THE UGANDA HUMAN RIGHTS COMMISSONS' POSITION ON THE NATIONAL BIOTECHNOLOGY AND BIOSAFETY BILL 2012

1.0. BACKGROUND TO THE BILL

The National Biotechnology and Biosafety Bill (Bill) was tabled as by the Ministry of Finance in February 2013. The memorandum to the Bill notes that there is no specific law regulating research, development and use of biotechnology in Uganda. In addition, it is noted that several provisions relating to biotechnology are scattered in various laws that cover several sectors, like natural resources, industrial development and environmental protection whose administration and management is entrusted to various agencies and departments of Government. The National Council for Science and Technology (UNCST) under the Uganda National Council for Science and Technology Act (Cap 209) currently handles the research aspects of modern Biotechnology[1] while standard setting for food and drugs is handled by the Ministry of Health, Ministry of Agriculture, Animal Industry and Fisheries (Foods and Drugs Act 1964 (Cap 278) and Ministry of Tourism, Trade and Industry. It has been further noted that though in 1993, the drug element was subsumed in the Food and Drugs Act (Cap 278) under the National Drug Authority (NDA), the food element was left unaddressed and to date no amendment has been made the Food and Drugs Act (Cap 278) to address technological developments in the food industry such as food additives, contaminants and packaging.[2]

It should be further noted that there is currently no institution or authority that is solely responsible for the Food safety in Uganda. The Plant Protection Act (Cap 31) provides for the Ministry of Agriculture, Animal Industry and Fisheries to regulate the introduction of exotic plants and micro-organisms; and the Public Health Act (Cap 281) under Ministry of Health sets the standards for sanitation, vaccination and prevention of infectious diseases. In 2009 the National Biotechnology Policy was passed which guides the promotion and regulation of biotechnology use in the country.

[1] Memorandum to the National Biotechnology and Biosafety Bill, 2012 (i).
[2] U.S. and Ugandan Food Safety Systems Report 2008: A challenge to create development partners By Patricia Bageine Ejalu,5.

2.0 SUMMARY OF THE CONTENTS OF THE BILL

The Bill seeks to: facilitate the safe development and application of biotechnology; facilitate and promote research, development and use of modern biotechnology; establish procedures for bio-ethical consideration in biotechnology research; strengthen consumer protection and public understanding of products and the benefits of biotechnology; facilitate safe use of biotechnology to address national development challenges in food security. In addition, the Bill seeks to facilitate healthcare, biodiversity conservation and industrialization; promote capacity in biotechnology research, development and innovation; promote technology transfer and benefit-sharing in the development and use of modern biotechnology; and to build strong institutional relationships among biotechnology stakeholders.

2.1POSITIVE ASPECTS OF THE BILL

The UHRC welcomes the efforts made towards drafting a Bill to regulate research, development and use of biotechnology in Uganda that is in line with the National Objectives of Direct Principles of State Policy which highlight the role of the state in adopting appropriate policies and enacting enabling legislation to stimulate agricultural, industrial, technological and scientific development.[3] The Bill seeks to promote the safe development of biotechnology in Uganda in order to exploit and promote science and modern biotechnology in the modernizing of agriculture (by addressing drought, introducing disease and pest resistant crops or animals), protection of the environment, enhancing public health and industrialization. The Bill could therefore contribute to the realisation of the right to adequate standard of living and adequate food for Ugandans under Article 11 of the ICESCR.

(i) Scope of the Bill

The Bill covers the different stages in the development of a Genetically Modified Organism (GMO) from approval of each stage of research; risk and safety

[3] Objective XI (ii) of the 1995 Constitution of Uganda.

assessment and management; general releases into the environment; and import, export and transit process for GMOs.[4]

(ii) Establishment of mechanisms to enforce provisions of the Bill

The Bill provides for establishment of mechanisms for instance the National Focal Point (Ministry of Environment); Competent Authority (National Council for Science and Technology); National Biosafety Committee (which will regulate confidential business information including research procedures); Registrar and the Institutional Biosafety Committees to regulate the research, development and the general release of GMOs and for other related matters. These clauses are in line with Article 2 of the Cartagena Protocol on Biosafety (CPB) that requires state parties to take necessary and appropriate legal, administrative and other measures to implement its obligations under the Protocol.[5] In addition, appointment of inspectors under Clause 34 and 35 will enable monitoring to ensure compliance with the Bill and the directives of the Competent Authority.

(iii) Safety measures and risk assessment

Under Clause 7, Clause 10 and Clause 14 of the Bill one of the functions of the Competent Authority, National Biosafety Committee and Institutional Biosafety Committees is to ensure safety of biotechnology to human health and environment during development, testing, handling, transfer, release and use of a GMO. In addition, under Clause 29 every applicant is expected to carry out a risk and safety assessment at each stage of development of a GMO which are to be reviewed by the Institutional Biosafety Committee (laboratory research and contained testing) and Competent Authority (General release and confined testing). These clauses are in line with Article 22(1) and Article 39 of the 1995 Constitution which provides for the right to life and the right to a clean and healthy environment; Article 12(1) of the CESCR which provides for the right to health and reiterates Article 2(2) of the CPB. In addition, under Clause 29

[4] Clauses 15-18 and 29-30 of the National Biotechnology and Biosafety Bill, 2012.

[5] Uganda ratified the Cartagena Protocol on Biosafety in 2001. The objective of the Cartagena Protocol on Biosafety is to provide for an adequate level of protection in the field of safe transfer, handling and use of living modified organisms from modern biotechnology that may have effects on the conservation on the sustainable use of biological diversity taking into account risk to human health and specifically focusing on trans boundary movement.

safety measures and procedures are provided for in the event of unintentional release of a GMO which is consistent with Article16 (3) of the CPB.[6]

(iv) Right to information

Under clause 7 (i) the Competent Authority has the function of promotion of public awareness and education concerning activities provided in the Bill which enshrines the right to information.[7] The Competent Authority has a duty to sensitize the public on GMOs and to coordinate their participation in order to ensure consumer protection.

(v) Protection of confidential business information

Protection of confidential business information under Clause 39 is an important provision especially in light of sensitivity of scientific and biotechnology experiments/testing. Though the Competent Authority is expected to make information available to the public, the regulatory system must balance the competing interests of the applicant, who may want to keep some information confidential for business purposes. A regulatory system with no protection for trade secrets and proprietary information, might not receive any applications because private enterprises would not be able to successfully market a product if certain information is not kept confidential. Thus, a good regulatory system must also protect from disclosure of confidential business information of applicants.

(vi) Remedies

Remedies in case of breach are provided for instance in the form of a restoration order under (Part V) granted by Competent Authority. The restoration order direct persons in breach of the Act who have for instance caused damage by unintentional release of GMO to restore conditions as they

[6] Article 16 (1)states that Parties shall, establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and trans boundary movement of living modified organisms.

[7] Article 5 of African Model Law on Biosafety provides for notice to the public about upcoming decisions in which they can comment, requires that information relevant to the decision be made available before the public's comments are due, and ensures that the decision-maker looks at the public's comments before making a decision.

were before the release of GMO or levy a charge which is a reasonable estimate of the cost of any action to restore the environment in its former state. Part VIII of the Bill provides for punitive actions in case of offences committed in the form of imprisonment and or commensurate fines which also extends to person(s) working in a body corporate.

2.2 HUMAN RIGHTS CONCERNS ARISING FROM THE PROVISIONS OF THE BILL

Though the objectives of the Bill are commendable, there are human rights concerns that arise from the primary obligation of the state to provide an adequate level of protection in the safe transfer, handling and use of GMOs in order to ensure that there are no adverse effects of GMOs on health and the sustainable use of biological diversity especially biological diversity of indigenous and local communities. The UHRC is concerned with various aspects of the Bill including: provisions on public awareness: food safety and security: clear safety standards: fair and equitable sharing of benefits: inadequate proportionate based reviews; and minimal representation of the Ministry of Agriculture, Animal Industry and Fisheries.

2.2.1 Inadequate public awareness and participation

The UHRC notes that there has been inadequate public awareness and participation about the introduction of GMOs and Biosafety. These activities have been done on a small scale with limited involvement of relevant stakeholders like farmers and consumers on impacts of GMOs. Clause 7 (i) of the Bill only mandates the Competent Authority to promote awareness and does not specify the right of the public to participate in decision making process. Article 23 of the CPB obliges State Parties to promote and facilitate public awareness, education, participation and access to information concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity. The public should be consulted in decision making process regarding GMOs which is in line with the precautionary principle, which forms the basis of the African Union's Revised African Model Law on Biodiversity.[8]

[8] As above, Article 8.

The UHRC therefore recommends that:
Clause 7 (1) be amended to provide for open and transparent consultations with the public and provide for a mechanism for consultation; and
The Competent authority should take into account the views of the public when making or reviewing its decisions.

2.2.2 Lack of clear safety standards to ensure food safety and security

One of the objectives of the Bill is to facilitate safe use of biotechnology in order to address food security. In order to do this the Bill has adopted a comprehensive definition of a GMO that does not distinguish GMOs based on the products they produce which encompasses GMOs for food, feed and industrial purposes. However, the Bill does not adequately address issues of food safety and security.[9] For instance, there are no laid out procedures of what will be considered in conducting food safety assessments.[10] In addition, the Bill does not provide the option for the local communities to have genetic modification free zones.

The Bill does not have explicit provision for food labeling for consumers to distinguish between GMO and non-GMO products though it has been noted that concern about *the safety of GM foods is the single most important obstacle to public acceptance of biotechnology products.*[11]

The UHRC recommends that

The Bill should provide for identification of GMOs for any person manufacturing or importing a GMO; and
Local communities should have genetic modification free zones.

2.2.3 Inadequate safety standards of approving a GMO Organism

Though the Bill provides for institutions which would approve GMO at the various stages (Biosafety Committee and Competent Authority) and lays out the requirements for approval in schedules it does not explicitly lay out the criteria

[9]www.biovisioneastafrica.com last accessed in June 2013.
[10]Comparative Analysis of the National Biosafety Regulatory Systems In East Africa by Gregory Jaffe January 2006, 24.
[11] Codex Food Safety Standards and Guidelines surrounding GMOs should be adhered to on how to conduct food safety risk assessments for GE organisms and their food products. (Codex Alimentarius Commission in FAO).

for the refusal or granting of the approval.[12] The Bill does not explicitly provide for whether the criteria will be based on risk to the environment, animal or human health, food safety and security.[13] In addition, it is not clear whether this criteria will be applied for instance on possible environmental impacts caused by GMOs including on loss of biodiversity because of dominance of GM strains or the direct and indirect side effects of GMOs on life support systems in the environment such as air, water and soil.[14] In addition, the Bill does not outline which socio-economic considerations are to be taken into consideration and whether such socio- economic considerations would include impacts on farmers income and welfare; ethical values, cultural practices such as the 'knowledge, innovations, practices and technologies of indigenous and local communities' in saving, sharing and multiplying seed in order to sustain food systems and food security.[15]

The approval of GMOs is dependent on the information provided by the applicant which is based on the assumption that the information is the most recent peer reviewed information.

The UHRC recommends that:

The criteria for the refusal or granting of the approval of a GMO be specifically laid out;
The criteria should provide for the most recent peer reviewed information about the GMOs and the Competent Authority should be given the option to conduct the risk assessment; and
The Bill should explicitly provide for what constitutes socio-economic considerations in the event of introduction of GMOs.

2.2.4 Fair and equitable sharing of benefits from utilizing genetic resources

Fair and equitable sharing of benefits that arise from the use of genetic resources has to be viewed in light of the intricacies of Intellectual property

[12] Section 69 of The Environmental Management Act, 2004 of Tanzania provides for a general criteria which states that Genetically Modified Organisms should not harm, cause injury or loss to the environment and human health including socio economic, cultural and ethical concerns.
[13] Schedule 3 Form 1, Form 2 and Form 3.
[14] *www.academicjournals.org/ajest/PDF/pdf%202012/FEb/Mtui.pdf* - Cached (accessed on 21st August 2013).
[15] n 10 above, 31-33.

rights of GMOs. Intellectual property rights have implications on accessibility to technology and products considering the growing trend towards tighter controls of intellectual property promoted by the World Trade Organization's agreement on trade-related aspects of intellectual property rights (TRIPS).[16]

Biotechnology companies with patent rights do not only have patent rights to restrict the use of GMOs but could inevitably control the saving, sharing and multiplication of seed and the cost of patented seed.[17] This issue will be of great concern in Uganda where the large percentages of farmers are not well conversant with these rights and may not be able to afford patented seed.[18] In addition, the Bill does not provide explicit criteria to guide the approval for instance whether the GMOs would be beneficial to the country whether this will be based on significant risk, contribution to sustainable development or is line with ethical values and does not undermine local community or indigenous knowledge of communities.[19]

The UHRC recommends that:

Explicit criteria be laid out in the Bill to guide the Competent Authority on when to approve the introduction of GMOs.

2.2.5 Inadequate Proportionate Based Review

Clause 25 of the Bill provides for expedited review of an application for research and general release of a GMO in cases where the research has been approved by a competent authority or where the research has been done in comparable systems has been approved by a competent authority established at the regional level or where the general release of a GMO poses minimal risk to human health or the environment. This approach is not in line with the precautionary approach considering that eco-systems are incomparable.[20]

The UHRC recommends that:
Clause 25 should be amended to provide for the case to case risk assessment and;

[16] www.ielrc.org/content last accessed *on 10th May 2013.*
[17] Bowman v. Monsanto Co. U.S No. 11–796 Supreme Court Decision of May 13, 2013.
[18] www.ielrc.org/content last accessed on 10th May 2013.
[19] n 8 above, Article 8 (7).
[20] Principle 15 of the Rio Declaration on the Environment and Development.

Clause 25(e) be retained which provides for an instance which provides an exception where an application had been previously considered by the Competent Authority.

2.2.6 Limited access to information

Under Clause 22 (3) (b) an application for the approval for general release of GMOs is published only in the official website of the Competent Authority and gazette which a small section of the public has access to. It is important for the public to be aware of the GMO produced, its benefits and risk assessment to the health and environment through national newspapers and appropriate electronic media. In addition, this would enable the public raise any issues in regard to the application and give time to the Competent Authority to respond to any issues raised.[21]

The UHRC recommends that:
An application for approval of a general release of a GMO should be placed in news papers of national circulation, in other electronic and print media which should be made available to the public and affected local communities and;
A provision be included for a time frame within which the public should respond and the competent authority consider their concerns.

2.2.7 inadequate oversight mechanisms

The Bill neglects the central role of the Ministry of Agriculture, Animal Industry and Fisheries in this process and yet the ministry is responsible for any agricultural developments in Uganda and has a primary role in ensuring food security. This is coupled with the challenge of: adequate capacity to manage existing laboratories for instance in the case of unintentional release of GMOs; avoiding bio-security risks; ensuring adequate risk and safety assessments; and managing the potential adverse effects on human health and the environment. If both human and physical infrastructural resources are pulled together funding for biosafety activities could be addressed.[22]

The UHRC recommends that the Ministry of Agriculture, Animal Industry and Fisheries be given a primary role to strengthen the oversight mechanisms.

[21] Section 19 of the Kenyan Biosafety Act No. 2 of 2009.
[22] *www.academicjournals.org/ajest/PDF/pdf%202012/FEb/Mtui.pdf* - Cached last accessed on 21st August 2013)

2.2.8. The sanctions and redress for breach of the provisions.

The sanctions and redress for breach of the provisions are very light compared to the high level of risk associated with the development of GMOs and potential adverse effect caused to public health and environment. The penalties range from twenty four currency points for obstructing the Competent Authority to one hundred and twenty currency points for engaging or making a general release of a GMO without approval.[23]

Liability has been vaguely defined giving protection to corporations with offences and penalties in regard to body corporates not specifically spelt out.[24] In addition, redress for breach in form of a restoration order is limited to restoration of the environment and levying of a charge and liability does not encompass redress in case of harm to human and animal health or damage to the livelihood of communities.

The UHRC recommends that:

The strict liability approach be used as opposed to fault based liability principle. A person, who imports, arranges transit, makes use of releases or places on the market a GMO or product of a GMO should be liable for any harm occasioned by such GMO or product of GMO which would ensure effective operationalising of the precautionary principle [25]

The penalties for breach of the provisions of the Act should be made more stringent taking into account the high level of risk attributed to the development of GMOs and potential adverse effect caused to public health and environment.[26] and;

Liability should be extended to include compensation in case of harm to human and animal health to the communities which have suffered due to the release of a GMO.

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[23] As above 16,Clause 37.
[24] As above Clause 38.
[25] National Biotechnology and Biosaftety Bill, 2012: COS perspective, presented by Barbara Ntambirweki-Karugonjo of ACODE at Hotel Africana on 7th June 2013, 3
[26] Under the Kenyan Biosafety Act a person who contravenes any provision of the Act is liable on conviction to a fine not exceeding twenty million Kenyan shillings, or to imprisonment for a term not exceeding ten years or both.

2.3 Conclusion

The National Biotechnology and Biosafety Bill, 2012 mainly focuses on facilitating rather than finding a balance between facilitating and regulating the promotion of safe development and application of biotechnology for development and general release of genetically modified organisms (GMOs) in Uganda. The UHRC therefore recommends that the Bill is reviewed to address the human rights concerns that have been highlighted in order to fulfill the primary obligation of the state to provide an adequate level of protection in the safe transfer, handling and use of GMOs.