1- BACKGROUND

In February 1999, when the negotiations of the Cartagena Protocol on Biosafety were stalled, the African Group and the Organization for African Unity (OAU, now the AU) developed the African Model Law on Safety in Biotechnology. Its purpose was to provide for a harmonized approach towards biosafety in Africa and serve as a model legal instrument for developing national biosafety legislations. The Cartagena Protocol was finally adopted in January 2000. It was developed within the context of the Convention on Biological Diversity and sets minimum international standards on biosafety. However the Protocol does not adequately deal with all the critical priority needs of African countries. Therefore, further work on the African Model Law was supported by the OAU Assembly of Heads of State and Government in July 2001. It was developed to be used by the African States in support of the implementation of the Cartagena Protocol and to address its weaknesses at an African context.

At its third ordinary session, held in July 2003 in Maputo, the Executive Council of the AU further adopted Decision EX/CL/Dec.26 (III), which stressed the need for Member States to equip themselves with human and institutional capacities to deal with biosafety issues within the framework for the implementation of the Biosafety Protocol. The decision also endorsed steps taken by the AU Commission to put in place an Africa-wide biosafety system and programmes to strengthen the abilities of Member States to deal with biosafety issues.

The AU-BMZ Biosafety Project was therefore developed within the above context to provide the AU with the necessary capacities and effective instruments to support its Member States in implementing the Cartagena Protocol on Biosafety and the African Model Law on Safety in Biotechnology. The implementation of the first substantive activities of the project started in January 2006. In 2007, the AU initiated a revision of the African Model Law in the light of new developments in the technology and acknowledging the common priorities with regard to biosafety in Africa.
2- OBJECTIVES, STRATEGIES, TOOLS AND APPROACHES

The objectives of the Project include the following:

1. Development of an AU Strategy to implement the provisions of the Cartagena Protocol on Biosafety and the African Model Law on Safety in Biotechnology and its application at national and regional levels;

2. Maintenance of a network of continuous information exchange between the AU Biosafety Unit and the National Focal Points of the Cartagena Protocol on Biosafety;

3. Provision of strategic options to strengthen existing technical and laboratory capacities at regional, sub-regional and national levels to identify GMOs and products thereof.

Throughout 2006, the key performance areas of the activities for the project have hence been classified as follows:

- Establishment of the Biosafety Unit and the empowerment of its staff;
- Organization of a Preparatory Meeting for African Delegates on the international negotiations of the COP-MOP 3;
- Establishment of the Technical Advisors Committee on Biosafety; and
- Development of an African Strategy on Biosafety and started the revision of the African Model Law on Safety in Biotechnology

The AU being the top political organ of the region, the project takes the approach of dealing with Member States/governments. Therefore, all activities/documents developed have to go through the appropriate political structure of the AU. As a result, decisions are taken after an experts review of the documents/proposals is undertaken. Thereafter a meeting of the concerned Ministers is held to consider the recommendations of the Experts. The decisions are ultimately passed to the Heads of State and Government Summit for final adoption.

The Project has implemented the following activities:

- The establishment of a Biosafety Unit within the AUC Department of Human Resources, Science and Technology;

- A Preparatory Meeting for African Delegates was held 11-12 March 2006 in Curitiba, Brazil, for the COP-MOP3. The meeting resulted in a well-prepared African Group that was in a better position for the negotiations. The workshop also provided a platform to develop a common position of the AU Member States on the crucial issues addressed in the negotiations;

- A Technical Advisors Committee on Biosafety has been established which will give general technical guidance on the activities and outputs of the AU Biosafety Project. The Committee held two meetings, 5-7 July 2006 and 16-17 October 2006, in Addis Ababa, Ethiopia;
- A joint Regional Experts Meeting on Biosafety, together with the Department of Rural Economy and Agriculture of the Commission, was held to discuss the African Strategy on Biosafety and the African Position on GMOs for Food and Agriculture;

- The African Strategy on Biosafety was adopted by the Extraordinary Conference of African Ministers Council on Science and Technology held 20-24 November 2006 in Cairo, Egypt; and

- The revision of the African Model Law on Safety in Biotechnology has started. The revision will consider the common priorities of African countries and the current status of biotechnology development.

Strategies that will be taken up in 2007 include the conducting of sub-regional workshops for discussions towards the implementation of the African Strategy on Biosafety and the revised Model Law. Also, a Parliamentarian Meeting has also been planned to take place.

Further, two studies will be conducted on:

- GMO commodity flow in Africa; and
- African Capacity on GMO identifications.

It had been agreed that the Project will also be issuing a series of publications (issue papers or guidelines) in the following key areas regarding biosafety:

I. Public participation
II. Confidential business information
III. Compliance and dispute settlement mechanisms
IV. Liability and redress
V. Risk assessment
VI. Identification and labelling
VII. Monitoring
VIII. Precautionary principle
IX. Guide to genetic engineering and related issues (i.e. introduction material for large scale public awareness)

3- PRACTICAL EXPERIENCES, BEST PRACTICES AND LESSONS LEARNED

The regional approach taken is believed to be the best way to deal with biosafety issues in Africa. However due to the political structure at the AU level, implementing all planned activities requires time. Therefore, the administration of such a regional project is challenging. On top of technical relevance, the activities of the project also need to be politically relevant to obtain acceptance and avoid impediments. Nonetheless, it has been recognized that fruitful results may be achieved with adequate preparation and collaboration among the concerned departments within the AU Commission.

Concepts for Regional Harmonization of Issues related to Biosafety in Africa
It is worth noting that the Project has also recognized the need for harmonization and collaboration (which has been under the international agenda). In October 2006, the Department of Human Resources, Science & Technology and the Department of Rural Economy & Agriculture of the AU convened the workshop “African Position on GMOs in Agriculture and Food Security” in Addis Ababa, Ethiopia. The workshop participants thus also reported on regional African biosafety initiatives and on approaches to harmonize biosafety issues on a regional basis.

The AU invited a broad range of experts, including National Focal Points for Biosafety and national experts in the field of science and technology from all AU Member States and various stakeholders including the biotechnology industry, consumer and environmental NGOs, farmers’ organizations, international organizations and research institutions.

The discussion on regional harmonization of biosafety issues can be clustered as follows:

i. Harmonization of technical and scientific matters
   ii. Harmonization of GMO-related legislation and decision-making
   iii. Harmonization of policies and recommendations

i. Harmonization of technical and scientific matters

The participants agreed that there is the need of and the possibility for regional harmonization in technical and scientific matters. The following fields were regarded as appropriate for harmonization:

- Research on biosafety issues;
- Developing and testing environmental and health risk scenarios;
- Detection and identification of GMOs and products thereof;
- Developing norms and standards for sampling and testing procedures;
- Reviewing risk assessment documents related to the planned introduction of a certain GMO or its products; and
- Drafting recommendations on how to make use of these risk assessment documents during the approval process.

ii. Harmonization of GMO related legislation and decision-making

Some participants called for the development of regional GMO-related legislation. The majority of participants agreed to the advantages such an approach would create, however, some were also concerned about the appropriateness of its current application. Despite the fact that the AU is the regional body that has the mandate to adopt legally binding rules for its Member States, existence of national GMO-related legislation existing in all Member States as a precondition is still not met.

A few delegates called for regional bodies that take GMO-related decisions on behalf of Member States. The examples of the European Union and European Commission were cited in this context. It was suggested that the Regional Economic Communities (RECs) could play such a role. The RECs deal with issues of trade and it is apparent that
decisions on the approval of GMOs and GMO products also have implications on trade. This link between GMOs and trade was the basis for considering these bodies to assume sub-regional decision-making positions. However, it was argued further that, despite their mandate in trade-related areas, the RECs do not possess the relevant authority in matters of biodiversity and the environment. As a result it was deemed equally important to avoid conflict of interest and as such the approach of using the RECs was rejected. Another reason for the rejection was that the issue of overlapping membership of some countries in more than one REC would make it difficult to call for legal harmonization at the REC level. Another challenge posed is that no African regional organization has a comparable legal and administrative system to be used as a reference.

Under these circumstances developing GMO-related legislation is recognized as the priority need at national levels. Therefore, the endeavours already commenced towards the development of biosafety regulatory regimes and the process leading to it should be appropriately tracked and speeded up.

**iii. Harmonization of policies and recommendations**

There is ample evidence of regional policies and recommendations issued by various organisations and workshops in Africa. Some of these documents were presented at the AU workshop in October 2006. The impact of such policies and recommendations in general depends on two different factors. On the one hand, these should be given legitimacy by the appropriate inclusion of representative organizations in the processes of adopting these documents. On the other hand, financial and human resources for implementing the policies and recommendations have to be mobilized to make them effective.

**Activities of the AU concerning harmonization of biosafety issues**

The AU has conducted two activities dealing with biosafety and biotechnology:

- The establishment of the African Panel on Modern Biotechnology; and
- The establishment of the AU Biosafety Unit

The main outcome of these activities so far is the African Strategy on Biosafety and the Report of the African Panel on Modern Biotechnology. The Executive Summaries are attached to this paper. Both documents were presented at the Conference of the African Ministers Council on Science and Technology (AMCOST) in November 2006 in Cairo. AMCOST decided to “work together to develop a 20 year African Biotechnology Strategy with specific regional technology goals to be implemented through the Regional Economic Communities and to develop and harmonize national and regional regulations that promote the application and safe use of modern biotechnology”.

The AU workshop, held in October 2006, adopted an African Position on GMOs in Agriculture that is attached to this paper. The GMO Position specifies several aspects of regional harmonization in biosafety and biotechnology.

The AU is a high level regional body with the possible mandate to adopt legally binding rules at the regional level. Harmonization of policies could therefore be realized
through this approach upon effective coordination and collaboration at the sub-regional level.

4- COMMUNICATION, COORDINATION, NETWORKING AND COLLABORATION

For the smooth operation of such an initiative, effective networking and communications are important. However, the experience in Africa is that communication and networking still require considerable improvement.

The project had utilized the following approaches for communication and networking:

- Note Verbales are sent to all the Embassies of Member States in Addis Ababa, to the Ministries of Foreign Affairs of the States and to the Ministries in Charge of Biosafety as appropriate on matters relating to the Project;

- A database of National Focal Points of the Biosafety Protocol has been developed and direct contact has been maintained as appropriate; and

- The AU Biosafety Project website has been established within the AU website which contains information on the Project as well as other relevant links and documents.

It is also believed that further collaboration with the CBD Secretariat may also be achieved through the provision of relevant information on regional meetings related to biosafety (Experts, Ministers, Summits etc.)

5- GENERAL VIEWS AND RECOMMENDATIONS

Common positions on biosafety and biotechnology could be a big challenge to attain within the continent. The best that could be done would be to have general guidelines on biosafety and biotechnology and to put a strong emphasis on information sharing. It is apparent these two issues need to be dealt with in a complementary manner.