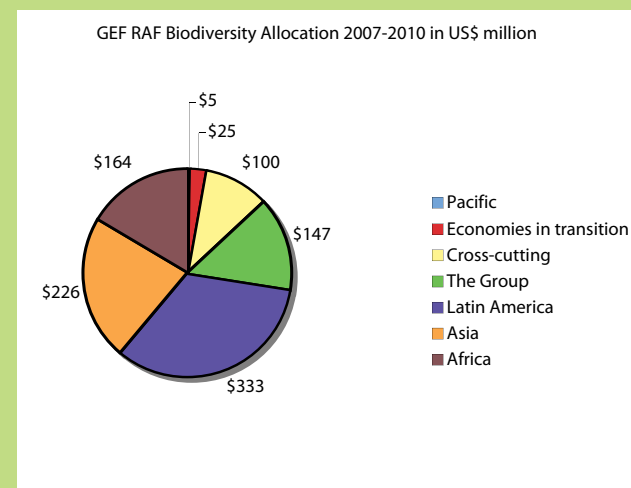
<sup>19</sup> GEF 2006c. Biosafety Strategy.

### Box 7: The RAF

At the conclusion of the negotiations for the fourth replenishment of the GEF Trust Fund in June 2006, 31 donor countries agreed to replenish the Trust Fund with US\$ 3.13 billion for the four-year period (2007-2010).

Funds available for biodiversity and biosafety during the next four-year period (US\$ 1 billion) will be allocated using a new Resource Allocation Framework, which allows some countries to receive individual allocations for the period and present projects in these focal areas according to their priorities.

The objective of RAF is to make GEF funds predictable for developing countries and enhance funding efficiency. The criteria for allocating funding to each country are determined according to two indexes, one using select criteria to establish their potential to create global benefits (Global Benefits Index) and the other based on past performance in implementing GEF projects (GEF Performance Index). According to these indexes, some countries receive individual allocations and the rest are allocated a fixed amount as a "Group." As a result, twenty-one African countries with individual allocations will receive grants ranging from US\$ 3.5 to 63.2 million. Countries in the "Group" will receive between US\$ 1 and 3.4 million for the biodiversity cluster up to a total of US\$ 146.8 million.



**Africa:** Countries with individual allocations: Algeria, Cameroon, Cape Verde, Congo DPR, Cote d'Ivoire, Egypt, Ethiopia, Kenya, Madagascar, Malawi, Mauritius, Morocco, Mozambique, Namibia, Nigeria, Seychelles, South Africa, Sudan, Tanzania, Uganda, Zambia.

**The Group:** 93 Countries with a group allocation including: Angola, Benin, Botswana, Burkina Faso, Burundi, Central African Republic, Chad, Comoros, Republic of Congo, Djibouti, Equatorial Guinea, Eritrea, Gabon, Gambia, Ghana, Guinea, Guinea-Bissau, Lesotho, Liberia, Libya, Mali, Mauritania, Niger, Rwanda, Sao Tome and Principe, Senegal, Sierra Leone, Swaziland, Togo, Tunisia, Zimbabwe.

Source: GEF, 2006.




**Box 8: GEF biosafety projects**

<b>Project, participants and GEF Grant (in million USD).</b>	<b>Description</b>
West African Regional Biosafety Project; Regional: Benin, Burkina Faso, Mali, Senegal, Togo; 6.100 US\$ million	The Global Goal of the project is to enable selected cotton-producing countries in West Africa to implement the Cartagena Protocol on Biosafety. This will be achieved through the development of common science-based, internationally accepted methods for risk assessment and management in the approval process of modern LMO biotechnologies.
Individual country projects to support the Implementation National Biosafety Frameworks; Cameroon (\$m 0.560); Egypt (\$m 0.908); Kenya (\$m 0.511); Mauritius (\$m 0.428); Namibia (\$m 0.672); Tanzania (\$m 0.777); Tunisia (\$m 0.849); Uganda (\$m 0.560)	The general objectives of these projects are to develop and strengthen the capacity of African Governments to implement the Cartagena Protocol on Biosafety by (i) supporting the entry into force and implementation of the national legislation, (ii) strengthening national biosafety facilities, (iii) training main stakeholders, (iv) establishing a good National Information System to be linked to the National Biosafety Clearing House; and (v) promoting public awareness.
Source: GEF project database, December 2006.	

three framework-type projects: (i) the Development of National Biosafety Frameworks Project, a project to assist 124 countries in setting up their frameworks for biosafety management at the national level, allowing them to meet the requirements of the Cartagena Protocol; (ii) the “Implementation of National Biosafety Frameworks” that provided additional grants for demonstration projects in 12 countries, including Cameroon, Kenya, Namibia and Uganda, to begin the implementation of their biosafety strategies; and (iii) the project on “Building capacity for the effective participation of Parties in the Biosafety Clearing House” assisting 139 countries.<sup>20</sup>

**Policy Consideration:** Within their internal priority-setting processes, countries should discuss the space given to biosafety projects within the biodiversity component group, and whether such amounts will be effective in promoting the development and safe application of biotechnology.

<sup>20</sup> GEF 2006c.

**OPTIONS FOR FUNDING BIOSAFETY THROUGH**

**GEF:** Discussions currently center on how to best use the resources available for the period and whether to place an emphasis on country-led initiatives coming out of national prioritization exercises or on regional projects seeking to harmonize regulations and increase cooperation throughout the continent. According to the new Biosafety Strategy, stock-taking assessments within project preparation stage will be used to determine the need or convenience for regional vs. country projects. An example of regional vs. country projects approved by GEF is given in Box 8<sup>21</sup> showing that proportional amounts allocated to countries were larger in the regional project than in country-led ones. Considering that funds for both types of projects will be subtracted from biodiversity RAF allocations to participating countries for the period, countries should carefully consider the most cost-effective alternatives to implement their biosafety strategies, based on opportunities for regional cooperation and cost-sharing, and specific needs at the national level.

**Policy Consideration:** African countries may consider whether the regional focus is cost-effective and if they achieve results while reducing impact on individual country allocations under the RAF.

**CANCELLATIONS IN THE GEF PIPELINE:** Due to a pipeline “overload” that as referred by GEF’s new CEO had reached an “unrealistic US\$ 1.5 billion, in some focal areas representing nearly 80% of their GEF-4 allocation,”<sup>22</sup> the GEF Council has enabled the CEO to cancel projects in the pipeline, that have not yet been approved by a GEF agency, with the objective of reducing the pipeline in more than half, to no more than US\$ 700 million.<sup>23</sup> Cancellation of GEF projects in the pipeline is bound to generate some difficulties for African countries which may have invested time and resources on their preparation, although many see this as a key step to rationalize GEF funding for the next period, thus benefiting all recipient countries.

**Policy Consideration:** The cancellations in the pipeline may be seen as an opportunity for Africa to present a coherent and strategic approach to biosafety and biotechnology financing, by presenting regional projects within RECs and the AU that pursue the policy objectives of the region.

**CONCLUSIONS**

This policy brief has evaluated the challenges ahead for African negotiators on biotechnology and biosafety during the year 2007. Africa is engaged in a regional process to harmonize approaches to biosafety and biotechnology promotion through RECs, and adopt framework documents to guide policy making. In particular, the AU and related bodies has adopted Africa’s Science and Technology Consolidated Plan of Action in August 2005, and established a High-Level African Panel on Modern Biotechnology, which presented its conclusions in July 2006. AMCOST has also proposed a 20-year biotechnology strategy

<sup>21</sup> GEF Project Database (December, 2006): <http://gefonline.org/home.cfm>

<sup>22</sup> GEF 2006e.

<sup>23</sup> GEF Pipeline: <http://gefonline.org/pipelinelist.cfm>

based on the High-Level Panel's recommendations at its meeting in Cairo in November 2006, which will be addressed at the AU Summit in January 2007.

Three core policy objectives derived from such documents were identified to guide this analysis, namely to: promote R&D in biotechnology to eradicate poverty and achieve sustainable development; build Africa's capacities to develop and safely apply biotechnology in agriculture, health, mining, industry and other areas like biofuels; and ensure policies are science-based and promote food security and economic growth. Based on these core guiding principles for policy-making agreed at the regional level, this brief presented proposals and ideas to apply them in biotechnology-related multilateral negotiations on environmental issues, specifically negotiations within the Cartagena Protocol on Biosafety, the Convention on Biodiversity and the Global Environment Facility.

Negotiations of a new liability regime within the Cartagena Protocol on Biosafety, which will take place during several meetings in 2007, present an opportunity for Africa to bring together a common position, as Africa already has a regional document, the African Model Law on Safety in Biotechnology addressing this topic. A pragmatic approach that focuses on measures to allow compensation of harm in a proportionate measure to risks, and a process that institutes measures that may be implemented in the short, rather than the long term, is proposed. These proposals stem from the need to keep efficiency considerations in mind, including the need to channel liability to firms operating within Parties' territories, as well as constraints that may be generated by the lack of participation of key exporting countries in the system. Another key concern is to ensure that research and development opportunities are not hampered by a liability regime, and that there are incentives for the private sector to exercise due diligence in the management of LMOs. This calls for a differentiation in the level of liability according to the exercise of due diligence, compliance with national regulations and whether the biotech products are under R&D or commercialized in the market.

In this sense, the relevant Draft Panel's recommendation that Africa should "adopt an evolutionary approach where regulatory systems develop hand in hand with technological opportunities and applications" should guide the way. In order to promote R&D for African biotech products, stronger liability requirements should be restricted to commercial products and not those under R&D, considering the restricted application of such research and relatively low risk. For example, liability for harm caused by LMOs used for research and development could be limited to cases where there is fault, i.e. when appropriate safety measures, for example to contain field tests, were not followed.

On the CBD ABS regime, Africa must consider that it holds rich biodiversity of great potential value, and ensure a strong regime to address misappropriation cases. This could be achieved by either a binding instrument or an appropriate combination of binding and non-binding elements. A strategy identifying a limited number of priorities would be most useful in the negotiating table, considering the time and resources that will be needed in the long run.

In order to promote R&D within Africa, negotiators can consider to place themselves also as users of genetic resources and not just providers; thus addressing facilitated access to genetic resources, with a view to developing African R&D in biotechnology and fostering local biotechnological innovation. It is key to also consider the inclusion of derivatives in the regime, as these are the products most likely to generate commercial benefits, to prevent ill-granted patents and ensure sharing of benefits from products currently in the pipeline.

Also, as issues related to misappropriation and patents on genetic resources are dealt with in numerous fora, such as WIPO, TRIPs, the International Plant Protection Convention and the FAO International Treaty on Plant Genetic Resources for Food and Agriculture, Africa should seek to develop a coherent position in all relevant fora. Including a disclosure requirement in the regime and recognizing the role and rights of local communities would be central in that regard.

A harmonized international regime would promote R&D in biotechnology to eradicate poverty and achieve sustainable development if it facilitates access to genetic resources for research and development; while establishing a formalized system of sharing of benefits deriving from the commercialization of such genetic resources or their derivatives towards the holders of the genetic resources and traditional knowledge. Capacity building and technology transfer are benefits that may be sought within the regime and would aid Africa in developing its own capacities to use its genetic resources.

Regarding the GEF, Africa must play a more active role in the decision-making process, presenting proposals to the GEF Council that represent a strategic approach to biosafety funding for the region. This requires Africa to analyze whether a regional or country focus is most cost-effective and review indicators for progress prior to the biodiversity strategy's approval, considering Africa's characteristics, to ensure the appropriate indicators of success are included.

GEF is the main source of international funding for building capacity on biosafety; therefore, the presentation of a coherent biosafety-project portfolio for GEF-4 is key for Africa to ensure that all allocations are utilized by the end of the period. Within their internal priority-setting processes, countries should discuss the space given to biosafety projects within the biodiversity component group, and whether such amounts will be effective in promoting the development and safe application of biotechnology. Africa should also follow closely indicators on global benefits for the biodiversity focal area, to ensure they reflect Africa's strategic approach to biotechnology.

It is key for Africa to consider that international negotiations within the CBD, Cartagena Protocol and GEF present opportunities to promote biotechnology R&D in the region and overcome the existing gap with developed countries, and such opportunities should not be lost. Biotechnology and biosafety issues are best addressed with a clear picture of priorities and constraints for the region, through a proactive approach, rather than a purely defensive one, and focusing on pragmatic solutions that enhance Africa's capacity for applying biosafety and obtaining benefits from the use of its genetic resources in order to support sustainable development and poverty eradication efforts.



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## ABBREVIATIONS AND ACRONYMS

ABS	Access to genetic resources and benefit-sharing
AMCOST	African Ministerial Council on Science and Technology
APB	NEPAD's High-Level African Panel on Modern Biotechnology
ASB	Draft African strategy on biosafety
CBD	Convention on Biological Diversity
COP	Conference of the Parties
HRST	Directorate of Human Resources, Science and Technology of the African Union
EU	European Union
G-77/China	Group of 77 and China
GEF	Global Environment Facility
JUSCANZ	Japan, United States, Canada, Australia and New Zealand Group
LMOs	Living modified organisms
NEPAD	New Partnership for Africa's Development
R&D	Research and development
RAF	Resource allocation framework
REC	Regional Economic Communities
TRIPS	Agreement on trade-related aspects of intellectual property rights
WIPO	World Intellectual Property Organization
WSSD	World Summit on Sustainable Development
WTO	World Trade Organization