Regulatory Affairs in Biotech Industry

Subject code :18BT81

INTRODUCTION

It is acknowledged that by 2050, the world will have to increase its food production by over 50% though on about the same landmass. This coupled with the rising world population and ever changing food preferences and urbanization will require the use of extraordinary measures to enhance agricultural production in order to satisfy the growing food demand, especially in developing countries. Thus, agricultural biotechnology is increasingly being seen as holding great potential for improving the food security situation in Sub-Saharan Africa. However the varied views that have been expressed on whether it should or should not be deployed for this purpose have had a negative impact on the development of policies and regulations to govern its use in many African countries. This has therefore led to a very limited uptake of agricultural biotechnology in Sub-Saharan Africa. Without the requisite regulatory regime, it will be difficult for Africa to make any meaningful advances in the use of biotechnology to address some of its food security challenges. It is for this reason that it is important for Africa to have a critical mass

of trained personnel who understand the necessity of having functional biosafety systems backed up by policies that provide the framework within which biotechnological applications can be used.

General objective of this module:

- To provide students with a broad understanding of international policy and regulation regimes including other agreements that govern the use of biotechnology and how these offer the framework for the development of national biosafety systems and to also expose students to various issues underlying the use and management of biotechnology.

Specific objectives:

By the end of this module the students will be able:

- To demonstrate through presentations and in discussions their understanding of different international policies, regulations and agreements that govern the use of biotechnology and show how these can be used as a framework for developing national biosafety laws.
- To demonstrate using specific case-studies an understanding of the effectiveness and reliability of biosafety regulations in governing the use of biotechnology
- To discuss in written essays their understanding of consumer rights and why labelling of genetically modified foods has become such a controversial issue.

- To discuss using presentations and in written essays the influence of politics and science in the regulation of biotechnology.
- To explain in written assignments the risks and benefits of genetic modification from a regulatory perspective
- To state and explain through group discussions and written essays the different processes of GMO containment.
- To discuss in written essays how cross-boundary transfers of GMOs is regulated.

Methods of course delivery

a. Lectures
b. Power-point presentations
c. Discussions in class
d. Group work
e. Field visits

Model 1 CARTAGENA PROTOCOL AND REGULATION FRAMEWORKS FOR BIOTECHNOLOGY

INTRODUCTION

Notwithstanding the great benefits that could be drawn from scientific progress since the discovery of the gene and its structure, a need for regulatory measures under the auspices of the United Nations Convention on Biodiversity. Protocol aimed at protecting the environment and strengthening the capacity of the developing countries to ensure biosafety have been formulated to compliment the national regulations and promote public confidence in biotechnology and the benefits they can derive from it. The resultant Biosafety instruments represent the primary source of law on the modern biotechnology and the address risks posed to the environment and human health when living modified organisms (LMOs) are released into the environment either for research of for commercial purposes. So far, there is no single comprehensive legal instrument that addresses all aspects of GMO s or the products of modern of biotechnology at international level. The relevant regulatory frameworks in place consist of binding instruments and non-binding policy documents which are outlined below:

1. The Convention on Biological Diversity (CBD: 1992)- this is the main international instrument that addresses biological biodiversity, the sustainable use of its components and the fair and equitable sharing of benefits arising from the use of the genetic resources. The conventions ensures the development of appropriate procedures for enhancing the safety of biotechnology in the context of the convention's overall goal of reducing potential threats to biological diversity. Article 8(g) of the convention called for a general framework under which contracting parties were to develop regulations to govern biotechnological advances. *"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 also into account the risks to human health."*This provided the impetus for the generation of the Cartagena protocol.
2. The Cartagena Protocol (2003) – is the protocol of the CBD which is a binding international instrument that provides for the subscribing parties (national entities) means and modalities for safe transfer, handling and use of living modified organisms (LMOs) that may have an adverse effect on biodiversity. It aims to reconcile the respective needs of trade and environmental protection with respect to rapidly growing global biotechnology industry. It also creates an enabling environmentally sound application of biotechnology and advocates the application of precautionary principle which requires appropriate decision to be made irrespective of the fact that the scientific information regarding the adverse effects of a living modified organism is insufficient. It allows for maximization of benefit from biotechnology while minimizing the possible risks to the environment and human health. It specifically focuses on the transboundary movements. The subscribing parties would have to take necessary and appropriate legal, administrative and other measures to implement the obligation of the protocol. It

excludes the LMO's which are pharmaceuticals for the humans in so far as they are governed by other relevant international agreements or organizations. Two international instruments, viz UNIDO Voluntary Code of Conduct for the Release of Organisms into the Environment (1992) and UNEP international technical guidelines for Safety in Biotechnology (UNEP guidelines- 1995 have been vital in the adoption of the protocol

3. UNIDO Voluntary Code of Conduct for the Release of Organisms into the Environment (1992) - This outlined the general principles governing standards of practice for all parties involved in the introduction of organisms or their products into the environment. It encouraged and assisted the establishment of appropriate national regulatory frameworks, particularly where no adequate infrastructure yet existed.
4. UNEP international technical guidelines for Safety in Biotechnology (UNEP guidelines-1995) - These guidelines were adopted by the Global consultation of Government designated experts under the auspices of UNEP. These guidelines provide technical guidance on evaluating biosafety, identifying measures to manage foreseeable risks and to facilitate processes such as monitoring, research and information exchange.
5. International Plant Protection Convention (IPPC) - Originally adopted 1951, amended 1979, and revised 1997. This is an international treaty for co-operation in plant protection. It incorporates a process for the development of international standards for phytosanitary measures. An interim commission on phytosanitary measures(ICPM) an open ended working group was set up to address issues of GMO's, biosafety and invasive species in relation to IPPC. It aims to secure common and effective action to prevent the spread and introduction of pests of plants and plant productions and to promote appropriate measures for their control. It allows parties to take phyto-sanitary measures to prevent the introduction and/or spread of pests, based on a pest risk analysis which covers both economic and environmental factors including possible detrimental effects on natural vegetation. Living Modified Organisms (LMO's) considered plant pests could fall within the scope of IPPC
6. The office Internationale des Epizooties (OIE) (1924) - Similar role to ICPM, in relation to animal health and disease. Produces and assesses scientific evidence and operates by consensus to develop harmonizing standards, guidelines and recommendations, especially for trade in animals and products of animal origin. Has carried out work on scientific evaluation of GMO's which are pharmaceuticals for animal and that are subject to AIA procedure. Has had an Ad hoc Working Group on Biotechnology since 1996, but still has no standards on this field.
7. Codec Alimentarius - Non-binding Code Developed by the Codex alimentarius Commission, a body of FAO/WHO which elaborates standards, general principles, guidelines and recommended codes of practice in relation to food safety and related issues .Significant in relation to LMO's because standards may be adopted in future on safety of foods derived from biotechnology. Committee of General principles is elaborating Draft on Working principles of Risk analysis. Committee on Food Labeling is preparing recommendations for the labeling of food obtained through biotechnology.
8. FAO's regional fisheries bodies - Members of this group if interrelated institutions have adopted codes of practice on the use of introduced aquatic and marine species and GMO's. Work is ongoing in collaboration with International Center for Living Aquatic Resources Management (ICLARM) and OIE to develop appropriate biosafety policies for

aquatic genetic resources. Release of genetically modified aquatic organisms in the environment will be subject to AIA procedure of the protocol

9. Convention on Access to Information – deals with Public Participation in Decision-making and Access to Justice in Environmental Matters (1998). The convention entered into force in 2001. Its measures are both binding and non – binding in character. However, the guidelines on the subject are non-binding. It 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". It protects the right of every person of present and future generations to live in an environment adequate to their health and well being and also guarantees the rights of access to information, public participation in decision-making and access to justice in environmental matters. The convention is applicable to any biotechnological advances that may impact on the environment.
10. The World Trade Organization (WTO) – the relevant provisions in the WTO agreement apply to biotechnology in various ways. The parties subscribe the various packages of trade agreements including the General Agreement on Tariffs and Trade (GATT), Sanitary and Phytosanitary (SPS, 1994) agreements, the Technical Barriers on Trade (TBT, 1994) agreement. The SPS provides enactment of laws, decrees, regulations, requirements and procedures relating to sanitary and phytosanitary concerns. It protects the human, animal and plant life or health. The TBT provides standards for that ensure elimination of unfavorable treatment of the member countries' products including those related to agricultural and industrial biotechnology. Of course there have been notable conflicts between the WTO agreements and the Cartagena protocol and attempts have been made to address these conflicts in the preambular sections of the protocol.
11. The United Nations Convention on the Law of the Sea (1982) – is limited to pollution of the marine environment.
12. The UN Food and Agriculture Organisation (FAO)
13. 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 CARTAGENA PROTOCOL

a) Definition of a Protocol

A Protocol is a binding international instrument, separate from, but related to another treaty. A protocol must be individually negotiated, signed and eventually ratified. It is only binding on States that become Parties to it and creates separate rights and obligations for them, as any other treaty. It is related to a 'parent' treaty, through substantive, procedural, and institutional links. Most importantly, a protocol under a specific treaty must comply with the parent treaty's provisions authorizing and regulating the adoption of protocols under its auspices. Any protocol adopted as a result of these 'enabling' provisions in the parent treaty must comply with them. In particular it may not deal with subjects which are beyond the purview of these provisions, or if these provisions are not restrictive in this regard, with subjects which are beyond the purview of the parent instrument. Such enabling provisions usually restrict participation in a protocol to Parties to the parent treaty.

In addition, the parent treaty usually defines basic institutional and procedural links between the two instruments, for example it may indicate that provisions in the treaty itself (e.g. related to dispute settlement)will also apply to any protocol adopted under it. The protocol itself may, however, add further links to the parent treaty, for example by designating mechanisms existing under the treaty (e.g. the Conference of the Parties) also to serve the protocol. This is the case for the Cartagena Protocol.

b) History of Cartagena Protocol

The Cartagena Protocol is a protocol of the Convention on Biological Diversity (CBD). On November 1995, the Conference of the Parties (CoP) to the Convention established an Open-ended Ad Hoc Working Group on Biosafety and gave it a task to develop a draft protocol on biosafety, focusing specifically on transboundary movement of any LMOs resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity. Reference was made to Article 19.3 which provides for Parties to consider the need for and modalities of a protocol on the safe transfer, handling and use of living modified organisms (LMOs) that may have an adverse effect on biodiversity.

The protocol named Cartagena Protocol was finalized and adopted on January 29, 2000 and came in to force in September 2003. During its formulation a number of contentions arose and five distinct negotiating groups emerged : 1) The Miami Group: Argentina, Australia, Canada, Chile, Uruguay, USA; 2) The Like-minded Group: the G77 countries (less the three members in the Miami Group); 3) The European Union; 4) The Central and Eastern Europe Group and ; 5) The Compromise Group: Japan, Korea, Mexico, Norway and Switzerland, later joined by Singapore and New Zealand. An initial failure of agreement on the Cartagena protocol was attributed to clash between trade and environmental objectives at the international level. Even

after ratification of the protocol by a number of countries, there is still a challenge by lack of participation by the major exporters of the products of biotechnology.

After the Protocol was opened for signatures in 2000, and interim extraordinary of COP in January 2000 established an intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP) to undertake preparatory work for decisions to the taken a the first meeting of the parties. The CBD COP requested countries to designate a national focal point for the ICCP and to inform the Executive Secretary of the CBD accordingly

c) Cartagena Purposes

The protocol provides international regulatory framework which reconciles the respective needs of trade and environmental protection with respect the biotechnology industry. It enables environmentally sound application of biotechnology, maximizing benefit from biotechnology while minimizing risk to environment and to human health.

d) Cartagena Approach

It is majorly precautionary. It ensures an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms that may have adverse effects on the conservation while taking also into account risks to human health. It focuses on transboundary movements.

e) Key Cartagena issues

The major issues of the protocol are the scope of the protocol, the precautionary principle, the relationship to other agreements and handling of redress to liabilities that may accrue.

f) Live Modified Organisms based Food, Feeds or Processing (LMO-FFPs)

Was the protocol supposed to cover class of LMO's know as LMO- FFPs-LMO that are intended for direct use as food or feed or for processing? Those opposed to including these commodities in the protocol argued that since they are not intended for introduction into the environment, they posed no threat to biodiversity and should not be restricted. LMOs intended for introduction into the environment such as seeds and microorganism can mutate, migrate, and multiply and consequently pose unexpected threats to native species. Other argued that LMO- FFPs would anyway get into the environment. They also argued that the LMO- FFPs could also pose risks to human health eg risks from biodiversity impacts and direct contacts (allergenic reactions) rather risk on food safety grounds.

Protocol intended to have LMO- FFPs within its scope and that they would be subject to Advance Informed Agreement (AIA) provisions. This was opposed by those cited difficulty of subjecting such massive volume of traded goods to AIA and claimed it was unworkable.

Eventually, LMO– FFPs were not subject to the AIA procedure that covers other LMOs, but are covered by a separate, less restrictive, procedure outlined in Article 11. Parties making a final decision about the domestic use of an LMO must notify the other Parties of the decision through the Biosafety Clearing-Houses.

g) Pharmaceuticals

This was another concern because they are produced largely from biotechnology but do not pose threats to biodiversity and are covered by other agreements. Exception are the LMO's which are used as drugs.

h) Transit and contained use

Treatment of LMO'S that are in transit or are destined for 'contained use' in facilities with special safety procedures to prevent release to the environment. This is only workable in nations where control mechanisms that control 'leakages' are possible. It also calls upon the transit nations to put up mechanisms that ensure adherence to the protocol, which is a special challenge especially to the developing nations where costs for doing these must be borne by the tax payers.

i) Risk Assessment

The condition that the LMO's must be subject to risk assessment before import is challenged by the limits of the existing scientific knowledge on risk, human capability and physical capacities to carry out the risk assessment.

j) Advanced Informed Agreement Procedure

Applies prior to 1st international transboundary movement of LMO's except for the following: Most pharmaceuticals for humans; LMOs in transit to a third Party; LMOs destined for contained use; LMO– FFPs (discussed below), and; LMOs that have been declared safe by a meeting of the Parties. These exclusions (particularly the exclusion of LMO– FFPs) mean that the AIA covers only a small percentage of traded LMOs—basically, only those destined for direct introduction to the environment of the importer, such as seeds and microorganisms

The party of export is obliged to notify (or ensure notification) in writing to the party of import, before the first intentional import of any given type of LMO. The Party of import has 90 days to acknowledge receipt of the notification and advise that it intends to proceed with the protocols decision procedure, or according to its domestic regulatory framework.

The decision procedure works as follows: A risk assessment must be carried out for all decisions made. Within 90 days of notification, the Party of import must inform the notifier that either it will have to wait for written consent, or that it may proceed with the import without written consent. If the verdict is to wait for written consent, the Party of import has 270 days from the date of notification to decide either to: approve the import, adding conditions as appropriate,

including conditions for future imports of the same LMO; prohibit the import; request additional information, or; extend the deadline for response by a defined period

k) Science and precaution

The precautionary principle says that in some cases— particularly where the costs of action are low and the risks of inaction are high. Preventive action should be taken, even without full scientific certainty about the problem being addressed.

In practice this gives governments a fair amount of discretion in setting environmental policy. Fears are that the precautionary principles could be used as an excuse to restrict trade in harmless goods, to protect domestic producers. It is argued that such restriction should be based on sound science and rigorous risk assessment. And even sound science could also be argued to be a form of restriction.

m) Relationships to other international agreements.

These include law of the sea, international transit and transportation arrangements and international health agreements that address human pharmaceuticals and most importantly rules embodied in World Trade Organization (WTO). Similarly, provisions Millennium Environmental Assessment (MEA) have had a potential to conflict with GATT/WTO. The WTO rules are not liked by those whose major concern are environmental protection.

n) Liability and redress

How should a liability and redress mechanism be created for any damage resulting from the transboundary movements of LMOs? In some form this should involve exporter, and an insurance agency. There is a positive consensus that this arrangement is good and question is just how and when this should be implemented.

o) Bilateral, Regional and Multilateral agreements and arrangements

Parties may enter into bilateral, regional and multilateral agreements and arrangements regarding intentional transboundary movements of LMO’s

p) Biosafety Clearing House (BCH) and National Focal Point

Biosafety Clearing House (BCH) is an information exchange mechanism established under the aegis of Cartagena Protocol on Biosafety. It facilitates sharing of information on, and experience with LMOs. Thus BCH serves as a "one-stop shop" where users can readily access or contribute relevant biosafety-related information. All information flow through BCH via the internet.

Each party shall also designated one national focal point responsible on its behalf for liason with the secretariat of the Cartagena Protocol.

q) Risk assessment

Must be carried out following standard procedures. It should be carried out by competent national authorities and involves risks at handling, transportation, packaging and identification. Safety in accordance with relevant international rules and standard must be adhered to.

THE US REGULATION

United States of America (USA) does not subscribe to the Cartagena Protocol and biotechnology derived products are regulated under same frameworks that govern health, safety, efficacy, and environmental impacts of similar products derived by more traditional methods. It is the Federal government's policy that no new laws were needed to regulate Biotechnology Derived products (adopted 1986). The main basis for the policy are that the process of production pose no unique of special risk and that the commercial product, regardless of its manner of production, should be regulated based on the product's composition and its intended use. Further, microbial pesticides developed from biotechnology would be regulated in the same manner as other microbial pesticides.

Biotechnology derived products range from foods, animal feed, human and animal drugs, chemicals, biologics, pesticides, plant pests and toxic substances. It should be noted that no single statute or federal agency is dedicated to the governance of biotechnology products. However, the following agencies are concerned with regulation of BD varied ways:the Food and Drug Administration, (FDA) ; the Department of Agriculture, (USDA); and the Environmental Protection Agency (EPA).

The FDA is concerned with safety of food and animal feed, and safety and efficacy of human drugs and biologics, and animal drugs. Four (4) centers within the FDA, the Center for Food Safety and Applied Nutrition (CFSAN); the Center for Veterinary Medicine (CVM); the Center for Drug Evaluation and Research (CDER), and the Center for Biologics Evaluation and Research (CBER).

EPA is responsible for use of pesticides and setting allowable levels (tolerances) of pesticide residues in food, and for the regulation of non-pesticide toxic substances, including microorganisms.

USDA is responsible for the safety of meat, poultry and egg products; for regulating potential agricultural plant pests and noxious weeds; and for the safety and efficacy of animal biologics. Within USDA, the Animal and Plant Health Inspection Service (APHIS) has the major responsibility for biotechnology regulation, plus responsibilities for the Food Safety and Inspection Service (FSIS). At least ten different laws and numerous agency regulations and guidelines cover s BD products and these include 1). The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) (EPA); 2). The Toxic Substances Control Act (TSCA) (EPA); 3). The

Food, Drug and Cosmetics Act (FFDCA) (FDA and EPA); 4). The Plant Protection Act (PPA) (USDA); 5). The Virus Serum Toxin Act (VSTA) (USDA); 6). The Public Health Service Act (PHSA)(FDA); 7). The Dietary Supplement Health and Education Act (DSHEA) (FDA); 8).The Meat Inspection Act (MIA)(USDA); 9). The Poultry Products Inspection Act (PPIA) (USDA); 10).The Egg Products Inspection Act (EPIA) (USDA); and

Key challenges of the regulations have been fitting biotechnology products into precise product categories for example crop plants that were genetically modified to make their own pesticide. These may simultaneously be a plant pests, food, and pesticides. Also animal could be genetically engineered to make a protein in its milk that can be extracted to create a medical drug or diagnostic. On the other hand a food plant could be altered to make proteins that could be extracted to make industrial chemicals. As a result of these challenges EPA has develop new regulations specifically applicable to "plant-incorporated protectants".In general, agencies have developed a number of regulations and guidelines that address the application of existing laws to BD products.

THE EUROPEAN UNION REGULATIONS

a) Background

The European Union is food secure and is net exporter of food commodities. Globally, by 2009 134 MHa of arable land grew transgenic crop while in Europe only 0.1 MHa was covered (Total Arable land in Europe 101 Mha).The EU has achieved strong performance in farming sector as a result of common Agricultural Policy (CAP). Factors of production especially labor have been optimized.

b) EU Regulations

The European Union regulations are implemented by European Food Safety Authority (EFSA). EFSA severely limits the cultivation and import of GMO crops , food, and feeds - forgone benefit. By 2011, the EU regulations had only allowed three evens of approval for cultivation GM crops i.e Maize MON810, maize HT T25 and potato EH92-527-1 (BASF Amflora). The products derived from or containing GMOs are strictly controlled with a zero tolerance for unauthorized GMOs. Authorization is given after a thorough risk assessment processes and availability of a validated method for detecting, identifying, and quantifying the GMO in food or feed. Method for detection is validated by Joint Research Center (JRC) based in Institute for Health and Consumer Protection in Ispra, Italy. EU policy on GMO respects the consumer's right-to-know by ensuring clear labeling and traceability of GMOs and the critical threshold for labeling is 0.9%. GMO analysis is based on the detection of known DNA sequences (targets) that are characteristic for GMOs in raw materials (seed, plant tissue) or in food or feed products. JRC develops, produces and distributes certified reference materials (CRMs) for use in the analyses.

AFRICAN REGULATIONS

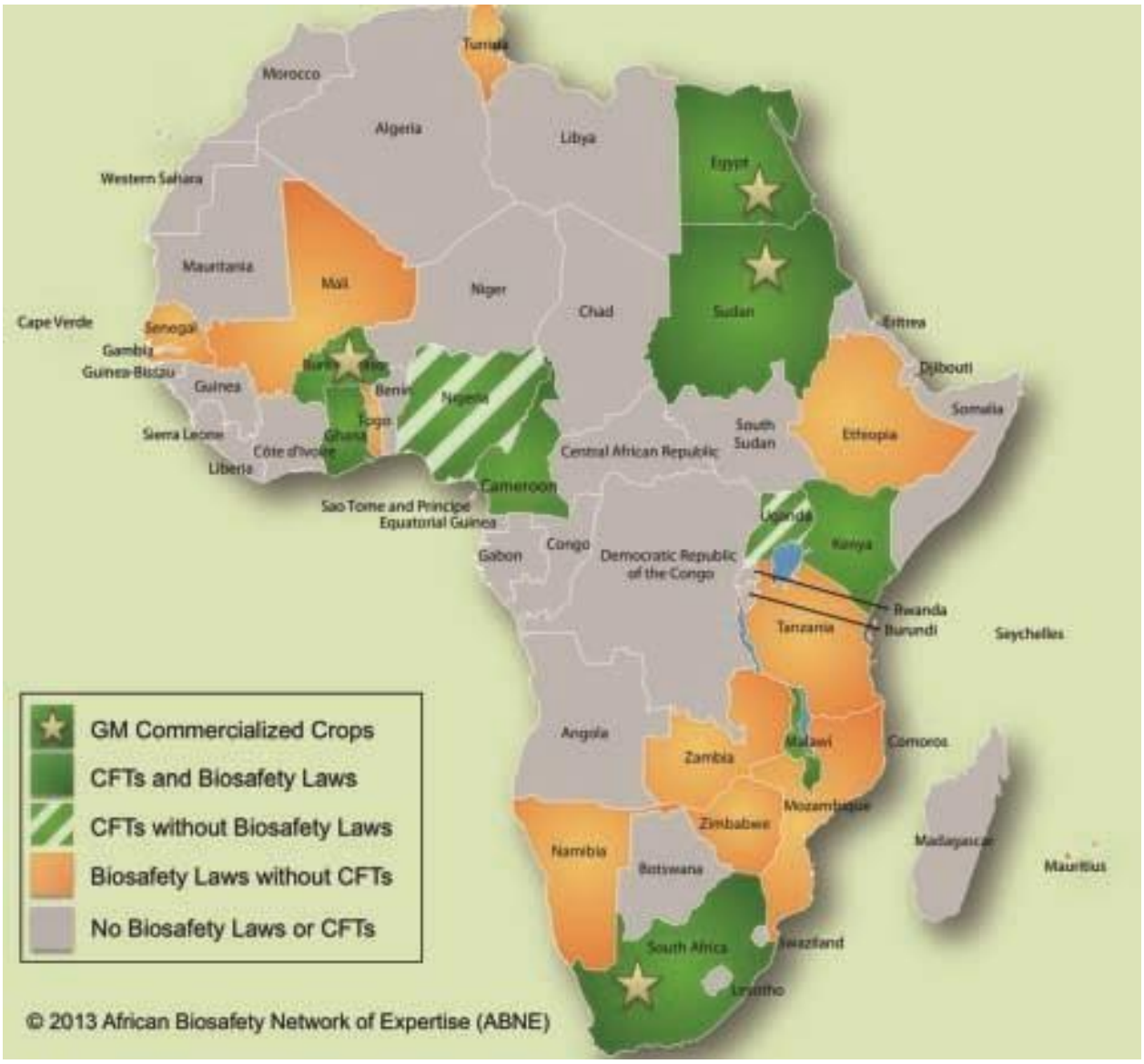
a) Regulation of GMO in Africa

Modern biotechnology is associated with potential for resolving constraints ranging from inherently low crop yield to stress related issues ranging from pests, diseases and drought. Major concern about GM technology in Africa have been on safety, ethical and trade-related issues on health of the consumers and the environment. The African countries are at various levels of espousing the Cartagena protocol and given the peculiar African conditions an African law was endorsed at AU meeting in August 2003 at Maputo. It is more restrictive and comprehensive than Cartagena protocol on import, export, transit, contained use, release and placing on the market of any GMO whether intended for release into the environment for use as pharmaceutical, for food, feed of processing or as a product GMO. African Model Law provides for this issue and this should serve as a good precedent for the national legislation.

Some additional protective measures are outlined within the African Law are that it requires AIA procedure to all categories of GMO'S, productions of GMO and their uses. It mandates labeling and identification in order to ensure traceability for GMO's and genetically modified foods. It clarifies that the burden of liability and redress for harm caused by GMO'S to human health, the environment and resultant economic loss if borne by the exporter but does not spell out how this is to be carried out. In consonance with article 8(g) of the CBD it advocates precautionary principles to activities relating to the GMO'S which are within the scope of the model law. It has been touted as a legislation drafted by Africans for Africans, in view of the unique circumstances in Africa is hoped that it would be more acceptable to African in the context of their development.

b) Status of uptake and implementation of the Cartagena protocol

All countries in Sub-Saharan African except Somalia are Parties to the CBD. However, only a few countries have embraced Cartagena protocol and set up fully functional National Biosafety Frameworks (NBFs, South Africa, Burkina Faso, Sudan and Egypt, Kenya, Malawi, Nigeria, Ghana, Cameroon). Four countries Burkina Faso, Sudan, South Africa and Egypt have permitted commercialization. The mandates the NBFs have been spelt out as articulating policy on biotechnology, formulating laws and regulations on biosafety constituting a regulatory regime for biotechnology, providing an administrative system for handling applications and issuance of permits and setting up a mechanism for public participation in biosafety decision-making process. Ultimately the NBFs should ensure reduction on risks to biological diversity and human health.



Four categories of countries with regard to progress on implementation of the Cartagena Protocol:

1: *Fully-functional biosafety frameworks, (Dark Green)*

2: Interim biosafety frameworks, (yellow)

3: 'work-in-progress' (Brown)

4:Without NBFs.(Light Brown)

c) African Biosafety Network of Expertise (ABNE)

Role of ABNE is of note. It was formed by the partnership of NEPAD and Michigan University with support of Bill and Melinda Gates Foundation. It supports building of functional systems in Africa and works with national governments. It provides up-to-date training, information, technical assistance, and networking opportunities in biosafety to regulators and their support systems

d) New Partnership for Africa's Development (NEPAD)

This is an initiative of African Union (AU) aimed at stimulating Africa's development. It addresses uptake of technology such as GM technology. It is thought that in spite of the varied shortfalls of the GM technology it would reduce chemical pesticide use by 37%, increases crop yields by 22%,increases farmer profits by 68% and bring about yield gains. It been note that yield gain are larger for insect-resistant crops than for herbicide-tolerant crops. In general, yield and profit gains are higher in developing countries than in developed countries

e) African Cases – South Africa

South Africa blazes the trail on biotechnology in the African continents and it had already formulating regulations that specifically addressed biotechnology long before the drafting of the Cartagena protocol. Genetically modified organisms act came into effect on December 1, 1999 and their first field trials with GMO's was in 1994 and from 1997 several multinationals were allowed to grow and import GMO's even before the act came into effect. There was a glaring omission of a policy framework upon which laws could be based. The regulatory framework enshrined in the act did not seem to provide adequate biosafety regime with regards to the GMO's. The GMO act also applied to living and products of the LMO's and contrary to the Cartagena protocol absolves developers of GMO from liability and shifts liability to the users of GMO's. In addition, precautionary principle enshrined in the Cartagena protocol was ignored. It was therefore over protective to the biotechnology industry. In 2004 the department of agriculture attempted to incorporate the provisions of the Cartagena Protocol on Biosafety into the act.

South Africa has permitted commercialization of GMO'S and has set up suitable public and private laboratories; and has more than 160 ongoing biotechnology projects. Examples are glyphosate tolerant Eucalyptus, genetically inserted bromoxynil, Bt cotton, maize, and soya. South Africa established South African Genetic Experimentation (SAGENE) Committee as the national body on biotechnology research and development and 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. The national biotechnology strategy addresses regulatory and legal issues. It has created awareness in government departments and agencies of the role of biotechnology in meeting health and socio-economic needs. The main impetus for 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 the present and future generations.

The Environment Conservation Act, No. 73 of 1989 provided for mandatory requirements for Environmental impact assessment for GMOs but had limited scope. The Foodstuffs, Cosmetics and Disinfectants Act, No. 54 of 1971 set out control measures to ensure food safety but had Limited scope as it was deemed to require clear labeling of GMOs only. The national Environmental Management Act No. 107 of 1998 set down minimum standards for decision making in environmental management and appeared to be limited to the provision of incentives to civil society to monitor enforcement of environmental laws.

f) African Cases - Kenya

Kenya signed the Cartagena Protocol on Biosafety in 2000 and ratified it in 2003. National Biotechnology Development Policy Published in 2006 and the National Biosafety Committee (NBC) was formed under (NCST: Science and Technology Act Cap 250). The Biosafety Act enforced in 2009 and National Biosafety Authority (NBA) was set up as the National Focal Point with the following mandated: establish and maintain a Biosafety Clearing House (BCH) that is web based and linked to the international BCH; Promote public awareness on biosafety and biotechnology; enforce the provisions of the Biosafety Act; and provide advisory services on matters of biosafety. The NBA implements its mandate through various regulatory agencies namely:Kenya Plant Health Inspectorate Service (KEPHIS), Directorate of Veterinary Services (DVS), Department of Public Health (DPH), Kenya Bureau of Standards (KEBS), National Environmental Management Authority, (NEMA), Kenya Wildlife Service (KWS), Kenya Industrial Property Institute (KIPI) and Pesticides Control Products Board (PCPB)

g) Role of Regulatory Agencies

The regulatory agencies monitor approved GMO activity to ensure compliance with conditions of approval; inform authority of any significant new scientific information indicating that an approved activity that pose biosafety risks not previously known; inform authority of unintentional or unapproved introduction of a GMO into the environment and; proposes mitigation measures.

The Biosafety act 2009 provided for gazzetment of regulations that would be important for the implementation of the Act and to date regulations for contained use; environmental release; import, export and transit; and labeling have been released. The other auxiliary legal framework which appears to have been the most relevant before the Biosafety act 2009 was the Environmental Management and Coordination Act (EMCA) enacted in 1999 and came into effect 2000. It required Environmental Impact Assessment for major developments in biotechnology including introduction and testing of genetically modified organisms. It is hoped that the Biosafety act is more comprehensive and will offer more regulation than the EMCA which appeared impotent with regard to control of importation of the GMO products. Apparently

the Biosafety act does not contrast between the traditional and modern biotechnology. Traceability, labeling, liability and redress are not dealt with but safe transfer, and handling are provided for. The scope of contained use is stretched too far to accommodated broad scenarios that may be harmful. The act 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 GMO's. The act apply to adverse effects on the environment and less with issues related to biodiversity and human health and is therefore short of implementing the minimum standard established in the Cartagena Protocol and African Model law.

Discussion questions

1. The benefits and challenges of Cartagena Protocol agreement to the African Nations.
2. Discuss the steps required and challenges faced by different African countries in setting up and implementing provisions for fully functional National Biosafety Frameworks.
3. With appropriate examples outline benefits that would accrue to an Africa Nation upon a full implementation of Cartagena protocol under the following subtitles:

   a. Human health

   b. Biodiversity

   c. Economic well being

   d. Benefit sharing

4. Compare and contrast the conception and uptake of modern biotechnology in Europe and USA.

REFERENCES

ABNE (2016) ABNE in Africa-Towards Building Functional Biosafety Systems in Africa.

Adenle, A. A., Morris, E. J. & Parayil, G. (2013) Status of development, regulation and adoption of GM agriculture in Africa: Views and positions of stakeholder groups. Food Policy, 43, 159-166.

Aerni, P. & Bernauer, T. (2006) Stakeholder attitudes toward GMOs in the Philippines, Mexico, and South Africa: The issue of public trust. World Development, 34, 557-575.

Andanda, A. P. (2006) Developing legal regulatory frameworks for modern biotechnology: The possibilities and limits in the caseof GMOs. African Journal of Biotechnology, 5, 1360-1369.

CBD (2000) Cartagena Protocol on Biosafety to the Convention on Biological Diversity.

CBD (2011) The Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety.

Falck-Zepeda, J. B. (2009) Socio-economic considerations, Article 26.1 of the Cartagena Protocol on Biosafety: What are the Issues and What is at Stake?

Falck-Zepeda, J., Wesseler, J. & Smyth, S. J. (2013) The current status of the debate on socio-economic regulatory assessments: positions and policies in Canada, the USA, the EU and developing countries. World Review of Science, Technology and Sustainable Development, 10, 203-227.

Juma, C., Serageldin, I., Ba, A. T., Bokanga, M., Daar, A., Diarra, C. M., Egziabher, T. B. G., Makhubu, L., Mokhobo, D., Mughogho, L., Nzietchueng, S., Sarpong, G., Sendashonga, C. & Shembesh, A. (2006) Freedom to Innovate Biotechnology in Africa's Development. Draft Report of the High-Level African Panel on Modern Biotechnology of the African Union (AU) and the New Partnership for Africa's Development (NEPAD).

Makoni, N., Mohamed-Katerere, J. & Chenje, M. (2006) GMO-Emerging Challenges - Genetically Modified Crops. Africa Environmental Outlook 2, Our Environemnt, Our Health (ed UNEP), pp. 300-328.

Marcoux, J. M., Gomez, O. C. C. & Létourneau, L. (2013) The Inclusion of Nonsafety Criteria within the Regulatory Framework of Agricultural Biotechnology: Exploring Factors that Are Likely to Influence Policy Transfer. Review of Policy Research, 30, 657-684.

Marques, M. D., Critchley, C. R. & Walshe, J. (2015) Attitudes to genetically modified food over time: How trust in organizations and the media cycle predict support. Public Understanding of Science, 24, 601-618.

Patterson, L. A. & Josling, T. (2005) Regulating biotechnology: comparing EU approaches. Environmental Policy in the European Union: Actors, Institutions, and Processes (ed A. Jordan), pp. 183-200. Earthscan, London, Sterling VA.

Ramjoue, C. (2008) A review of regulatory issues raised by genetically modified organisms in agriculture. CAB Reviews: Perspectives in Agriculture, Veterinary Science, Nutrition and Natural Resources, 3, 96.

Snipes, K. & Kamau, C. (2012) Kenya Bans Genetically Modified Food Imports. Biotechnology and Other New Production Technologies. Global Agricultural Information Network, Nairobi.

Wohlers, T. E. (2015) The Role of Risk Perception and Political Culture: A Comparative Study of Regulating Genetically Modified Food. Risk and Cognition, Intelligent Systems Reference Library (eds J.-M. Mercantini & C. Faucher).

Model 2: SOME RELEVANT INTERNATIONAL REGULATION REGIMES FOR BIOTECHNOLOGY

INTRODUCTION

In this unit a number of international legal instruments applied in the regulation of biotechnology will be discussed in the light of health, safety, international trade and genetic resource utilization. The regulations of interest include the General Agreement on Tarriffs and Trade (GATT)the Sanitary and Phytosanitary (SPS) Agreement, Technical Barriers to Trade (TBT) agreement, Codex alimentarius, Convention on Biological Diversity (CBD), The Cartagena Protocol on Biosafety, Agreements on Trade Related Aspects of Intellectual Property Rights (TRIPS), International Union for the Protection of New Varieties of plants (UPOV), and any other relevant treaties.

THE GATTs

The GATTs came into force in January 1948. It was a multilateral agreement regulating international trade in goods. Its objective was to reduce the barriers to international trade through the reduction of tariffs, quotas and subsidies and eliminate preferences, on a reciprocal and mutually advantageous basis. The GATT was replaced by the WTO in 1995. Currently, its functions are run through the WTO's Council for Trade in Goods (Goods Council) which is made up of representatives from all member countries.

WTO AGREEMENTS, HEALTH AND SAFETY

The Sanitary and Phytosanitary (SPS) and the Technical Barriers to Trade (TBT) agreements are specific WTO agreements dealing with food safety and animal and plant health and safety and with product standards in general. Both agreements were negotiated before commercialization of any genetically modified (GM) plants or food commodities and therefore lack provisions that are specific to these products. Each of the agreements attempts to identify means of meeting acceptable food, health and environment safety standards while avoiding disguised protectionism.

THE SPS AGREEMENT

The SPS agreement sets out the basic rules for food safety and animal and plant health standards. The agreement encourages nations to adopt existing international standards, guidelines and recommendations but permits individual countries to define better standards provided these are based on a sound scientific risk assessment and do not discriminate against imports. Under the SPS Agreement the national sanitary and phytosanitary measures established should be consistent with international standards, guidelines and recommendations. Most WTO member governments participate in the development of the standards with the help of experts in the relevant fields. Where the national requirement leads to a greater restriction of trade, the country

may be asked to provide scientific justification, demonstrating that the relevant international standard would not suffice.

The SPS agreement applies to regulations intended to protect the environment and biodiversity against introductions of alien species and living modified organisms (LMOs) through trade, in line with Articles *8(g) and 8 (h)* of the Convention on Biological Diversity (CBD). All countries maintain SPS measures to prevent the spread of pests, pathogens or diseases among animals and plants, and to ensure safety of food. SPS measures are any actions, processes or methods applied:

14. To protect animal or plant life from pests, diseases, or pathogens;
15. To protect human or animal life from risks arising from contaminants, toxins, additives or disease-causing organisms in their food;
16. To protect human life from diseases borne by plants or animals;
17. To prevent or minimize other damage to a country from the entry, establishment or spread of pests.

The SPS Agreement seeks to maintain the sovereign right of any government to provide the level of safety and health protection it deems appropriate (*Protection),* and to ensure that these rights are not misused to create unnecessary barriers to international trade (*Protectionism*). *Article 5.7* of the SPS agreement allows countries to temporarily adopt restrictive measures, on grounds that a complete risk assessment may not be possible in the short term because of scientific uncertainty and where there is lack of adequate evidence to support decision making. When there is temporary restriction the countries involved are required to obtain all the information for a full risk assessment within a reasonable period and must not impose the restrictive measures indefinitely in the absence of scientific evidence of risk just as a precaution. The requirement for an appropriate assessment of actual risks contributes to increase in transparency of sanitary and phytosanitary measures. The SPS Agreement encourages systematic risk assessment for all relevant products.

Sanitary and phytosanitary measures sometimes vary, depending on the country of origin of the food, animal or plant product concerned, taking into account differences in climate, existing pests or diseases and /or food safety conditions. The SPS Agreement makes provision for such differences and requires that governments recognize disease-free areas and appropriately adapt their requirements to products from these areas. Under the SPS agreement, governments may select alternative measures of protection that are not more restrictive to trade than required to meet their health objective. Furthermore, they could adopt equivalent measures proven to provide the same level of health protection elsewhere. This would ensure that protection is maintained while safely meeting consumer needs.

To foster transparency of SPS governments are required to inform other countries of any new or changed sanitary and phytosanitary requirements which affect trade, and to set up offices to respond to requests for more information on new or existing measures. The open communication of information and sharing of experiences provides a basis for developing better standards and works positively for consumers and trading partners.

TECHNICAL BARRIERS TO TRADE (TBT) AGREEMENT

The purpose of the TBT Agreement is to prevent WTO members from using technical regulations, testing, standards and certification procedures as cover up measures to protect domestic industries from foreign competition. The agreement serves to minimize obstacles to trade among countries. At the international scale certain regulations may be regarded as technical barriers to trade. These include:

1. Health and environmental standards and regulations
2. Labelling of products
3. Symbols and packaging marking.

In the food sector based on agricultural produce, the TBT agreement applies to all rules excluding those specifically covered by the SPS agreement. The TBT agreement disapproves of the requirement for labelling of some products where 'like products' are not labelled (See Article 2.1). For example, products derived from genetically modified (GM) crops that have been assessed and found to be substantially equivalent to their conventional counterparts would be considered "like products" under the TBT and therefore should not require specific labelling. Unfortunately, substantial equivalence is not always an acceptable outcome of risk assessment of GM products to some people.

Mandatory labelling of GM products, or similar demands are illegitimate under the TBT agreement (Article 2.2). A consumer desire for such a measure within the WTO would not be viewed as a legitimate objective within the context of Article 2.2 of the TBT agreement. According to this article, regulatory measures that might disrupt trade must be designed to achieve a legitimate objective and not be unnecessarily restrictive to trade. Here, mandatory labelling would amount to discrimination of certain products making the requirement illegitimate and '*with the effect of creating unnecessary obstacles to international trade'.*

The TBT agreement encourages the use of international standards but also recognizes the right of governments to adopt the standards they consider suitable in different situations (Articles 2.4). For instance, standards for human, animal, plant life or health, to promote the protection of the environment or to meet certain consumer interests. The agreement also sets out a code of good practice for both governments and non-governmental or industry bodies to prepare, adopt and apply voluntary standards (Articles 3 and 4; Annex 3). The decisions on product conformity to relevant standards must be fair and equitable (article 5). The agreement also encourages acceptance and adoption each other's procedures for assessing whether a product conforms. This helps avoid multiple testing of products by exporters to different countries. Provisions governing recognition of conformity assessment procedures by government agencies are presented in article 6 of the TBT.

Question: Are there some areas of conflict between the SPS and the TBT agreements?

CODEX ALIMENTARIUS

This is a collection of international food safety standards adopted by the Joint FAO/WHO Codex Alimentarius Commission. The Codex Commission addresses a variety food safety issues including health and nutritional implications of GM food. The Codex Alimentarius Commission was created in 1962 by the FAO and the WHO with the aim of establishing harmonised internationally agreed norms, directives, recommendations, or codes of practice designed to protect the health of consumers and ensure that procedures followed in the trade of food products are fair.

The Codex works through reaching consensus, to develop and adopt new standards or norms of food safety. The Codex standards are adopted on the basis of systematic risk analysis and independent scientific advice from expert bodies. The Codex provides guidelines and procedures for food analysis and sampling, risk assessment for determining the safety of foods derived from GMOs, food labelling (including GM versus non-GM, presence of allergens, nutritional composition), pesticide and veterinary chemical residues in foods, food hygiene and food contaminants such as Aflatoxins.

In the context of the SPS Agreement, the Codex is responsible for maintaining international standards relevant to food safety that should be recognized by the WTO, and for determining whether national measures are sufficiently supported by scientific principles to comply with WTO requirements. It is important to note that some Codex guidelines conflict with those of the TBT agreement. For example, there is likely discrimination of substantially equivalent products that must be labelled according to the Codex guidelines. On this ground, there remains one big question: *Which agreement should be applied to products of biotechnology?*

There is need for harmonisation of regulations on biotechnology, based on a close examination of the safety measures and their implications. However, it will be difficult to find *one size that fits all* considering that individual countries and/or trading blocks might have divergent opinion about the processes and products of biotechnology prohibitive to unified application of a common set of the international regulations. *Look out for the latest developments on attempts at harmonisation of regulations on (food) products of GM origin.*

THE CONVENTION ON BIOLOGICAL DIVERSITY (CBD)

Biodiversity or biological diversity refers to all life forms. The CBD was among the key agreements adopted at the 1992 earth summit of the United Nations Environment Program in Rio de Janeiro. The CBD sets out commitments for maintaining the world's ecological base as man undertakes economic development. As an international treaty, the CBD identifies a common problem, sets overall goals, policies and general obligations, and organizes technical and financial cooperation among member states. The objectives of the CBD are to promote:

1. The conservation of biological diversity,
2. The sustainable use of the components of biodiversity, and

3. Fair and equitable sharing of the benefits from the use of genetic resources (i.e. access to genetic resources & transfer of relevant technologies, considering rights over the resources & to technologies).

The CBD requires governments undertake to conserve and sustainably use biodiversity. The signatories to the treaty must develop national biodiversity strategies and action plans, and integrate the strategies and action plans into broader national plans for environment and development in fields of agriculture, natural resource management, transportation, energy and urban planning.

THE CARTAGENA PROTOCOL ON BIOSAFETY

The Cartagena Protocol on Biosafety is a supplementary agreement to the CBD that seeks to protect biological diversity from potential risks posed by living GMOs (LMOs) to human health and the environment, by encouraging safe transfer, handling and use of the LMOs. The protocol applies to all LMOs that may have adverse effects on the conservation and sustainable use of biological diversity and takes into account risks on human health. It focuses on trans-boundary movements of LMOs and establishes procedures for regulating the import and export of LMOs. The biosafety protocol advances a precautionary approach to the movement of LMOs through consideration of associated risks. It also establishes an advance informed agreement (AIA) procedure which should ensure that countries are provided with the information necessary to make informed decisions before agreeing to import LMOs. Through its biosafety clearing house (BCH), the Cartagena Protocol on biosafety facilitates exchange of information on LMOs that supports adherence to the AIA procedure.

Key aspects of the Biosafety Protocol related to living GMOs are summarized below:

1. Requirement of a scientifically sound risk assessment to guide decision making on importation of LMOs for environmental release (Article 15)
2. Need to adopt measures & strategies for prevention, management and control of risk (Article 16.1-16.2)
3. Need to prevent unintentional trans-boundary movements of LMOs (Article 16.3)
4. Need to undertake appropriate observation of LMOs prior to use (Article 16.4)
5. Cooperation of Parties in identifying LMOs and their traits that may pose risks, and taking appropriate management measures (Article 16.5)
6. Guidelines for Safe Handling, Transport, Packaging and Identification of LMOs (Article 18)
7. Information sharing-through the Biosafety Clearing-House to facilitate compliance and informed use of LMOs (Article 20)
8. Development or strengthening human and institutional capacities in Biosafety (Article 22)
9. Promotion of public awareness and participation in issues relating to safe transfer, handling and use of LMOs by Parties (Article 23)

10. Socio-economic considerations from the impact of LMOs on the conservation and sustainable use of biodiversity in reaching a decision on their importation (Article 26)
11. Liability & redress in the event that introduction of LMOs causes damage to biodiversity (Article 27 and in the Nagoya Protocol)

TRADE-RELATED INTELLECTUAL PROPERTY RIGHTS AGREEMENT (TRIPS)

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) is an international agreement administered by the WTO. It was formed at the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) in 1994 and came into force in January 1995. The TRIPS agreement introduced intellectual property law into the international trading system for the first time. It is considered to be the most important and comprehensive international agreement on Intellectual Property rights. The TRIPs agreement covers the protection and enforcement of intellectual property rights (IPR). To obtain easy access to international markets opened by the WTO, all members are must enact the intellectual property laws mandated by TRIPS. The TRIPs agreement has set minimum standards for the implementation of intellectual property rights (IPR) at national level. The rationale for the WTO adopting rules on intellectual property minimum standards on rights and enforcement obligations was that intellectual property is inherent in many/most goods that are traded.

INTELLECTUAL PROPERTY RIGHTS (IPR)

IPR refers to legal rights granted by governments to persons to control use of certain products of human intellectual effort and creativity. They usually give the creator an exclusive right over the use of his/her creation for a certain period of time. Property rights give the holder of the rights the ability to stop others from reproducing or copying, using, transferring or selling the proprietary subject matter. As already mentioned, the TRIPS Agreement provides the minimum standards allowing members to provide more extensive protection of their intellectual property if they so wish.

The TRIPs recognizes seven categories of IPR namely; Patents, Trademarks, Copyrights, Trade Secrets, Industrial Designs, Lay-out designs of integrated circuits, Geographical Indications. Among these, Patents, copyrights, trademarks, trade secrets and plant breeders' rights are the major forms of IPR associated with plant biotechnology. They each provide exclusive and time-limited rights of exploitation of biotechnology innovations.

Biotechnology generates processes and products of commercial value, all together called intellectual property (IP). IP includes thoughts, ideas, information and tangible products of commercial value. The IP in plant biotechnology includes processes and products resulting from recombinant DNA technology e.g. GM plants, cell fusion (somatic hybrids), tissue culture, and conventional plant breeding (plant varieties).

a) Types of IPR

Trade Secrets

Trade secret protection involves maintaining control over disclosure and use of information by imposing penalties. The claimant to a trade secret only allows information access to those who agree to keep it secret. Trade secrecy protection guards confidential information with commercial value from use by competitors. Trade secrets associated with biotechnology include F1 Hybrids and their pureline parents, DNA sequence information, hybridization conditions, cell lines and corporate merchandise plans, among others.

Trade secrets in biotechnology are difficult to keep due to the broad research component, which usually involves several partners. Disclosure of a trade secret before the granted period ends the protection and warrants compensation of the intellectual as well as punishment of the unauthorized users. The key requirement of a trade secret protection is sustained confidentiality. The s*ubject matter* of a given trade secret is the identifiable information that is maintained as a secret.

Trademarks

A trademark is the reservation of a (distinctive) word or symbol in association with a product or service for the purpose of marketing. Trademarks are used to distinguish the goods of different companies and therefore serve to give identity to the goods. They are used by the public to choose whose goods they want to buy. Examples in biotechnology include laboratory equipment, vectors for recombinant DNA research, laboratory consumables, etc known by their trademarks. Examples of trademarks in agriculture may apply to Individual products e.g. *FlavrSavr*^{TM} tomato or firm level products like *Pioneer Hi-bred Maize*.

Copyrights

Copyrights in biotechnology protect the manner in which biological information is stored, organized, retrieved and modelled. Copyrighting prohibits copying of the databases, search tools or modelling tools but does not protect the information in the databases. For example, DNA or protein sequences in various public databases can be accessed and used freely but the databases holding them are copyrighted. This type of protection lasts between 50 and 75 years.

Copyright protection is applicable to all forms of publication as printed materials, video-recordings, taped information and computer software

Patents

A patent provides the holder with the ability to exclude all others from possession, production, using, transferring, selling or importing an invention. It protects a process, product or both. To patent an innovation one must:

1. Demonstrate that the invention was not previously described/known (Novelty)
2. Have an inventive step / be a notable extension of existing art or knowledge (Non-obvious to someone skilled in the field of science)

3. Show that the invention is industrially applicable (Utility e.g. in agriculture or other industry)

These requirements make it difficult to patent plants, animals, essentially biological processes of producing plants and animals, ideas and theories. Possible patentable examples in biology include purification of a bacterial strain, identification of a rare mutant, and genetically modified organisms

Patents are governed by various bodies. The Paris Convention for the Protection of industrial Property agreements sets the priority rules. The Patent Cooperation Treaty (PCT) sets the international framework for searching and examination. The Patent law Treaty, is a supplement to the PCT responsible for patent filing. The TRIPs also has some rules on patent protection and oversees IPR enforcement. In addition to these there are also regional patent conventions in the various continents and national bodies or IP offices.

To obtain a patent, an inventor must apply for it from the desired patent office (national or regional). His/her invention must meet all the requirements for patenting. The inventor has the obligation for procedural disclosure of the invention during patent processing.

Patenting is important for a number of reasons. Patents encourage, safeguard and reward intellectual and artistic creations. They also protect investment in the development of technology. Patents facilitate fast and wide dissemination of new ideas and technologies by way of joint ventures, licensing, etc. They help the inventor to provide the fruits and benefits of his creation and invention to the public. They motivate invention and foster fair competition. Patents also protect consumer choices and help society to achieve the balance of rights and obligations.

PLANT VARIETY PROTECTION AND THE UPOV

New crop varieties are developed and protected through Plant Breeder's Rights (PBRs). The PBRs give exclusive *marketing rights* to the plant breeder who develops a particular variety. The Food and Agriculture Organisation's (FAO) International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) makes provision for Farmer's Rights. They are distinguishable from patents by granting farmers privileges to save seed for subsequent seasons.

PBRs were first put in place in 1961 under the International Union for the Protection of New Varieties of Plants (UPOV). The UPOV was created for protection of new plant varieties for the following reasons:

1. To give plant breeders an opportunity to receive reasonable returns on their investment from marketing their variety
2. To provide incentive to continue investing in plant breeding
3. In recognition of the moral right of the innovator to get acknowledged and remunerated for his/her effort
4. Because patent right was difficult to work with and unsuitable for plant variety protection

UPOV aims to encourage the development of new plant varieties for the benefit of society. It helps to harmonize variety protection between countries in order to prevent distortion of trade. The UPOV Convention acts were amended in 1972, 1978 and 1991 to enable the admission of new members (1978 act) and offer better protection of new varieties (1991 act).

Requirements for variety protection under the UPOV system

For a plant variety to qualify for protection under the UPOV system, it must satisfy four requirements viz.,

1. Distinctness (D) = It must be different from other varieties
2. Uniformity (U) = should be homogeneous 'in its relevant characteristics',
3. Stability (S)= it must be true-to-type under repeated propagation and
4. Satisfy a novelty requirement as for patents.

Satisfaction of the DUS criteria is conducted by the national authority responsible through performance trials. Under the UPOV 1978 act, any variety that is distinct in one *recognized* trait can be protected. Plant Breeders Rights are usually granted for 20 years.

Role of the UPOV

The UPOV harmonizes of laws and practices of the protection system of member countries. It has established guidelines for DUS testing of testing. The UPOV helps produce technical questionnaires for variety testing. The questionnaire has to differ from others of the same species. New traits can be added to the evaluation to aid distinction of closely related or similar varieties. The UPOV plays a key role in facilitating cooperation among member states when evaluating varieties, to make the process of protection cost effective. For example, one member conducts tests for others or one member accepts the result produced by others as the basis for granting plant breeder's right. Through the UPOV the plant breeder is able to enforce the right given in all member countries and is protected from exploitation.

The breeder only gets the protection for *developing* a variety, not just selection. The UPOV does not give rights to genes or gene combinations. Once protected, a variety is free for use by other breeders in their crosses.

ACCESS TO GENETIC RESOURCES & SHARING OF BENEFIT

The main functions of IPR are to provide incentives for investment into creative processes that transform basic insights into commercial goods and to encourage access to protected creations. IP regimes seek to determine the extent of protection while maintaining public access to innovation. Article 15 of the CBD provides for implementation of its objective 3 on 'fair and equitable sharing of benefits*'* recognises the right of States over their biological resources and that each country determines access to the resources (Article 15.1). Access should be on 'mutually agreed terms' (Article 15.3) following 'informed consent' of the country of origin (Article 15.4 & 15.5).

Article 8j of the CBD makes provisions to encourage *equitable* sharing of the benefits arising from utilization of traditional knowledge, innovations and practices by promoting wider application of traditional knowledge and/or practices upon approval of the communities to access and use, and involving the communities in sharing the benefits. Other CBD provisions covering ABS are:

1. Fair, mutual and consented access to and transfer of technology (Article 16)
2. Exchange of information (Article 17) involving facilitation, training, repatriation to the source
3. Promoting technical and scientific cooperation (Article 18) in conservation
4. The handling of biotechnology and distribution of its benefits (Art 19.1 and 19.2) ensuring participation in research, priority access to results & benefits

The Nagoya Protocol, a supplementary agreement to the CBD addresses in detail the issues on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization. The protocol aims at sharing the benefits arising from the utilization of genetic resources in a fair and equitable way appropriate access to genetic resources, appropriate transfer of relevant technologies, taking into account all rights over those resources and to the technologies generated from them, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components.

REFERENCES

1. Cardwell, R. and Kerr, W. A. (2008). Protecting Biotechnology IPRs in Developing Countries: Simple Analytics of a Levy Solution. *Journal of Agricultural Economics, Vol. 59, No. 2, 2008, 217–236*

2. Dunwell, J. M. (2005). Review: intellectual property aspects of plant Transformation. *Plant Biotechnology Journal 3, pp. 371–384*

3. Halfon, S. (2010). Confronting the WTO: Intervention Strategies in GMO Adjudication. *Science, Technology, & Human Values 35(3), pp 307-329*

4. Hing, C. B. and Back, D. L. (2009). A Review of intellectual property rights in biotechnology. *Surgeon 7; 4: 228-31*

5. Jördens, R. (2005). Progress of plant variety protection based on the International Convention for the Protection of New Varieties of Plants (UPOV Convention). *World Patent Information 27, pp 232–243*.

6. Kerr, W. A., Hobbs, J. E. and Yampoin, R. (1999). Intellectual Property Protection, Biotechnology and Developing Countries: will the TRIPs be effective? *AgBioForum–Volume 2, Number 3 & 4 Pp 203-211*.

7. Lalitha, N. (2004). Diffusion of agricultural biotechnology and intellectual property rights: emerging issues in India. *Ecological Economics 49 187– 198*

8. Le Buanec, B. (2006). Protection of plant-related innovations: Evolution and current discussion. *World Patent Information 28, pp 50–62*

9. Salazar, R., Louwaars, N. P. and Visser, B. (2007). Protecting Farmers' New Varieties: New Approaches to Rights on collective innovations in Plant Genetic Resources. *World Development Vol. 35, No. 9, pp. 1515–1528.*
10. Sechley, K. A. and Schroeder, H. (2002). Intellectual property protection of plant biotechnology inventions. *TRENDS in Biotechnology Vol.20 No.11 pp 456-461.*
11. Solleiro, J. L. (1997). Intellectual Property rights and the growth of biotechnology based industries in developing countries. *Biotechnology Advances, Vol. 15, Nos. 3/4, pp. 565-582*
12. Thiele-Wittig, M. and Claus P. (2003). Plant variety protection—A fascinating subject. *World Patent Information 25, pp 243–250*
13. www.wto.org

4.3. Model 3: RISK AND SAFETY APPROACHES TOWARD BIOTECHNOLOGY 4hrs

Public trust and confidence in emerging technologies such as genetic modification may be interpreted as a statement about public recognition of its legitimacy. Public concerns to genetically modified organism which focuses mainly on the environment and health are the main constraints to research, production and commercialization of the GMO based products (Makoni et al., 2006). The concerns stemming from uncertainties are around impacts and risks of the GMO along with poor communication and dissemination of relevant information. The public mistrust is informed by past experiences with industries with regards to chemicals, pesticides especially DDT, tobacco, and pharmaceuticals that turned out harmful both to the environment and human health (Carson, 1963; Mohamed-Katerere, 2003). In Africa there are worries about possible dumping or attempts of the industrialized nation to recoup their costs of research and development without regards of the concerns of the public. The said public concerns revolve around ethics, food security, livelihoods, farmers' and consumer rights' and non inclusive policy issues (Makoni et al., 2006).

Recent research suggests that public attitudes toward emerging technologies are mainly driven by trust in the institutions promoting and regulating these technologies. In absence of detailed knowledge of biotechnology, the individual usually rely of social trust bestowed on the institutions as a heuristic to reduce complexity of science and risk management decisions (Critchley, 2008; Siegrist, 2000). For example trust is normally positively associated with trust in the scientist and regulators (eg the government, for as long as the media coverage is low (Marques et al., 2015). The media in all forms play a big role in shaping public opinion and more recently the media coverage of risks claimed by Seralini in a series of publications have influenced public perception of GMO's negatively worldwide (Marques et al., 2015; Mesnage et al., 2015; Séralini et al., 2007; Séralini et al., 2011; Séralini et al., 2013; Séralini et al., 2014; Séralini GE, 2009). In Kenya, the Seralini's report led the Ministry of Public health to call for a ban on importation of GMO's undermining its an authoritative National Biosafety Authority set up by the same government. This ban persisted beyond the retraction of the Seralini's controversial paper in 2013 (DeRosier et al., 2015; Snipes and Kamau, 2012; Willingham, 2012).

Alternative views maintain that trust should be seen as a consequence rather than a cause of such attitudes. If the public is not convinced their interest is at the forefront then the consequences may be economic vulnerability of the industrial sector associated with the particular technology, and potential for the escalation of critical media interest.

The prevalent disharmonies between the national regulatory frameworks have exacerbated the public distrust and yet the public demand for input into the local regulatory activities that may militate against a global governance.

TRUST IN INSTITUTIONS AND INFORMATION SOURCES

Social trust in the institutions and experts that are involved in technologies such as biotechnology and management of risks thereof is important for shaping the attitudes of the public (Frewer et al., 2004). The trustworthiness and competence of sources of information as well the scientific communication of information about uses of a technology is important in understanding the public attitude toward the modern biotechnology (Frewer, 2003). Typically the key institutions that are concerned comprise the scientists, research institutions, universities, industry and the government. These institutions promote, are concerned with strategic development, regulate and comprise researchers in modern biotechnology. Development and implementation of modern biotechnology thus depend on public perceptions and attitudes towards it. Trust of the institutions concerned with the technology is dependent on a combination of competence, transparency, public interest, interest in the environment and honesty (Lang and Hallman, 2005). Generally, the most trusted institution are the evaluators (scientists) followed by the environmental watchdogs while the industry and the government are the least trusted in a study in the US (Lang and Hallman, 2005). However, the relative level of trust in the various institution varies and in general is a reflection on the level of the perceived risk by the public (Lobb et al., 2007). It is currently becoming important to develop a means to involve the public explicitly in the debates about technology innovation and commercialization in order to reshape the uneasy relationship between science and society (Frewer, 2003). It should be remembered that it is the experts that drive the regulatory processes but it is the lay public that decide the acceptability of the regulations, associated technology and the resultant consumer product. Therefore it is important to develop best practice in science communication about the risks and benefits of genetically modified food (GMF). Public trust in processes of science and in scientific and regulatory institutions is the key driver to acceptability of GMO technology and its products. How then do you integrate values held by society into processes of regulatory decision making and scientific innovation?

TRUST IN SOURCES OF INFORMATION

As aforementioned credibility and trust of information is usually multidimensional and particularly dependent on competence of the information source and the subject under consideration.

Two major dimensions that determine trust are a) competence - the expertise of the communicator and their ability to transmit the information in a caring manner and b) honesty – truthfulness or trustworthiness of the communicator. The communicator should be credible, reliable and have no vested interest. The subject under consideration affect perceptions in many aspects. The more complex the subject the more difficult it is for it to win social trust and also trust may be influenced by contextual information such as the type of organism involved. It has been demonstrated that morality value is taken into consideration by the public and that the

public would differentiate between perceived natural and unnatural processes; and intrinsic or extrinsic dimensions (Frewer, 2003). Extrinsic concerns relate to the balance between perceived benefit and risk of technology and the outcome of this could be different depending on whether a plant or an animal is involved, with the latter facing more resistance. On the other hand, intrinsic morals relate to the application of technology and are rooted in the belief that genetic manipulation it tantamount to playing God (Dietrich and Schibeci, 2003). However, placing trust in regulatory authorities, lessen the gap in attitudes between the plant and animal based biotechnology and in general trust in the government is a better predictor of the of support of GM of plants while trust in scientist or their institutions (universities, research institutes) is a better predictor of acceptability of GM in animal food based product since the scientist are perceived to those who are capable of tampering with nature (Hossain and Onyango, 2004; Pardo et al., 2009)

Uncertainties

Uncertainty about the GM technology is one of the cause of widespread suspicion towards it (Klümper and Qaim, 2014). Communication about GMFs should include discussion of potential uncertainties associated with risk management (whether related to unintended effects on human health or the environment). Failure to do so may increase public distrust in information sources and regulators, although risk perceptions themselves may be unaffected. Indeed, information dissemination activities must focus on uncertainties and the unknowns, as much as the purported benefits. Generally, when there a perceived scientific uncertainty concerning the potential impacts of a new technology on the part of certain stakeholders and actors in a debate, non-scientific considerations like ethical, social and economic issues come to the fore.

CONCERNS ABOUT GENETICALLY MODIFIED ORGANISMS

There are both safety and nonsafety concerns of the Genetically Modified Organisms. The safety concerns covers safety to the environment and human health.

There are uncertainties about the potential for negative environmental impact associated with the production processes or agricultural practices involving GM crops. This is in spite of the positive results of several field trials (including in the developing countries) and large scale commercial planting of GM crops. There is insufficient work on the effect of the biodiversity especially in the biodiversity rich areas of the developing countries. This is also underlined in the article 26 (1) of the Cartegena protocol which states “The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities” (UN-CBD, 2000). However, the World Trade Organizations (WTO; through the

Sanitary and Phytosanitary and Technical Barriers to Trade measures) as opposed to the the Cartegena protocol emphasizes decision making procedures that rely on rules and regulations that are centered on the scientific risk assessment and less on non-safety issues. Actually the Sanitary and Phytosanitary provision allows members to take into account economic factors when assessing risks to plants and animals.

GMO's may impact non-target species such as pollinators and other beneficial birds and insects. Cross-pollination between GM and non-GM (and organic) crops or between GM crops and wild plants —"genetic drift" or "genetic pollution" have been reported. Also the introduction of non-native or "exotic" species into the environment may displace native species and lead to the spread of GMOs as weeds or "volunteers". While the Modern biotechnology generally reduces the overall quantities of pesticides used it may also have an indirect effects of increasing quantities of some particular pesticides like glyphosate and change agricultural practices.

With regards to human and animal health two principles areas of concern are allergenicity of foodstuffs as a result of introduced proteins and the potential transfer of antibiotic resistance, as a result of the use of antibiotic resistance marker genes in the production of GMOs

The nonsafety concerns of the modern biotechnology are invariably ignored in the nations the have espoused GMO'S like US and Canada. These nations base their regulatory decision with regard modern biotechnology solely on scientific risk assessment (Marcoux et al., 2013). Nonsafety concerns may include economic considerations such as loss of export market shares, lowering effects on prices, sustainability, societal utility, the effect on rural employment, and impacts on agronomic practices especially for the small and medium scale farming practices that are common in Africa (Marcoux et al., 2013).

A nonsafety concern of socio-economic impacts of the GMO's is a key concern. There are potential distributive impacts of GMOs i.e. under what conditions would GM seeds be made available to farmers and to what restrictions would they be subjected to. Will availability of the seeds be assured or the farmers will be subjected to restricted distribution of the seed by the monopoly of the industrialized country producers of the seeds? The GMO's may have impacts on the traditional varieties of crops relied upon by farmers in developing countries and may affect centres of origin and centres of diversity of agricultural biodiversity.

Other issues are related to justice like food security, religious and cultural beliefs, traditions, protection of traditional crops varieties and animal species, duties to future generations, and environmental and animal ethical issues. Specifically, for the developing countries, distribution of burden and benefit between the poor and rich countries and people requires attention and there is a need to protect indigenous and vulnerable members of the society. There other subtle but important issues like the perceived 'unnaturalness' of the GM foods and respect for genetic integrity that are a concern (Marcoux et al., 2013). Others feel that biotechnology tampers with nature and could possible result in some unintended effects which may be unpredictable and unknown to science. Attempts to address the nonsafety issues in regulatory processes have been proposed in order to account for relevant and legitimate pieces of information concerning

agricultural biotechnology even though this increases costs of development of new technology (Falck- Zepeda and Zambrano, 2011).

The other major concern is the fact that known conservative perceived safe methods of improving food security have not been optimally exploited. Many in Europe argue that world food shortage could be resolved by redistribution and better prevention of loss during storage among others (DSTI, 2000).

With regard to human health and environmental concerns, most developing countries have tended to emphasize their lack of capacity to assess and manage the risks associated with GMOs. These concerns were strongly expressed during the negotiation of the Cartagena Protocol on Biosafety. Developing countries were, on the whole, strongly in favor of the adoption of the Protocol, They supported: a stringent safety assessment, advance informed agreement procedure, incorporation of the precautionary principle, possibility to take socio-economic considerations into account when deciding whether to allow imports of a specific GMO, and the primacy of the Protocol over relevant WTO obligations. The developing countries have stressed issues of uncertainty, capacity, social and economic concerns, and priorities relating to food security and the protection of human health and the environment.

SOCIO-POLITICAL ATTITUDES AND VALUES

Attitudes and interest of the stakeholders towards risks and benefits of genetically modified organisms have a great influence on the public opinion and policy outcomes in Africa and developed countries (Aerni, 2005). In this case, attitude refers to the psychological tendency that is expressed by evaluating a particular entity with some degree of favor or disfavor. The cognitive, affective, and behavioral response that result from attitude relate to the process of evaluation. Thus psychological tendency may be thought of as a psychological bias that predisposes an individual towards a positive or negative evaluative responses. Thus individual who holds a negative attitude towards GMFs, for example, may use cognitive, aff ective or behavioural responses to reject GMF products or may display other behaviours that are congruent with this attitude. Attitudes are not directly observable but can be inferred from observable responses such as responses to questionnaires or interviewers. social scientists usually measure attitudes along a bipolar continuum that ranges from extremely positive to extremely negative and includes a neutral reference point. Attitudes towards relatively abstract concepts (for example, the integrity of nature) have also been of interest and are normally termed ‘values’. Both attitudes and values should be considered when investigating people’s responses to modern biotechnology as both influence an individual’s evaluative response. It is wrongly felt that Africans are more concerned about everyday risks and less about long term effects of new technologies.

Effect of Information

An individual's perception of risk and benefit of a new technology is determined by personally selected sources of information, values, interests and individual's experience. For agricultural biotechnology, the general public must rely on information distributed through mass media, by representatives from industry, government, public interest groups and academia. An individual will judge trustworthiness or the sources of information based on socially communicated values, social status, professional affiliation, interest and worldview. Attitude change with some additional information, exposure to event, object or situation eg after tasting of GMF, after individuals interpretation of information about GM and individual's believe about motives of information sources or societal actors like the industry or regulators. Attitudes will not change if information regarding a novel technology is hard to comprehend. Information is normally processed via any of two routes viz:

- Central – considerable amount of effort spent in trying to understand the piece of information. Involves cognitive elaboration of issues under consideration. It is thought to be more enduring and resistant to counter-persuasion. At the same time it is more predictive.
- Peripheral – no amount of time is spent to process the information. Rather the trusted information source will receive positive evaluation. It applies external cues to permit inference of merits. A certain level of credibility of sources is a precondition for the information to influence attitudes.

There are 2 orthogonal approaches for information processing:

a) Rational– Emotion free, evidence based, Characterized by conscious and mental effort, using objective reasoning to come to a true answer and willingness to adjust in light of new facts

b) Intuitive– Builds on personal experiences, feelings, concrete images, and narratives. It is emotionally appealing.

The revolution which gave rise to digital genetic code gave a common language to all industries dealing with GMO and organic compounds.

Failure of risk communication will shape the opinion (negatively) of the public. Generally, the mass media is more likely to report scandals and bad news and the industry and business communities has adjusted to that by increasing media events interms of PR conferences, inaugurations and presentations. Such programs are meant ot promote the companies' image and project the goodwill of the company. These activities have made the public debate on GMO seem more like a fight on the media turf rather a a risk dialogue. Business, science and social systems favor growth and so do the protest group. The former recognizes that new options have to be adopted with their attendant risks while the latter has also grown in size and effectiveness. The protest groups receive more donations and their political attention depends on media attention and social networking, a fact that has been greatly facilitated by the progress in the modern information technology. In the scenario of Africa and other developing countries, the political stakeholder's opinion, play a key role as a relevant source of influential information(Aerni, 2005).

ACCEPTANCE OF PARTICULAR APPLICATIONS OF GENETICALLY MODIFIED FOODS

Risk perception is socially constructed, and that it is the psychological representation of risk that defines people's responses to a particular hazard, rather than the technical risk estimates traditionally provided by expert

Understanding of risk perception is probably the 1st step in understanding possibility of uptake of modern biotechnology. There is some evidence that, in the area of technology innovation, people will tolerate risk if they perceive some direct benefit to themselves. Benefit believed to have a higher consumer acceptance for modern biotechnology are: those that relate to sustainability –innovations that enable reduction in energy expenditure and discharge of pollutants during primary production, manufacturing or processing; those that will benefit disadvantaged individuals; and those that will improve the health of the consumers.

The Eurobarometer survey

Extensive public opinion survey carried out in Europe on attitude towards biotechnology. It involved 16000 respondents and was done in 2001. The findings were that in general, Europeans had a positive view of science and technology, and at the same time they no longer regarded scientific advance as a universal panacea for all problems. The attitudes towards GMF's was generally negative in Europe compared to the New Zealand, Japan and Canada where the attitudes are more positive. Also the genetic technology is usually more favored for medicine than food; for animals than plants; and the males than females. Other variables that correlate with acceptance are worldviews, moral and 'naturalness' attributes and trust in the institutions producing and regulating use of the genetic technology-based products. Trust in the watchdogs negatively correlate to acceptance of the GM technology. A common agreement in all the countries surveyed was that the regulations were best developed, implemented and monitored by international organizations like the WHO rather than national regulatory agencies. In Africa, stakeholder surveys identify the potential for biotechnology to resolve the increasing levels of food deficit and rising poverty but progress of the technology is hampered lack trust (eg suspicion of hidden agenda in Zambia (Bett et al., 2010)), favored adoption of precautionary principles applied in Europe which is highly influenced by cultural relationship between the elite Africans and Europe, and poor capacity to tailor the technology for the peculiar African situations. In addition, the resistance to introduction of GMF in the developing countries may be attributed to international and national NGO activities that oppose the introduction of the technology in agriculture.

DEMAND FOR INFORMATION ABOUT GM

When introducing any new, potentially controversial technology, it is extremely important to provide information that addresses the concerns of the public directly, rather than information that focuses on technical risk estimates alone. The information of GMF is only relevant and important if the consumers can comprehend it. It should address the consumers concerns and go beyond the substantial equivalence and address other concerns of the public like the environmental impacts. Substantial equivalence is a concept upon which safety of GMF is based and was developed by OECD and elaborated upon by FAO/WHO. In this concept the GMF is compared with its traditional comparator which is considered safe. The outcome of this comparison only guides further risk assessment tests which involve immunological, biochemical and toxicological tests. The shortcomings of the principle of substantial equivalence include inability to characterize isogenicities of comparators to the GMF, limited abilities to detect unintended effects and limited information on natural variations in many cases.

ISSUES OF TRACEABILITY OF GM FOODS AND INGREDIENTS

EU has GM-food and feed labeling regulation. For non scientific and political reasons it fixes a threshold of 0.9% above which there must be a label (arbitrarily). Aim of the label is to provide freedom of food choice for the consumer but this labeling also has the effect of giving a price premium to non-GMO food producer. Labeling has the effect of serving as a warning to the customer. On the extreme – there has been introduced a new category of label 'GM free' for food that have <0.1% in France. There are also case of Zero tolerance for GMO's where no trace is permitted which actually translated to a cut off at the detection limits of analyses. The European cautious approach to biotechnology has been informed by the lowered confidence in regulatory agencies due to food scandals (eg the mad cow disease, and Belgian dioxin contamination of food), less need for increased food production, and controversial publications regarding health risks (eg Séralini series of publications on carcinogenicity of GMF). In contrast to the EU, the USA has no GMO thresholds or obligatory GMO labeling. Analysis of GMO is based on the intrinsic characteristic of organism or products and not on the process of producing it. However, the US litigation system offers adequate protection to the public. Tort liability is established when harm from the defendant's action is more likely than not and legal system allows litigations to proceed on a contingency basis, that is without the need of the litigant paying costs a priori. Lawyers are paid a percentage of damage on successful litigation, a fact that givens incentive to sue for high damages as their fees depend on it. This will subsequently encourage the biotechnology firms to oblige to regulations and voluntary regulatory procedure in order to discourage damage claims (Ramjoue, 2008). However, in the recent past the USDA/APHIS has considered specific GMO regulations to curtail unwarranted contamination of US food with foreign GMO's. This was informed by the recent claim of ill effects suspected to be associated with Aventis Starlink Maize and unauthorized contamination of noodles by Chinese insect-

resistant rice, Xianyou63 (Bt63) already found in noodles.

Coexistence regulations have been formulated according to the principle of substantiality by national governments in EU. These are the regulations that govern the extent (proximity) to which the GMO could be allowed to grow alongside the natural product. These regulations or conditions vary. For example there are heterogeneous buffer zones between the GMO and GMO free crops in different countries – upto 800 m for maize in Luxembourg.

NON-INVOLVEMENT OF PUBLIC DECISION MAKING PROCESSES

Developing countries have demanded more involvement in the discussion of trade and environment issues in the WTO. They support the harmonization of international standards, enhanced participation in international standard-setting bodies, capacity building for the implementation of international standards. They are concerned about the WTO/TRIPS agreement which seeks to set a minimum standard for patent protection of a new crop varieties. This may increase dependence of the smallholders on the multinational companies or even prevent access to the new technology. They also fear the lack of legal protection of local knowledge and natural resources. They want to ensure informed consent before biosprospecting and fair benefit sharing with local communities. Public awareness and participation – is entrenched in the Biosafety Protocol. The obligation to involve the public in decision-making on GMOs is qualified by a reference to national laws and regulations. The Protocol also provides for the protection of confidential information.

Food safety standards

The Genetically Modified Organisms have mostly benefited farmers but not the consumers, that is they have conferred benefit of productivity per given level of input without transferring reasonable benefits to the consumers. These changes that have mostly benefited the farmers include abiotic and biotic stress resistance, herbicide resistance, and insertion of genes that express pesticidal proteins (key example being the *Bacillus thurigensis* alpha endotoxin). However, the second generations GMOs are characterized by modifications that are complex and often beneficial to the consumer. These consumer targeted benefits include improved nutritional characteristics, enhanced food security, targeted health benefits, reduction of diet related diseases (eg hypo allergenic wheat or apples varieties) and improved processing properties .

The GMO are describes as organisms altered in a way that does not occur through natural mating or genetic recombination and the processes include recombination DNA technique; direct introduction of DNA; or cell or protoplast fusion technique. The following biotechnology techniques are not considered GM: *invitro* fertilization, natural transformation, polyploidy induction and classical breeding techniques. The classical breeding techniques are based on genetic diversity and achieved through crossing, tissue culture, mutant lines (either achieved chemically by use of alkylating agents or physically by irradiation) or by use of transposons.

Predominantly, GM is restricted to modification of a single gene leading to expression of a new gene or production of a new protein or induction / suppression of genes. When more than one trait is desired, then crossing of modified organisms with one another is carried out and well-known example is the Golden rice whose genes are said to be stacked.

In the case of cisgenesis genetic modification is done with a natural gene from sexually compatible or same species of plant. The transfer of genes occur in organisms that would otherwise be able to conventionally interbreed. The gene of interest is transferred 'clean' and the so-called 'linkage drag' of deleterious genes associated with desired trait will not hamper or impede the breeding process. By contrast, transgenesis refers to transfer of genes between organisms that are closely related. Cisgenic and conventionally breed plants are considered to bear similar hazards by European Food Safety Authority (EFSA) while transgenic and intragenic are associated with novel hazards by EFSA. In general, cisgenesis is considered safer and the Dutch government has advocated for its exclusion from the European GMO regulation.

Genetically Modified Organisms are often rigorously evaluated for safety sometimes unfairly. Some conventionally plants may even be riskier. It would be better if novel foods which are defined by the European union as food or food ingredients that have hitherto not been used for human consumptions to significant degree to be screened on the basis of scientific criteria by comparing them with plant varieties that are already in the market.

Safety assessment is usually done according to traditional toxicological principles of risk assessment. The hazard is identified, characterized and associated exposure factors taken into consideration. Two possible outcomes of safety assessment are that toxicity that has a threshold effect are established i.e. the acceptable daily intake (ADI) is give or a non threshold effect is established for example the virtual safe dose (VSF) for example intake that corresponds to an estimated risk of one in a million. There a number of qualitative and quantitative methods that are available for safety assessment of food and food chemicals. These methods of risk assessment apply tools including animal based toxicology, in-vitro toxicology, hazard characterizations and exposure assessment. With respect to micronutrients in supplements or fortified foods or feeds often adverse effects could result for exposure of extreme doses either too low (deficiency) or too high (excessive) leading to a range of recommended levels or recommended daily allowance and upper tolerable limit (UL). The range of RDA varies with food/nutrient item and organisms. In a number of cases the novel foods are assessment for specific defined toxic components like glycoalkaloids in potatoes, nitrated in leafy vegetables, or psolaren levels in new varieties of celery. Globally, it is accepted that the novel food and feed should be assessed on basis of comparative risk of its respective traditional counterpart especially with a direct parent line that has a history of safe use. With respect to genetically modified foods or feeds safety assessment includes analysis of the genetic sequence inserted into the host plant, the place of insertion in to the host genome and extent of expressions of the of novel gene. Key macro and micronutrients and where necessary anti-nutrients and natural toxins

are also analyzed.

In Europe, OECD has developed a consensus document containing existing knowledge on known crops and its key components for use during the regulatory assessment of novel food or feed. In 1993 OECD formulated the concept of substantial equivalence as a guiding tool for the assessment of GMO foods Three scenarios are envisioned for genetically modified plant or food: (i) substantially equivalent; (ii) substantially equivalent except for the inserted trait; and (iii) not equivalent at all. Safety issues included in the consensus document are – genetic modification process, safety of new proteins, occurrence and implications of unintended effects, gene transfer to gut microflora, allergenicity of new proteins, Role of new food in diet and influence of food processing. The following non-safety issues affect decision making on growth and use of GM in Africa: Food security; Health-related impacts; Coexistence of LMOs; Impacts on market access; Compliance with biosafety measures; Macro-economic impacts; Impacts on biodiversity; Economic impacts of changes in pest prevalence; Farmers' rights; Intellectual Property Rights; Impacts on consumer choice; Use of pesticides and herbicides; Cultural aspects; Labour and employment; Land tenure; and Gender impacts and Rural-urban migration. There is concern that GM may increase dependence of farmers on the large corporations for planting material handle retrogressive monopoly practices, and fear of unsuitability of the GM crops for smallholder farmers. There is also the moral concern of unethical patenting of life, food neophobia and subjecting Africans to food that has been rejected elsewhere. Generally, given the GMO are technology based and with lack of homegrown products in Africa, it is feared that this technology may detrimentally increase dependence on the West.

Limitation to hazard assessment my arise due to detection of differences that may be unrelated to genetic alterations or differences be muffled by differences arising from other causes. For this reason, it is recommended (by international advisory report of FAO/WHO, OECD, and EFSA) that samples of the plants to be tested should be grown in different locations (environmental conditions) and in different climatic conditions. Thereafter additional toxicological tests may include in silico testing, in vitro digestibility testing, and in vivo animal toxicological tests. The animal study is normally indicated when the composition of the novel feed if extensively modified or when there is uncertainty about occurrence of some unintended effects. Also more emphasis in testing should be laid in novel food/feed whose nutritional and toxicological levels are in close proximity to one another. Human premarketing and post marketing surveillance should be considered in this case. Exposure assessment entails establishing potential intake of the novel food/feed and information on specific consumer group.

International Life Sciences Institute (ILSI) document defines three scenarios in which the novel food or food ingredient is characterized as: (i) substantially equivalent to a reference food/ingredient; (ii) sufficiently similar; or (iii) not sufficiently similar. For novel foods and novel food ingredients that are not substantially equivalent, nutritional and toxicological data, and data concerning allergenic potential, need to be considered. Three scenarios are considered where the source of the transgene may be: a commonly allergenic food; a less commonly

allergenic food or other known food source; or without a history of allergenicity. It should be noted that the concept of substantial equivalence ignores the context in which the food products are produced to brought to the consumer. Foods quality should consider the environment and society and thus the 'ethical equivalence' should be taken into consideration (Pouteau, 2000). This espouse factors that show moral value contained in the food product.

Codex Alimentarius is a FAO/World Health Organization (WHO) body that elaborates standards, general principles, guidelines, and recommended codes of practice in relation to food safety. It has relevant processes addressing principles of risk assessment for genetically modified foods and related labeling and other issues. Working Principles for Risk Analysis guide work within the framework of the Codex itself. The codex addresses, *inter alia*, issues of scientific uncertainty and incomplete scientific data in the standard-setting process. The shortfall for Africa is that the Codex has less participation of developing countries in the Codex committees and other bodies the working practices of the Codex. Nevertheless: the Codex Alimentarius Commission of FAO/WHO is committed to the international harmonization of food standards. Food standards developed by Codex Alimentarius should be adopted by the participating national governments. The Codex ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology has the task to develop standards, guidelines and other recommendations for genetically modified foods.

DIFFERENCES IN FOOD SAFETY REGULATION IN DIFFERENT JUSRIDICTIONS

Greater regulatory diversity exists in the developing world than the binary logic of polarization around EU versus US. Competing trade imperatives interact with domestic politics and priorities, with multiple nodes of power and actor coalitions negotiating policy directions that combine elements of both US and EU regulatory approaches. In general, there is a scientific consensus on how to evaluate GMO derived novel food and feeds.

In Europe safety assessment, is pivoted on regulations on GM food and feeds and on other types of feeds that have not been in the European market in significant quantities. The basic strategy is comparative safety assessment and if not adequate comparator a full toxicological and nutritional assessment is carried out. For GM Food or feeds a regulation provides a legal basis for market approval process and in addition ingredients including enzymes and nutrients are subject to the same assessment. The European commission seeks advise from the EFSA which serves as the scientific panel of GMF and further solicit comments from the member states.

In the US, basic strategy for safety assessment is also comparative analysis. Producers of the novel food or feed have to demonstrate that it is similar to the traditional comparator except for the introduced trait. If the introduced trait expresses a pesticidal protein, then the protein would be subject to risk assessment in the traditional manner. Importantly, in 1992, the Food and Drug Administration published their position that food and feed derived from GM pose no unique safety concerns and should not be regulated

differently than the traditional food and feeds. Products from GM and traditional breeding schemes can evaluated voluntarily when their composition is substantially different from the parent lines.

In Japan, the Food and Sanitation law governs to rules to be followed with GM food and feed. Safety assessment for GM food and feed has been made mandatory since 2001. Food Safety Commission was set up 2003 to assess GMF, including GM derived additives. Animal feeding tests is only prescribed when safety analysis do not sufficiently confirm safety of the GM Food, feed and their additives.

INTEGRATED ASSESSMENT TOOLS

Finally, this unit will also highlight the need for an integrated assessment tool that might help in the consideration of important environmental aspects involved in health and food safety. International consensus has been arrived at on safety assessment. Concept of substantial equivalence (SE) has been developed as part of a safety evaluation framework. The SE concept provide the starting point of safety evaluation. GMO is compare with its closest traditional/conventional counterpart. Identification is made of intended and unintended differences on which part of safety assessment should be assessed. SE is based on the idea that existing foods can serve as a basis for comparing the properties of genetically modified foods with the appropriate counterpart. Differences and similarities are subject to further toxicological investigations. The principle of substantial equivalence has proven adequate, and that no alternative adequate safety assessment strategies are available.

REFERENCES

1. Adenle, A., Jane Morris, E. & Parayil, G. (2014). Status of development, regulation and adoption of GM agriculture in Africa: Views and positions of stakeholder groups. *Food Policy* 43: 159–166. Retrieved march 18, 2014, from http://www.sciencedirect.com/science/article/pii/S0306919213001346#

2. Aerni, P. (2005). Stakeholder attitudes towards the risks and benefits of genetically modified crops in South Africa. *Environmental Science & Policy*. 8: 464-476.

3. Amin, L., Azlan, N. A. A., Hashim, H. & Ahmad, J. (2011). Ethical perception of modern biotechnology. *African Journal of* Biotechnology. 10(58): 12435-12447.

4. Hall, C. & Moran, D. (2006). Investigating GM risk perceptions: A survey of Anti-GM and environmental campaign group members. *Journal of Rural Studies,* 22: 29-37.

5. Kikulwe, E. M., Wesseler, J. & Falck-Zepeda, J. (2011). Attitudes, perceptions, and trust: Insights from a consumer survey regarding genetically modified banana in Uganda. *Appetite* 57: 401-413.

6. Ceccoli, S. & Hixon, W. (2012). Explaining attitudes toward genetically modified foods in the european union. *International Political Science Review*. 33: 301-319.

7. Christoph, I. B., Bruhn, M. & Roosen, J. (2008). Knowledge, attitudes towards and acceptability of genetic modification in Germany. *Appetite* 51: 58-68.

8. Costa-Font, M., Gil, J. M. & Bruce, T. W. (2008). Consumer acceptance, valuation of and attitudes towards genetically modified food: Review and implications for food policy. *Food Policy* 33: 99-111.

9. Davies, K. M. (2007). Genetic modification of plant metabolism for human health benefits. *Mutation Research*. 622: 122-137.

10. Executive, S. (2003). Genetically modified foods for human health and nutrition: The scientific basis for benefit/risk assessment. *Trends in Food Science & Technology* 14: 173-181.

11. Frewer, L. J., van der Lans, Ivo A., Fischer, A. R. H., Reinders, M. J., Menozzi, D. & Zhang, X. (2013). Public perceptions of agri-food applications of genetic modification - A systematic review and meta-analysis. *Trends in Food Science & Technology* 30: 142-152.

12. Grunert, K. G., Bredahl, L. & Scholderer, J. (2003). Four questions on European consumers' attitudes toward the use of genetic modification in food production. *Innovative Food Science and Emerging Technologies* 4: 435-445.

13. Huang, J., Qiu, H., Bai, J. & Pray, C. (2006). Awareness, acceptance of and willingness to buy genetically modified foods in urban China. *Appetite* 46: 144-151.

14. Kramkowska, M., Grzelak, T. & Czyżewska, K. (2013). Benefits and risks associated with genetically modified food products. *Annals of Agricultural and Environmental Medicine* 20(3): 413-419.

15. Sparrow, P. A. C. (2010). GM Risk Assessment. *Molecular Biotechnology* 44:267-275.

16. McLean, M., Foley, M-E. & Pehu, E. (2012). The status and impact of biosafety regulation in developing economies since ratification of the Cartagena Protocol

17. Ramjoue, C., 2008. A review of regulatory issues raised by genetically modified organisms in agriculture. CAB Reviews: Perspectives in Agriculture, Veterinary Science, Nutrition and Natural Resources 3, 96.

18. Aerni, P., 2005. Stakeholder attitudes towards the risks and benefits of genetically modified crops in South Africa. Environmental Science & Policy 8, 464-476.

19. Bett, C., Ouma, J.O., De Groote, H., 2010. Perspectives of gatekeepers in the Kenyan food industry towards genetically modified food. Food Policy 35, 332-340.

20. Carson, R., 1963. Silent spring Hamish Hamilton, London, UK.

21. Critchley, C.R., 2008. Public opinion and trust in scientists: The role of the research context, and the perceived motivation of stem cell researchers. Public Understanding of Science 17.

22. DeRosier, C., Sulemana, I., James Jr, H.S., Valdivia, C., Folk, W., Smith, R.D., 2015. A comparative analysis of media reporting of perceived risks and benefits of genetically modified crops and foods in Kenyan and international newspapers. Public Understanding of Science 24, 563-581.

23. Dietrich, H., Schibeci, R., 2003. Beyond public perceptions of gene technology: community participation in public policy in Australia. Public Understanding of Science 12, 381-401.

24. DSTI, O., 2000. GENETICALLY MODIFIED FOODS Widening the Debate on Health and Safety, OECD Publications: Paris.

25. Falck- Zepeda, J.B., Zambrano, P., 2011. Socio- economic Considerations in Biosafety and Biotechnology Decision Making: The Cartagena Protocol and National Biosafety Frameworks. Review of Policy Research 28, 171-195.

26. Frewer, L., 2003. 10. Societal issues and public attitudes towards genetically modified foods. Trends in Food Science & Technology 14, 319-332.

27. Frewer, L., Lassen, J., Kettlitz, B., Scholderer, J., Beekman, V., Berdal, K.G., 2004. Societal aspects of genetically modified foods. Food and Chemical Toxicology 42, 1181-1193

28. Hossain, F., Onyango, B., 2004. Product attributes and consumer acceptance of nutritionally enhanced genetically modified foods. International Journal of Consumer Studies 28, 255-267.

29. Klümper, W., Qaim, M., 2014. A Meta-Analysis of the Impacts of Genetically Modified Crops. PloS one 9, e111629.

30. Lang, J.T., Hallman, W.K., 2005. Who does the public trust? The case of genetically modified food in the United States. Risk analysis 25, 1241-1252.

31. Lang, J.T., Hallman, W.K., 2005. Who does the public trust? The case of genetically modified food in the United States. Risk analysis 25, 1241-1252.

32. Lobb, A., Mazzocchi, M., Traill, W., 2007. Modelling risk perception and trust in food safety information within the theory of planned behaviour. Food Quality and Preference 18, 384-395.

33. Lobb, A., Mazzocchi, M., Traill, W., 2007. Modelling risk perception and trust in food safety information within the theory of planned behaviour. Food Quality and Preference 18, 384-395.

34. Makoni, N., Mohamed-Katerere, J., Chenje, M., 2006. GMO-Emerging Challenges - Genetically Modified Crops, in: UNEP (Ed.), Africa Environmental Outlook 2, Our Environemnt, Our Health, pp. 300-328.

35. Marcoux, J.M., Gomez, O.C.C., Létourneau, L., 2013. The Inclusion of Nonsafety Criteria within the Regulatory Framework of Agricultural Biotechnology: Exploring Factors that Are Likely to Influence Policy Transfer. Review of Policy Research 30, 657-684.

36. Marques, M.D., Critchley, C.R., Walshe, J., 2015. Attitudes to genetically modified food over time: How trust in organizations and the media cycle predict support. Public Understanding of Science 24, 601-618.

37. Mesnage, R., Defarge, N., de Vendomois, J.S., Seralini, G.-E., 2015. Potential toxic effects of glyphosate and its commercial formulationsbelow regulatory limits. Food and Chemical Toxicology 84, 133-153.

38. Mohamed-Katerere, J.C., 2003. Risk and rights: challenging biotechnology policy in Zimbabwe, IDS Working Paper 204. . Institute of Development Studies, Brighton, UK.

39. Pardo, R., Engelhard, M., Hagen, K., Jørgensen, R.B., Rehbinder, E., Schnieke, A., Szmulewicz, M., Thiele, F., 2009. The role of means and goals in technology acceptance. EMBO reports 10, 1069-1075.

40. Pouteau, S., 2000. Beyond substantial equivalence: ethical equivalence. Journal of Agricultural and Environmental Ethics 13, 273-291.

41. Ramjoue, C., 2008. A review of regulatory issues raised by genetically modified organisms in agriculture. CAB Reviews: Perspectives in Agriculture, Veterinary Science, Nutrition and Natural Resources 3, 96.

42. Séralini, G.-E., Cellier, D., de Vendomois, J.S., 2007. New analysis of a rat feeding study with a genetically modified maize reveals signs of hepatorenal toxicity. Archives of Environmental Contamination and Toxicology 52, 596-602.

43. Séralini, G.-E., Mesnage, R., Clair, E., Gress, S., De Vendômois, J.S., Cellier, D., 2011. Genetically modified crops safety assessments: present limits and possible improvements. Environmental Sciences Europe 23, 10.

44. Séralini GE, d.V.J., Cellier D, Sultan C, Buiatti M, Gallagher L, Antoniou M, Dronamraju KR. , 2009. How Subchronic and Chronic Health Effects can be Neglected for GMOs, Pesticides or Chemicals. . Int J Biol Sci 5 438-443.

45. Séralini, G.E., Mesnage, R., Defarge, N., 2014. Conclusiveness of toxicity data and double standards. Food and Chemical Toxicology 69, 357–359.

46. Siegrist, M., 2000. The influence of trust and perceptions of risks and benefits on the acceptance of gene technology. Risk analysis 20, 195-204.

47. Snipes, K., Kamau, C., 2012. Kenya Bans Genetically Modified Food Imports, Biotechnology and Other New Production Technologies. Global Agricultural Information Network, Nairobi.

48. UN-CBD, 2000. Cartagena Protocol on Biosafety to the Convention on /biological Diversity-text and annexes. Secretariat of the Convention on Biological Diversity.

49. Willingham, E., 2012. Séralini paper influences Kenya Ban of GMO imports. Forbes.

Model 4: THE PRACTICE OF DEALING WITH RISKS BY BIOTECHNOLOGY

CONTAINED USE OF GMO

a) The definition of contained use

Any activity in which micro-organisms are genetically modified or in which such GMMs are cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit their contact with the general population and the environment.

b) Introduction to contained use

Covers any activity involving genetically modified micro-organism/organism carried out under containment.

It relates to the actual process of genetic modification, including the use, storage, transport and destruction of GMOs.

Contained use facilities can be microbiology laboratories, animal houses, green houses or industrial production facilities.

Most of contained use activities involve organisms which do not cause disease and are very unlikely to survive in the environment outside containment facility

However, some contained use activities are carried out with more hazardous organisms whose escape from containment could be dangerous to human and environment.

Risk assessment is hence important for all activities and control measures put to protect people and environment.

c) Need for control and legislation

In EU there is legislation for control and formulation of measures for contained use activities. The contained use of Genetically Modified Micro-organisms regulation, 2008 (Legal Notice 127 of 2008).

For example the Malta Environment and Planning Authority (MEPA) is tasked with the implementation of these regulations in Malta.

The legislation requires the applicant to carry out a thorough risk assessment, which is then reviewed by MEPA in conjunction with the Biosafety Coordinating Committee.

d) Obligation under legal notice 127 of 2008

Anyone carrying out contained activities must comply with the legal notice particularly

1. Notify MEPA of their intension to use their premises for contained use activities for the first time
2. Carry out an assessment of the risks to human health and the environment of every contained use activity before it begins, reviewing and revising the assessment as necessary
3. Establish a genetic modification safety committee to advise on risk assessment;
4. Apply the necessary containment and control measures indicated by the risk assessment.

e) Classification of GMOs

EU legislation classify GMOs into four classes:

1. Class 1- activities of no or negligible risk
2. Class 2- activities of low risk
3. Class 3- activities of moderate risk
4. Class 4- activities of high risk.

Most genetically modified plants are considered to be class 1 because they are not usually modified to contain DNA sequences from human disease causing organisms. Class 4 is reserved for highly dangerous human and animal pathogens.

g) Public register and confidentiality claim

Legal notice 127 of 2008 has provisions for public access to notifications of both premises and activities.

All information is accessible to the public, except where a specific confidentiality is made by the applicant and deem valid by MEPA.

f) Application procedures

When undertaking genetic modification procedures for the first time, premises must be registered with MEPA specifying their first activity by submitting an application for first time use.

Activities for class 1 and above need to notify MEPA of each new activity through an application for individual contained use activities.

g) There are different notification processes required for different classes of micro-organisms

1. Application form for notification for first time use
2. Application form for individual contained use activities.

WORKING WITH BIO-AGENTS AND MODIFIED ORGANISMS

a) Introduction

Biological agents are microorganisms (fungi, bacteria, excretory products, viruses, cell cultures and endo-parasites) which could be harmful.

If any changes has been made to their DNA they become GMOs

Biological agents are classified into 4 categories. Category 1 the least harmful and 4 the most harmful.

Cell also fall under the definition of biological agent. Cell lines suppliers therefore use the same classification, depending on the micro-organism that could be present in the cell.

GMOs are classified based on the activity with the modified organism (small scale for research, educational and development purposes or non-small scale) and the origin of the modified organism (microorganism, plant, animals, etc.)

The classification determines the administrative procedures to be followed.

The possible harmful effects of the GMO to the environment or health when released determine the containment level.

Based on EU directive 98/81 four containment levels are distinguished.

The rules and guidelines for the classification of the correct danger level was issued by the Genetic Modification Committee and supervised by a biological safety officer

b) Legislation and necessary permits

The rules on working with biological agents are used as protective measures for employee and third parties against pathogenic microbes

Two permits are needed in order to work with GMOs:

1. The Environment Management Act permit, aim at licensing types and number of workplaces for GMOs activities setting up rules for these places.

2. The GMO permit, aim at prescribing general and specific safety requirements when carrying out activities with GMOs.

c) Based on GMOs decree activities with GMOs are classified into

1. Contained use (activities with GMOs in laboratories, research green houses, animal research facilities and processing facilities).

2. Introduction into the environment (activities such as field test and marketing GMOs products).

For contained use a notification must be obtained from GMOs decree in order to determine the work instructions. And a permit under the Environmental Management Act must have been issued for the spaces.

Introduction to the environment is also subjected to a permit from the GMOs decree.

In both cases the Labour Inspectorate must be notified.

It is necessary to apply for permits at least 3 to 6 months in advanced.

Example of implementation at the University of Twente (UT) in The Netherlands

At UT the Executive Board has the final responsibility for health, safety and environment.

This responsibility has been delegated to faculty manager who has the following responsibilities with respect to biological agents and GMOs

1. Organizational and financial management responsibility of GMO activities in the faculty
2. Providing staff capacity development to enable the responsible staff (RS) member performs his/her duty
3. Installation and maintenance of necessary technical and structural facilities.

d) Performing hazard identification and risk assessment at UT

Apart from the permits required, hazard identification and risk assessment is done before starting any activities with GMOs and biological agents.

The assessment focuses on the hazard to the environment, and the nature, extent and duration of exposure of the employee.

e) The following taken into account

1. Information on the biological agent:

- Classification of activities with GMOs risk category of the biological agent.
- Information on diseases, which the employee could contract
- Information on symptoms of allergy and poisoning as a result of exposure.

2. Characterization of activities and sources of infection

- What activities are carried out using biological agents
- What possible sources of infection can be pointed out

3. Employees exposed to biological agents:

- Which employees could be exposed to the biological agents? This includes employees who could be exposed indirectly (students, cleaning staff, transport or maintenance staff).
- Are there any risk groups that could be exposed (pregnant women, children, people with reduced immunity)
- Performing hazard identification and risk assessment at UT cont..

4. Measurements

- Determining measures to be performed in case of any infection of the spaces.

5. Action plan:

- State which measures are in place to prevent infection.
- The measures to be taken depends on the risk catergory.
- Compulsory containment level is important for activities with GMOs and pathogenic biological agents.

CONFINED FIELD TRIAL (CFT)

a) Introduction

A CFT is an experiment of growing a regulated GM plant in the environment under specified terms and conditions that are intended to mitigate the establishment and spread of the plant.

A single CFT may comprised of; reproductive isolation, site monitoring and post harvest land use restriction.

Experimental plants could be species/varieties/hybrids grown in a confined trials prior to approval for their environmental release.

CFT is restricted to a particular research field. Three considerations are taken into account:

1. CFTs are small one hectare maximum
2. An experimental activity for data collection
3. The trials are conducted under conditions known to mitigate:

a. Pollen or seed mediated dissemination of the experimental plant.

b. Persistence of the GM plant or its progeny in the environment.

c. Introduction of the GM plant or plant products into human food or livestock feed pathway.

b) Regulatory Authorities Involved in CFTs

The activities involving the use of GMOs and products are regulated by many organizations, e.g. in the USA, they are regulated under rules of the manufacture, use/import/export and storage of hazardous microorganisms/GMOs or cells under the Environment Protection Act 1986.

These rules and regulations are implemented by the Ministry of Environment and Forests, Dept. of Biotechnology and state governments.

Five competent authorities has been provided for in the rules to handle various aspects such as:

a. Recombinant DNA advisory committee (RDAC)

b. Review committee on genetic manipulation (RCGM)

c. Genetic Engineering Approval Committee (GEAC)

d. Institutional Biosafety Committee (IBSC)

e. District Level Committee (DLC)

RDAC is advisory in function.

IBSC, RCGM and GEAC have regulatory functions

IBSC and DLC are for monitoring purposes.

In addition MEC has been set up by the RCGM to monitor the field performance of GM crops.

c) Regulation of CFTs at the level of Application

A lot of information is required for submitting an application to conduct CFTs.

The application form are completed on ready made format for various biosafety Research Trials.

The application procedure is a long one including; when to apply, involvement of other institutions, authorization/approval process, etc.

d) General Requirements for CFTs

1. Restriction on the size and number of CFT sites to maintain the integrity of the system as follows:

a. Biosafety Research Level 1 are limited to 1 acre

b. Biosafety Research Level 2 trials are limited to 2.5 acres

2. Monitoring of CFTs:

Members of the MEC, SBCC, DLC and SAU have the authority to inspect CFTs at planting/growing/harvesting and post harvest land restriction. As well as inspection of storage facilities.

3. Records and Reporting:

Keeping of records such as; compliance records, field trials reports, planting information, harvest information, etc.

4. Reproductive Isolation of CFTs:

These include spatial isolation (minimum spatial isolation distance depends on reproductive biology of the plant).

Removal of floral parts before pollen maturity.

Bagging of flowers.

Termination of trials prior to flowering.

Temporal isolation of pollination (planting earlier or later than any nearby sexual compatible plants).

5. Deposition of material from CFTs:

No harvested material or by product from CFT may be used as human food or livestock feeds.

All plants materials from CFTs must be disposed off by methods approved by RCGM/GEAC (e.g. dry heat, steam heat, incineration, deep burial, chemical treatment, crushing or burying on the trial site.

6. Post harvest land use restriction and post harvest monitoring:

In addition to reproductive isolation of the trial site during growing season of the CFTs, establishment of progeny plants on field trial site should be prevented during subsequent growing seasons.

RCGM/GEAC would establish a post harvest period for various plant species on a case by case basis.

COMMERCIALIZATION OF GM PLANTS

a) Introduction

Plant products of Biotechnology have been available in the market for some time now. These crops benefits both farmers and consumers. Framers gain higher crop yields, increased flexibility in management practices, have lower production cost and higher income. Customers have healthier crops (i.e. crops grown with fewer pesticides or healthier nutritional characteristics).

From the first generation GM crops (e.g. maize) two main areas of concern have emerged namely; risk to the environment and risk to human health, which have influenced commercialization of GM products.

b) Concern about risk to human health

Gm food have been consumed by millions of people world wide for more than 15 years now with no reported ill effects.

In Europe GM crops are tightly regulated by several government bodies. The European Food Safety Authority and each individual member detail risk assessment of GM crops and derived food and feeds.

In USA, the FDA, the EPA and USDA, Animal and Plant Health Inspectorate all are involved in the regulatory process for GM crop approval.

Consequently, GM plants and products undergo extensive safety testing prior to commercialization.

GMOs used in food, feed and seeds for GM crops must obtain authorization before they enter the market.

The product must be safe to both human and animals.

Consumers, farmers and businesses must be given the freedom of choice to either use or reject products made from GMOs (labeling is the key)

REFERENCES

1. https://www.mepa.org.mt/igmos-containeduse
2. https://ec.europa.eu/food/plants/gmo/authorisation/contained/index_en/htm
3. https://www.utwente.nl/hr/en/health-safety-environment/safety/biological_agents_gmo/working-bio-agents
4. http://www.igmoris.nic.in/files/giudelines
5. http://www.uncst.go.ug/dmdocuments
6. http://www.unep.org/DEWA/Africa/docs/en/aeo-2chapters/aeo-2_ch09
7. http://isaaa.org/resources/publication/brief/49/executive summary/default.asp

CASE STUDIES

- 1. Analysis of how provisions within Cartagena protocals on Biosafety provide the legal frame work for regulating the cross boundary transfers of GMOs and their products.
- 2. A group exercise on formulation of a GMO regulatory system for a specific African country.

Model 5: CONSUMER RIGHTS AND LABELING

INTRODUCTION

A major dilemma for modern societies is to decide on the "right" balance between benefits and risks of new technologies like biotechnology. The debate about the use of genetic engineering in agricultural production thus reveals substantial differences in perception of the risks and benefits associated with this new biotechnology (Nielsen *et al*., 2003). Every technological advance carries some risk of adverse effects, and it becomes a juggling exercise for policy makers to weigh up the benefits and the risks in order to decide: "How safe is safe enough?" (Slovic, 2000). Thus when it comes to foods that are genetically modified through biotechnology, beliefs about the risks and benefits of both their production process and of the resulting product contribute to consumer acceptance or rejection of these foods (Van Den Heuvel *et al*., 2006). This has therefore led to the emergence of a strong advocacy for consumer rights in the developing and developed world with consumers wanting to know all sorts of things about how products are made or who made them and with respect to GM foods their risks/benefits. Central to this push is that people feel that they should have access to all relevant information to make informed decisions that comply with their personal and political beliefs (Robertson, 2003). Specifically some consumers believe they have the right-to-know whether they are purchasing genetically modified food so that they can live in what they believe is the healthiest and safest way (Robertson, 2003). Worldwide studies have shown that consumer concerns about genetically modified (GM) foods are rising and that acceptance of GM foods among countries varies (Curtis, McCluskey and Wahl, 2004) but this is not so in the US and in many developing countries (Acrni, 2001). Thus given the rise in consumer awareness about their rights concerning various issues, one question that needs to be clarified and answered is what constitutes the rights of a consumer and why should they be granted?

WHAT ARE CONSUMER RIGHTS?

Generally this is the belief that all consumers have the right to know what they are buying. President John F. Kennedy believed that people should know what they are buying and outlined four basic consumer rights in a speech which is now known as the Consumers Bill of Rights. Kennedy believed consumers should have the right to safety, the right to be given information, the right of choice, and the right to be heard (https://www.reference.com/business-finance/consumer-rights-ad76c7a0341becaf#)

DEFINITION OF CONSUMER RIGHTS

Consumer rights refer to a consumer's right to safety, to be informed, to choose and to provide manufacturers with information concerning their products when they make a purchase. Manufacturers who violate consumer rights are subject to lawsuits by their customers (https://www.reference.com/government-politics/definition-consumer-rights-b6e96d7d128e8f18)

CONSUMER CONCERNS AND PERCEPTIONS

Genetic modification has been applied to many crops including those which are intended for food and animal feed. It has been hypothesized that a number of factors (demographics, education, trust, perception of risks and benefits and knowledge of biotechnology) may influence acceptance of GM foods (Lusk and Sullivan, 2002). However little agreement has been reached concerning the influence of these factors (Israel and Hoban, 1992; Frewer *et al*., 1998; Nestle, 1998). The Attitude Model proposes that consumer attitudes are determined by risk and benefit perceptions which in turn are determined by general attitude and knowledge about GM foods (Verdurme and Viaene, 2003). In different countries the way these crops have been received has been quite varied. In the European Union (EU), for example, a *de facto* moratorium in 1998 led to the suspension of approvals for new genetically modified organisms, following consumer concerns and rejection of the products and pending the adoption of revised rules to govern the approval, marketing and labeling of GM foods (Frewer *et al*., 2011). The moratorium, however, came to an end in 2005 (Costa-Font et al., 2008). In the EU Public concerns have largely been driven by information from research results which suggest that GM agri-food technology is associated with perceived risks and relatively low perceived benefits (Pidgeon *et al*., 2005). Perceptions of unnaturalness, ethical concerns, failure to implement an efficacious traceability policy and disparity between developed and developing countries (in terms of economics and sovereignty over decisions) have also been associated with negative societal responses (Uleland and Frewer, 2005). Public concerns have also been fueled by technical risk assessments (and hence regulatory systems) being based on incomplete levels of scientific knowledge (Frewer et al. 2011). Despite this many other studies have now also shown that many in Europe would be willing to try GM products (Townsend and Campbell, 2004), or accept GM products offering a defined benefit and at the right price (Noussair *et al*., 2004; Knight, Holdsworth and Ermen, 2007). In China, a study conducted to gauge the awareness, acceptance and willingness of consumers to buy genetically modified foods, showed that the percentage of consumers approving of and willing to buy GM foods was high, with acceptance rates being much higher than all other countries that had previously been reported in literature while the percentage of those opposed to GM food has generally been relatively low (Zhang *et al*., 2006). In Trinidad, a study carried out to establish public awareness and perception of genetically modified foods found out that the Trinidadian public was concerned with the toxic effects of GM foods on health (41.6%), allergenic effects (28.3%), altered immune response (22.1%) and antibiotic resistance (8.0%) while on the converse increased productivity of crops and availability of foods were perceived as the main benefits of GM foods (43.8%), while other benefits (less than 30.0%) were thought to be improved health and disease control, economics, pest resistance and improved nutrition (Badrie *et al*., 2006). In a New Zealand study, 75% of respondents agreed with the statement that the "risks from consuming genetic engineered food is unknown", while only 8 per cent disagreed (Scully, 2003). However, when the same consumers, were required to rank eight food issues in terms of perceived risks (food poisoning, additives/colouring, spray residues, additives – preservatives, antibiotics, irradiation, hormones and genetically

engineered/genetically modified organisms), only 10% thought that genetically engineered/genetically modified food was the most risky. Recently a study revealed a split in within European consumers on several dimensions, mainly classified into three groups regarding their perception of GM food – those who are 'optimistic' (25%), 'pessimistic' (58%) and 'undecided'(17%) (Costa-Font *et al*., 2008). Honkanen and Verplanknen (2004) found that the Nordic population generally had a negative attitude towards GM food while surveys conducted in Poland showed that consumers in general had a significant distrust of genetic modification especially with regard to food products (Szczurowska, 2005).

There appears to be a relationship between moral and ethical considerations and consumer attitudes towards genetic modification (Loureiro and Hine, 2004). However, in contrast, Vilella-Vila *et al*. (2005) conclude that moral issues appear not to be relevant for attitude formation as far as GM foods are concerned. Veeman *et al*., (2005) analyzed other aspects such as education and knowledge and found that they had significant influence on consumer perceptions regarding food biotechnology. It has also been found that socioeconomic and demographic attributes such as age, ethnicity, residence and income level were directly correlated with consumers attitudes towards GM food (Costa-Font et al., 2008). A study conducted by Grunert *et al*., (2003) concluded that the general attitude to GM in food production has a strong influence on the perception and evaluation of concrete food products. In general, the most common associations to the attribute 'produced by GM' are that the product is unhealthy, that the technology is unfamiliar and untrustworthy, that it harms nature and that it is ethically wrong (Grunert *et al*., 2003).

CHOICE TO SELECT

Politicians and environmental groups in Europe and elsewhere say GM labeling is about consumer choice and consumer rights and is not even a health issue (Carter and Gruere, 2003) and so there appears to be universal agreement that consumer choice needs to be enhanced through effective labeling, to allow consumers to choose between competing GM and GM-free food products (Phillips and McNeill, 2000). Civil society groups and consumers have thus taken hold of the idea that mandatory labeling of these foods will not only empower consumers to select their own diet but also enhance long-term monitoring and surveillance of GM foods to detect unanticipated risks of the products (Smyth and Phillips, 2003). Often GM food labeling is justified by a consumer's alleged right to know and then choose. However, in the US, for example, the Food and Drug Administration (FDA) considers itself to lack the authority to mandate labeling based solely upon a consumer's "right to know" the method of production if the final product is considered safe (Jones, 2014). Nevertheless, in response to the interests of various groups including food manufacturers and private certifying agencies, the FDA has announced guidelines for food manufacturers who wish to voluntarily label their products as containing, or not containing, genetically modified ingredients (U.S. Federal Register, 2001). For example, it has given guidance language for voluntary GM labels and therefore encourages, for instance, messages that communicate a firms reasons for using genetic modification (e.g. to

reduce saturated fats) but discourages messages that convey that the long term effects of GM content are unknown (Roe and Tiesl, 2007). A recent poll conducted in the US shows that many Americans applaud the FDA's policy on labeling while a consumer survey carried out by the International Food Information Council Foundation (IFICF) indicated that 63 percent of Americans approved the FDA's current voluntary policy for labeling GE foods with only four percent naming "biotech" as something they wanted information about on their food labels (Jones, 2015). However other surveys give a completely different picture of the public's attitude about labeling. For example a poll conducted by the Associated Press-Gfk revealed that 66 percent of Americans favor GE food labels, twenty-four percent did not care, seven percent opposed labels and of the 66 percent who were pro-labeling only 42 percent said that the presence of GE ingredients in food is extremely or very important in determining "whether a food item is a healthy choice or not" (Clare, 2015). It has been noted by some that if 80–90% of North American consumers truly wanted products free of GM elements, then the demand for certified organic products and those few foods labeled as GM-free would be growing correspondingly in North America as it is in Europe, which is not the case, and therefore goes to confirm the assertion that when consumers are faced with actual purchase choices, the presence or absence of GM labeling does not appear to be of great importance to the majority of the North American retail market (Smith and Phillips, 2003). It is therefore also apparent now that the key question that many governments and social advocacy groups seem to miss is whether labeling for GM content will provide consumers with product information and market choice that increases their ability to buy what they want (Smyth and Phillips, 2003). When the willingness of consumers in the USA and UK to pay for labeling was assessed by offering them the choice between two identically priced boxes of breakfast cereal, one box labeled GM and the other labeled non-GM and then asked which of the two they would chose if they were priced the same, 71% of UK respondents chose non-GM, 2% chose the GM cereal and 23% were indifferent while in the USA, 44% chose the non-GM product, 6% preferred the GM product and 22% had no preference (Moon and Balasubramanian, 2002). Similar surveys of willingness to pay in other countries e.g. New Zealand, Norway, and Japan elicited varied results but one conclusion has been that every market has some consumers that perceive GM foods as equivalent to conventional food purchases (Smyth and Phillips, 2003).

WHAT IS LABELING?

The use of genetically modified organisms (GMOs) in agriculture has been a topic of great debate and focus for quite some time now both in the public domain and in political circles. As a direct result of this an issue that has emerged and is eliciting a lot of discussions in many countries is the labeling of GMO products. In countries like the US heated debates have centered on this issue but still no consensus has been reached on what would be the best approach of dealing with it.

Labeling has been described as a means of delivering information to consumers on characteristics of products that they are not able to evaluate (Caswell, 2000a). These

characteristics have been referred to by economists as credence attributes (Caswell & Mojduszka, 1996) and by using labels, can be transformed it into search attributes which consumers can learn about by looking at a products package (Caswell, 2000b). Labeling therefore requires definition of the attribute to be labeled (e.g., what is a "GMO"?) and segregation of products with and without the characteristics throughout the supply chain from seed inputs to the supermarket shelf (Caswell, 2000a). Thus, for example, a GMO product with special characteristics can be voluntarily labeled to allow those who are selling it to capture the consumers' willingness to pay for those characteristics (Caswell, 2000a). Accordingly, the goal of label information is to help consumers identify the food products that best match their preferences, thus helping consumers spend wisely (Byrne, 2009).

STATUS OF LABELING WORLDWIDE

Currently there are 64 countries worldwide that have adopted labeling regulations. However the characteristics of the regulations vary greatly from country to country (Table 1). The United States, the largest producer of GM crops together with countries like Argentina, Mexico, Canada and others have published voluntary labeling guidelines for non-GM food (Phillips and McNeill ,2000). Voluntary labeling guidelines dictate rules that define which foods are called GM or non-GM and allow food companies to decide if they want to use such labels on their products (Gruére, 2014). On the other extreme the European Union (EU) has adopted stringent mandatory labeling regulations alongside other countries like Russia, Hungary, Czech Republic, Indonesia, Poland (Gruére *et al*., 2009) and Switzerland (Phillips and McNeill, 2000). Mandatory labeling requires that food handlers (processors, retailers and sometimes food producers or restaurants) display whether the targeted product/ingredient contains or is derived from GM materials (Gruére, 2014). Some other developing countries have taken a position on GM food, sometimes adopting mandatory labeling policies that do not seem to respond to genuine consumer concerns and that may be unenforceable (Gruére *et al*., 2009).

Table 1: Status of National Rules for Labeling GM Foods

Status	Labels	Coverage	Effective date
Australasia			
Australia & New Zealand	M	GM content in processed foods, fruits, vegetables; 1% tolerance.	December 2001
Asia			
China	M	All foods containing GM content.	May 23 2001
Hong Kong	V/M	All foods containing GM content; 5% tolerance.	Estimated 2003
Indonesia	M	Article 41, Provisions on Biosafety of Genetically Engineered Agricultural Biotechnology Products, requires labels.	NA
Japan	M	MAFF regulations exempt additives, animal feeds, and any ingredient representing less than 5% of content.	April 1 2001
Russia	V	Decree No. 12 (1999) refers to labeling of GMOs.	NA
South Korea	M	Processed foods with GM corn, soybean or bean sprouts (and potatoes in 2002); if one of top 5	March 1 2001

		ingredients; 3% tolerance.	
Taiwan	M	Processed foods containing GM corn or soybeans; 5% tolerance.	By 2005
Sri Lanka	B	Currently ban production or imports of GM products.	Ongoing
Thailand	M	GM content in all foods and raw products; 3% or 5% tolerance.	End 2001
Africa			
Ethiopia	M	All products.	NA
South Africa	M	New law proposed.	2002
Europe (National)			
Austria	M	Prefer a ban on GM foods rather than labels.	NA
Czech Republic	M	All products of GM origin or ingredient.	NA
France, Ireland, Spain	M	Want to label GM additives and preservatives.	NA
Hungary	M	Products containing/derived from GM material (excluding feed and novel food).	N
Netherlands	M	Propose mandatory labeling for animal feed.	NA
Poland	M	Conform to EC 219/90 and 220/90.	NA
Slovenia	M	Conform to EC 219/90 and 220/90.	NA
Switzerland	M	Conforming to EC 219/90 and 220/90.	NA
United Kingdom	M	Grocery store and restaurant foods on sale in UK before September 1, 1998; not for additives/flavorings/food.	March 1 1999
European Union	M	Dir. 90/220: law requiring labeling of all foods and food products containing GMOs; no tolerances set.	1990 May 15 1997
	M	Reg. 258/97: 1% tolerances; mandatory labeling of foods; no regulation for chymosin, additives or feeds.	
	M	Reg. 1139/98: specific rules for GM soy and maize.	May 26 1998
North & South America			
Argentina	V	No required labels; voluntary labels allowed.	Ongoing
Brazil	B/M	Ban currently in force; propose labels for products	End 2001
Canada	V	containing more than 4% GM content. Voluntary standards being developed; labels not used in interim.	2001 or beyond
Mexico	M	Senate has approved a bill for GM foods to be labeled as "transgenic" or "made with transgenic products."	NA
United States	V	GM food must be "substantially equivalent" food; exporters will meet EU standards.	2001

Note. B = Ban on GM products; M = Mandatory Labeling; V = Voluntary Labeling. Adopted from Phillips and McNeill (2000)

THRESHOLD OF LABELING

The labeling threshold is a reliable bench mark that enables food and feed producers to distinguish between agricultural products from different cultivation systems and place them on the market accordingly and also gives consumers the opportunity to make informed choices between different types of products (GMO Compass, 2017). The threshold for labeling GM products can be applied to each ingredient in a product or only to three or five major ingredients in a product and its level can range from 0.9-5%, except in China (Gruére, 2014).

Table 2: Sample of International Guidelines for Labeling GM Foods

Country	Labeling Scheme	%Threshold for GM unitended material	Are some biotech foods and processes exempt
Canada	Voluntary	5%[C]	N/A
United States	Voluntary	N/A	N/A
Argentina	Voluntary	N/A	N/A
Australia and New Zealand	Mandatory	1%	Yes
European Union	Mandatory	0.9% [a]	Yes
Japan	Mandatory	5% [b]	Yes
South Korea	Mandatory	3% [b]	Yes
Indonesia	Mandatory	5% [C]	Yes

N/A means not applicable Source: Carter and Gruére (2003)

[a] Proposed threshold in the EU, lowered from 1%

[b] Top 3 ingredients in Japan and top 5 ingredients in S. Korea

[c] Not yet operational

LABELING REGULATIONS

Since 1990, the Codex Alimentarius Commission, an International Standards setting body for food has sought to develop guidelines for labeling biotech foods but so far there has been no agreement on the international standards (Carter and Gruére, 2003; Randall, 2010). The approaches taken in different countries towards GM food labeling differ greatly (Sheldon, 2002). Since 2000, more than forty countries have adopted regulations for labeling GM food, but the characteristics of the regulations and their degree of implementation vary greatly (Gruére, 2010). In 2006 during the 34th session of the Codex Alimentarius Commission, Codex Committee on Food Labeling (CCFL), a working group was tasked to consider 'the rationale for Members' approach to the labelling of food and food ingredients obtained through certain techniques of genetic modification/genetic engineering' and to 'identify the current standards, regulations, acts/decrees, etc. among current Members with respect to the mandatory and voluntary labeling of foods and food ingredients obtained through certain techniques of genetic modification/genetic engineering' (CAC, 2007). The working group identified seven main approaches to labeling of GM foods which can broadly be categorized as voluntary and mandatory labeling (Table 3). All of the approaches require positive labeling when there are differences in the characteristics of the final product that could have a material effect on the consumer, for example, changes in the composition of the food or introduction of allergens (Albert, 2010).

There is a major dichotomy between countries that have adopted voluntary labeling and those that have adopted mandatory labeling. One camp, including the European Union, Japan, Australia, and New Zealand, among others, is pursuing mandatory labeling programs for GM food products, although in some cases voluntary labeling is retained for non-GM products while the second camp, which includes the United States (U.S.), has voluntary labeling as its main strategy, with labeling being required if important end characteristics of the product, such as its allergenic potential or nutritional content, are changed (Caswell, 2000).

Table 3. Main approaches to labeling of GM foods

1. Mandatory GM labeling as such of all foods derived from or containing ingredients derived from organisms produced using gene technology (food consisting of, containing or produced from GMOs).
2. Mandatory GM labeling as such of GM foods and food ingredients where novel DNA and/or protein are present in the final food.
3. Mandatory GM labeling as such of GM food where it is significantly different from its conventional counterpart and where GM labeling is required in addition to the significant change.
4. Mandatory labeling of GM foods where it is significantly different from its conventional counterpart and where only the significant difference is labeled, but not the method of production.
5. Voluntary labeling (voluntary labeling guidelines for foods that are or are not products of genetic engineering).
6. No special labeling requirement for bioengineered foods as a class of foods.
7. Labeling requirements under development.

Source: CAC, 2007, p.2

a) Mandatory labeling

Mandatory labeling requires that all producers of genetically manipulated products or other products considered by consumers as "unsound" or "unsafe" – declare themselves as such through product labels (Kirchoff and Zago, 2001). This is backed by a key tenet in countries that have adopted mandatory labeling policies which says that consumers have a right to know whether or not biotechnology was used to produce the foods they consume and this right to know is not circumscribed by safety considerations or notions of "sound science" though if safety concerns are unresolved, then the right to know argument is strengthened (Caswell, 2000). Gruére (2010) points out that even among these countries labeling regulations differ widely according to:

i) Coverage: countries may require labeling for a list of particular food ingredients or all ingredients that include detectable transgenic material; highly processed products derived from GM ingredients, even without quantifiable presence of transgenic material; animal feed; additives and flavorings; meat and animal products fed with GM feed; food sold at caterers and restaurants; and unpackaged food,

ii) Threshold level for labeling of GM ingredients: can be applied to each ingredient or only to three or five major ingredients; and its level ranges from 0.9% to 5% (with the exception of China) and

iii) Labeling content: "genetically modified" item on the list of ingredients, or in the front of food packages.

One of the major differences in regulations among countries with mandatory labeling depends on whether the regulation targets the presence of GM in the finished product or on GM technology as a production process (Gruére, 2010). In the former case, only products with detectable and quantifiable traces of GM materials or ingredients are required to carry a label while in the latter case, any product derived from GM crop has to be labeled, whether or not it contains any traces of GM material (Gruére, 2010). However, there is less agreement on whether final products

which do not contain any GM material should be labeled if they were derived from a GM crop and whether a food should be labeled because of the process of production (Albert, 2010).

In 2003, the European Parliament enacted two complementary laws regarding GM food: Regulation (EC) 1829/2003 which requires labeling for human food and animal feed containing genetically modified organisms, 'to enable consumers to make an informed choice,' while Regulation (EC) 1830/2003 'guarantees the traceability and labeling of genetically modified organisms and products produced from GMOs throughout the food chain to facilitate monitoring' (European Parliament, 2003a; European Parliament, 2003b). Through these two pieces of legislation the EU thus effected mandatory labeling. A consumer in Europe would therefore assume that an unlabeled product does not contain GM ingredients because there is a mandatory positive label, i.e. those products that do contain such ingredients must be labeled (Albert, 2010). However, even with mandatory labeling, standards are still inconsistent and consumers are not necessarily provided with greater choice, as seen in Japan and the EU where it is virtually impossible to find products on the food shelf labeled as containing GM ingredients (Carter and Gruére, 2003). The Japanese government requires mandatory labeling when GM material is present in the top three raw ingredients and accounts for 5% or more of the total weight in contrast to the EU where the threshold applies to each ingredient and South Korea where the tolerance level is 3% of the top 5 ingredients (Carter and Gruére, 2003).

In Brazil, food products containing over 1% of authorized, genetically modified ingredients must show this information on their labels (Decree No.4860of April 2003- Brazil, 2003). However, a recent study detected the presence of GMOs above the authorized 1% in 36% of food products sampled which demonstrated that many Brazilian food industries had not yet complied with the legislation observing consumer requirements (Branquinho *et al*., 2010). In 2009 South Africa passed the South African Consumer Protection Act 68 of 2008 (SACPA) into law (Viljoen and Marx, 2013). The main aim of the Act is to protect consumers in South Africa from unfair trade practices, improve consumer awareness and confidence through a legal framework that also provides a system for consumer redress (SACPA, 2009). A notable inclusion in the Act was the mandatory labeling of genetically modified products or ingredients in food (Viljoen and Marx, 2013). The Act provides in section D: 24 that "any person who produces, supplies, imports or packages any prescribed goods must display on, or in association with the packaging of those goods, a notice in the prescribed manner and form that discloses the presence of any genetically modified ingredients or components of those goods in accordance with applicable regulations." (SACPA, 2009). Under the regulations given by SACPA, it is mandatory for a product to be labeled as containing a "genetically modified organism" if the threshold of genetically modified ingredients or components in the product is at least 5 % (SACPA Regulation 293, 2011). In a recent study to determine the implications of mandatory labeling under the Consumer Protection Act in South Africa, it was found that 58% of maize products and 39% of soybean products contained 5% genetic modification, therefore suggesting that the majority of food products were implicated by the South African Consumers Protection Act 68 of 2008 in terms of GM labeling (Viljoen and Marx, 2013). The study also revealed that of the products labeled to indicate an absence of genetic modification, 28% needed to be labeled as containing genetic modification.

The application of GM labeling differs among countries, mainly in terms of terminology, inclusion and exclusion criteria and in threshold levels that compel labeling as well. For example, thresholds to allow tolerance for the adventitious presence of approved genetically

modified organisms with mandatory labeling range from 0% (China), 0.9% (EU and Russia), 1% (Brazil, Australia, New Zealand and Saudi Arabia), 3% (South Korea) to 5% (Japan, Indonesia, Taiwan and Thailand). The question one may therefore ask is why there are such wide differences in approaches to GM labeling across countries? Several possible explanations have been given e.g. food scares in the EU and Japan have made consumers not believe scientists and politicians who say GM food is safe and environmental groups have thus harped on this fear by raising unscientific concerns about GM food safety, support by environmental and consumer groups for mandatory labeling for the sake of consumer choice, European Union policy influencing labeling policies in other countries like Australia, Russia, Poland and Czech republic (Carter and Gruére, 2003).

b) Voluntary labeling

Canada, the United States (US), Argentina, and Hong Kong have adopted a voluntary labeling strategy. In the United States, the Food and Drug Administration (FDA) has responsibility for regulating all processed and packaged foods, animal feed, food additives, veterinary drugs and human drugs that are derived from agricultural biotechnology (Executive Office of the President, Office Science and Technology Policy, 1986). The agency's approach to regulation of GM foods was explained in 1992, when the FDA issued the 'Statement of Policy: Foods Derived from New Plant Varieties; Notice"(Albert, 2010). The 1992 policy stated:

"The regulatory status of a food, irrespective of the method by which it is developed, is dependent upon objective characteristics of the food and the intended use of the food (or its components). Consumers must be informed, by appropriate labeling, if a food derived from a new plant variety differs from its traditional counterpart such that the common or usual name no longer applies to the new food, or if a safety or usage issue exists to which consumers must be alerted". (Food and Drug Administration, 1992, 22991).

However in 2001, the FDA reviewed its approach after public, industry and trade concerns were raised regarding the 1992 policy approach. Thus it released a new draft policy: 'Guidance for Industry, Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering' (FDA guidance) (Food and Drug Administration, 2001). This approach provided guidance for producers who wished to inform consumers that their product doid not contain GM ingredients, i.e. negative labeling (Albert, 2010). It also draws attention to the United States Department of Agriculture rules for organic foods (National Organic Program final rule; 65 FR 80548) which has requirements for certifying that a product is organic and also provides for adequate segregation of food throughout the distribution chain to give the assurance that non-organic foods do not mix with organic foods (Albert, 2010). The FDA believes that the practices and recording keeping that substantiates the "certified organic" statement is sufficient to substantiate the claim that a food was not produced using bioengineering (FDA, 2001). In 2015 the FDA issued a final guidance outlining its recommendations to food companies on the voluntary labeling of foods as to whether a food is or is not derived from genetically engineered (GE) plants (Covington, 2015). It reiterated its position first elucidated in 1992, that, as a class, GE foods do not differ in any meaningful or uniform way from foods not derived from GE plants, nor do they present any different or greater safety concerns than foods not derived from GE plants and that genetic engineering is a process for developing new plant varieties, but the use of this process does not necessarily have any effect on the attributes of the food derived from such plants. The guidance read as follows:

- Claims should use the terms “not bioengineered,” “not genetically engineered,” and “not genetically modified through the use of biotechnology” in place of “Non-GMO” to convey that a food was not derived from GE plants, because these terms are more scientifically accurate. FDA states, however, that it does not intend to take enforcement action solely because a claim uses the acronym “GMO.”
- Claims should not use the terms “GMO free,” “GE free,” “does not contain GMOs,” and “non-GMO” because these claims convey that a food is “free” of GE ingredients and “free” conveys a total absence of GE material.
- Claims should not suggest or imply that a food is safer, more nutritious, or otherwise has different attributes than other comparable foods solely because the food was not genetically engineered, or FDA may find the claim to be misleading. In addition, FDA may consider a claim to be misleading if it fails to reveal certain material information (e.g., a prominent statement that a minor food ingredient was not produced with GE if consumers could be misled to believe that the entire product was not produced with GE or a statement that a food was not produced with GE when the food is incapable of being produced with GE).
- Claims must be substantiated, taking into consideration the specifics of the claim, which may include:
    - *Documentation of handling practices and procedures, including segregation procedures*. Manufacturers that have control over production of raw commodities should document whether or not the raw commodities are produced using GE, including segregation procedures. Other manufacturers may rely on certifications or affidavits from suppliers in the food production and distribution chain.
    - *Compliance with USDA organic certification requirements*. A claim that a food is not derived from GE plants can be substantiated by records demonstrating compliance with the U.S. Department of Agriculture’s (USDA’s) certified organic regulations.
    - *Use of validated test methods*. Validated analytical methods may be useful in confirming the presence of GE material, but most often will likely not be sufficient to substantiate that a food is not derived from GE plants, particularly highly processed foods such as oils. (Covington, 2015).

In South Africa, the South African Foodstuffs, Cosmetics and Disinfectants Act 45 of 1972 (Regulation 25 of 2004) set into motion the labeling of GM food if it differed from its conventional counterpart in terms of nutritional composition, storage and preparation or if it contained an allergen or a human or animal gene (Department of Health, 2004). By 2008, voluntary labeling in South Africa was allowed for products with consumer value added traits such as improved nutrition or reduced allergenicity but there was no express provision for GM labeling in terms of consumer preference despite the fact that some South African companies were applying voluntary GM labeling (Botha and Viljoen, 2008). However the situation has since changed after the passage into law of the South African Consumer Protection Act 68 of 2008 within which was included a provision for mandatory labeling of genetically modified products or ingredients in food (SACPA, 2009).

CONCLUSION

There appears to be universal agreement that consumer choice needs to be enhanced through effective labeling, to allow consumers to choose between competing GM and GM-free food products but the debate is no longer about whether or not to develop a labeling system for GM foods but rather how to develop a system that provides real consumer choice without unduly interrupting international trade in agri-food products (Phillips and McNeill, 2000).

REFERENCES

Albert, J. 2010. New technologies and food labeling: the controversy over labeling of foods derived from genetically modified crops. In. J. Albert (Ed). Innovations in Food Labeling. FAO and Woodhead Publishing Limited, Oxford, Cambridge, Philadelphia and New Delhi.

Brazil Decree No. 4680, April 24, 2003. Regulates the information access [Law No. 8078, September 11, 1990] concerning food and ingredients containing or produced from genetically modified organisms. D. O. U. Official Journal of Brazil, Brasilia, Brazil. Available at: http://www.anvisa.gov.br/e-legis

Byrne, D. M. 2009. Cloned meat, Voluntary Food Labeling, and Organic Oreos. *Pierce Law Review* 8(1/4): 33-72.

CAC. 2007. Codex Committee On Food Labeling, Thirty-Fifth Session, Ottawa, Canada, 30 April–4 May 2007, Labeling Of Foods And Food Ingredients Obtained Through Certain Techniques Of Genetic Modification/Genetic Engineering: Proposed Draft Guidelines For The Labeling Of Foods And Food Ingredients Obtained Through Certain Techniques Of Genetic Modification/Genetic Engineering : Labeling Provisions (At Step 4). Report of The CCFL Working Group On Labeling of Foods And Food Ingredients Obtained Through Certain Techniques Of Genetic Modification/Genetic Engineering, Oslo 6–7 February 2007. Joint FAO/WHO Food Standards Program. Rome: FAO/WHO

Carter, C. A. and Gruere, G. P. 2003. International Approaches to the Labeling of Genetically Modified Foods. Available at: http://www.agmrc.org/media/cms/cartergruere_929BEB69BA4EE.pdf

Clare, J. Mary C. 2015 AP-GfK Poll: An Appetite for Labeling Genetically Modified Foods. Available at: http://ap-gfkpoll.com

Covington. 2015. Food labeling: FDA Issues Final Guidance on Voluntary GE Claims on Food Products, One Week After Requesting Information and Comments on "Natural" Claims. Available at: http://www.cov.com/-/media/files/corporate/publications/2015/11/food_labeling_fda_issues_final_guidance_on_voluntary_ge_claims_on_food_products.pdf

Department of Health. 2004. Explaining GMO Food Labeling. Available at: www.doh.gov.za/search/index.html

European Parliament. 2003a. Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on Genetically Modified Food and Feed. *Official Journal of the European Union* L268: 1–23.

European Parliament. 2003b. Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the Traceability and Labeling of Genetically Modified Organisms and the Traceability of Food and Feed Products Produced from Genetically Modified Organisms and Amending Directive 2001/18/EC. Official Journal of the European Union L268/24: 24–28.

Executive office of the President, Office of Science and Technology Policy. 1986. 'Coordinated Framework for Regulation of Biotechnology' Action: Announcement of policy; Notice for Public Comments. Federal Register 51, 23302, June 26.

Food and Drug Administration. 1992. Part IX Department of Health and Human Services, FDA, 'Statement of Policy: Foods Derived from New Plant Varieties; Notice'. Federal Register, 57, No. 104, 22984–23001, May 29.

Food and Drug Administration. 2001. 'Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Notice'. Federal Register, 66, No. 12, 4839–4842, January 18.

Frewer, L.J., Howard, C. and Aaron, J. L. 1998. Consumer Acceptance of Transgenic *Crops Pesticide Science* 52: 388-93.

GMO-Compass. 20117. GMO Labeling Guidelines: Why a threshold? Available at: http://www.gmo-compass.org/eng/regulation/labelling/89.gmo_labelling_guidelines_threshold.html

Gruére, P. G. 2014. Labeling Policy of Genetically Modified Food. International Food Policy Research Institute. Brief Number 7. Available at: https://pbs.ifpri.info/files/2014/04/GMO-Food-Labeling-Policies.pdf

Grunert, K. G., Bredahl, L. and Scholderer, J. 2003. Four questions on European Consumers' Attitudes Toward the use of Genetic Modification in Food Production. *Innovative Food Science and Emerging Technologies* 4: 435–445.

Honkanen, P. and Verplanknen, B. 2004. Understanding Attitudes Towards Genetically Modified Food: The role of Values and Attitudes Strength. *Journal of Consumer Policy* 27: 401-420.

Israel, G. D. and Hoban, T. J. 1992. Concern About Eating Genetically Engineered Food. *South Rural Society Journal* 9 (1): 23-43.

Jones, P. 2014. GE Labeled Food Fight Continues. ISB News Report. Available at: http://www.isb.vt.edu/news/2014/Apr14.pdf

Kirchhoff, S. and Zago, A. 2001. A Simple Model of Voluntary vs Mandatory Labeling of GMOs. Working Paper 7/01. Available at: http://www.univr.it/documenti/AllegatiOA/allegatooa_28695.pdf

Knight, J., Mather, D., Holdsworth, D. and Ermen, D. 2007. Genetically Modified Food Acceptance: An Experiment in Six Countries. *Nature Biotechnology* 25 (5): 507-508.

Lusk, J. L. and Sullivan, P. 2002. Consumer Acceptance of Genetically Modified Foods. *Food Technology* 56 (10): 32-7.

Monteserrat, Costa-Font, J. M. Gil and Traill, W. B.2008. Consumer Acceptance, Valuation of and Attitudes Towards Genetically Modified Food: Review and Implications for Food Policy. *Food Policy* 33: 99-111.

Moon, W. and Balasubramanian, S. 2002. Public Perceptions and willingness-to-pay a Premium for Non-GM Foods in the US and UK. *AgBioForum* 4: 221–223.

Badrie, N., Titre, M., Jueanville, M. and D'Heureux-Calix, F. 2006. Public Awareness and Perception of Genetically Modified/Engineered Foods in Trinidad, West Indies. *British Food Journal* 108 (3): 192-199.

Nestle, M. 1998. Food Biotechnology: Labeling will Benefit Industry as Well as Consumers. *Nutrition Today* 33 (1): 6-12.

Nielsen, C. P., Thierfelder, K. and Robinson, S. 2003. Consumer Preferences and Trade in Genetically Modified Foods. *Journal of Policy Modeling* 25: 777–794.

Noussair, C., Robin, S. and Ruffieux, B. 2004. Do Consumers Really Refuse to Buy Genetically Modified Food? *The Economic Journal* 114: 102-21.

Phillips, P. W. B and McNeill, H. 2000. A Survey of National Labeling Policies for GM Foods. *AgBioForum* 3(4): 219-224.

Roe, B. and Teisl, M. F. 2007. Genetically Food Labeling: The Impacts of Message and Messenger on Consumer Perceptions of Labels and Products. *Food Policy* 32: 49-66.

SACPA. 2009. Consumer Protection Act, 2008. *Government Gazette*, 526(31286): 3-186

SACPA Regulation 293. 2011. Consumer Protection Act, (68 of 2008) Regulations, *Government Gazette*, 550(34180): 3-88.

Slovic, P. (2000), The Perception of Risk, Earthscan, London.

Sheldon, I. 2002. Regulation of Biotechnology: Will we Ever "Freely" Trade GMOs? *European Review of Agricultural Economics*. 29(1): 155-176.

Townsend, E. and Campbell, S. 2004. Psychological Determinants of Willingness to Taste and Purchase Genetically Modified Food. *Risk Analysis* 24 (5): 1385-1393.

United States Federal Register, January 18, 2001, 66, 4839.

Van Den Heuvel, T., Van Trijp, H., Gremmen, B., Renes, R. and Van Woerkum, C. 2006. Why Preferences Change: Beliefs Become More Salient Through Provided (Genomics) Information. Appetite 47 (3): 343-51.

Scully, J. (2003), "Genetic Engineering and Perceived Levels of Risk. *British Food Journal* 105 (1/2): 59-77.

Szczurowska, T. 2005. Poles on Biotechnology and Genetic Engineering. TNS OBOP Plant Breeding and Acclimatization Institute, Radzikow, http://www.ihor.edu.pl

Smith, S. and Phillips, P. W. B. 2003. Labeling to Manage Marking of GM foods. *Trends in Biotechnology* 21: 389-393.

Verdurme, A. and Viaene, J. 2003. Consumer Beliefs and Attitude Towards Genetically Modified Food: Basis for Segmentation and Implications for Communications. *Agribusiness*, 9 (1): 91-101.

4.4. UNIT 6: POLITIZATION, SCIENTIZATION AND DEMOCRATIZATION IN THE DEBATE ON BIOTECHNOLOGY 2 hrs

This unit will examine the roles played by politics and science in the regulation of biotechnology and therefore will give consideration to the following aspects: the emergence of the concept of 'scientization' of politics and the relationship between scientific expertise and making of political decisions regarding biotechnology; differences between 'scientization of politics' and 'politicization of science' and how this has impacted the regulation of biotechnology; how industry has used the political authority of science to influence policy making in biotechnology and the drawbacks this trend has generated; the emergence of ''democratizing science movements'' and how this has challenged and impacted the political authority of science in the regulation of biotechnology.

INTRODUCTION

The debate on the virtues and perils of biotechnology in the production of transgenic

crops that started in 1983 has intensified and become quite contentious with the commercialization of transgenic foods in recent years. It has become political and emotional to the extent that it is now delaying and/or preventing the worldwide adoption of this important technology in addressing critical and urgent problems of food security and the environment. Plant Biotechnology is now considered the best hope for meeting the food needs for the ever-growing human population, for conserving the dwindling land and water resources and preventing or reversing environmental degradation. By 2050 the world population will have reached 12 billion, thus food production will have to be tripled to meet the growing demand. This increasing demand will have to be met mainly by increasing productivity on land already being cultivated but with less water and under and worsening environmental conditions and this is where biotechnology has stepped in. The first ever transgenic crops were produced in 1996 and now years later these crops are being engineered for a whole range of traits e.g. resistance to herbicides (soybeans, canola), insects (cotton, maize) and viruses (papaya and squash). By eliminating, or significantly reducing, the losses caused by weeds, pests and pathogens, transgenic crops increase productivity and thus help to conserve land, water, energy and other resources that would be needed otherwise to produce the same amount of food with non-

transgenic plants. The acreage of land under transgenic crops has been increasing steadily of the years and so has the market. By 2003 the total market for transgenic seed exceeded $3 billion. Plant biotechnology is thus no longer an abstract science with only promise and potential, but rather a powerful agricultural technology that is beginning to increase productivity by reducing or eliminating losses caused by weeds, pests and pathogens. It is also having a positive impact on human health and the environment by reducing the use of agro-chemical. However, all this notwithstanding, anti-biotechnology activists continue to call for a moratorium or outright ban on the planting and/or use of transgenic crops and since they have been very vocal many government's have listened to them and placed restrictions on the commercialization of transgenic crops. Politics has therefore now taken centre stage and the opponents of plant biotechnology have taken the initiative in presenting a highly distorted and misleading account of biotechnology to the public. However the influence of science on political decisions touching on agriculture has also had more else the same effect as the influence of politics on decisions

EMERGENCE OF THE CONCEPT OF SCIENTIZATION OF POLITICS

The relationship between experts and politics has been an abiding topic of concern to political theorists since the 1960's. Early investigations of this focused on the growing political influence of scientists and the problem of technocracy. Habermas (1970) referred to these transformations as the "scientization" of politics, a shift toward a technocratic model of governance in which politics is replaced by a scientifically rationalized administration. In the 1960's and 1970's political theorists articulated a variety of threats that scientization posed to democratic values, some focusing on the power held by those who control technical information and others more concerned about the camouflaging of value-laden political decisions with the logic of scientific rationality. Many of the concerns raised decades ago about the scientization of politics are no less relevant today. Industry groups routinely use a concept of "sound science" to maintain the upper hand in political deliberations about a variety of contentious issues, most prominently the regulation of biotechnology. The political authority of science may be expanding often to the benefit of industry, but there are also countervailing trends. Weingart (1999) points out that the increasing use of science to legitimize political decisions based on its presumed objectivity and disinterestedness, is paradoxically self-destructive. Decision makers depend on scientific

knowledge for the resolution of complex problems, yet scientific experts are rarely able to provide definitive answers. This leads to escalating competition for scientific advice, whether in the courts, regulatory bodies or policy making institutions. As the public becomes increasingly aware that "science can be used to legitimize different political positions and decisions", the basis of legitimization – the presumed non-partisan nature of scientific knowledge – would seem to be undermined. Instead of shifting way from technocratic tendencies, many institutions have sought to maintain the political authority of science through a number of strategies, such a s conceling schisms within the scientific community and controlling messages repeated in the media

EFFECTS OF THE SCIENCITIZATION OF POLITICS

One effect of the sciencitization of politics is to suppress debate often to the benefit of industry. Paradoxically it has also fueled the emergence of social movements – in many examples the use of scientific expertise to legitimize undesirable political decisions has been met by fierce opposition (give examples). The social movements that challenge the expanding political authority of science are referred to as "democratizing science movements" because they "attempt to reclaim citizens" power by making lay knowledge legitimate in science, policy and public debate

REFERENCES

1. Frow, E., Ingram, D., Powell, W., Steer, D., Vogel, J. & Yearley, S. (2009). The politics of plants. *Food Security* 1: 17-23.
2. Gisler, P. & Kurath, M. (2011). Paradise lost? ''Science'' and ''the public'' after Asilomar. *Science, Technology & Human* Values. 36: 213-243.
3. Kinchy, Abby J. (2010). Anti-genetic engineering activism and scientized politics in the case of ''contaminated.'' Mexican maize. *Agriculture and Human Values* 27: 505-517.
4. Kingiri, A. N. & Hall, A. (2012). The role of policy brokers: The case of biotechnology in Kenya. *Review of Policy Research*. 49(4): 492-522.
5. Miller, H. I. (1996). When politics drives science: Lysenko, Gore and US biotechnology policy. *Social Philosophy and Policy* 13(2): 96-112.

6. Miller, H. I. & Conko, G. (2000). The science of biotechnology meets the politics of global regulation. *Issues in Science & Technology*. 17(1): 47-54.
7. Salter, B. & Jones, M. (2002). Regulating human genetics: The changing politics of biotechnology governance in the European Union. *Health, Risk & Society*. 4(3): 325-340.
8. Tencalla, F. (2006). Science, politics, and the GM debate in Europe. *Regulatory Toxicology and Pharmacology*. 44: 43-48.