

Review

Biotechnology Regulatory Conundrum: Balancing Innovation and Oversight in the Case of GMOs

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This paper looks at attempts that have been made to develop legal regulatory frameworks for modern biotechnology. The discussion is limited to the regulation of Genetically Modified Organisms (GMO) technology by the two leading producers and exporters of GMOs in Africa: South Africa and Kenya. The international and regional regulatory regimes are analysed for comparative purposes since the two countries have partially based their regulatory frameworks on these regimes. The methodology used is analytical; the challenges that are posed by GMO technology are analysed from public policy and legal perspectives. The main argument that is advanced is that the challenges that are frequently viewed merely as problems ought to be considered as indicators of possibilities and limits in regulating this fluctuant field. Ideas on the factors to be considered in developing appropriate regulatory frameworks for biotechnology are put forth to serve as a wake up call to policy makers and legislators that have to deal with such issues. It is concluded that a holistic approach should be used in addressing the pressing issues that are raised by biotechnology generally and GMOs in particular.

Key words: Biotechnology, GMOs, Kenya, Law, Regulations, South Africa.

INTRODUCTION

Advances in biotechnology often present both opportunities and challenges to the regulatory authorities. However, the analysis of such advances “is almost always focused on the challenges rather than the opportunities (UNCTAD Secretariat, 2000). Pessimistic pictures are often painted particularly with regard to agricultural biotechnology. In South Africa, the general public tends to view biotechnology as being synonymous with genetically modified organisms (GMOs) (Montari et al., 2004). This is as a result of common local and international media reports. It is thus not surprising to come across sensational media reports such as “GM technology fails local potatoes” (Gathura, 2004), “GM mosquito not fit enough”, (McDowell, 2004) and “Activists angry at Genetically Modified Food Changes” (Kahn, 2004).

The worrying situation is that the general approach in dealing with biotechnology and genetically engineered crops “tends to be portrayed in an antagonistic manner, leaving little room for constructive discussion. As a result,

little opportunity exists for efforts to achieve a balance between factors such as the different needs of the public sectors, the complex requirements of farming systems...and the continuous pressure to achieve food security in developing countries” (Cohen et al., 2004).

Scholars have equally joined in propagating the pessimistic attitude, for example, one of the recently published text books containing a series of chapters on biotechnology is entitled “Biotechnology- the Making of a Global Controversy (Bauer et al., 2002) and a short article which appeared in the New Jersey Law journal soon after Merck & Co. announced the withdrawal of “its blockbuster arthritis drug viox because it could increase the risk of heart attacks and strokes” bore the sensational title; “Vioxx Becomes a Class Act” (O’Brien, 2004).

The main argument that is advanced in this paper is that the incidents that are viewed merely as problems and challenges ought to be considered as indicators of possibilities and limits in regulating this fluctuant field. In

essence, the paper is a wake-up call to policy makers and legislators that have to deal with such issues to use a holistic approach in addressing the pressing issues that are raised by biotechnology generally and GMOs in particular.

The paper briefly looks at attempts that have been made to develop legal regulatory frameworks for modern biotechnology. The discussion is limited to the regulation of GMO technology in two countries: South Africa and Kenya. The international and regional regulatory regimes are briefly mentioned to pave way for the discussion because the two countries have partially based their regulatory frameworks on these regimes.

The main reasons for choosing South Africa and Kenya are: they are among the leading producers and exporters of GMOs in Africa (Joroghe, 2001) and they are currently grappling with the development of legal regulatory frameworks for biotechnology. The South African situation is very useful for the discussion since the process of developing a regulatory framework for biotechnology has been marked by contracted debates and even litigation (Biowatch South Africa, 2004a).

ISSUES AND CONCERNS IN THE REGULATION OF BIOTECHNOLOGY

The prevailing situation of pessimism and antagonism may, arguably, be attributed to the fact that the laws and regulations that govern such advances have not been effectively developed. This is evident from the fact that the current legal frameworks are beset by the following problems:

The legislative processes leading to the enactment of laws and regulations are often splintered

Many organisations, which have different focal points, are involved in the process. Examples of such focal points are: biosafety (the need to protect human health and the environment from the possible adverse effects of the products of modern biotechnology), biodiversity and public health concerns. Two examples can be used to illustrate this: First, Article 5 of the Biosafety Protocol does not deal with the transboundary movement of living organisms, which are pharmaceuticals for humans. This omission was well intentioned as it was aimed at avoiding duplication of efforts since the World Health Organisation (WHO) would deal with such issues. The reality however is that WHO does not deal with biosafety or biodiversity issues and in any case it can only issue recommendations.

The second example concerns the introduction of genetically modified maize in Kenya, which was initially targeted for the year 2008 but will be delayed for a further two years till 2010. The reason for the delay is that safety regulations for the Insect Resistant Maize for Africa

(IRMA) project have to be revised to bring them in line with national and international standards by focusing on the probable threats that GM maize could pose to human health and the environment (Chege, 2004). Interestingly, the regulatory issues were not exhaustively covered in the original project plan (Chege, 2004). The project is a joint venture between the Kenyan government and international research institutes and it aims at developing a variety of maize that is able to resist attack by stem borers and major insect pests. Some of the donors, particularly the Rockefeller Foundation, are hoping that the inclusion of extra regulations will not slow the pace of the project. Joe DeVries of the Rockefeller Foundation was quoted as saying “it is clear that [this type of GM] maize has been tested and proven to work elsewhere hence there is no need for unnecessary regulations” (Chege, 2004). It is interesting to note that while the donors are more concerned with the expeditious completion of the project, the government regulator (the Kenya Plant Inspectorate Service) and IRMA are more concerned with broader issues such as breeding, facilities, permits and the social as well as economic implications of introducing GM maize to Kenyan farmers. This precautionary measure is understandable given the fact that the failure of GM potato in Kenya is still fresh in mind. Critics used this failure to confirm their fear that “bio-engineered techniques tried elsewhere may not be replicated in Africa with similar results” (Gathura, 2004). The initial gene construct for the potato was done at the Monsanto laboratories, in USA, using virus resistant technologies and was imported to Kenya in 2001. It took Monsanto nine years to develop a coat protein responsible for virus resistance. This was donated to Kenya Agricultural Research Institute (KARI) royalty free (Gathura, 2004).

Mock trials were initiated in five provinces (Western, Nyanza, Central, Coastal and Eastern). Subsequent local investigations proved that the technology had failed to produce a virus resistant strain. It is yet to be determined “whether the gene expression was adequate or it failed to address the diversity of virus in this region or just that the gene construct was inappropriate” (Gathura, 2004).

Decentralised organisational framework with governmental and intergovernmental organisations having overlapping jurisdictions

A clear example of this situation is the administrative structure that is provided for under the Biosafety Bill of Kenya. Clause 5(1) establishes an administrative authority known as “the National Biosafety Authority”. The board members of the authority mainly consist of government officials from the eight regulatory agencies that are stipulated in the First schedule to the Bill viz., Ministry of Health, Department of veterinary services, Kenya Bureau of Standards, Kenya Plant Health Inspectorate Services, Kenya Industrial Property Office, Kenya wildlife Services, Pest Control Products Board and

the National Environmental Management Authority (NEMA). Other members are drawn from both public and private sector.

Section 3 of South Africa's Genetically Modified Organisms Act also establishes a council known as the Executive Council for Genetically Modified Organisms. The council comprises of not more than eight members (the proposed amendment Bill provides for ten members- under Clause 3 (a)) drawn from diverse government departments viz., the Department of Agriculture, the Department of Arts, Culture, Science and Technology, the Department of Environmental Affairs and Tourism, the Department of Health, the Department of Labour and the Department of Trade and Industry.

The establishment of one national authority is in line with the provisions of Article 19 of the Cartagena Protocol, which requires parties to designate one national focal point to be responsible on its behalf for liaison with the Secretariat. The manner in which the diverse regulatory authorities are incorporated into the national authority and council, in Kenya and South Africa respectively, may be a commendable way of ensuring that the overlap in their respective jurisdictions does not lead to overregulation. This is the case in view of the fact that each of these government departments is charged with the responsibility of administering other Statutes that may impact on GMOs. Conflicts may however arise due to overlaps in such authorities' jurisdictions. An illustration of this is the inherent conflict between South Africa's section 78(1) of the Biodiversity Act and the GMO Act. The said section of the Biodiversity Act provides that no permit for release of GMO should be issued in circumstances where the Minister of Environmental Affairs and Tourism believes that it may pose a threat to the environment or any indigenous species unless a prior Environmental Impact Assessment (EIA) has been conducted. The Minister is expected, under section 78(2), to convey such belief to the authority that is charged with the responsibility of issuing permits under the GMO Act. The lacuna in this regard is that there is no provision in the GMO Act, which requires the Minister to be notified before applications for release are granted under the GMO Act.

Interestingly, there are many issues that regulatory authorities have to contend with. These are: the complexity of biotechnology, fiscal restraints and globalisation. Each of these issues is explained below.

Complexity of biotechnology: Regulation is a matter of "assignment of authority to a decision-making body that is in a position to make decisions based on the facts of the particular cases that are presented to them" (Dworkin, 1996). The facts in question may originate from any sector of the society and the assignment of authority is usually done through legal structures or institutions. The vital role of law in the regulation of biotechnology in this regard is assignment of authority to the institutions or

agencies that are duly empowered to deliberate on the issues at stake.

The regulation of activities related to biotechnology requires economic and social trade-offs because the issues that law seeks to regulate are also subject to other processes that influence the operation of law. Law must reckon with the societal spheres that constitute the 'environment of biotechnology'. The societal spheres in this context consist of the active roles that "economic, legal, mass media, political..." and other factors play in setting the agenda for the debates (Bauer et al., 2002). Modern biotechnology is equally characterised by scientific uncertainty and there are competing goal valuations. The different societal spheres focus on different aspects of biotechnology at different times and they have their particular logical approaches which may lead them to pay attention to totally different issues. For example: Economists may focus on different economic issues such as investment opportunities and stock market performance. The media focuses on the 'news' value of particular developments such as novelty, human interests or scandal. The important role that this sphere plays in framing issues in the public domain should not however be disregarded. Law focuses on rights and duties, safety of the advances, access to the products or information relating to biotechnology and benefit sharing. Public policy making (particularly in science) "involves setting directions and priorities, establishing and assuring ethical and safe standards for the conduct of scientific and technological products" (Holman et al., 1978).

The regulatory authorities in question may have roles in different capacities ranging from fostering investment in research and development, maintaining amicable international economic relations and protecting their respective governments' citizens from any harm that may arise from the products of biotechnology. Such diverse roles may give rise to conflict of interests. A clear illustration of this situation is the manner in which many European countries reacted to the emergence of the biotechnology industry in the 1990s: "The state's role was perceived to be restricted to providing a congenial environment for industrial performance, and it was no longer considered appropriate for the state to promote other social goals when regulating biotechnology" (Bongert, 2002).

Fiscal restraint: Regulation of any activity that affects the public is often costly in terms of setting up the necessary institutional frameworks. Though regulations have the advantages of laying down standards directly, avoiding complexity and having an apparent fairness, law-making "is a lengthy and costly procedure" (Government of the Republic of Kenya). Such regulatory costs may have spillover effects on the consumers and tax payers. Regulations can equally "be expensive to monitor and enforce. They quickly become outdated and require frequent and expensive revisions" (Government of the Republic of Kenya).

Globalization: The main challenges of globalisation are Lack of frameworks for coordinated action in the regulation of biotechnology; institutional overload and inability to agree and set priorities. This is evident from the manner in which various regions and nations have resorted to using diverse regulatory standards that take into consideration their unique concerns because, in some cases, they may not find the recommended international standards suitable for such concerns.

THE LEGAL REGULATORY FRAMEWORKS IN PLACE

The development of legal regulatory frameworks has been marked by adoption of new legislation and amendment of older laws to respond to the new challenges (FAO's Legislative Study, 2003). This is the case since legislation essentially deals with biosafety, food safety and consumer protection in respect of which either new legislation is needed or existing legislations should be amended.

Most regulatory instruments have focused on GMOs, as there is a lot of ongoing debate in this area. FAO's Legislative study clearly captures the nature of law that governs modern biotechnology:

“Biosafety instruments represent the primary source of law on modern biotechnology in the world today. Biosafety instruments address the risks posed to the environment and human health when GMOs are released into the environment either for research (e.g. small scale or field-testing) or for commercial purposes. Biosafety instruments also address contained use of GMOs.”

There is however no single comprehensive legal instrument that addresses all aspects of GMOs or the products of modern biotechnology at the international level. The frameworks in place consist of binding instruments and non-binding policy documents. A brief description of these instruments is given below.

International frameworks

A number of international legal instruments govern biotechnology at this level as shown in Table 1. Non-binding documents are not included in the table as, strictly speaking they may not be considered to be part of the legal framework. Two instruments that specifically deal with GMOs, and have greatly influenced the national frameworks under discussion, are the Convention on Biological Diversity and the Cartagena Protocol.

The Convention on Biological Diversity (CBD)

The Convention on Biological diversity was finalised in May 1992 and entered into force on 29th December 1993.

It is the main international instrument that addresses biodiversity issues (Cartagena, 2000). It addresses two main issues with regard to biotechnology: “it provides for access to and transfer of technologies, including biotechnology and ensures the development of appropriate procedures for enhancing the safety of biotechnology in the context of the Convention's overall goal of reducing all potential threats to biological diversity” (Cartagena, 2000).

Article 8(g) of the Convention provides for a general framework under which contracting parties have attempted to develop regulations to govern biotechnological advances. The article provides as follows:

“Each contracting party shall as far as is possible and appropriate...Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking into account the risks to human health.”

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity (Biosafety Protocol)

The protocol was finalised and adopted on 29th January 2000. It came into force in September 2003. It was developed pursuant to Article 19, paragraph 3 of the CBD, which “sets the stage for the development of an international legally binding instrument to address the issue of biosafety.” It aims at reconciling “the respective needs of trade and environmental protection with respect to a rapidly growing global industry, the biotechnology industry.” It, arguably, “creates an enabling environment for the environmentally sound application of biotechnology, making it possible to derive maximum benefit from the potential that biotechnology has to offer, while minimising the possible risks to the environment and to human health.”

The Protocol's salient features are:

- It advocates for the application of precautionary principle, which requires appropriate decisions to be made irrespective of the fact that scientific information regarding the adverse effects of a living modified organism is insufficient (Articles 1, 10(6) and 11(8)).
- It encourages parties to take necessary and appropriate legal, administrative and other measures to implement the obligation of the Protocol (Article 2).
- It respects state parties' sovereignty particularly with regard to their obligations under international law.
- It does not apply to the transboundary movement of living modified organisms which are pharmaceuticals for humans insofar as they are governed by other relevant international agreements or organisations (Article 5).

Table 1. Binding international regulatory instrument for biotechnology.

	Regulatory instrument	Relevance to biotechnology
1	The United Nations Convention on the Law of the Sea (1982)	Limited to pollution of the marine environment.
2	Convention on Biological Diversity (CBD) (1992)	Very relevant as it governs “the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources” (Article 1).
3	The World Trade Organisation’s (WTO Agreement on the Application of Sanitary and Phytosanitary Measures (1994)	Quite relevant as it provides for the enactment of laws, decrees, regulations, requirements and procedures relating to sanitary and phytosanitary concerns that may affect trade.
4	The WTO’s Agreement on Technical Barriers to Trade (1994)	Provides for standards of ensuring the elimination of unfavourable treatment of trading member countries’ products. This is relevant to biotechnological industrial and agricultural products.
5	The UN Food and Agriculture Organisation (FAO) International Plant Protection Convention (IPPC) (1997)	Aims at securing “common & effective action to prevent the spread and introduction of pests of plants and plant products and to promote measures for their control” (Article 1).
6	Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (1998)	Protects the right of every person of present and future generations to live in an environment adequate to his/her health and well being and guarantees the rights of access to information, public participation in decision-making & access to justice in environmental matters. The convention is thus applicable to any biotechnological advances that may impact on the environment.
7	The CBD Cartagena Protocol on Biosafety (2000)	Aims at “ensuring an adequate level of protection in the field of safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements” (Article 1).
8	The International Treaty for Plant Genetic Resources for Food and Agriculture (2001)	Deals with the conservation and sustainable use of plant genetic resources for food and agriculture and equitable sharing of benefits arising out of their use (Article 1).

The suitability of the regulatory environment enshrined in the protocol is contentious. The specific contentious aspects are highlighted in part three of this paper.

Regional frameworks

To pave way for a discussion of the selected national frameworks, this section is limited to the African region as a discussion of other regions is beyond the scope of this paper.

THE AFRICAN MODEL LAW ON SAFETY IN BIOTECHNOLOGY

The model law was endorsed at the meeting of the African Union in Maputo in August 2003. It is more comprehensive than the Cartagena Protocol insofar as it applies to “import, export, transit, contained use, release or placing on the market of any genetically modified organism whether intended for release into the environment, for use as pharmaceutical, for food, feed or processing or a product of a genetically modified

organism” (Article 2). The provisions of the Model Law have been influenced by the Biosafety Protocol but it adopts “more protective measures than the agreed minimum set out in the protocol” (Mayet, 2003). Some of the additional protective measures are summarised below.

- It requires that advanced informed agreement (AIA) procedure be applied to all categories of GMOs, products of GMOs and their uses. It is interesting to note that the Biosafety Protocol only requires the AIA procedure to apply outright to the first time a GMO is imported for direct introduction into the environment of the importing party.
- Mandatory labeling and identification (Article 11).
- Traceability for GMOs and genetically modified food.
- Liability and redress for harm caused by GMOs to human health, the environment and resultant economic loss (Article 14).

It is stated in the Preamble that the precautionary principle should be applied to activities relating to GMOs,

Table 2. Regulatory instruments for biotechnology in South Africa.

	Statute	Scope	Relevance to biotechnology
1.	The Genetically Modified Organisms Act No. 15 of 1997	Applies to the genetic modification of organisms and development, production, release, use and application of genetically modified organisms as well as the use of gene therapy (Section 2).	Provides for measures to promote responsible development, application and use of GMOs. It appears to be more focused on biosafety issues.
2.	The Environment Conservation Act, No. 73 of 1989	Provides for mandatory requirements for Environmental impact assessment for GMOs.	Limited scope
3.	The Foodstuffs, Cosmetics and Disinfectants Act, No. 54 of 1971	Sets out control measures to ensure food safety.	Limited scope as it may be deemed to require clear labeling of GMOs only.
4.	The national Environmental Management Act No. 107 of 1998	Sets down minimum standards for decision-making in environmental management	Appears to be limited to the provision of incentives to civil society to monitor enforcement of environmental laws

which are within the scope of the Model Law. This approach is consistent with Article 8(g) of the CBD, which requires parties to regulate and manage risks associated with GMOs and products of GMOs. In view of its broad scope, the Model Law has been commended as a “piece of Legislation drafted by Africans for Africa, taking into account the unique circumstances of the continent” (Mayet 2003).

Selected National frameworks:

FAO’s Legislative study established that at the national level, “there does not appear to be any single law addressing all aspects of biotechnology. Instead, the primary focus is on GMOs.” A clear illustration of this is the situation obtaining in South Africa and Kenya that are currently grappling with the development of legal frameworks for the regulation of biotechnology. The ongoing developments in these countries are discussed in this section.

SOUTH AFRICA

The South African situation is interesting insofar as it was the first African country to approve transgenic crops for commercial purposes and is the leader in agricultural biotechnology research and development on the continent (Joint Report, 2002). It “started to address issues related to genetic engineering as early as the late 1970s through the establishment of the South African Genetic Experimentation Committee (SAGENE) as the national advisory body on biotechnology research and development.” An attempt has been made to develop a national biotechnology strategy in which it is acknowledged that “it is the government’s responsibility to ensure that new biotechnology products or services do not threaten the environment or human life or undermine ethics and human rights” (National Biotechnology Strategy for South Africa, 2001).

In view of the foregoing, South Africa has been correctly described as “blazing a trail for African biotechnology” (Montari et al., 2004). The national biotechnology strategy addresses regulatory and legal issues as well. It has also “created awareness in government departments and agencies of the role of biotechnology in meeting health and socio-economic needs.”

The main impetus for legal regulation is section 24 of the Constitution, which provides for ‘inter-generational equity’, and places an obligation on the state to protect the environment for the benefit of present and future generations. This provision appears to be limited to issues related to biosafety but its scope could be extended to the regulation of advances in biotechnology that may impact on health and the environment. In line with this obligation, the state has enacted a number of statutes that are relevant for the regulation of biotechnology. Table 2 shows the scope of each statute.

The discussion in this section focuses more on the Genetically Modified Organisms Act for the reasons that were mentioned earlier.

The Genetically Modified Organisms Act

The Act came into effect on 1st December 1999. It is worth noting that the first field trials were allowed in 1994 and since 1997, several multinational companies were allowed to grow and import GMOs even before the GMO Act was in place! This situation has made many critics to argue, and rightly so, that the Act “was passed hastily and without adequate public participation in order to address a situation in which GMOs were already being used in agriculture without any effective controls or regulatory oversight” (Biowatch, 2004a). The glaring omission in this regard is the absence of a concise policy framework on which the legal framework can be based. Consultation with the relevant stakeholders is an indispensable requirement in the regulation of biotechnology. Such consultation ensures that diverse views are consid-

ered so that no stakeholders are left with the feeling that there has been regulatory capture by one sector that may have vested interests in the biotechnological development that is being regulated.

It has been argued that the regulatory framework enshrined in the Act does not “constitute an adequate biosafety regime that ensures GMOs are appropriate and do not cause harm to the environment, or to human health” (Mayet, 2000). The Act is equally limited in scope as it only applies to viable living GMOs and not products of GMOs. Section 1 of the Act appears to absolve developers of GMOs from liability and shifts liability to users of GMOs. Such a provision amounts to overprotection of the biotechnology industry.

On 8th October 2004, the Department of Agriculture published an amendment Bill for comments (Government Gazette No. 26848). The purpose of the amendment is, inter alia, to incorporate the provisions of the Cartagena Protocol on Biosafety into the Act. In the same way that the GMO Act was drafted without public participation, there was equally no public involvement in the drafting of the amendments. Civil societies have termed the amendments as “an insult to years of civil society engagement with the government” (Biowatch, 2004b). The civil society has rejected the amendments as inadequate and is calling for a complete redraft of the Act after proper public consultation. The memorandum and objects to the subsequent Bill however shows that all stakeholders’ views that were received when the Bill was first published have been taken into consideration (Government Gazette number 27913 of 26th August 2005).

The main contention is that the Act and the proposed amendments are inconsistent with the constitution and other legislations insofar as the Act and the proposed amendments do not give effect to the citizens’ rights to environmental protection, safe and healthy food, administrative justice and access to information.

Other major weaknesses of the Act (and the proposed amendments) that have been noted are:

- The precautionary principle is not implemented. Section 24 of the Constitution obliges the state to protect future generations and this may require the state to take precautions when the possible risks of science are uncertain. The Section provides as follows:

“Everyone has a right-

- a) to an environment that is not harmful to their health or well-being; and
- b) to have the environment protected, for the benefit of present and future generation, through, reasonable legislative and other measures that-
 - i. Prevent pollution and ecological degradation;
 - ii. promote conservation; and
 - iii. secure ecologically sustainable development and use of natural resources while promoting justifiable eco

conomic and social development.”

- iv. This principle is equally entrenched in the National Environmental Management Act. Section 2 (4) (a) (vii) of this Act requires that a risk-averse and cautious approach be applied, taking into account the limits of current knowledge about the consequences of decisions and actions.

- The “polluter pays” principle is not complied with.

This is the case insofar as liability still rests on the consumers and farmers. The fact that the issue of liability has not been adequately addressed in the Biosafety Protocol is not an excuse for having such an unfair provision in a national legislation. Besides, the African Model Law provides for this issue and this should serve as a good precedent for the national legislation.

KENYA

The legal framework, which arguably attempts to deal with GMOs, is currently contained in the Environmental Management and Co-ordination Act. It was enacted in 1999 and came into force in 2000. It requires Environmental Impact assessment (EIA) for certain categories of projects. One of such projects that are listed under the Act is ‘major developments in biotechnology including the introduction and testing of genetically modified organisms’. It is not clear whether or not the current influx of GMOs in the country were subjected to EIA as required under the Act. Plans are underway to enact a statute that will deal solely with GMOs and biotechnology generally. Much as the Bill is still pending, it is worth discussing in this paper since it shows a glimmer of the opportunities and limits involved in attempting to develop a regulatory framework in such a country.

The Biosafety Bill of Kenya (2003)

The Bill was drafted almost three years ago and is yet to be tabled in Parliament for debate (Okoth, 2004). Analysts fear that “the policy and legal gap has left Kenya vulnerable to dumping...supermarkets are bursting with imported un-labeled GM products. Even the occasional food aid brought to the country is mostly transgenic” (Okoth, 2004). Although the government has denied the release of GM products to farmers, there is evidence to the contrary. For example in the year 2000, Consumer Information Network in Kenya “put the US government to task over the importation of un-labeled GM yellow maize into the country, the US responded that when it is exporting to another country, it abides by the rules of that country” (Okoth, 2004).

The Bill is “an Act of Parliament to regulate biotechnology and biosafety matters and for connected purposes” (Biosafety Bill 2003). A closer look at the

sections however reveals that the Bill only deals with GMOs and not biotechnology as such. The use of the term 'biotechnology' is equally ambiguous as it is important to distinguish between traditional and modern biotechnology. The provisions of the Bill are intended to be in addition to the requirements imposed by any other Act but it does not deal with GMOs that are pharmaceuticals for human use. The other Act that is envisaged in this case is the Environmental Management and Co-ordination Act, which focuses more on environmental law generally.

The limited scope of the Bill is influenced by the Cartagena Protocol, which prescribes the minimum standards for parties. It has however been argued that it is "extremely worrying that the Kenyan Bill has not made an attempt to fully implement the minimum standards established by the Protocol" (Comments on the Bill). The Bill thus appears to be inconsistent with the Biosafety Protocol and the African Model Law. The following main weaknesses have been noted in the comments on the Bill:

- The bill promotes genetic engineering and not biosafety.
- The objectives of the Bill as set out in Clause 4 apply to adverse effects on the environment and do not at all engage with issues related to biodiversity and human health. In particular, the decision of the heads of states of the African Union's meeting in Maputo in July 2003 that the African Model Law should be used as a basis for developing biosafety regulatory frameworks has not been complied with. This is the case since issues such as traceability and labeling; liability and redress are not dealt with in the Bill. The Clause only provides for safe transfer and handling. It has been argued, and rightly so, that the regulatory framework should include "the regulation of import, development, transport, handling, packaging, identification, use, export, transit, contained use, release or placing on the market of GMOs resulting from modern biotechnology" (Comments on the Bill).
- The scope of 'contained use' is stretched too far to accommodate broad scenarios that may be harmful.
- The Bill excludes the regulation of living modified organisms from its scope yet the Biosafety Protocol only excludes the regulation of the transboundary movement of such organisms. This is a fundamental omission in the Bill.
- Clause 14(2) relies on the industry's self-regulation insofar as it leaves the industry to determine the information that is worth disclosing to the regulatory authority in terms of the risks and benefits of GMOs.

THE POSSIBILITIES AND LIMITS: AN APPRAISAL

The possibilities and limits of creating appropriate legal frameworks for modern biotechnology may be gleaned by critically looking at the suitability or otherwise of the

frameworks that have been discussed in the foregoing sections of this paper. These are mainly the Cartagena Protocol (at the international level) and the attempts that have been made by South Africa and Kenya to develop legal frameworks for biotechnology.

De Greef argues that "the protocol is a poorly informed platform, almost devoid of serious inputs from the field of reputable biotech and biosafety research...in the absence of the scientific community as a stakeholder, fringe science and political ideology has taken the place of an informed process" (De Greef, 2004). His evidence for this argument is as follows:

"At the first meeting of the parties (MOP1) of the Cartagena Protocol, there was no representation of the scientific community as a stakeholder, as against more than 100 representatives from the nongovernmental organisation (NGO) community with rabidly antisience and antitechnology agenda. The 'scientific information' sessions of the meeting were dominated by fringe figures who have been widely discredited in the scientific community, but who, in the absence of a reputable voice for science, are seen as the providers of scientific information to this process. In total, over 20 'information sessions' about biotech were organised around the MOP1, most of them presenting lurid tales about 'the existing and proven dangers of biotech.' Not a single presentation was made about the promises and the benefits of genetically modified (GM) crops."

De Greef identifies two main areas in respect of which the protocol is a threat to the future of public research of GM crops. First, the exchange of research material has become more due to the requirement of Advanced Informed Agreement (AIA) for import of GM organisms intended for release in the environment. This is because no distinction is made in the protocol between an experimental release and a commercial release. This is particularly true of GM plants produced in the European Union member states. Second, "the negotiations for Liability & Redress regime in the protocol entirely ignore the scenario in which the technology developer is say, a Consultative Group on International Agriculture Research (CGIAR) centre or national university or a governmental agency from a developing country. The negotiations are likely to use scenarios about the seed sector and the food chain familiar to the private sector... and from there to extrapolate towards a general requirement for containment and segregation of GM and non-GM crops that is simply not achievable for most subsistence crops, and out of question for crops in centers of genetic diversity." He proposes that a platform of public research sector research institutes be created to give a voice to their concerns and needs and that the position of public goods research sector be defended when considering the impact of regulatory options that are debated.

In terms of the main features of the Protocol, the exclusion of GMOs that are pharmaceuticals from the Protocol's scope is questionable. This is because available information "so far shows that no pharmaceuticals for humans are covered by any other agreement or organisation in their condition as a GMO and are therefore covered by the Protocol" (Institute for Sustainable Development and Third World Network, 2000).

It is clear from the discussion of the selected national regimes that both Kenya and South Africa hastily joined the league of states that support GMOs without appropriate legal and policy frameworks in place. On 23rd June 2004, the President of the Republic of Kenya opened a greenhouse facility located at Kenya Agricultural Research Institute (KARI). This was reported as an official government endorsement of GMOs in the country. In his speech he stated that the development of a policy for biotechnology research and the use of the resultant products were at an advanced stage and that Bills to support the policy were being prepared for consideration by Parliament. Analysts have wondered "under what policy and legal regime then is the greenhouse built and maintained?" (Makoloo, 2004).

There are possibilities and limits in developing legal frameworks for modern biotechnology. The limits ema-

nate from the fact that the legal framework cannot be used in isolation without properly reckoning with the

societal spheres that influence the legislative process. All the factors that influence such societal spheres must in turn be accorded the appropriate importance that they deserve. This can be achieved if all views are taken into account through public discourse, which often precedes public policy formulation from which policy frameworks that are useful in legislation can be based. Proper choice of policy options determines the effectiveness of regulations. For this reason, any regulations that are not preceded by proper policy development are bound to be limited in their scope.

CONCLUDING REMARKS

What emerges from the foregoing discussion is that the biotechnology industry is not easy to regulate because biotechnology is a dynamic field thus, as Gale correctly notes, "laws governing such [a] field[s] to be effective, must change, adapt and evolve as the field changes, adapts and evolves" (Gale, 1993). The main factors to be considered in developing regulatory frameworks for biotechnology are:

- Broader public consultation that considers all relevant stakeholders' views.
- Maintaining flexibility without losing credibility.
- Establishment of a concise policy framework on which the legal framework can be based.

My proposal is that the development of legal regulatory frameworks should be based on well thought out policy

frameworks. For example, at national levels, there should be consultation with stakeholders and transparency as well. It is equally important to acknowledge and appropriately utilise the shared functions of different societal spheres for purposes of developing sound policies.

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