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**AFRICAN MINISTERIAL CONFERENCE
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AU/EXP/ST/17(III)

**AFRICAN MODEL LAW ON SAFETY
IN BIOTECHNOLOGY**

**EXPERTS MEETING ON THE
REVISED AFRICAN MODEL LAW ON
SAFETY IN BIOTECHNOLOGY
AUGUST 20-23, 2007
ADDIS ABABA, ETHIOPIA**

REPORT

1. INTRODUCTION

The African Union Experts Meeting on the revised Model Law on Safety in Biotechnology was held from 20-22 August 2007, in Addis Ababa, Ethiopia. The initiative of revising the Model Law was due to the need of African countries to have a harmonized position in matters of Biosafety. Therefore, acknowledging the common priorities of African countries, the current status of development of modern biotechnology and the controversial legal issues related to Biosafety, hence a revised African Model Law on Safety in Biotechnology has been developed and presented for the discussion. The Meeting brought together African stakeholders in the matters of biosafety to deliberate on the first draft of the revised Model Law.

2. PARTICIPATION

The meeting was attended by 66 participants (National Focal Points of the Cartagena Protocol on Biosafety, Representatives of Science and Technology, Representatives of Civil Society Organizations, Lawyers) from 25 Member States of the African Union (Burundi, Côte-d'Ivoire, D.R.C, Ethiopia, Gabon, Ghana, Guinea, Kenya, Liberia, Libya, Madagascar, Mali, Mozambique, Namibia, Nigeria, Senegal, Republic of Seychelles, Sudan, Tanzania, Swaziland, Chad, Togo, Uganda, Zambia, Zimbabwe), Regional Economic Communities (RECs) (CEN-SAD), African Regional Institutions, the Secretariat of the Convention on Biological Diversity, Representative of the German Technical Cooperation (GTZ), and Resources Persons.

3. OPENING THE MEETING

On behalf of the AU Commission, Dr. Beatrice Njenga, acting Director of the Department of Human Resources Science and Technology (HRST) welcomed participants to the meeting. Dr. Njenga stated that African states need to harmonize their positions in matters of biosafety and biotechnology so as to attain strong positions in the international fora. She also mentioned that the Commission through its Biosafety Unit would work towards building international negotiation and cooperation capacities of AU Member States. Then she pointed out the relevance of the following African regional workshop on capacity building and exchange of experiences on risk assessment and risk management of LMOs. Having briefly highlighted the significance of the present workshop Dr. Njenga wished participants successful deliberation.

4. ORGANIZATION OF THE WORK

Participants elected the following participants as members of the bureau for the present meeting:

1. Ethiopia: Dr Tewolde Berhan Gebre Egziabher as the Chairperson;
2. Nigeria: Mr. Matthew Dore as the First Vice-Chairperson;
3. Zambia: Dr. Dorothy Kangwa Mulenga as the Second Vice-Chairperson;
4. Libya: Dr Abdulmunem Abulayha as the Third Vice-Chairperson and
5. Gabon: Mr. Jean Bruno Mikissa as the Rapporteur.

5. ADOPTION OF THE AGENDA

The draft agenda and the work program were adopted as presented by the Chairperson. The following comprised the agenda items:

1. Opening of the meeting
2. Adoption of the Agenda
3. Organization of work
4. Progress Report of the AU Biosafety Project
5. Discussion of the revised Model Law
6. Presentation of the document on the African Position on GMOs for Food and Agriculture
7. Closure of the meeting

6. PROGRESS REPORT OF THE AU BIOSAFETY PROJECT

Mr. Bather Koné from the Department of Human Resources Science and Technology, Biosafety Unit made a brief presentation on the progress made by the Project. It was mentioned that the Project envisions providing the AU with the requisite 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

Implementation of the first substantive activities of the project started in January 2006. It was mentioned that the project duration is for three years. It was stated that the estimated budget for the Action plan of 2007 was 930,700 USD. The presentation also included the background of the first version of the African Model Law on Safety in Biotechnology completed before the adoption of the UN Cartagena Protocol on Biosafety. The revision of the Model is therefore needed to address Africa's ambitions for biosafety and biotechnology.

Mr. Koné stated that to date the following were the achievements of the Project:

- The establishment of the Biosafety Unit within the HRST Department, Biosafety webpage posted on the AU website;
- The Preparatory Meeting of African Delegates held from 11-12 March 2006 in Curitiba, Brazil, for the negotiations on the Conference of the Parties serving as Third Meeting of Parties (COP-MOP 3) to the Cartagena Protocol on Biosafety, which 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 of the negotiations;
- Establishment of the Technical Advisors Committee (TAC) for the Biosafety Project which held two meetings;
- A joint Regional Experts Meeting on Biosafety together with the Department of Rural Economy and Agriculture was held to discuss the African Strategy on Biosafety and the African Position on GMOs for Food and Agriculture;
- Development of the African Strategy on Biosafety which was endorsed along with the Report of the High Level African Panel on Biotechnology through the

Cairo Declaration (EXT/AU/EXP/ST/Decl/13(II)\Rev.1) and the AMCOST (EXT/AU/MIN/ST/Rpt. (II)) in November 2006; and

- Development of the first draft revised African Model Law on Safety in Biotechnology

It was stated that the further activities of the Project would focus on the completion of the Model Law and its implementation both with the strategy, the maintaining of continuous information with the National Focal points of the Cartagena Protocol on Biosafety, support of Member States in international negotiations relating to the Biosafety Protocol and the provision of strategic options to strengthen the existing technical and laboratories capacities for the detection of GMOs.

7. PRESENTATION ON THE DRAFT REVISED AFRICAN MODEL LAW ON SAFETY IN BIOTECHNOLOGY

The Consultant, Prof. Patricia Kameri-Mbote, presented the Draft Revised Model Law. In her presentation, Prof. Mbote outlined the perspectives surrounding the revision process. She informed the meeting that she was able to come up with the present draft as a result of the inputs from the technical advisors committee (TAC) and the Biosafety Unit. She recalled the revision process as outlined in the terms of reference for the work. It was mentioned that the following briefly comprise among the key elements of the TOR:

- An analysis of the Model law in light of current standing legal issues of the Cartagena Protocol on Biosafety
- Reference to developed national biosafety laws of African countries
- Identification of concerns of countries/conflicting issues not in Model Law
- Discussion with key regional stakeholders
- Harmonization of national laws on biosafety based on trends towards common positions

It was mentioned that the impact of the use of GMOs on biodiversity, socio-economic impacts and issues of liability and redress have generally been identified as the primary areas of concern of African countries. What is more, it was recalled that, a significant number of African countries are parties to the Biosafety Protocol, which only sets minimum standards with regards to regulating biotechnology. It was also noted that some pertinent issues of the Biosafety Protocol are still under negotiation.

Prof. Mbote stated that the context for revising the Model Law looked into the relevant issues that call for the revision process. The following were the directions followed in the draft revised Model Law :

- The Model Law would guide countries by giving technical options in dealing with the regulation of issues related to biosafety
- It would operate within a context
- Would be readily adaptable to suit local needs and to meet national objectives
- The citation '*African Model Law on Safety in Biotechnology*' is still maintained
- Some additions have been made to the Preamble
- A two-pronged objective has been added

- Added some definitions & removed others (Article 1)
- The scope has been edited but would include all GMOs (Article 2)
- Modifications have been made to the article on Institutional arrangements (Article 3) such as the roles of National Focal Points, the Competent Authority, the National Biosafety Committee and Institutional Biosafety Committees
- Article 4 (Application) (d) is revised to clarify GMO R&D procedures and to include monitoring and evaluation as well as disposal of wastes
- Article 5 is amended to include awareness through addition of para 6
- On article 6 previous paragraph 1 is removed as not a decision-making procedure issue
- On article 8 the link to patent has been removed since this issues should be covered under IPR laws
- Art 9 dealing with risk management has been tied to Annex IV to amplify ways of managing risks
- Art. 10 on unintentional release & emergency measures has been aligned to Art 17 of the Protocol
- A new article on capacity building has been added
- Regarding liability and redress, Art. 15 puts in place a liability system that is not based on strict liability to have more flexibility on case-by-case scenarios
- Art 16 list out offences and penalties is left to countries to decide and relate to national criminal laws
- Annexes of Model Law are maintained as these are more definitive to the African context

With regards to further discussion the following are among those presented:

- How far time lines stipulated under the Biosafety Protocol should be adopted
- Nature of liability
- Issues that are still under negotiation
- Periodic review
- A regional biosafety clearing house (should it be anchored under the revised text)
- Harmonization of regional and sub-regional initiatives

ESTABLISHMENT OF A WORKING GROUP

A Working Group was formed to compile the recommendation of the Experts' Meeting on the Revised Model Law on Safety in Biotechnology. It was agreed that the Working Group to undertake this task should be composed of a representative from each of the five groups represented among the participants of the Experts' Meeting. The following are the members of the Working Group representing their respective clusters:

1. Capt. Mandiaye Ndiaye from Senegal representing National Focal Points;
2. Dr. Dorothy Mulenga from Zambia representing focal persons of science and technology;

3. Mr. Gebremedhin Birega from the African Biodiversity Network representing Civil Society Organization;
4. Dr. Nuri Ibrahim from the CEN-SAD representing the Regional Economic Communities (RECs); and
5. Ms. Mahlet Teshome from the AU Biosafety Unit representing the Secretariat/African Union Commission

The Working Group discussed its mode of operation and came to a consensus that the members would meet periodically and exchange among themselves the recommendations suggested and agreed upon by the Experts' Meeting. The Group elected Dr. Dorothy Mulenga to report to the plenary the recommendations compiled by it. Editorial suggestions being made will generally be taken note of by the Secretariat and the correction will duly be made.

The Working Group is established to focus on concrete recommendations emerging as a general consensus from the Meeting. Taking this into consideration, the detail recommendations on the Model Law emanating from the Meeting have been captured by the working group and have been annexed to this report.

On the other hand there were dissenting opinions of the minority on the overall revised Model Law specifically from AfricaBio. It was generally stated that as it stands the revised Model Law is even more restrictive than the original document and does not facilitate the appropriate use of biotechnology. It was argued that the restrictive approach while it fulfils the mandate of countries and organizations participating on the meeting will not assist Africa with developing competitive, productive and sustainable agriculture. It was strongly requested that this differing opinion should be clearly reflected in the minutes of this meeting.

8. DISCUSSIONS ON THE AFRICAN POSITION ON GMOS FOR FOOD AND AGRICULTURE

Dr. Sarah Olembo from the Department of Rural Economy and Agriculture made an elaborate presentation on this agenda item. She stated that the lack of information to guide policy makers has led to uncertainty and confusion in many African Governments' responses to the many social, ethical, environmental, trade and economic issues associated with the development and application of modern biotechnology. As a result it was stated that, now, there exists a lack of an African consensus and strategic position to modern biotechnology. In addition she underlined that there is a build-up of different groups whose interest is to exploit uncertainty in policymaking, regardless of what the actual situation for Africa may be. She added that both pro and anti biotech advocacy groups have affected the African decision on Genetic engineering such that the picture is presented in its extremes as an either "for" or "against" Gene Technology.

It was further mentioned that currently Africa's challenge is to increase agricultural production, protect human, animal and plant health as well as the environment, to maximize the benefits from the use of biotechnology while minimizing risks and to develop standards, protocols and methodologies for testing genetically modified products. However it was stated that the threats that hinder Africa from facing this challenges are inadequate coherence among various ministries dealing with GMOs and biotechnology, inadequate support and inconsistent policies towards GM products and inadequate regional standards and weak regulatory and enforcement mechanisms.

In this light, Dr. Olembo mentioned the efforts made at the AU level such as:

- The development of the African Model Law on Safety in Biotechnology and the revision process to adapt it to current technical developments;
- The establishment of the High Level African Panel on Modern Biotechnology with a mandate to advise Africa on matters of modern biotechnology and its implications for agriculture, health and the environment;
- The development of the African Strategy on Biosafety which is centered on six pillars such as the 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 sustainability mechanism.
- A workshop on African Common Position on GMOs which aimed at gathering information on risks, challenges and myths surrounding the development of modern biotechnology in Africa specifically genetic engineering and to guide policy makers accordingly;

Like wise regional initiatives have also been made through the RECs such as the:

- SADC Position
- COMESA Position
- ECOWAS Initiatives
- EAC Initiatives

The details of the positions are available on the paper (African Common Position on GMOs in Agriculture), which were circulated in the meeting.

In the ensuing discussion, Dr. Olembo mentioned that the document was yet to be adopted by the African Ministers of Agriculture and as it stands now it is a document only reviewed by Experts in the field. It was generally suggested that all stakeholders should commit themselves towards playing a role towards facing the challenges mentioned and ensuring that the recommendations are implemented.

9. CLOSURE OF THE MEETING

At the closure of the meeting, the Chairperson made closing remarks by thanking the participants for their unreserved contributions. The Biosafety Unit was

also duly recognized for coordinating a meeting with diverse participation from almost all stakeholder groups.

On behalf of the Director of the Human Resources Science and Technology Mr. Bather Koné requested all participants to make efforts to set aside their differences with regards to issues of biotechnology and biosafety and move forward towards meeting the challenges of Africa and defending its interests. He duly recognized the significant achievements made on the three days discussions and generally conveyed the gratitude to all participants for their inputs in the first draft of the revised African Model Law and for smooth deliberations on such a critical subject matter.

The meeting was adjourned at 1825 hours on 22nd August 2007.

ANNEX

RECOMMENDATION ON THE REVISED AFRICAN MODEL LAW

Upon thorough discussions, the following are the recommendations adopted by the plenary on the revised African Model Law.

General Recommendations

1. Issues covered by the Model Law should include components of conservation and sustainable use of biodiversity
2. Timelines that are consistent with the Protocol should be incorporated in the Revised Model Law so that Parties to the Protocol also fulfil their international obligations
3. Regarding liability and redress, the Revised Model Law should also consider the ongoing discussions on the issue and could be developed further based on the decision reached
4. The Revised Model Law should not be inclined towards genetically modified organisms (GMOs) in food and agriculture and should consider other instances where GMOs and products are used in pharmaceuticals and live vaccines
5. Regarding risks to health both human and animal health should be addressed consistently by the Revised Model Law
6. Products of GMOs should be regulated under the Revised Model Law
7. Usage of the term person should be made consistently throughout the document (to mean legal or natural person)
8. When listing the various activities that the law regulates consistency needs to be maintained
9. Environment is incorporated under biological diversity therefore, the word environment should not be listed with biological diversity wherever it had been applied
10. Align the French version of the Revised Model Law with the English version
11. The title of the revised law should be ***African Model Law on Biosafety***
12. Under the preamble a statement needs to be inserted that recognizes the right on the interests of local communities

Specific Recommendations

Objective

1. An article number should be inserted
2. The precautionary principle as the basis of the Biosafety Protocol should be part of the objective of the Revised Model Law
3. The element of conservation of biological diversity should be incorporated in the objective.
4. Socio-economic considerations are critical to African countries and this issue should be reflected within the objective.

Based on the above suggestions the following amendment is made to sub (a):

"To contribute to ensuring an adequate level of safety for the protection of biological diversity, human and animal health, socio-economic

conditions and ethical values in the making, safe transfer, handling and use of genetically modified organisms and products of genetically modified organisms resulting from modern biotechnology."

4. Sub (b) is adopted as it stands.

Art.1. Definitions

1. Under advance informed agreement, the actors involved should clearly be stipulated and therefore the article should read as:

"Advance informed agreement means consent given by the Competent Authority based upon the full disclosure and taking responsibility for the accuracy of all relevant information by the applicant before any import, export, transit is undertaken on any genetically modified organism or a product of a genetically modified organism."

2. Editorial developments should be made on the definition of an applicant
3. The definition of the Biosafety Clearing House is adopted as it stands
4. The definition of Competent Authority is adopted as it stands
5. In the definition of a contained use, the addition of the word '**approved**' should precede 'facility, installation or other physical structure...' to ensure that the contained use is undertaken within an approved fitting.
6. The definition of 'release' should be alphabetically arranged and is adopted as it stands
7. Under the definition of 'export', movement referred should clearly stipulate those of a GMO or a product of a GMO. The inclusion hence is as follows:

" Export means the intentional transboundary movement of a GMO or a product of a GMO from one country to another."

8. Under 'exporter' the reference to legal and natural person should be deleted and replaced with 'person' since this word is defined in the Model Law
9. The word 'living' should be deleted from the definition of a GMO so that it reads:

"Genetically Modified Organism means any organism that possesses any novel combination or expression as a trait of genetic material obtained through the use of modern biotechnology."

10. In order to be consistent, the same developments recommended under 7 should apply to the definition of import
11. In order to be consistent, the same developments recommended under 8 should apply to the definition of importer
12. The word 'living' should be deleted from the definition of a living organism and it should be the definition of an 'organism' instead. To this effect, for the purpose of this law the organism's constituting it should be enumerated. Based on this consideration the developed definition is as follows:

"Organism means any biological entity capable of transferring or replicating genetic material including sterile biological entities, viruses, viroids and plasmids."

13. Transit and transitor should form definitions each on its own
14. Under the definition of 'modern biotechnology' based on the above points the words 'living modified' should be deleted and the rest is maintained
15. Regarding the definition of a national focal point reference should be made to the Context Document for Revising the Model Law as it presents a clearer and elaborate meaning. The modification hence should read as:

" National Focal Point means the entity designated to be responsible on behalf of a country for liaison with the Secretariat of the Cartagena Protocol on Biosafety and the Biosafety Clearing House to facilitate the exchange of information among the relevant bodies and authorities."

16. The definition of 'notification' is accepted as it stands
17. The definition of a 'person' is accepted as it stands
18. The definition of 'placing on the market' is accepted as it stands
19. The definition of a 'risk assessment' should refer to the direct and indirect potential impacts addressing the probability of a risk on case-by-case bases. For consistency transit should also be included here.

Hence the developed version should read as:

" Risk Assessment means the identification and evaluation of the direct and indirect potential impacts of a GMO or a product of a GMO on the biological diversity, human and animal health, socio-economic consideration and ethical values of the country which may be posed by the making, import, transit, contained use, release or placing on the market of a genetically modified organism or a product of a genetically modified organism. This may include the evaluation of secondary and long-term effects."

20. Socio-economic considerations should be defined rather than socio-economic impact. The clear stipulation of social and economic and cultural elements should be reflected. The development hence reads as:

"Socio economic conditions means the economic, social or cultural conditions, livelihoods, knowledge, innovations, practices and technologies of indigenous and local communities including the national economy."

21. The inclusion of the definition of the word 'making' should be made, as the research and development aspects of the making are not impliedly captured under the related provisions. Based on this the definition reads as:

" Making a GMO or a product of a GMO means research on or development of a GMO or a product of a GMO under conditions of containment or release into the environment in field trials."

22. Addition of a definition for unintentional release should be added to the list which reads as the following:

"Unintentional release means a release that takes place without authorization under circumstances where the release could not possibly be avoided, despite every effort made to comply with this law."

Art. 2. Scope

Accepted as it stands

Art. 3. Institutional Arrangements

1. Art. 3(2) (d) should be modified to read as: **" to cause the establishment and monitor the activities of Institutional Biosafety Committees at relevant institutions or nominate independent panels or any other body of experts, as appropriate, as technical and scientific advisors on issues of biosafety."**
2. Art. 3(2) (f) should include public participation along with public awareness and education

3. An additional sub article which follows the above should be included which reads:
"establish a mechanism to provide for the public participation in the decision-making process."
4. Under Art. 3(2)(i) the phrase 'grant an approval' should be deleted and replaced by ***'to grant or deny approvals'***
5. Under Art. 3(3) the issue of conflict of interest should be clearly addressed
6. Under Art. 3(3) the word 'policy' should be deleted considering the fact that the National Biosafety Committee does more than give policy recommendation.
7. Under Art. 3(4) the word inter-alia should be added after Institutional Biosafety Committee

Art. 4. Application

Adopted as it stands

Art. 5. Public Awareness and Participation

1. The sub articles under Art. 5 should follow the sequence involved in the procedure of public awareness and participation. Therefore a rearrangement of the sub-articles is recommended.
2. The deletion of the phrase 'in cases where' should be made since the Competent Authority would under all conditions arrange for a public consultation with regard to a transaction dealing with a GMO or a product of a GMO. The establishment of mechanisms of a public participation should be included under this sub article.
Based on the above the developed Art. 5 read as:

1. ***The Competent Authority shall, upon receipt of the information referred to under Article 4(3) and Article 4(4), make available the said information to the public and relevant government authorities***
2. ***The Competent Authority shall make available to the public:***
 - i. ***Information on any genetically modified organism or a product of a genetically modified organism, which has been granted or denied approval for making, import, contained use, release or placing on the market; and***
 - ii. ***Any risk assessment report with respect to the genetically modified organism or the product of a genetically modified organism.***
3. ***The Competent Authority shall promote awareness and education of the public and those conducting activities on genetically modified organisms or products of genetically modified organisms subject to the law concerning biosafety matters through the publication and dissemination of this law, as well as guidance documents and other materials aimed at improving the understanding of biosafety and related authorization and notification requirements.***
4. ***The Competent Authority shall establish a mechanism of public participation and shall arrange for a public consultation and/or public hearing with regard to any proposed making, import, contained use, release or placing on the market of a genetically modified organism or a***

product of a genetically modified organism, this fact shall be announced nationally not less than 30 days before the decision is made shall be given for consultation without prejudice to Article 12(1).

5. *The public may make comments within such a period and in such a manner as may be specified by the Competent Authority.*
6. *The Competent Authority shall, in making or reviewing its decision, take into account the views and concerns of the public expressed in accordance with paragraphs (2) and (3) of this Article "*

Art. 6. Decision Making Procedure

1. Insert the application of the timeline stipulated in the Biosafety Protocol on the decision-making procedure.
2. Include 'use' under Art. 6(4) where it states "...the assessment is to be conducted at each step of the development or use..."
3. Under Art. 6(6) the phrase no risk should be removed and only significant risk should be maintained considering the fact that no technology could have zero risk. This modification should be reflected consistently through out the Model Law where risk is referred.
4. Under Art. 6 (9), the insurance should cover the period of liability. The term 'other arrangements' should also be made more specific. The new sub article should read as ***"The Competent Authority shall, as a condition for approval, require the applicant to furnish evidence of insurance cover or other financial guarantees sufficient to meet the obligations under this law that extended till the period of liability specified in Article 15(6)."***

Art. 7. Review of Decision

Adopted as it stands

Art. 8. Risk Assessment

1. Inclusion of the statement: "...which is subject of an application" should be added to Art 8(1) to complete the provision
2. Inclusion of the ethical values element should be made for consistently
3. The text of Art. 8(2) should make a correct alignment with the reference made to Art. 7(4) of the Biosafety Protocol, which deals with the exemption of the advance, informed agreement procedure on the intentional transboundary movement of LMOs identified by the decision of the COP-MOP as being not likely to have adverse effects. Accordingly the modification is as follows:

" The advance informed agreement procedure shall not apply to any application on the import, export or transit of a GMO or a product of a GMO that has been identified in a decision of the COP-MOP as being not likely to have adverse effects on the... as per Art. 7(4) of the Cartagena Protocol on Biosafety."

Art. 9. Risk Management

1. Art. 9(2) the last word, 'may' should be deleted and replaced by 'shall'

2. Art. 9(2)(e) and (g) should reflect the modifications recommended under socio-economic consideration and ethical values
3. The periodic reports submitted to the Competent Authority are for review and therefore this phrase should be included

Art. 10. Unintentional Release and Emergency Measures

1. Unintentional or accidental release should be used together throughout this provision
2. Art. 10(2) (d) should read as: '***The emergency measures already taken by the applicant or the measures to be taken by the government.***'
3. Art. 10(3)(b) should be split into two sub-articles to cover the dissemination of the information locally as well as internationally. Therefore the modification reads as:

- (b) "***Inform other relevant government and non-government organizations within the country***
- (c) "***Inform the Competent Authorities or other relevant government organizations in countries likely to be affected and the Biosafety Clearing House.***"

Art. 11. Identification and Labelling

1. This provision should be aligned to the decision reached at COP-MOP3 on the issue

Art. 12. Confidential Business Information

Adopted as it is

Art. 13. Export

Adopted as it is

Art. 14. Capacity Building

Adopted as it is

Art. 15. Liability and Redress

1. The Revised Model Law should consider the decisions reached on liability and redress that are ongoing at the international level and should accordingly be revisited where appropriate
2. The reference that is being made to harm or damage should be done so in a harmonized manner throughout the document
3. The definition of socio-economic considerations in this provision should be maintained which enumerate all relevant list of activities that ought to be covered under this provision
4. The last part of Art 15 (1) ("The harm shall be fully compensated") should stand as a separate sub article under Art. 15(4) which should read as:

" Any harm, damage, injury or loss caused by a GMO or a product of a GMO shall be fully compensated.

(a) In case of harm to the environment, biological diversity...

(b) In case of harm to human and animal health.... (insert from old African Model Law)."

5. The French version of the draft Revised Model Law should include the making of or production of a GMO or a product of a GMO in this provision
6. During joint and several liability the courts have discretion in determining the modality of distributing liability on a case-by-case basis
7. The term 'loss of life' should be included in Art.15 (5) on the last part
8. The time limit given to bring an action in respect to harm or damage should be raised to 20 years
9. The Secretariat should align the Revised Model Law in light of issues that are not covered under the Revised Model Law but which are under discussion at the international level (working group on liability and redress) These issues are liability and redress dealing with:
 - Illegal transboundary movements
 - Jurisdiction of courts
 - Transit
10. Under Art15 (6) An inclusion of a statement should be made on the application of time limit of other national laws to read as:

" The time limit to lapse in other legislation shall not apply to damages related to this law"

Art. 16. Offences and Penalties

1. Transit should be included as offences among the lists of Art.16 (1)
2. Disclosure of confidential information should be included as an offence under the lists of Art. 16(1)
3. Failure to report damage should be included as an offence under the lists of Art. 16(1)

Art. 17. Appeal

1. The wording 'appeal' should be reconsidered as it also deals with administrative recourse rather than just judicial decision
2. Art. 17(1) should include the phrase "within and outside of the Competent Authority' to clarify the adjudicatory and administrative authorities being referred to
3. Art.17 should be considered vis-à-vis Art 7 on review of decisions and any overlap should be taken care of
4. Under Art.17(1) the appropriate wording for 'receipt' should be made to communicate the idea of the notification of decision by the Competent Authority both to the applicant and the general public
5. Sub (2) should include the word 'approval' and should read: **" 'Decision' includes any act, omission, approval..."**

Art. 18. Transitional Provisions

Adopted as it stands

Art. 19. Annexes

Adopted as it stands

Art. 20. Entry into force

Adopted as it stands

Annexes

Participants are asked to study the annexes and send their observations and comments within the date to be set by the Secretariat. Failure to send in any feedback to the Secretariat would be taken as approval of the Annexes.

The following were the outcomes of assignments given to groups, which have been adopted by the plenary.

Conflict of Interest

(A new provision)

Members of the Competent Authority and National Biosafety Committee shall declare their interests, on a case-by-case basis, with regard to the exercise of any functions as provided by this Law .

Public Consultation

(A new provision in Article 5)

(1) The Competent Authority shall take measures to provide for open and transparent consultation with the public, including the holding of public hearings in order to solicit the views of the public in regard to any matter dealt with in this law .

Package of provisions for unintentional release/adventitious presence in bulk shipments -new provisions

(Two new definitions for these provisions)

“Unintentional release” means a release that takes place without authorisation in terms of this law , and takes place as a result of the **adventitious presence of GMOs** with non-GMO shipments of food aid and non-GMO shipments imported for direct use as food, feed and processing, but excludes an accident.”

“Adventitious presence of GMOs” is the thresholds levels set by the CA, as contemplated by Article xx

Amendments of Article 10

Change title to Accidents and Emergency Measures

Delete reference of 'unintentional release' in Article 10(1) (b);

Article xx

The Competent Authority shall put in place appropriate thresholds for the adventitious presence of GMOs that are contained in non-GMO shipments imported for the purposes of aid food and placing on the market as direct use for food, feed and processing.

1. Notwithstanding the provisions of Article x (1) above, the Competent Authority shall endeavour not to set threshold levels above a level of 0.9% for adventitious presence of GMOs.
2. The provisions of Article xx (2) and xx (3) shall not apply to GMOs imported where if there is a high probability that such GMOs may be cultivated (*zero tolerance for contamination of seeds imported*).
3. An Exporter shall be required to declare that there is no adventitious presence in GMOs imported other than as aid food and placing on the market for direct use as food, feed and processing as contemplated in this section.

Article xy. Documentation and Identification

- (1) Subject to the provisions of Article xy(2), the Competent Authority shall take measures to ensure the use of an appropriate document to accompany GMOs imported, in order to give effect to the Cartagena Protocol on Biosafety, taking into account international rules and practises for the identification of GMOs. (*GMOs imported for contained use for instance*)
- (2) The Competent Authority shall take measures to ensure the use of an appropriate document, including the stand alone document as set out in Annex V (Norwegian stand alone document) that should accompany GMOs imported as aid food, and placing on the market for the purposes of direct use as food, feed and processing.
- (3) The Competent Authority shall ensure the documentation referred to in Article xy(2) above, clearly states:
 - (a) that the shipment contains GMOs;
 - (b) whether the GMOs constituting the shipment has been approved in the country of export;
 - (c) that the GMOs are for aid food or placing on the market as direct use as food, feed or processing and no other use;
 - (d) the common, scientific, and where available, commercial names of the GMO;
 - (e) the transformation event code of the GMO or where available, as key to accessing information in the Biosafety Clearing-House, or its unique identifier code; and
 - (f) The Internet address of the Biosafety Clearing-House for further information

4. The Competent Authority shall provide for the taking of appropriate measures for redress in the event of non-compliance with the provisions contained in this Article, including the return and repatriation of the GMOs in question, at the expense of the exporter.

Community Rights for GMO Free Zones

(A new provision)

Taking into account the provisions of Article 26 of the Cartagena Protocol on Biosafety and the provisions of the Convention on Biological Diversity on the conservation and sustainable utilization of biological diversity:

1. The Competent Authority shall develop policies that protect the rights of communities to declare GMO free zones.
2. The Competent Authority shall take measures for the creation of geographical areas that are declared as 'GMO free zones' where the release of any GMO is prohibited.

**ANNEX TWO
PARTICIPANTS LIST**

**Experts Meeting on the Revised African Model Law on Safety in Biotechnology and
Workshop on Risk Assessment & Risk Management of Living Modified Organisms
AU Conference Center, 20-25 August 2007, Addis Ababa**

(*Participants who participated on the second meeting with the SCBD)

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