

## **APPROACHES TO BIOSAFETY LEGISLATION IN AFRICA**

#### **Options to Facilitate National Decision-Making**



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#### APPROACHES TO BIOSAFETY LEGISLATION IN AFRICA

Options to Facilitate National Decision-Making

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## List of Acronyms

ACODE	Advocates Coalition for Development and Environment
AIA	Advance Informed Agreement
CBD	Convention on Biological Diversity
СНМ	Clearing House Mechanism
СРВ	Cartagena Protocol on Biosafety
GEF	Global Environment Facility
LMOs	Living Modified Organisms
NBF	National Biosafety Framework
UNEP	United Nations Environment Programme
R&D	Research and Development
SIs	Statutory Instruments

## Acknowledgements

The idea of exploring the various options for dealing with biosafety legislation at the national level was concieved during the High Level Policy Dialogue on National Biosafety Frameworks organised by ACODE in July 2004. During that dialogue, it was apparent that participants needed analytical information on the approaches to national biosafety legislation. We therefore, acknowledge the contribution of all the participants at the dialogue who provided initial thoughts to the ideas discussed in this briefing paper.

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## **Executive Summary**

The advent of modern biotechnology has posed enormous challanges to policy makers all over the world. The challenges largely flow from the need to avert and/or mitigate the potential adverse effects to biodiversity and human health. In a bid to manage the potential risks associated with modern biotechnology, countries are engaged in developing National Biosafety Frameworks (NBFs) of which biosafety legislation forms a major component. However, the lack of progress in the biosafety legislation processes in different countries is largely attributable to the lack of clarity on available legislative approaches.

In this policy brief, we analyze the four major approaches to biosafety legislation which include: Principal legislation, Subsidiary legislation, Piecemeal approach and Non legally binding Instruments. While we recognize the fact that there can not be a single best approach for all countries due to the diverse socio-cultural, economic and political settings, we analyze the implications of each approach.

We conclude by emphasing that whatever legislative approach a country adopts, it should conform to good legislative practices and the spirit of the Cartagena Protocol on Biosafety. Such practices include among others: public participation, transparency, clarity of purpose and parliamentary oversight. Countries that are at cross roads as to which legislative approach to adopt in dealing with biosafety legislation will find this policy brief a very useful guide. The analysis made in this brief may also prove useful in other legislative processes other than biosafety legislation.

### 1. Introduction.

With the adoption of the Cartagena Protocol on Biosafety(CPB)<sup>3</sup>, countries all over the world are now engaged in the process of developing National Biosafety Frameworks (NBF)<sup>4</sup>. This process has not been easy particularly for developing and least developed countries which face a number of problems. Countries engaged in these processes are faced with the problem of inadequate funding, acute shortage of relevant legal and technical expertise, unclear institutional mandates and low levels of awareness about the Protocol.

In designing their biosafety legal regimes, these countries are particularly faced with the policy challenge of deciding which legislative approach to adopt. While a number of countries have decided to proceed by way of enacting new legislation altogether to deal with biosafety issues<sup>5</sup>, others have decided to handle biosafety concerns under existing legislation, yet others are still at cross roads debating which way to go. Even those that had initially decided to enact new legislation or those proceeding under existing legislation seem not contented whether or not they made the right choices<sup>6</sup>. Indeed, the issue of which legislative approach to adopt in dealing with biosafety legislation is now a hard question for policy makers. Although this question has been

<sup>&</sup>lt;sup>3</sup> The protocol was adopted on 29<sup>th</sup> January 2000 in Montreal by delegates of over 130 parties to the Convention on Biological Diversity (CBD)

<sup>&</sup>lt;sup>4</sup> NBF is a combination of policy, legal, administrative and technical instruments for the safe handling and application of modern biotechnology and its products at the national level.

<sup>&</sup>lt;sup>5</sup> For instance in E. Africa, Kenya and Tanzania have adopted this approach.

<sup>&</sup>lt;sup>6</sup> For example initially Zimbabwe had decided to deal with biosafety legislation through amendment of the Research Act yet it has now constituted a team to enact a new biosafety law and repeal the Research Amendment Act, 1998.

raised at different fora<sup>7</sup>, none of these have clearly articulated the options that policy makers could consider in making legislative decisions.

This paper therefore analyzes the various approaches to the development of national biosafety legal frameworks. While we are cognizant of the fact that there is no single best approach, the paper provides a synthesis of the advantages and disadvantages associated with each of these approaches. Indeed, the approach taken by any country ought to be determined by its socio-economic, political and cultural context. It is hoped that by setting out these legislative options clearly, the paper can stimulate further debate and dialogue to facilitate the resolution of this outstanding legal problem in many countries.

### 2. The Cartagena Protocol on Biosafety

The CPB<sup>8</sup> is the first comprehensive international agreement that sets rules to govern international relations regarding the transboundary movement of Living Modified Organisms (LMOs). The Protocol covers a broad range of issues relating to the transboundary movement, transit, handling and use of all LMOs that may have adverse effects on the conservation and sustainable use of biological diversity<sup>9</sup>. It establishes an Advanced Informed Agreement (AIA)

<sup>&</sup>lt;sup>7</sup> The question again featured prominently at the High Level Policy Dialogue on Biosafety Frameworks in Sub-saharan Africa, 15<sup>th</sup>-16<sup>th</sup>July2004, Kampala, Uganda. The dialogue was organised by ACODE and was attended by delegates from Zambia, Zimbabwe, Egypt, Kenya, Tanzania and Uganda. See High Level Policy Dialogue on Biosafety Frameworks in Sub-Saharan Africa. National Biosafety Frameworks: Whose Agenda? ACODE Public Policy Dialogue Series, No. 5, 2004.

<sup>&</sup>lt;sup>8</sup> The Protocol is a subsidiary agreement to the Convention on Biological Diversity, 1992. See Articles 19 (3) and 28 of the CBD.

<sup>&</sup>lt;sup>9</sup> Article 4.

procedure that would apply to all shipments of LMOs<sup>10</sup>. In Article 11, the Protocol lays down the procedure to be followed by the Parties when dealing with LMOs that are intended for direct use as food or feed or for processing.

The protocol further lays down minimum international standards to be applied to risk assessment and risk management associated with the transboundary movement of LMOs<sup>11</sup>. These standards are elaborated in detail in Annex III to the Protocol. The Protocol provides for handling, transport, packaging and identification of LMOs<sup>12</sup> and imposes an obligation on the Parties to designate competent authorities and national focal points for the Protocol<sup>13</sup>. In Article 20, the Protocol establishes a Clearing House Mechanism (CHM) to facilitate exchange of information with regard to LMOs. The Protocol puts particular emphasis on capacity building, public awareness and participation<sup>14</sup>.

As we have argued elsewhere,<sup>15</sup> the issue of liability and redress was considered as an unfinished agenda<sup>16</sup>. The process of negotiating an international regime on the issue was mandated at the First Meeting of the Parties in February 2004<sup>17</sup>.

Generally, the Protocol presents major legislative challenges for the parties in a number of ways. First, the scope of the Protocol as spelt out in Article 4 can be subject to different

<sup>&</sup>lt;sup>10</sup> Articles 7 -10

<sup>&</sup>lt;sup>11</sup> Articles 15 and 16.

<sup>&</sup>lt;sup>12</sup> Article 18

<sup>&</sup>lt;sup>13</sup> Article 19

<sup>&</sup>lt;sup>14</sup> Articles 22 and 23

<sup>&</sup>lt;sup>15</sup> See Tumushabe G., Naluwairo R., 2004. COP-MOP 1 Decision on Liability and Redress: Analysis of Implications and Challenges for Eastern and Southern Africa. ACODE Policy Briefing Paper No.4, 2004. ACODE, Kampala.

<sup>&</sup>lt;sup>16</sup> Article 27

<sup>&</sup>lt;sup>17</sup> See UNEP/ CBD Decision BS- 1/8. UNEP / CBD, Global Biosafety: From Concepts to Action, 2004 pp 80 - 83

interpretations. The Article provides that the "Protocol shall apply to the transboundary movement, transit, handling and use of all living modified organisms....." The ordinary interpretation of this statement, especially when read in conjunction with Article 1, is that reference to "transit, handling and use" relates to the transboundary movement of LMOs. This interpretation would bring LMOs that are developed and used within national jurisdiction out of scope of the Protocol.

However, there are a number of provisions that suggest that the Protocol could apply to LMOs whether they have been subject of a transboundary movement or generated and used within national jurisdiction. The reference to "adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health..."18 suggests that the intention of the parties was to make the Protocol apply to both of these cases. This argument is strengthened by article 2(4) which provides that "nothing in this Protocol shall be interpreted as restricting the right of a party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in the Protocol...." It therefore appears that the reference to ".....and specifically focusing on transboundary movements" was not intended to be exclusive but rather to emphasize the need to regulate transboundary movements of LMOs.

The Protocol also refers to LMOs "that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human health..." This

<sup>&</sup>lt;sup>18</sup> The Protocol makes reference to "risks to human health" more than 10 times. See Articles 1, 2(2), 4, 7(4), 10(6),11(8), 12(1), 15(1), 16(2&5), 17(1&4), 18(1) and 23(1).

may suggest that the intention of the parties was to deal with a limited scope of LMOs and particularly those where there is compelling evidence of their potential effect. This phrase is not in line with the precautionary principle which is the cornerstone of the Protocol. It therefore appears that a country seeking to develop legislation on biosafety would have to ignore the restrictive nature of this phrase.

Like all other international legal instruments, the CPB requires the Parties to implement its provisions at the national, regional and international level. Thus, the Protocol requires that *"Each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations under the Protocol"*<sup>19</sup>. This statement is a provision of general rule of international treaty law as embedded in the Vienna Convention on the Law of Treaties<sup>20</sup>. This provision therefore requires State parties among other things, to come up with national legal frameworks to regulate the transfer, handling and use of LMOs.

It is important to note that the Protocol does not prescribe any specific approach that States parties should take in enacting biosafety legislation. Indeed, the Protocol requirement is for State parties "to take appropriate measures......" This therefore means that the discretion as to which legislative approach to adopt rests with individual states. But the rider is for States to ensure that any approach they adopt is necessary and appropriate.

<sup>&</sup>lt;sup>19</sup> See Article 2 (1)

<sup>&</sup>lt;sup>20</sup> Article 26 of the Vienna Convention on the Law of Treaties, 1969 provides for the Principle of Pacta Sunt Servanda which means that every treaty in force is binding upon the parties to it and must be performed by them in good faith.

# 3. Potential Legislative Approaches to Biosafety.

In determining which legislative approach to adopt in developing national biosafety legislation, the question initially resolves on whether or not the individual country's circumstances call for the adoption of a mandatory or voluntary approach. For countries that choose voluntary approaches, biosafety guidelines are normally developed. The guidelines do not create any legally binding obligations or rights, nor do they establish proper procedures for redress and remedy. Since the adopted this approach in the light of the absence of adequate national legislation on biosafety<sup>21</sup>.

However, a number of factors make it compelling for countries to develop national legislation to implement their obligations under the Protocol. First, the history of the Cartagena Protocol on Biosaftey which is punctuated by persistent efforts on the part of various States to water down some of its provisions suggests that there is a big likelihood of non-compliance on the part of those Parties. National legislation therefore becomes an important instrument to ensure the effective implementation of the Protocol. Secondly, most of the countries especially in sub-Saharan Africa including those that have signed or ratified the Protocol do not have adequate laws to cover all issues spelt out by the Protocol<sup>22</sup>.

<sup>&</sup>lt;sup>21</sup> This is the approach that Uganda and Kenya had initially adopted.

<sup>&</sup>lt;sup>22</sup> See for example P. Kameri-Mbote., 2004. Towards a Liability and Redress System under the Cartagena Protocol on Biosafety: A Review of the Kenya National Legal System. ACODE Policy Research Series No.8, 2004. ACODE. Kampala. See also P.J. Kabudi., 2004. Liability and Redress for Damage Caused by the Transboundary Movement of Living Modified Organisms under the Cartagena Protocol on Biosafety: A Review of the Tanzania Legal System. ACODE Policy Research Series No. 9, 2004. ACODE. Kampala.

In addition, due to the uncertainties surrounding the potential adverse impacts of LMOs on biodiversity, public health and livelihoods, there is considerable public demand that comprehensive legal regimes be developed to mitigate those impacts in the likelihood that they occur.

Consequently, a number of countries, with the support of UNEP- GEF and other bilateral donors, are engaged in the process of enacting laws to respond to the CPB. Given these ongoing processes, there are potentially four legislative approaches that are open to countries that take the strategy of developing legislation on biosafety. These include: developing subsidiary legislation based on an existing law; amending existing laws that relate to biosafety, enacting an entirely new legislation on biosafety, or enacting biosafety legislation covering different stages of modern biotechnology research and development process as and when it is deemed necessary.

#### 3.1. Subsidiary Legislation Approach

Subsidiary legislation is often contained in Statutory Instruments (SIs) and developed under an existing principal legislation or Act of Parliament <sup>23</sup>. Subsidiary legislation may take the form of regulations, guidelines<sup>24</sup>, orders, rules or by-laws.

## The power to promulgate subsidiary legislation must be granted by an Act of Parliament to a Minister or a designated

<sup>&</sup>lt;sup>23</sup> It is important to note that in countries such as Uganda, principal legislation has been referred to by different names at different times. These include; Ordinances, Decrees, Statutes or sometimes Legal Notices. Whatever name is used, principal legislation is considered to have the same legal authority when it comes to its legal effect.

<sup>&</sup>lt;sup>24</sup> Guidelines are considered subsidiary legislation only if they are developed pursuant to a provision of a principal legislation.

government agency or official. It is important to note that under national constitutions, the power to make laws is vested with the legislature. However, there are a number of reasons why Parliament may delegate its legislative powers. These reasons may include the busy schedule of the legislature, the complexity or technical nature of the issue to be legislated on, or the need for flexibility in the legislation process. Whatever the reasons for delegated legislative powers, the agency of Government exercising such powers must act within the limits of that delegated authority.

The consequence of acting out of the powers conferred by the principal legislation or not following proper procedure is to render the subsidiary legislation null and void <sup>25</sup>. Thus, a mere serious procedural error by the agency concerned could lead to an instrument being declared invalid. For example, in the case of Agricultural Training Board v Aylesbury Mushrooms Ltd. (The Aylesbury Mushrooms Case)<sup>26</sup>, where there was a duty to consult interested organizations before regulations were made, it was held that mere sending of a letter to one organization did not amount to consultation. This is why, if a country adopts this approach and enacts regulations on biosafety, it should ensure that there is adequate authority under the enabling legislation to support this approach and that proper procedure is followed.

A review of the on going processes on biosafety legislation shows that a number of countries have tried to proceed by

<sup>&</sup>lt;sup>25</sup> The subsidiary legislation can be rendered null and void based on grounds of substance of the instrument or procedure followed in making it.

<sup>&</sup>lt;sup>26</sup> [1972] 1 All ER 280 cited in Wade and Bradley, Supra note 21. pg 637.

way of drafting regulations. In most cases, the laws establishing national councils for science and technology have been taken as the enabling statutes<sup>27</sup>. Most of these laws largely deal with establishing institutions for the development, management and promotion of science and technology. Other essential elements that are covered by the Cartagena Protocol are not covered by the existing laws on science and technology, food safety, public health or agriculture. Yet, the draft biosafety regulations of a number of countries also cover those elements such as placing on the market, risk assessment and management, import and export of GMOs, Liability and Redress for damage resulting from GMOs, among others. It is therefore unlikely, that the current delegated mandates under these laws cover all the biosafety issues to be legislated upon within the scope established by the Cartagena Protocal on Biosafety.

It is nevertheless important to observe that where there is adequate delegated authority, proceeding by way of subsidiary legislation tends to be faster, flexible and less costly. However, for purposes of policy, it is important to note that even those countries that have purported to proceed by way of regulations haven't made much faster progress in finalizing these processes. This is largely on the account of the fact that policy makers are still uncertain as to whether this is the right approach or, whether or not the existing principal laws actually give them adequate delegated authority to legislate in this area.

<sup>&</sup>lt;sup>27</sup> Uganda is one of the examples in this category.

#### 3.2. Amendment of Existing Legislation

In a number of cases, countries may opt to amend existing legislation to provide for certain matters that were not originally covered at the time of enacting a particular legislation. This happens where there have been subsequent developments in the legislated discipline or where new information that was not originally available has emerged. In such cases, Government may introduce proposals for amending an exiting law to take care of those situations. Although amendment to principal legislation takes the form of a full legislation process and follows similar procedures as in the case of new legislation, it is often much easier to pass such amendments than engage in enacting an entirely new legislation<sup>28</sup>.

The possibility of taking this approach to biosafety legislation has been regularly considered at different regional and national policy meetings. However, the approach also has its major deficiencies. First and foremost, the breadth of issues to be addressed in biosafety can hardly be adequately addressed through mere amendment of existing law however significant such an amendment can be. If the law was not initially made to specifically address modern biotechnology, it is difficult to later bend it to effectively address the intricate and complex issues that LMOs present.

<sup>&</sup>lt;sup>28</sup> In fact, commenting on the original draft of this brief, Jaffe argued that there is no distinction between amending an existing legislation and enacting an entirely new legislation (personal e-mail communication with the authors dated 28/10/2004). We tend to disagree with Jaffe's reasoning on the basis of the fact that in practice, amendments to existing laws tend to be approached in a much more simple way than enacting new legislation where a comprehensive participatory process is often mandatory. In any case, because of the range of issues to be addressed in biosafety legislation, this would require amending a host of pieces of principal legislation covering food safety, laboratory research, quarantine legislation, public health and environmental legislation, etc.

Secondly, the controversies and uncertainties surrounding modern biotechnology are also such important public policy issues that the public feels uncomfortable to leave them to be addressed under existing legislation. Issues of biosafety span a big spectrum of public policy concerns. They cover broad issues including agriculture, medicine, trade, food safety, food security, environment, public health and national security, etc. Consequently, amending the different pieces of legislation covering this area could be a herculean undertaking. This is because, amending each of these pieces of legislation would require introducing those amendments under separate bills and would have to be handled by different institutions. This would make this approach more complex and costly in terms of time, financial resources and manpower. Because of the multiplicity of the bills, it would also overstretch the legislative agenda of Parliament.

The advantage of this approach to biosafety legislation may only be considered visa avis that of proceeding by way of subsidiary legislation. First, since an amendment of existing law would follow the usual procedure of enacting legislation, this gives the public an opportunity to be engaged in the process to some extent <sup>29</sup>. Secondly, by leaving the process in the ambit of the legislature, the approach allows for proper parliamentary scrutiny and oversight over the matters being legislated upon. It is therefore a preferred approach than taking the route of subsidiary legislation.

<sup>&</sup>lt;sup>29</sup> In practice, the extent of public involvement in the amendment process is largely dependent on the good will of the agency sponsoring the amendment.

## 3.3. The Piecemeal Approach to Biosafety Legislation

Another potential approach that countries may consider in developing national legislation to biosafety is to proceed by piecemeal legislation focusing on those areas that actually need legislation. It is important to recognize that most African countries, perhaps with only the exception of South Africa, are not engaged in LMO related activities. In Kenya, it is only recently that approval has been granted for greenhouse trials with Bt Maize. Consequently, it may be argued that countries are expending a lot of energies in developing legal regimes to respond to GMO products produced by other countries and private companies. Yet, it is not clear whether this is one of the policy objectives being pursued by any or all these countries.

If the primary policy objective of national biotechnology policies is to develop national science and technology Research and Development (R & D) in biotechnology, the piecemeal approach would be the most appropriate approach to take. In this case, countries would develop either principal legislation or regulations covering the different stages of the biotechnology R & D process as and when it is deemed necessary. Regulations could therefore be developed under the science and technology or research legislation to cover laboratory research using target genes or technologies. Once the research programme has reached a stage for greenhouse trials, regulations can be developed for this stage of the R & D process again proceeding under the relevant legislation covering research and development. Issues of commercialization and placing on the market which

stimulate the debate on food safety and environmental safety among others would therefore come further downstream and would not affect science and technology capacity development objectives.

However, this approach could also face some challenges especially if the technology holding companies are interested in selling their products rather than supporting the development of science and technology R & D capacity in African countries. If the objective is the former, these companies may be reluctant to provide their technology for research unless they are guaranteed that products will be put on the market so that they can make money out of their research investments. In this case, both the countries and technology holders would have to work towards aligning their interests and ensure that there is mutual benefit created by the emerging legal regime.

#### 3.4. Developing New Principal Legislation

The other approach that African countries could take to develop national biosafety laws is to develop entirely new principal legislation covering all matters within the scope of the Cartagena Protocol. Indeed, new principal legislation is often mandatory where potential amendments to existing laws are not tenable or where no principal legislation exist delegating adequate legislative authority to another body or agency of Government.

Although there is no strict procedure to be followed in enacting new principal legislation, developing an entirely new law involves many stages and the involvement of many actors. Ordinarily, the relevant agency of Government that is faced with gaps in existing laws will initiate a legislation process, engage in the necessary consultation, draft a bill to be presented to Cabinet and then Parliament once Cabinet endorsement has been obtained. The figure below represents a simple procedure of enacting principal legislation in Uganda.

## Illustrative Cycle of Enacting Principal Legislation in Uganda



Source: Rules of Procedure of the Parliament of Uganda (undated)

There are a number of compelling reasons why this approach may be suitable for developing national biosafety legislation. First, we have already stated that biosafety issues requiring legislation are multifaceted and complex. They cover broad areas such as transboundary movement, handling, use, research, risk assessment and risk assessment procedure, field trials, product development and commercialization, etc. The CPB also requires the designation of relevant institutions to handle matters related to the implementation of the Protocol. Advanced Informed Agreements is another area that requires elaboration through national legislation. Taking the approach of amending existing laws or proceeding by way of subsidiary legislation may not provide the necessary "legislation space" or delegated authority to cover such complex issues.

Secondly, developing a comprehensive new principal legislation provides the best opportunity for broader public participation in regulating the transboundary movement of LMOs. Public participation and public awareness are some of the essential features of the Cartagena Protocol <sup>30</sup>. As shown in the figure above, the principal legislation process provides various 'spaces' and opportunities where the public can provide their input. It is important to point out that although public participation is possible under the subsidiary legislation approach, this is largely dependent on the good will of the agency exercising delegated authority. This is especially so because the majority of the principal laws mandating the making of the subsidiary legislation do not provide for consultation with relevant stakeholders as prerequisite for such legislation.

<sup>&</sup>lt;sup>30</sup> See Article 23

In the case of principal legislation, the requirement for public participation is taken as paramount and failure to consult the public may undermine the legislative process itself and slow down progress. It is also important to emphasize that given the public concerns about GMOs, significant public involvement in the biosafety legislation process is an essential strategy for building public confidence in both the legal and regulatory process. Consequently, sidestepping the requirements for public participation would not only undermine the legislative process but would also go contrary to the spirit of the Protocol.

Thirdly, this approach gives the legislature the opportunity to discharge its legislative responsibility and provide general oversight over the process. The consideration of any legislation at committee stage and the opportunities given to the public to appear before the pariamentary committee hearings in many countries is a fundamental element in building public ownership of the outcomes of the legislation process. Given the complexity of the biosafety issues, parliamentary oversight is essential.

However, it is important to acknowledge that taking the law on biosafety through the entire legislation process will be no mean task and is likely to be affected by a number of factors. First, in many African countries, there are already pro and anti-GMO entrenched lobbies that will prove difficult to manage and building the necessary consensus will take long to achieve. Massive public education campaigns and awareness programmes must precede any attempts at enacting legislation no matter what approach is taken. The

current public awareness and consultation initiatives supported under the ongoing initiatives are mere tokenism considering the nature and complexity of the problem.

Secondly, Government agencies sponsoring biosafety laws must do their preparation properly and set out the objectives and principles of the legislation in no uncertain terms. These principles and objectives should be clearly linked to the national objectives on biotechnology and there must be adequate guarantees for public health safety and food security, etc. However, these agencies are not helped by the ambiguous nature of the current draft national policies. For example, the draft National Biotechnology and Biosafety Policy for Uganda is still unclear on national objectives and targets for the development of biotechnology, the strategies to achieve those objectives and the timeframes within which these strategies would be implemented and objectives achieved <sup>31</sup>.

Thirdly, the heavy involvement of countries promoting the proliferation of GMOs such as the United States of America and other bilateral partners is likely to undermine public confidence in the process of legislation and increase public suspicion on the intentions of these players. National agencies developing national biosafety legislation therefore must demonstrate that the process has been dictated by national needs and interests and is not conforming to the agenda of donor countries and transnational biotech companies.

<sup>&</sup>lt;sup>31</sup> See. Republic of Uganda., 2003. National Biotechnology and Biosafety Policy (draft).

#### Table showing Legislative Approaches to Biosafety in selected sub-Saharan African countries

No.	Country	Legislative Approach	Status of the process
1.	Uganda	Developing Biosefty Regulations under the Uganda National Council for Science and Technology Act, 1990.	Draft regulations in place but the process stalled partly due to lack of guidance on the right approach.
2.	Kenya	Attempted to draft regulations which were rejected by Parliament and the process is now ongoing to enact an Act of Parliament.	Draft Bill is before cabinet for Approval.
3.	Zambia	Enacting Act of Parliament	First draft undergoing stakeholder consultations and refinement.
4	Zimbabwe	Initially tried to deal with biosafety issues by amending the Research Act, 1998 and developing regu- lations there under but now a team has been constitute to draft a full Act of Parliament to deal with biosafety matters and repeat the Research Amendment Act.	First draft undergoing stakeholder consultations and refinement.
5.	South Africa	Has had GMO Act since 1997.	The Act is being amended to align it with the Cartagena Protocol on Biosafety.
6.	Ethiopia	Developing an Act of Parliament	The first draft has been undergoing peer review and stakeholder consulta- tions are yet to start before the draft is committed to parliament for the first reading.

## 4. Conclusion

The development of national laws on biosafety has either been slow or has stalled in a number of African countries. This is mainly because there is lack of clarity on the alternative options available to policy makers confronted with the task of developing NBFs. In this policy briefing paper, we have attempted to lay down the various alternative legislative approaches possible. We have also tried to highlight the advantages and disadvantages of each of these approaches. In conclusion, it is important to emphasize that it has not been our intention to give the impression that there is any single best approach to biosafety legislation. Rather, the approach chosen will often vary from country to country depending on each country's peculiar circumstances, policy and legislative objectives. However, given the complexity and multiplicity of the issues to be addressed in biosafety legislation, the process should conform to certain criteria that are consistent with good legislative practices and the spirit of the Cartagena Protocol on Biosafety. Such practices should include clarity of purpose and legislative objectives, wide public participation and parliamentary oversight.

# 5. Other ACODE Publications in these Series

- 1. Mpeirwe A., (2003), WTO Negotiations on GeographicalIndications: A Case for Non-Discrimination of Products of Interest to Developing Countries. ACODE Policy Briefing Paper No.1, 2003.
- 2. Tumushabe G., (2004), Type II Partnerships As a Strategy For Implementing WSSD Outcomes : Considerations to Guide Government Decision Making. ACODE Policy Briefing Paper No.2, 2004.
- 3. Mugyenyi O., (2004), Status of EPA Negotiations: Eastern and Southern Africa Approach and the Challenges to Effective Negotiations. ACODE Policy Briefing Paper No.3, 2004.
- 4. Tumushabe G., and Naluwairo R., (2004), COP-MOP I Decision on Liability and Redress : Analysis of Implications and Challenges for Eastern and Southern Africa. ACODE Policy Briefing Paper No.4, 2004.
- 5. Naluwairo R., and Tumushabe G., (2004), Uganda's Position on GMOs: Whose Position? Reflections on Uganda's Policy Making Process on GMOs. ACODE Policy Briefing Paper No.5, 2004.



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