

CENTRAL ISSUES IN MODERN BIOTECHNOLOGY LAW AND POLICY IN MALAWI.

By

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INTRODUCTION

There is a growing controversy in Malawi and around the globe regarding the modification of living organisms through the use of genetic technology. Biotechnology has now been widely accepted as a new way of generating products and processes that find application in medical, agricultural, environmental and industrial sectors of the economy. Biotechnology is a body of techniques that uses biological systems, living organism, or their derivatives to make or modify products and processes.¹ The rapid changes and advances in biotechnology techniques have permitted increasingly the radical industrial redesign of life forms. Living modified organisms produced through biotechnology contain genetic combinations that would never occur in nature. Consequently, their characteristics and consequential environmental impacts may be difficult to predict.²

Although modern biotechnology has demonstrated its actual and potential utility, there are ethical and safety concerns about the potential risks to biodiversity and human health posed by genetically modified organisms.³ The use of genetically modified organisms has raised concerns about the new environmental risks created by this new technology. Some contend that these concerns are similar to those related to the introduction of exotic organisms in a country.⁴ Among the contentious issues at international and national level is the whole question of safety to the environment, plants animals and human beings, in as far as the development, use and application of biotechnology is concerned.⁵ Proponents of the bioengineering of seeds and plants claim that genetically modified foods are the next generation of agricultural technology⁶ and that genetically modified organisms may be the necessary link in the effort to solve most of the worlds major problems, including hunger and disease. Opponents of genetic modification of crops are however concerned about the dangers of **'playing god'** and the potential risk to humans and the possible negative environmental impacts from the use of biotechnology.⁷

¹ Article 2 of the Convention on Biological Diversity.

² Dr L.T. Chitsike, Existing Trade Agreements and Protocols Relevant to Biotechnology and Biosafety and their Implications to Member Countries, Proceedings of a Regional Workshop on Biotechnology and Biosafety, Kadoma, Zimbabwe, 16-18 July 2001, p.20

³ J. Glazewski, *Environmental Law in South Africa*, (Butterworths, 2000).

⁴ F. Zandvoort and F.J. Morris, Biotechnology Seminar Paper : Policy and Planning for Biosafety: Synthesis of an African Workshop, April 1995, p

⁵ G.N.W. Thitai and J. Wafula, Risk Assessment and Risk Management, Proceedings of a Regional Workshop on Biotechnology and Biosafety, Kadoma, Zimbabwe, 16-18 July 2001,p8.

⁶ H.N. Ellison, "Genetically Modified Organisms: Does the Current Regulatory System Compromise Consumer Health?", *Penn State Environmental Law Review*, pp345-363.346

⁷ Ellison, p346.

The possibility of risk from GMOs forms the basis for a major conservation approach namely; biosafety. Biosafety ensures the safe and judicious application of biotechnology with a view to maximising its potential benefits while minimising adverse effects on human health and the environment.⁸In this context the British Medical Association has observed:

*.....The best strategy for dealing with environmental risks, where we are confounded by profound uncertainties , is to act cautiously, and to embark on a systematic programme of research to improve our understanding; an approach known as the precautionary principle . This principle should be applied for the foreseeable future to GM (genetically modified) crop release and the introduction of GM products into the food chain until the health and environmental impacts of GMOs are fully assessed and in the public domain.*⁹

This emphasises the point that the precautionary principle is at the centre of the biotechnology/biosafety issues. There is need to strike a proper balance between the major benefits of biotechnology technology to quality of life and considerations of environmental impacts of technology. A central issue surrounding the debate about genetically modified organisms is whether the regulatory system in Malawi is adequate to protect consumers and the environment from the possible adverse effects of GMOs.

Biotechnology research and development has also given rise to serious concerns regarding the sourcing of research materials and equitable sharing of benefits of research between the developing countries (the major sources of research materials) and developed countries (which have the necessary technical expertise for biotechnology).¹⁰ Questions regarding intellectual property rights which these developed country research teams acquire from materials and indigenous knowledge acquired from developing countries have also arisen. Most developing country experts consider such biopiracy as an international crime that harms developing countries. This is because they are compelled to buy products from their own biodiversity at unaffordable prices merely because the developed country firms have provided the research skills and the financial resources necessary to transform biodiversity products into marketable products.

It is in the light of the foregoing that we consider the law and policy relating to biotechnology in Malawi. More specifically, the paper considers the extent to which the law provides an appropriate regulatory environment for activities in support of biotechnology research and development. It will also explore the extent to which the current biotechnology regulatory system complies with international standards.

POLICY ENVIRONMENT

The Science and Technology Policy, 2002 considers research science and technology to be central to national socio-economic development. The government of Malawi in 1998 endorsed the VISION 2020 which sought to spur economic development through science and technology. The Malawi Poverty Strategy Paper also recognises

⁸ Chitsike, p 20.

⁹ British Medical Association, "The Impact of Genetic Modification on Agriculture Food and Public Health" 18 May 1999.

¹⁰ Banda, p2.

science and technology as crucial to socio-economic development planning.¹¹ Additionally, the policy recognises biotechnology as potential solution to most of Malawi's socio-economic concerns and emphasises the government's responsibility for creating an enabling environment for the development of biotechnology. Equally important is the government's obligation to address matters of biosafety.

The above notwithstanding, the broad Science and Technology policy does not adequately and comprehensively address most controversial issues surrounding the development of biotechnology in Malawi. This means that biotechnology research and development is largely evolving in a policy vacuum and necessitates the development of a comprehensive policy to address Malawi's biotechnology and biosafety concerns.

MALAWI'S INTERNATIONAL OBLIGATIONS

Malawi is a signatory to a number of international agreements that have implications on how it can exploit biotechnology. The Convention on Biological Diversity (CBD), for instance, addresses all aspects of biodiversity including; fair and equitable sharing of benefits derived from biotechnology, protection of traditional access to genetic resources and safety of activities relating to modified living organisms.¹² The Convention is now supplemented by the Cartagena Protocol on Biosafety to which Malawi is a signatory.¹³

State obligations under the Convention

The Convention obliges states to adopt measures relating to the use of biological resources to avoid or minimise adverse impacts on biological diversity. States are also obliged to protect and encourage customary use of biological resources in accordance with traditional practices that are compatible with conservation and sustainable use.¹⁴

Article 8 (g) of the convention makes specific reference to biosafety by providing that that each contracting party shall as far as possible and as appropriate:

establish means to regulate, manage and control the risks associated with the use and release of genetically modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity.

The article also encourages the state to take into account the risks to human health.

Under Article 8(j) states have an obligation to respect, preserve and maintain knowledge and innovations and practices of indigenous communities that have a bearing on conservation and sustainable use of biodiversity and promote its wider application with the approval and involvement of the holders of such knowledge.

¹¹ Malawi Government, National Science and Technology Policy, 2002, p. i.

¹² M. Sunkin, D.Ong and Robert Wight, Sourcebook on Environmental Law, (Cavendish Publishing, 2002) , p584.

¹³ The Protocol was adopted on 29 January 2000. 50 ratifications were required for the Protocol to come into force. The 50th instrument of ratification was deposited on the 13th of June 2003.

Consequently the Protocol will come into force on the 11th of September 2003. Malawi signed the Cartagena Protocol on May 24, 2000

¹⁴ Article 10 of the Convention.

States are also supposed to encourage equitable sharing of the benefits arising from the utilisation of such knowledge.

Access

The convention also provides a general legal framework regulating access to biological resources and the sharing of benefits arising from their use.¹⁵ There is a close link between access and the issue of property rights. The issue of access has come to the fore partly due to the fact that biotechnology provides new ways of acquiring intellectual property rights over inventions originating from biological resources and indigenous knowledge. Developing countries have a special interest in this matter since most of the world's biodiversity is found within their territories.

The Convention tries to strike a balance between the sovereign rights of donor states over their biological/genetic resources and the access rights of the users by providing that access must be given on mutually agreed terms and subject to prior informed consent of the country of origin. Donor countries of biological resources have a right to obtain a fair share of the benefits derived from use.¹⁶

The Convention also requires Malawi to facilitate access and transfer to other Parties biotechnology that is relevant to the Conservation of and sustainable use of biodiversity, or technologies that make use of genetic resources but do not occasion damage to the environment.¹⁷ It is also obliged to enact legislation or make policies that aim at facilitating the transfer of technology between the public and private sectors, and within the private sector. This is of course subject to the rule that member states must ensure that the rights are supportive and do not run counter to existing intellectual property rights.

Control and use, including safe management of biotechnology

While recognising the potential benefits of modern biotechnology States recognised the need to address the biosafety aspects of GMOs at the United Nations Conference on Environment and Development in 1992. Agenda 21 makes specific provision for the environmentally sound management of biotechnology.¹⁸ The Convention on Biological Diversity is the first international legal instrument outside the EC to suggest that biosafety was a matter of concern to the international community.¹⁹ Article 8 (g) of the Convention imposes a duty on States to “establish and maintain means to regulate, manage and control the risks associated with the use and release of living modified organisms resulting from biotechnology.”

¹⁵ P. Cullet, *The Convention on Biological Diversity*, IELRC Briefing Paper 2003-1, p3. Article 16, 17 and 18 of the Convention impose an obligation on developed countries to share biotechnology with developing countries.

¹⁶ Benefit sharing can take the form of monetary benefits and non-monetary benefits such as the sharing of research and development results, participation in product development, training related to genetic resources and access to scientific information, transfer of technology etc.(CBD and the Bonn Guidelines, 2002).

¹⁷ Article 16.

¹⁸ Agenda 21 Chapter 16, Emphasises the need for biosafety by encouraging environmentally sound management of biotechnology. Chapter 34 also deals with “Transfer of environmentally sound technology.”

¹⁹ Glazewski, 309

The Convention is now supplemented by the Cartagena Protocol on Biosafety. The Protocol seeks to protect biological diversity from the potential risks by living modified organisms resulting from modern biotechnology.²⁰ More specifically the protocol addresses questions of safe transfer, handling and use of living of living organisms resulting from modern biotechnology that may have adverse effects on biodiversity, taking into account risks to human health.”²¹ Although the protocol mainly governs transboundary movements of LMOs, domestic biotechnology regulatory systems are closely intertwined with the provisions of the Protocol.²²

Article 2 of the Cartagena Protocol obliges states to take necessary and appropriate legal measures to implement its obligations under the Protocol. More specifically the parties shall ensure that the, development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces and risks to biological diversity, taking also into account risks to human health. ²³ The Protocol enshrines a precautionary approach and reaffirms the precautionary language in Principle 15 of the Rio Declaration on Environment and Development.²⁴

Risk Assessment

Decisions to import living modified organisms are subject to risk assessment requirements. Risk assessment is a process of gathering diverse data to identify possible risk in research and development involving genetically modified organisms.²⁵ Any party wishing to import living modified organisms is supposed to undertake a risk assessment pursuant to the Protocol. The risk assessment shall be done in a scientifically sound manner. The risk assessment aims at identifying and evaluating the possible adverse environmental and health effects of introducing the said living modified organism.²⁶

Risk management

Article 16 of the protocol requires states to establish and maintain appropriate mechanisms to manage and control risks associated with biotechnology. These include observation of imported or locally developed LMOs for an appropriate period (commensurate with their life cycle) before putting them to use.

INTERNATIONAL STANDARDS AND EXISTING/PROPOSED LAW

Public participation in biotechnology policy and management

Principle 10 of the Rio Declaration emphasises the point that environmental issues are best handled with the participation of all concerned citizens. To this end Article 23 of the Cartagena Protocol obliges states to encourage participation in matters of biosafety and endeavour to ensure public awareness of biosafety issues. Ensuring

²⁰ Cartagena Protocol on Biosafety: About the Protocol.

²¹ Article 1.

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²³ Article 2 (2).

²⁴ See Article 1of the Catagena Protocol on Biosafety. The precautionary approach states that where irreversible damage to the environment might be occasioned state action to protect the environment may be needed before scientific certainty of harm is established.

²⁵ Page 9 risk assessment.

²⁶ Article 15 of the Protocol.

meaningful participation entails access to information that is in the hands of public officers. This information includes information on biotechnology considering that inadequate information flow creates uncertainties which may act as a barrier to technology adoption.²⁷

The Malawi Constitution recognises the significance of information as a tool of public participation in the bill of rights. Section 37 guarantees the right of every person to access information held by the state in so far as such information is required for the exercise of his/her rights. However the right to public participation in the development and management of biotechnology has serious practical limitations in so far as Malawi is concerned. Among the major obstacles to participation are legal illiteracy, public ignorance, misinformation, polarised views relating to biotechnology and misunderstanding of biotechnology. Currently there is very little awareness of biosafety and biotechnology. The little information there is on biotechnology and biosafety is confined among policy makers and scientists and, to a lesser extent, media circles.

Adequate and balanced information is yet to reach the resource poor farmers who are the final users beneficiaries the technologies being developed. Obviously there is need to enhance public awareness at the grass roots levels and to point out clearly and objectively the benefits and risks of adopting technologies developed so far.

Commercial confidentiality

The major challenge to access to information, however, may be commercial confidentiality. Due to the high research and development costs of modern biotechnology and strong forms of legal protection that are associated with them, such as intellectual property rights, researchers and investors are not keen to have commercially sensitive information leak to competitors.²⁸

There are certain provisions of the Biosafety Act which have serious implications for the right of access to information. Section 33 of the Act prohibits the disclosure of any information with respect to any manufacturing process or trade secrets obtained by any person who enters upon any premises which he has entered pursuant to this Act. It also prohibits the disclosure of any information obtained by any person pursuant to this Act except in the performance of his duties and to an authorised person. This blanket prohibition of disclosure of information may unduly restrict transparency and the right of access to information. Consequently, it has serious implications on the transparency and public scrutiny of the risk assessment process.

The South African GMO Act on the other hand is more sympathetic to the right of access to biosafety information in that it exempts some forms of disclosure from the confidentiality clause. Section 18 of the Act prohibits the disclosure of information acquired by any person in the course of his duties. However, section 18 (2) stipulates that certain information shall not be kept confidential, namely:

- The description of genetically modified organisms, name and address of the applicant and the contained use or release and the location of use.

²⁷ Odame et al ,p 25.

²⁸ D. Glover, J. Keely and P. Nevell, Public Participation and the Cartagena Protocol on Biosafety: A Review for DFID and GEF, p 38.

- The method and plans for monitoring of the genetically modified organisms and for emergency measures in the case of an accident.
- The evaluation of foreseeable impacts, in particular any pathogenic or ecologically disruptive impacts.

The Science and Technology Bill and Biosafety Act

Malawi has taken up some aspects of biotechnology and biosafety by passing the Biosafety Act and drafting the Biotechnology Bill. The documents make specific references to biotechnology and its environmental and health aspects. Recognising the inextricable link between the development of biotechnology and the existence of a biosafety system these documents complement each other in addressing Malawi's biotechnology and biosafety concerns. However, the above instruments have certain shortfalls.

First, although the Science and Technology Bill, aims at advancing science and technology it falls short of dealing with the promotion and protection of indigenous knowledge systems. It also does not clearly put in place a clearly defined scheme to promote indigenous innovation and make biotechnology and its products accessible to the local communities. The Bill is also silent on international co-operation and equitable sharing of benefits of biotechnology.

Although clause 42 of the Science and Technology Bill requires the consideration of the safety of a biotechnology before granting a licence, it does not make any prescriptions for any risk assessment exercise. This is not in line with article 16 of the Cartagena Protocol which obliges States to establish and maintain appropriate mechanisms to regulate and control risks associated with the use, handling and transboundary movements of living modified organisms.

Once the Protocol comes into force Malawi will be duty bound to have in place a risk assessment and management regime in line with the Protocol. There is therefore need for diligence in getting the mechanisms put in place and operationalised.²⁹ However, unlike the South African Genetically Modified Organisms Act, which explicitly requires any applicant for a permit to use facilities for the production of genetically modified organisms or to release them into the environment to submit a risk assessment report, the Biosafety Act is silent on this matter.³⁰

The other gap in the Biosafety Act is the fact that it does not articulate principles on which biosafety legal and administrative mechanisms should be founded. Most conspicuous is the absence of the precautionary approach as an objective. Considering the uncertain nature of releasing GMOs into the environment and the irreversible negative environmental harm that it may occasion, there is need to introduce the precautionary principle into the Biosafety regulations.

²⁹ H. Odame, P. Kamari-Mbote and D. Wafula, Globalisation and the International Governance of Modern Biotechnology: The Implications for Food Security in Kenya, Final Report Prepared for the FIELD/IDS Project on Globalisation and the International Governance of Modern Biotechnology, IELRC Working Paper No. 2003-2, p25.

³⁰ Section 5.

The Consumer Protection Bill, 2003

The objective of the Bill is to protect the rights of the Consumers and to address the interests and concerns of the consumer. The Bill contains several clauses, which have serious implications for biotechnology and may even restrict research and development in this area. The Bill among other criminalizes abusive advertising.³¹ The definition of abusive advertising includes advertising that “infringes environmental values or is capable of leading consumers to behave in a manner detrimental to their health or safety.”³² The Bill further defines a “safe product” as a product that does not present any risk to health and environment when used for a purpose for which it is expected.³³

Several provisions in the Bill deal with the right to consumer education and information including information on technology, quality and risks.³⁴ These provisions aim at helping a consumer to make reasonable choices. In relation to biosafety, Clause 35(1) imposes an obligation on the supplier to provide information to the consumer on goods and to indicate whether the goods are genetically modified or not.

Administration

The Ministry of Commerce is the main government organ responsible for consumer protection affairs. Part III of the Consumer Protection Bill confers upon the Minister power to establish a Consumer Protection Council consisting of six members appointed from: a consumer body of Malawi, an economic body, the Chamber of Commerce, the Law Society, a trade union and women’s organisations. The Council will also have ex-officio members from the Ministry of Commerce, Malawi Bureau of Standards, the Pharmacy, Medicines and Poisons Board, Ministry of Justice and Local Government.

The powers of the Council include promotion of consumer awareness programmes, dissemination of consumer information, formulation of consumer policy, cross institutional collaboration to ensure that the quality of imported technology complies with Malawi standards, formulation of legislative proposals, carry out inspections relating to consumer issues and recommending minimum standards to government.

Surprisingly, even though the Council’s mandate in addressing consumer biosafety issues overlap with that of the Department of Environmental Affairs no representation from the department is provided for under the Bill. This might adversely affect the co-ordinated implementation of the Bill when it is passed.

Labelling and advertising

Clause 35 of the Consumer Protection Bill imposes an obligation on the seller to indicate to the consumer whether the goods are genetically modified or not. It also

³¹ Clause 45 and 48.

³² Clause 2

³³ Clause 2.

³⁴ Clause 3(b).

imposes a duty on the manufacturer to label every genetically modified product. The supplier or trader is also supposed to give the consumer a manual showing the technical characteristics, application of the technology and safety precautions. Clause 19 of the Consumer Bill the Consumer Protection Council power to request an advertiser to withdraw an advertisement which contravenes the provisions of the Bill and to caution some traders. Similar provisions are found in Part V of the Biosafety Act which deals with the labelling of GMO products. The Act prohibits the sale of GMOs without labelling them in accordance with the regulations made under it.³⁵ It also prohibits the false and misleading description of GMOs.³⁶

The Minister responsible for consumer protection matters may, in consultation with council make regulations for the better carrying out of this Act. Regulations made under this clause may include those governing labelling and advertising of GMOs.³⁷ Parts V and VI of the Biosafety Act gives similar mandates to the Minister responsible for environmental affairs. Section 28 of the Biosafety Act confers upon the Minister responsible for the environmental affairs powers to make regulations prohibiting the issue of advertisements relating to GMOs.

This means that there are two parallel systems of addressing consumer biosafety concerns under two pieces of legislation. Unfortunately the law has not put in place mechanisms to co-ordinate the activities of the above Ministers. This is bound to create problems in practice when it comes to enforcement.

Nevertheless, the Consumer Protection Bill attempts to mitigate the impact of duplication and overlap by defining its role as complementary in that it enhances other laws relating to consumer protection.³⁸ Hopefully, the Consumer Protection Council will use its mandate to liase collaborate with the Department of Environmental Affairs on how best to address biosafety concerns. The need to harmonise the provisions of the instruments to avoid duplication and unnecessary overlapping of mandates may, however, not be overemphasised.

Pesticides Act, 2000

The objective of the Act is to control and manage the production and use of pesticides. The Act defines “pesticide” as any substance intended to be administered on animals, plants or humans for destroying or controlling any pest. The definition also includes plant growth regulators, agents to prevent the premature fall of fruits and substances applied to crops after harvest to prevent deterioration.³⁹ The Act does is silent on biological control of pests.

The major weakness of the Act is that it focuses so much attention on the control of pesticides rather than reducing the impact of pesticides through pest management strategies which do not depend heavily on pesticides but rely on biotechnology. The integrated pest management strategies entail the monitoring of pests and using natural/genetically engineered enemies to suppress them. Sometimes sex pheromones

³⁵ Section 26(1).

³⁶ Section 26(2).

³⁷ Clause 56 of the Consumer Protection Bill.

³⁸ See Clause 54.

³⁹ Section 2 of the Act.

are used to interfere with communication between sexes so that they stop breeding.⁴⁰ Scientists may additionally genetically engineer pest resistant varieties thereby significantly reducing the need for pesticides.

These methods may have serious impacts on the environment hence the need for biological pest control methods to be regulated under pest control regulation.

Anatomy Act, 1991.

The Act makes provision for donation and use of bodies or parts of bodies of deceased persons for educational, scientific, research, therapeutic and diagnostic purposes. The Act repealed and replaced the Human Tissue Act. The major gap in this Act is that it does not address questions of human 'gene therapy' or even cloning which is a proper subject of an Act of this nature. The South African Human Tissue Act, 1983 for example regulates matters relating to human gene therapy.

Public Health Act, 1948.

The Public Health Act is an Act that consolidates the law relating to public health. Public health matters are mainly the concern of the Minister and local authorities. The Minister has authority under the Act to ensure the safety of most domestic and imported foods.

Part XIII of the Act has implications for biosafety in that Section 106 prohibits the sale or importation of unwholesome food and gives powers to certain public officers to destroy the same. Even though, the Act does not define the word "unwholesome" it is clear that the drafters had in mind food that is unsound, contaminated, adulterated or infected. However, the application of this Act may extend to products of biotechnology considering that the development of genetic engineering has raised so many questions as to the safety of food derived from these techniques. Indeed, a panel of the US National Academy of Sciences concluded that even though genetically engineered food is basically safe, the potential exists for undesirable effects such as allergic reactions and higher toxicity.⁴¹ Under rule 9 the Minister responsible for health may make rules that require the examination of food samples that are suspected to be unwholesome. He can also make rules prohibiting the importation of any food which is unwholesome or likely to cause injury to health. Section 110 confers upon the Minister powers to specify food quality standards.

Similarly under section 2 of the Meat and Meat Products Act, 1975, the Minister may make regulations prescribing minimum standards to which carcasses or meat products may conform and for condemning any products as unfit for human consumption. It is possible to extend the question of unfitness to the fact that the product is genetically engineered. However, the Act does not directly address food safety concerns relating from genetic engineering. Consequently, there might be need for these Acts to explicitly address Public Health concerns in relation to GMOs. Norway for example enacted legislation which provides for the assessment of risk to the environment and public health upon the release of genetically modified organisms.⁴²

⁴⁰ Rabbie, p530.

⁴¹ Ellison, p 362.

⁴² Decree Relative to Impact Assessment Pursuant to the Genetic Engineering Act, 1993.

The Plant Protection Act, 1969

The objective of this Act is to provide for the eradication of pests and diseases and to prevent the introduction and spread of pests and diseases destructive to plants. Section 12 of the Act has implications for biotechnology. Under the provision the Minister may, *inter alia*, make regulations providing for the methods of planting and controlling the importation of plants. In some jurisdictions provisions of this nature have been interpreted as empowering the Minister to prohibit the importation of alien species which might cause harm to flora and also living modified organisms for the same reason. This is on the basis that the effect of the release of GMOs into the environment might be similar to introduction of exotic plants into the country.⁴³ However, there is still need to explicitly address the issue prohibition of certain GMOs for purposes of protecting plant resources.

Patents Act, 1958.

Patenting is a central feature of economic development within the biotechnology sector.⁴⁴ Companies believe they require patent protection to secure sufficient returns on their investments in research, development and commercialisation. To this end the international agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) requires the granting of patents in all areas of technology.⁴⁵

With the creation of the WTO in 1995, and the coming into force of the TRIPS agreement, all members of the WTO are required to revise their national patent laws to conform to the requirements of TRIPS guidelines.⁴⁶

The question of patents becomes prominent in biotechnology debates because of the apparent conflicts between the Convention on Biodiversity which seeks to conserve biodiversity and protect community rights and the TRIPS agreement which emphasises private property rights over community rights.⁴⁷ This is mainly because of the growing interaction and interdependence between indigenous knowledge and modern science in the field of biotechnology.

Whereas the TRIPS asserts intellectual property rights protection on life forms, the CBD asserts national sovereignty and the right to prohibit such protection. The CBD also promotes equitably shared benefits from use of biological resources and protection of traditional knowledge while TRIPS promotes private appropriation of benefits with no mechanism for acknowledging the role of traditional knowledge from which industrial applications may derive.⁴⁸

⁴³ F. Zandvoort and F.J. Morris, Biotechnology Seminar Paper : Policy and Planning for Biosafety: Synthesis of an African Workshop, April 1995, p

⁴⁴ Canadian Institute for Environmental Law and Policy, "A Citizen's Guide to Biotechnology: Helping Citizens to Have a Real Say in Biotechnology in Canada, March 2002, p16.

⁴⁵ Article 27.

⁴⁶ H. Odame, Kamari-Mbote and D. Wafula, Globalisation and the International Governance of Modern Biotechnology: The Implications for Kenya, p18, Article 1 of TRIPS: "Members shall determine the appropriate method of implementing the provisions of this agreement."

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⁴⁸ Article 27(1) patents shall be available for any inventions, whether products or processes and in all fields of technology.

Article 1 of TRIPS attempts to resolve the above conflict by allowing for some flexibility within domestic law by permitting states to exceed minimum protection standards that the TRIPS provides so long as such protection does not contravene its provisions. This provision could allow member states to enact legislation to protect traditional knowledge. Article 27(2) of TRIPS permits exclusion of certain products from patentability in the interests of protecting human, animal or plant life or health or to avoid serious prejudice to the environment.

Further, Article 27(3)(b) of TRIPS allows for the development of unique intellectual property rights protection systems for plants, animals, and essentially biological processes, creating an opportunity to develop alternative intellectual property rights regimes appropriate to the needs and conditions of local communities.⁴⁹

From a national development perspective the Patents Act is obsolete and is silent on a number of crucial concerns. For instance it does not address issues such as the protection of genetic resources and knowledge held by local communities. Malawi is also faced with challenges such as drafting of suitable and unique laws to protect the interests of local communities and indigenous knowledge systems. Additionally, Malawi has to promulgate policies that clearly define the relationship between the management of biological/genetic resources and intellectual property rights.⁵⁰ This can be done by developing appropriate policies to harmonise the apparent conflict between the TRIPS and the CBD in the areas of promoting indigenous knowledge and equitable sharing of benefits arising from the use of such knowledge.

General weaknesses of existing legislation

Most Acts having implications for biotechnology were adopted long before the application of genetic engineering to plants, animals and foods was imagined. Consequently, public authorities charged with their enforcement do not have any clear legislative authority for the evaluation of genetically engineered products from an environmental or human health perspective.

The multiplicity of agencies working in the biotechnology/biosafety sector increases the danger of duplication and reduces the efficiency of public oversight of Biotechnology regulation. The mandates of various institutions are unclear hence co-ordinated enforcement of biosafety regulations may not be achievable.

The Malawi regulatory system does not fully comply with international standards and this has implications on biotechnology and safety.

Recommendations and Conclusion

The above discussion has exposed some of the major issues affecting biotechnology research and development in Malawi. Recent events have revealed to us that even

⁴⁹ Global Biodiversity International Institute for Tropical Agriculture, *The Business of Biodiversity*,

⁵⁰ Pursuant to Article 16 (5) of the CBD which reads: “ The Contracting Parties, recognising the Patents and other intellectual property rights may have an influence on the implementation of this Convention shall co-operate in this regard subject to national legislation and international law to ensure that such rights are supportive of and do not run counter to its objectives.”

though developments in the area biotechnology are occurring so rapidly around the globe Malawi has not yet put in place proper systems to deal with the socio-legal implications of biotechnology research and development. Notwithstanding the tremendous progress that has made in developing a Science and Technology Policy, the Science and Technology Bill and the Biosafety Act, it is clear that the current regulatory system does not adequately address all the developmental and safety concerns of modern biotechnology. The area of biotechnology needs special attention in government policy. There is still need for Malawi to clearly articulate its vision, policy and strategy in the area of biotechnology.

As Kameri-Mbote puts it, there is no inherent goodness or badness in biotechnology. Like most technologies it has advantages and disadvantages. The concern should be on how to maximise the benefits while minimising its risks.⁵¹ There is need to exercise caution and judgment in the application of biotechnology. We need to approach biotechnology in a manner that that balances the need for public safety with opportunities that biotechnology provides.

Considering the implications and uncertain nature of releasing GMOs into the environment, it is imperative that the promotion of biotechnology R&D be accompanied by a comprehensive policy that creates an enabling framework for the development and commercialisation of biotechnology whilst safeguarding the environment from potential risks of modern biotechnology.⁵² In order to avoid a fragmented approach to the development and management of modern biotechnology it is important that biotechnology and biosafety issues be articulated in one policy document. The public should not be confronted by differing opinions from government departments on issues of national priority.

The policy may, *inter alia* consider the technological capacity gaps that hinder Malawi from harnessing its unique genetic resources, how to develop this capacity in this area. It may also consider legal and institutional mechanisms that may impact on the rapid development of biotechnology R&D. These include incentives, reform of investment policies, intellectual property rights regimes, promotion of indigenous knowledge and biotechnology transfer. The policy should also look at ethical issues associated with biotechnology and the best ways of assessing environmental and health risks of modern biotechnology. Obviously, these issues cannot be given fair treatment in a broad science and technology policy.

There is need to create an enabling legal framework for research and development of biotechnology. This entails conducting a thorough review of existing legislation with implications for biotechnology and to bring it in harmony with the Biosafety Act and the Science and Technology Bill. This involves identification of gaps and consolidation of some laws to minimise duplication or unnecessary conflicts. Modern-biotechnology related laws should also be brought in harmony with international standards. Apart from encouraging biotechnology research and development they must enhance close regulation of genetically modified products to ensure that the safe utilisation of GMOs.

⁵¹ P. Kameri-Mbote, *Biotechnology and Food Security in Africa: Some Policy Considerations*, IELRC Briefing Paper 2002-4, p2.

⁵² G.Z. Banda, *Policy and Legal Framework for Modern Biotechnology in Malawi*, p2

This necessitates the establishment of sound risk assessment and management regimes. It also entails the incorporation of the precautionary principle into Malawi's regulatory framework. This will ensure that Malawi's benefit from biotechnology without unduly compromising their health and environmental safety. The system should, while respecting commercial confidentiality, should be open to public scrutiny.

There is also need to improve institutional capacity to implement legislation and to harmonise biotechnology regulatory systems to avoid duplication of functions and unnecessary conflicts in biotechnology mandates.

The existing intellectual property laws need to be reviewed to comply with the TRIPS agreement and the convention on Biological diversity. These laws should protect the rights of origin of indigenous knowledge systems and national genetic resources.