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PREFACE

The content of this book is designed to introduce to undergraduate students in applied biological sciences and biotechnology key concepts and principles in biosafety and bioethics. It assumes the students have the basic knowledge in biotechnology tools and application. Consideration is also given to the non-biotechnology student with background in biology to be able use the book in understanding key issues on the concerns of biotechnology application.

Section 1 highlights keys issues which make application of biotechnology a matter of concerns to general public despite its benefits. Examples of numerous beneficial applications of biotechnology that raise safety concerns are examined in Section 2. The principles and practices of undertaking risk analysis are explored in Sections 3 and 4. Special attention is given on food safety and environment risk assessment procedures and practices genetically modified organisms and derived products. These issues on food and environment safety are the major sours of safety concerns and they are described in Sections 5 and 6. An effort is made in Section 7 to enable the reader to understand the core principles of risk assessment and application of precautionary principle as a tool in decision making in biosafety practices. This section also introduces the reader to the divergent approaches in application of the precautionary principle by different countries and international regulatory regimes or international treaties.

Section 8 is meant to acquaint the reader with the principles and practices applied in risk management and communication on safety concerns raised under risk assessment. Importance of risk communications and effective ways of achieving it is discussed in this section. This is followed by acquainting the reader with different conceptions and misconceptions on application of modern biotechnology in Section 9. This section also makes an overview of consequences of different perceptions and misconceptions on application of modern biotechnology and how to combat the misperceptions that affects acceptance of biotechnology applications.

The implication of ethical and social economic consideration in formulation of national and international biotechnology and biosafety policies, and regulatory systems is explained in Section 10, 11 and 12. In these sections the content of this section is designed in a manner of developing an

understanding on ethical, legal and social issues confronting application of modern biotechnology in agriculture, food, medicine, industry and environmental biotechnology. The content also touches on issues of “*Intellectual Property Rights*” as related to biotechnology innovation and commercialization. Furthermore, the content of the book also outlines the different international treaties and agreements that are associated with biosafety and bioethics issues related to applications of biotechnology. Debatable and controversial issues on application of biotechnology are presented without views in support or against proponents and opponents of biotechnology.

The last two sections of this book presents features and common approached used in developing biotechnology policies and regulatory systems. In Section 13 importance of having biotechnology policy and the linkages to other national and international policies is highlighted. Section 14 is designed to acquaint the reader with procedures of developing national biotechnology policies and biosafety frameworks. The focus is put on biosafety regulations on release and commercialization of genetically modified organisms and their products in line with Cartagena Protocol on Biosafety. In this section the importance of public consultation in the process of developing biosafety policies and regulatory systems is emphasised.

Although this content of this publication is directed to undergraduate students to impart basic knowledge in biosafety, bioethics and biotechnology governance. It can also be useful to any other reader who intends to get basic knowledge in the above subjects. These include those who are interested in participating in public debates on benefits and risks on biotechnology and means of mitigating the risks.

SECTION: 1

INTRODUCTION TO GENERAL CONCEPTS ON BIOSAFETY, BIOETHICS AND BIOPOLICY

1.0 Definition of Biosafety

For a long time biosafety principles were generally applied in microbiological and biomedical research laboratories with consideration of occupational health and safety of environment. In recent years biosafety principles were also applied to research involving rDNA techniques which result in production, handling, storing and transportation of Genetically Modified Organisms (GMOs) also referred to as Living Modified Organisms (LMOs). With this approach in understanding biosafety, different definitions of the term biosafety have emerged.

The following definitions can be applied to describe terminology biosafety:

Definition 1: Application of safety principles to laboratory practices in which potentially hazardous biological material or organisms are manipulated or handled.

Definition 2: Approaches in handling the perceived risks of GMOs released into the environment, such as their possible adverse impacts on biodiversity or human health. Approaches may include guidelines or legally binding instruments at the national and international level.

Generally biosafety practices deals with the application of safety principles in any environment where hazardous biological material or agents or microorganisms are handled, to minimize the potential harmful effects to human's health and environment. The hazardous biological material could be pathogenic organisms of known risks or those suspected to have harmful risks.

1.1 The Principles of Biosafety for Microbiological and Biomedical Laboratories

For a long time many countries have had biosafety regulatory mechanisms in all laboratories handling hazardous biological materials. These regulations require such laboratories to observe the following principles of biosafety. These principles includes:

- Increasing levels of personnel and environmental protection.
- Providing guidelines for working safely in laboratories involved in microbiological, biomedical and genetic modification activities.
- The guidelines describe practices, techniques, safety equipment and other facilities which will ensure safety.
- Laboratories require superiors or supervisors who are knowledgeable with biosafety procedures and practices.
- Personnel working in such laboratories need to know of potential hazards and have proficiency in practice and techniques of executing their work.
- Laboratories need to have biosafety manual specific to the kind of activities taking place in the laboratory, and risks that may arise from those activities. This requires laboratories handling hazardous biological material to be categories into biosafety levels depending on what type and category of risks they are designed to handle.
- The levels of biosafety vary with the type of activities taking place and the severity of associated risks to be regulated.

Laboratories should allow only those activities whose risks they can handle or which are manageable by the design and facilities available. The risks being avoided can be categorized into the following categories:

- Direct effects
- Indirect effect
- Immediate effects
- Delayed effects
- Cumulative long term effects

Then we have to ask ourselves why biosafety has been a global issue if it was initially meant to be a discipline providing guidelines for good laboratory practices in microbiology and biomedical activities. The answers will come from the understanding of benefits and several safety concerns of various applications of biotechnology.

1.2 Biotechnology: Benefits and Concerns

Advances have been made in application of biotechnology to offer a lot of benefits to human needs and environment. The use of recombinant DNA technology or modern biotechnology has generated a series of beneficial applications and products in agriculture, animal husbandry, medical application, environmental management and industrial production. Parallel to these promises are series of concerns on adverse impacts of biotechnology.

Worldwide, development in biotechnology application has generated a number of human health, environment, economic and social concerns on the safety of the technology. Many of these concerns have legal, policy and ethical aspects to the extent that they are addressed by national and global policies and regulations. In this book, safety concerns on application of biotechnology will be discussed under the current issues associated with the benefits and risk concerns on biotechnology: These issues will include:

- (i) Biosafety of genetically modified organisms (GMOs).
- (ii) Biopolicy: Guiding policy to biotechnology application and regulation.
- (iii) Biopolitics: Politicization of modern biotechnology issues with the political stream that influence public policy.
- (iv) Bioethics with respect to biotechnology: Refers to principles and practice of applying biotechnology without doing harm to humans and environment.
- (v) Biosecurity : Protection of high-consequence microbial agents and toxins, or critical relevant information, against theft or diversion by those who intend to pursue intentional misuse.
- (vi) Bioweapons: Use of biologic agents or toxins (e.g., pathogenic organisms that affect humans, animals, or plants) as weapons.
- (vii) Bioterrorism: Use of biologic agents or toxins (e.g., pathogenic organisms that affect humans, animals, or plants) for terrorist purposes.
- (viii) Bioeconomy: Economy depending on bioscience-based technology or biotechnology-based economic activities.

1.3 General Concerns of Using Recombinant DNA Technology Derived Products

Biotechnology covers scientific disciplines other than genetic engineering and recombinant DNA (rDNA) technology. The major concerns of biotechnology have always focused on application of rDNA technology that may have harmful effects. The general concerns cited in modern time are mainly:

- Development of new weapons for use in biological warfare.
- Development of genetically altered organisms which could harm the environment and human health.
- The technology may contradict nature and therefore may interfere with some people's beliefs and ethical values.
- The commercial value of biotechnology products has led to companies patenting genes and organisms. This is a scare to the public and some communities.

With these controversies of biotechnology to the public, it is important to get the public involved in informed debate on the development and application of recombinant DNA or gene technology or modern biotechnology. This is discussed under biosafety because it is essential to promote the usefulness of biotechnology while taking precaution to avoid the risk associated with it.

Prior to detailed discussions on safety concerns of recombinant DNA technology, it is important to know that this is a technology that has created a lot of benefits in medicine, diagnosis and production of therapeutic products. It has also revolutionized industrial production processes. However, much of all benefits associated with this technology are not recognized by the public.

Discussion Question:

Using your knowledge on biotechnology application list the potential risks that you think are associated with biotechnology applications.

SECTION: 2

OVERVIEW OF WIDE APPLICATIONS OF BIOTECHNOLOGY AND CONCERNS WORLDWIDE: CONTROVERSIES SURROUNDING IT.

2.0 Introduction

The application of biotechnology can be grouped into different categories depending on intended use of the technology or the main organisms being manipulated. These categories are:

- (a) Agriculture biotechnology that include animal and plant biotechnology
- (b) Medical and diagnostic biotechnology
- (c) Pharmaceutical biotechnology
- (d) Food biotechnology
- (e) Industrial biotechnology
- (f) Environmental biotechnology
- (g) Forest biotechnology
- (h) Marine biotechnology
- (i) Microbial biotechnology

Only a few applications of biotechnology which are at the centre of debates on potential risks of biotechnology application will be discusses in this course. The concerns which are listed are mainly the science based concerns as social and ethical concerns vary with the community moral standards, beliefs and cultural values.

2.1 Animal Biotechnology

Animal biotechnology can be characterized into four major categories. These include:

- (i) Producing transgenic animal to provide information on genetic function and regulation. The information gained can be used to understand human genetic diseases.

- (ii) Production of transgenic animals which can produce high value recombinant pharmaceutical proteins for human medicine. Also producing animals which can provide xeno-organs for xenotransplantation to humans. This include:
- Producing cows and goats that produce proteins with pharmaceutical use in their milk.
 - Transgenic pigs to provide xeno-organs to humans. Xenotransplantation could provide definitive solution to shortage of human organ and tissues for transplant.
- (iii) Transgenic animals for improved human food production. This include:
- Cloning of animals to obtain high productivity breeding stock
 - Producing fast growing, frost and disease resistant fish
 - Pest and disease resistant livestock
 - Transgenic animals with high feed conversion and faster growth by inserting a gene that produce growth hormone and achieve bigger size.
- (iv) Others include manipulation of fertilized egg and in-vitro fertilization to help breeding of endangered animal species or human assisted reproduction.

2.1.1 Concerns on Animal Biotechnology

There seem to be more public concern on animal biotechnology especially on production of transgenic animals than on transgenic plants. Most of these concerns are raised by fear that knowledge gained in animal biotechnology application can be used to humans.

General concerns on transgenic animal:

- Potential impact on the environment.
- Food safety on food derived from genetically modified (GM) animals.
- Health of animal (animal warfare).
- Unknown risk because permits to research on animals are issued without sufficient risk analysis.

In case of xeno-organ for xenotransplantation to humans, the risks perceived include:

- There is a high risk of suppression of recipient immunity.
- Exposure to infections or cross species infection due to transmission of pathogens. This can create a risk of zoonotic diseases.
- Potential for transmission of exogenous infections mainly viruses. This can spread diseases like HIV-AIDs to create a new epidemic.
- Pigs with high compatibility for xenotransplantation of organs to humans have high number of provirus that are inherent as part of pig genome. These can infect humans, though none these proviruses have shown to cause diseases.

In case of food safety:

- Major concern is the production of transgenic animals that may have compounds or agents which can harm the humans. The harmful effect could be allergenicity, toxicity, infectious virus and prions like those cited for causing mad-cow disease or BSE.
- Drug residues in animals produced for biopharmaceutical production can create drug resistance if consumed as food.

Transgenic animals produced for xenotransplantation organs should be used as food only after safety assessment. This is also applicable for animals produced for production of novel protein in milk. Any intentional use of such animals needs safety assessment before use as food.

2.2 Plant Biotechnology

The advances in plant biotechnology that has generated a lot of concerns are mainly those which involve production of transgenic plants for food through rDNA technology. Other plant biotechnology applications such as tissue culture have not received a lot of concerns, though they have not been properly accepted in some parts of the world especially in developing countries.

Application of plant biotechnology can be grouped into the following categories:

- (i) Micro-propagation of plants using tissue culture techniques.

- (ii) Production of transgenic plants with improved traits for improving agricultural yield and production of novel ingredients or products with various uses.
- (iii) Production of plants which can be used in environmental bioremediation (phytoremediation).

The benefits associated with plant biotechnology especially with production of transgenic plants are many. Among these are:

- Development of crops with resistance to diseases and pests.
- Crops with resistance or adaptations to environmental stress such as drought, frost, soil pH and low nutrient supply.
- Production of cereal crops with resistance to infection by fungal species causing aflatoxicity.
- Development of novel foods with improved supply of indispensable amino acids and vitamins. The case of “Golden Rice”.
- Production of transgenic food crops with better nutritive value, texture and palatability. The case of transgenic Soya with cholesterol reducing peptide.
- Transgenic crops with higher yields.
- Production of transgenic food crops to remove natural allergens and toxins. The case of cyanide reduction in cassava and allergenic proteins in groundnuts.
- Transgenic food crops with long shelf-life foods products to reduce post-harvest food loss. The case of FlavrSavr tomato.
- Plants that can be used as bioreactors for biopharmaceuticals, edible vaccines for humans and livestock. The case of alfalfa grass used for production of edible veterinary vaccines.

2.2.1 Concerns on Transgenic Plant or Plant Biotechnology

As mentioned before that the public is more concern on application of rDNA technology in animal than in plants. More practical concerns in the world have been raised on plant biotechnology because its wide application in major food crops makes it to be seen by many people.

Concerns on transgenic crops:

- Fear of contaminating the human food with genetically modified foods not meant for humans. The case of StarLink maize.
- Allergens and toxins in food.
- Unexpected results from transgenic plants which could harm humans and environment.
- Antibiotic resistance due to use of antibiotic resistance marker genes in marker assisted breeding.
- Gene flow and spread of trait to wild species and threat to biodiversity. More important to contamination of agro-biodiversity in centers of origin. (The case of Mexican maize being contaminated with transgenes).
- Social and economic impact to the society where GM crops can interfere with export trade.
- Production of transgenic crops which can replace cash crops in developing countries.

The details and specifics of these concerns will be covered in subsequent sections under food and environmental biosafety risk assessment (Sections 5 and 6).

SECTION: 3

BIOSAFETY PRINCIPLES AND PROCEDURES FOR RESEARCH INVOLVING MICROBIOLOGICAL, BIOMEDICAL MATERIAL AND rDNA MOLECULES: OVERVIEW OF BIOSAFETY LEVELS.

3.1 Introduction

As indicated in the introductory section of this book, biosafety can be defined with considerations of occupational health, environment and food safety. This has been the focus for a long time. Under the “*Cartagena Protocol on Biosafety*” the main focus has been on environmental safety. This can also be attributed to the fact that the protocol was conceived under the concerns of impact of human development on environment sustainability by the United Nations Convention on Environment and Development (UNCED) of 1992. This international convention raised needs of regulatory systems that take precaution of risks arising from biotechnology.

Generally biosafety principles and practices has to do with the regulation of biological products, research and development of biological products based on perceived negative impacts to human health and environment. The impact can be known or suspected risks.

Biosafety principles and procedures include the principle of containment as means of safe handling of potentially hazardous biological material that could be harmful to humans an environment. In implementing biosafety principles, guidelines are created. These describe the basic precaution of working with potentially harmful biological material such as infectious microorganisms, protozoans, insects, plants or animals.

With recent developments in biotechnology and particularly in rDNA technology biosafety guidelines have included precautions of handling rDNA molecules and transgenic organisms and their products. Biosafety guidelines also describe conditions of carrying out research that involves genetic engineering or genetic modifications of organisms (GMOs). Commercializing of products, releasing them into the environment and trading in such GMOs between countries is also regulated. With recent

world attention of perceived risk of GMOs, a principle of regulating the risk of GMOs has been synonymous with biosafety. It is also perceived to be a barrier to biotechnology application especially release of GMOs. This misperception will be discussed also in the book.

3.2 Biosafety Regulatory Mechanisms

Biosafety regulatory mechanisms on modern biotechnology should not be seen as a barrier to biotechnology research and developments. Instead biosafety principles and practices regulate the potential risks and allow access to the benefits of utilizing biological material and biotechnology products. It involves assessment of risks of use or exposure to biological material and other biotechnology products that may have harmful effect to man and environment. As a scientific discipline, risk assessment and management strategies constitutes important component of biosafety practices.

Thus biosafety regulation mechanisms may vary depending on the nature of work involved in handling biohazardous material or conducting research and product development. The variations could be:

- *Biosafety regulations for laboratories involved in the handling plant and animal pathogens. These are regulated under health considerations.*
- *Biosafety for laboratories handling rDNA and conducting transformations of plants, animals and microorganisms.*
- *Facilities used for GMO field trials and release.*

3.3 Development of Biosafety as a Scientific Discipline

Biosafety has developed as a science of assessment and containment of natural and manmade biological hazards that can drive a system from its health state into a pathological development. The science started as a local matter of safety of laboratory workers, to become a multidisciplinary science with implication at national and global scales. It is now a subject involving a number of international treaties and agreements (to be discussed later).

The developments in biosafety assessment included principles and guidelines for contained biotechnology applications for safety of humans and environment. This was necessitated by the growing concerns on modern biotechnological applications.

3.4 Overview of Biosafety Levels

All laboratories or facilities handling clinical and environmental samples should have standards that set the kind of work which could be done in those laboratories. The standards or guidelines should describe also the precautions to be taken to safeguard the human health and environment.

Depending on the level of risks perceived to be associated biological hazards to be handled in the laboratories. Biosafety regulations assign biosafety levels to these laboratories that match the level or scale of risks and containment of the risks. Generally the risks and containments are categorized into four classes and therefore biosafety levels (BSL) also fall into four levels (see Table below). The four levels of risk, containment and biosafety ranging from 1-4 are classified from lowest to the most lethal risk.

Four Levels of Biosafety

BSL 1: Material not known to consistently cause disease in healthy adults.

BSL 2: Associated with human disease. Hazard is from percutaneous injury, ingestion, or mucous membrane exposure.

BSL 3: Indigenous or exotic agents with potential for aerosol transmission; disease may have serious or lethal consequences.

BSL 4: Dangerous/exotic agents which pose a high risk of life-threatening disease, aerosol-transmitted lab infections or related agents with unknown risk of transmission.

3.5 Conclusion

At this level of understanding of what is biosafety, we also need to know, why we need biosafety regulations. The functions of biosafety regulations are considered to be:

- To protect the environment and human from potential risks of harmful biological agents.
- To ensure perceived risks which are not there does not hinder the product developments and biotechnology application.
- Help to inform the society of benefits and risks associated with biological material, and how to manage the risks that may arise.
- Biosafety regulations should not be perceived to be antagonistic to application of biotechnology but a means to ensure safe application. The mechanisms of ensuring safety use are discussed in subsequent sections.

SECTION: 4

CONCEPTUAL ISSUES IN RISK ANALYSIS: RISK ASSESSMENT

4.1 Introduction

The overriding principle of biosafety is the avoidance of risk to human health and safety, and to the conservation of the environment, as a result of the use for research and commerce of infectious or genetically modified organisms. In practice biosafety has to do with regulation of biological product of research based on perceived negative impacts to humans and environment (Section 2.2). As mentioned before, the impact could be known or suspected risks.

The practice also covers safe handling of hazardous biological materials such as infectious microbes, plants and animals. Thus biosafety practices have to have means of knowing the nature and magnitude of risk in order to avoid it. This process of determining the nature and magnitude of risk is what is known as “risk analysis”.

The process of risk analysis has three components. These are:

- (i) **Risk assessment:** This is a scientifically based process consisting of the following steps: i) hazard identification; ii) hazard characterization; iii) exposure assessment; and iv) risk characterization.
- (ii) **Risk management:** The process of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and if needed, selecting appropriate prevention and control options.
- (iii) **Risk communication:** The interactive exchange of information and opinions throughout the risk analysis process concerning hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties. It includes the explanation

of risk assessment findings and the basis of risk management decisions.

4.2 Biosafety Risk Assessment

4.2.1 What is Biosafety Risk Assessment (BRA)?

This refers to the practices of determining the risk of biological agents and their genetic materials. The approach of undertaking BRA has to be scientific-based. However, the process of undertaking BRA is influenced by social and political factors. The practice of BRA is also regulated by national and international standards such as those set under Cartagena Protocol on Biosafety (CPB)

4.2.2 Objective of undertaking BRA

The main objective of undertaking BRA under the CPB is to identify and evaluate the potential adverse effect or risks associated with the introduction of GMOs as products or being released in the environment. The category of risks referred to are on:

- Human health
- Environment (focusing on conservation and sustainable use of biological diversity in receiving environment)
- Food and feed quality (nutritional value, toxicity, allergenicity and other impacts)
- Economic and social impacts

In this regard BRA can be considered as means of characterizing the risk. Information generated in this risk assessment is meant to be used by competent authorities for making informed decision regarding the release of GMOs or handling of any other hazardous biological material which need safety precautions. In this section principles and practices of BRA will be discussed using examples of GMOs, though the same principles and practices are used in handling all biological hazardous materials perceived to have risks to human health and environment.

4.2.3 Basic Principles of Biosafety Risk Assessment

- BRA should be science based and be done using guidelines developed by competent authorities or relevant national and international organizations.
- It should be done on case-by-case. Meaning, information should vary with type of GMO or hazardous biological material, intended use and nature of receiving environment.
- Lack of scientific information should not be taken as acceptance of risk or absence of risk.
- Information generated should be easily understood and reach decision makers.

4.2.4 Components and Procedures of Biosafety Risk Assessment

As stated before, the main activities undertaken in BRA fall into the following components:

- Hazard identification
- Hazard characterization
- Exposure assessment
- Risk characterization

4.2.5 Process Followed in Biosafety Risk Assessment

Conducting risk assessment to establish potential risks associated with transgenic organisms or any other hazardous biological material is done following specified guidelines. The following is a description of processes followed in BRA of transgenic organisms:

- (a) Identification of genotypic and phenotypic characteristics of the GMOs/LMOs that may have adverse effects on human health and biological diversity of receiving environment.
- (b) Evaluation of the likelihood of adverse effect happening by taking into account of the level and kind of exposure of the receiving environment and nature of LMO.

- (c) Evaluating the level of risk consequences if the adverse effect occurs.
- (d) Estimating the overall risks posed by the GMOs/LMOs based on the evaluations made in section (a) and (b) of the likelihood and consequences to be caused by adverse effects associated with genotypic and phenotypic characteristics of the GMO to be introduced.
- (e) Use information obtained to make recommendations on whether the risks are acceptable or manageable. Also indicates whether there is need to identify the strategies to manage the risks.
- (f) In case there is uncertainty on the level of risks. There three option to follow:
 - Request further evaluation on specific issues of concern.
 - Implement appropriate majors to manage the risk in case they occur (risk management strategies).
 - Recommend undertaking monitoring of GMOs in the receiving environment once they have been released.

4.2.6 Definition and Measurement of Harm in BRA

In undertaking biosafety risk assessment, there terminologies which are applied that require definition. These include: Risk, harm, uncertainty and hazard.

What is Harm?

Harm is defined as an adverse effect of an action that results in injury or damage to human health or any valuable component of the environment. It could also refer to incidence that may result on any negative impact on human wellbeing and the environment. This may include any action that may result in loss of value of anything with economic or cultural value.

What is Hazard?

The **hazard** we talk about in BRA is the act or phenomenon which has a potential to produce harm or any other undesirable consequences. In the biologic or laboratory situation, you may be considering such hazards as

infections, zoonotic diseases, injuries, economic outcomes, etc. In modern biotechnology the phenomenon could be toxic, allergen in food, and transgene in which could escape into the environmental causing undesirable impact.

Also a hazard is considered to be an act or phenomenon that has potential to produce harm or other undesirable consequences to humans or what they value.

What is Uncertainty?

Uncertainty describes situation in which we cannot calculate the probability of hazard, but we know the type of hazard that may occur

What is a Risk:

A concept used to give meaning to things, forces, or circumstances that pose danger to humans or what they value.

$$\text{Risk} = \text{Hazard likelihood} + \text{Uncertainty}$$

4.2.7 Tools of Risk Assessment

- Guidance documents
- Risk group definitions
- Type of risks to consider

SECTION: 5

BIOSAFETY RISK ASSESSEMENT OF FOOD AND FEED DERIVED FROM TRANSGENIC ORGANISMS

5.1 Types of Food Derived from rDNA Technology

Environmental benefits of food derived from transgenic organisms mainly plants have been described in Section 6. The benefits associated with food safety and concerns of foods derived from GMOs will be addressed in this Section.

The food and feed derived from rDNA technology include food or feed from transgenic plant crops, animals, microorganisms and enzymes from microorganisms used in food processing. It also includes food derived from animals treated with hormones derived from rDNA technology, such as growth hormones. As stated before that biosafety is not an inhibitory process to technology development and application. One has to understand the overall driving force for production of transgenic foods has been to improve quality and quantity of food, and the production processes over conventional foods.

5.2 Benefits Associated with Food and Feed derived from rDNA Technology

It is always a better approach to understand both the benefits and risks associated with transgenic organisms or food derived from them. The following is a list of some of the benefits associated with food derived from rDNA technology:

- (a) Development of novel foods with improved supply of indispensable amino acids, reduced toxins and allergens.
- (b) Food with preformed antibodies to reduce risk to diseases
- (c) Food with better nutritive value, texture and palatability (i.e. Soya with cholesterol reducing peptide).
- (d) Developing cereals with resistance to infections by fungal species causing aflatoxin toxicity.

- (e) Food from plants with resistance to frost or drought.
- (f) Meat from animal obtained from cloning as means achieving high productivity.
- (g) Fast growing, frost and diseases resistant transgenic fish.
- (h) Food from fast growing transgenic animals with better feeding and food conversion. Examples of such animal inserted with a gene for higher production of growth hormones.
- (i) Food from animal treated with growth hormones derived from rDNA technology. This is done to achieve fast growth and high food yield.
- (j) Food processed with enzyme derived transgenic microorganisms.
- (k) Production of veterinary vaccines from transgenic plants used as animal feed.
- (l) Production of functional foods and feed with health benefits.

5.3 Scientific-Based Biosafety Concerns on Food and Feed Derived From rDNA Technology.

The main concerns on safety of food derived from transgenic organisms or organisms treated with rDNA hormones are mainly on safety of human health. The impact on human health could be from:

- Allergens
- Toxicity of novel proteins
- Dietary impact of nutritional changes
- Antibiotic resistance due to utilization of antibiotic resistance genes in food crops

5.4 Biosafety Risk Assessment Steps of Food and Feed Derived From GMOs

The use of food derived from GMOs is an issue which has raised both national and international food regulatory systems. The safety of food has to meet the food safety standards and the production processes has also to follow certain regulations.

One of these international regulatory systems to regulate the food derived from GMOs is the “*Codex Alimentarius*”. This consists of guidelines and procedures for food safety risk assessment, including assessment of food and

feed derived from GMOs or their products. The steps recommended by *Codex Alimentarius Commission* (CAC) for food safety assessment are:

(A) *Molecular characterization of transgenic food crop before it is placed on the market or released.*

It is important to have information which will be used by product evaluators to assess the safety of the GMOs or products derived from them. Information required includes:

- Description of the genetic material of the donor and recipients used in transformation of the organism used as food and feed.
- The nature and source of the gene vector.
- Description of the genetic modification or transformation methods and functional consequences.
- Characterization genetic modification (site of new gene, sequence transcription and expression of product).
- Expresses protein characteristics.
- Gene inheritance and stability.
- New gene detection and identification.

(B) *Assessment of toxicological aspects of the GMO-derived food and feed*

To assess the toxicological aspects of the GMO-derived food and feed requires undertaking a number of analyses to provide information on the safety of food or feed. The recommended analyses include:

- Comparative analysis of molecular characteristics and nutritional composition of the GMO and non-GMO variety. From this comparative approach arises the concept of “substantial equivalence” which will be discussed later. This should include information on expressed DNA sequence, marker DNA and potential allergenicity.
- Toxicological assessment on humans and animals healthy different food metabolites.
- Toxicity as a result of food processing.
- Whole food toxicological testing.
- Evaluate whether transgene increase natural toxins of food or feed (case of cassava).

Information derived from these analyses can provide a base for making decision on whether the food is safe or not. These analyses are normally conducted using guidelines provided by competent authorities.

(C) Assessment of allergenic aspects of GMO food (both edible and respiratory allergenicity)

Allergens are important source from novel food derived from biotechnology. Because of this source biosafety regulatory mechanisms demand the assessment of GMO derived food and feed for allergenicity properties. These assessments include:

- Screening for proteins with potential allergenicity to know whether they are expressed in edible parts or whole plant or at certain level of plant growth.
- Identify the source of transgene encoding the allergen.
- Conduct specific serum screening test on the allergenicity of the new protein.
- Testing the allergenicity of the whole GMO plant crop in comparison with the non-GMO variety.
- Determine occupational health hazard to farmers on pollen effect.

(D) Evaluating the nutritional aspects of the GMO-derived food

The approach is different from the evaluation of feed. The steps to follow are:

- Assess nutrient composition of the food.
- Assess the biological efficacy of the nutrient components of the food.
- Assess dietary intake and nutritional impacts.
- Assess the impact of non-nutritional components of the food.
- Where intentional modification of the food nutritional quality is done, then impacts of new biomolecules need to be tested.

(E) Evaluating the Nutritional Aspects of the GMO Feed

This is done for GMO-derived feed with enhanced nutritional characteristics such as bioavailability of nutrients. The steps include:

- Assess the bioavailability of nutrients from GMO derived feed relative to conventional feed crops.
- In case of GMO-derived feed to enhance animal performance through nutrient density or levels of nutrients. Then make a comparison of nutrients with conventional varieties supplanted with nutrients.
- Evaluate impact of GMO-derived feed on the food composition of animal fed with GM feed

(F) Post market evaluation of GMO-derived food and feed

This evaluation is done to confirm pre-market risk assessment to see if the products have unpredicted adverse effects. This helps to obtain information that can be used to predict long term effects on the health of consumer and nutritional status of the GMO-derived food or feed. This requires long term monitoring.

5.5 The Concept of Substantial Equivalence

The guiding principle of in evaluation of biotechnology derived foods by regulatory agencies in United States of America (USA) and European Union (EU) is the concept of “substantial equivalence”. This states that:

- *“If a novel food is found to be substantially equivalent in composition and nutritive characteristics relative to the conventional food, it can be regarded a being safe as the conventional food. Such novel does not require extensive safety testing or biosafety risk assessment”.*

The use of substantial equivalence approach provides a starting point for assessment of biotechnology derived food and feed. This would mean that:

- Characteristics of the GMO-derived food or feed that are different from conventional food or feed can then be a starting point of safety assessment of the novel food or feed.
- It also provides a guide of defining what is potentially hazardous in the biotechnology derived food.

SECTION: 6

ENVIRONMENTAL SAFETY: THE CASE OF ENVIRONMENTAL BIOSAFETY RISK ASSESSEMNT OF TRANSGENIC CROPS PLANTS

6.1 Introduction to Environmental Biosafety Risk Assessment

Agriculture and food crop production is among the areas where rDNA technology has had an impact to the society. This impact has also been associated with a lot of concerns on the safety of the technology than in other applications. The safety concerns has been a worldwide issue, this makes it essential to have special consideration in biosafety risk analysis.

The issues of environmental biosafety risk assessment requires balancing of benefits and risks, needs to be communicated to the public and policy makers for them to make informed decision on whether to accept the transgenic food crops or reject them. The acceptability referred here is not meant accepting the GM food crops as safe, but accepting them based on their benefits versus manageable and acceptable risks. In this part, the benefits, potential hazards associated with transgenic crops and concern are discussed. Also environmental risk assessment procedures are described IN this section.

6.2 Benefits Associated With Transgenic Food Crops

There numerous benefits which have been a driving force for development and commercialization of transgenic food and feed crops. These benefits are grouped into four major categories.

- (i) Plant crop attribute benefits. These include:
 - Increased crop resistance to pest and diseases
 - Increased resistance to abiotic environmental stress
 - Increased crop yield
 - Decreased production costs
 - Improved nutritional value

- Improved post harvest shelf life of fruits and vegetables
- Reduced allergens and toxin concentrations
- (ii) High quality and value of processed foods.
- (iii) Environmental benefits on agro-ecological systems.
 - Herbicide –resistant enables use environmental benign herbicides and increases flexibility in crop rotation.
 - Facilitation of non-till agriculture reducing soil erosion.
 - Increased yield per area of land use, reducing deforestation and loss of biodiversity.
- (iv) Improved diet, nutrition and human health benefits:
 - Through improved food quantity and quality.
 - Improved specific composition of the food to meet specific need (the case of edible vaccines).

6.3 Science-based Environmental Concerns on Release of Transgenic Crops

The environmental concerns on release of transgenic crops into the receiving environment are based on the nature of transformation and type of transgene introduced into the plant. These safety concerns can be categorized into the following categories:

- (a) Fear of Herbicide resistance transgenes escaping to the wild and weedy relatives. This could have the following consequences:
 - Increases fitness which can result in persistence and intensiveness;
 - Production of super weeds.
- (b) Insect resistance transgenes can produce toxins damaging non-target organisms including beneficial ones.
- (c) Antibiotics resistance marker genes can result in super pathogens, with resistance to regular antibiotics.
- (d) Fear of production of terminator genes that could lead to production of sterile seeds which could limit public access to genes or seeds of food crops.

6.4 Steps in Environmental or Ecological Impact Risk Assessment of Transgenic Food Crops.

In conducting ecological impact assessment of transgenic food crops, the same principles of risk assessment described in *Section 5.4* are applied. These steps include:

- (a) Identification of potential adverse effects or hazards or harm. These should address the following science based concerns:
 - Effect of the transgene on the fitness of the GMO within the ecosystem in which it is released (*Note variation of ecosystems*).
 - Assessing the ability of the GMO to escape and disperse in diverse communities or ecological ecosystems.
 - The ecological stability of the receiving ecosystem to be affected.
- (b) Evaluate the ability of the GMO to become established in the ecological system as risk can occur only when it is established. The ability to be established is determined by:
 - Influence of transgene on fitness.
 - Influence of transgene on adaptability, giving ability to be invasive.
 - Enhancing existing traits which could result in ecological imbalance.
 - Creating novel metabolic products with adverse environmental impact.
- (c) Evaluate the ability of GMOs to escape from agro-ecosystem, disperse and become feral. One should note the different agro-ecological systems will receive different impacts from the GM crop. This means the evaluation under risk assessment has to be area and crop specific.
- (d) Assess the likelihood of GM crops displacing other species in the ecosystem. This could be a risk to biological diversity as it can cause extinction of species. This can happen if natural biodiversity have lower fitness to compete with GM crop for resources.

SECTION: 7

PRECAUTIONARY PRINCIPLE IN BIOSAFETY RISK ASSESSMENT AND DIVERGENT INTERPRITATIONS

7.1 Background

After 1992, several international treaties, policies and regulatory systems addressing biosafety of genetically modified organisms and products derived from them have created. Many of these international treaties, policies and regulatory systems require compliance by member countries who are a party to their development or formulation. This includes having national biosafety policies and regulatory mechanisms. However it has been observed that there have been controversies in interpretation of the guiding principle in biosafety resulting in further difference in biosafety practices. This has affected trade and access to the benefits of rDNA technology development. The best example is the controversy on GMO food aid to African countries and the trade barriers of GMO food and feed imposed on USA food export to the EU, under the argument of food safety. These controversies will be discussed under the “*Different Interpretations of Precautionary Principle*”.

7.2 The Precautionary Principle

As stated before, the *Precautionary Principle* under the UNCED (Agenda 21) is a policy tool for making decision about risk management under condition of uncertainty. The principles states that “where there threat of serious or irreversible damage to the public health or environment, lack of scientific certainty shall not be used as a reason of postponing cost effective measures of preserving environmental degradation”.

This principle has received different definitions and interpretations in different countries and the subsequent national and international biosafety policies that followed the UNCED – Rio Declaration. The only common interpretation on of the principle is that it was meant to protect human health and environment from adverse impact of biotechnology. Based on this view, it has been a base for undertaking processes of risk assessment, risk management and risk communication in biosafety practices.

Some school of thoughts argues that, lack of certainty is not an excuse of not making a choice. This would mean in any technology development, where there is no proof of safety no product should be made using that technology. Others argue that this is wrong as there is no technology which has zero safety. Therefore there is no technology which could meet the requirement of zero safety. The precautionary principle as applied under the Cartagena Protocol on Biosafety can be used to rationalize bad choice or misused to create protectionisms in trade involving GMOs derived foods as has been the case between EU and USA.

7.3 Main Features of Precautionary Principle.

Before discussing the divergent views and application of the precautionary principle, it is important to note the features and application of the principle. These are:

- From ethical point of view, it requires that demands of the society to evaluate the technology in this case including biotechnology.
- Demands the needs to predict consequences of technology, and where the biotechnology application raises threats to human health or environment, precautionary measures should be taken even if some causes and effects relationship are not fully established scientifically.
- Also from ethical point of view, the principle demands that human development should be achieved without compromising environment health.
- It provides guiding principles of developing regulatory tools like risk management and biosafety regulation in general.
- Requires that biotechnology products should be regulated until compelling evidences proved that they are safe to the environment and human health.

These features reflect the strong emphasis of risk assessment approach in evaluating the safety of biotechnology to environment, public health, culture and social status of humans. At the same time, the precautionary principle assumes that where there is lack of scientific certainty in some cases, then risk analysis is required. This has lead to some policy makers and scientists to weigh the suitability of “Precautionary Approach” against the “Reactive Approach” regulatory system. These two approaches have resulted in the differences in interpretation of the Precautionary Principle by USA and EU. The USA is using the reactive approach to risk regulation of biotechnology

while EU has been using the precautionary approach. The different ways the precautionary principle is perceived is discussed in the following section.

7.4 Comparisons of Approaches to Biotechnology Risk Regulation.

There two risk regulation approaches which are being used to regulate the impact of biotechnology to human health, environment, culture and social status of human societies. These are known as “Reactive or Preventive and Precautionary Approaches”.

(A) Reactive Approach Regulation System: This approach has been adopted from the risk regulatory systems for agrochemical and human drugs known to cause severe side effects: This has the following features:

- Risks are dealt with once they have been established or when they happen.
- Products with risks lead to demand of better and risk free products.
- The decisions on need of regulation are based on what benefits the product give to the society. Where benefits outweigh the side effect the product is acceptable.

(B) Precautionary Approach Regulation System: This is considered to be a proactive approach, which was applied for the first time in regulation of rDNA technology products or GMOs. This has the following features:

- The hazards have to be assessed before products or GMOs are released into the receiving environment.
- Hazards have to be predicted before they happen or before products are marketed.
- Where products for commercialization are considered, the regulation system has to be part of the industrial production process.
- The regulations are not applied in experimental stage.
- There is likelihood for the regulation system to be restrictive to product development as not all risks can be predicted under natural conditions.

- Use of this regulation system creates additional costs in product development. This also delays products reaching the markets.
- The high costs involved in regulation of products from initial industrial development process to the point of commercialization, excludes poor nations and companies to venture into biotechnology product development.

7.5 Impact of Divergent Risk Regulation Approaches on Biotechnology on Developing Countries.

The divergent approaches to risk regulation have many implications both on the biotechnology development and development of policies related to application and regulation. This has had impact also on trade involving biotechnology derived foods and acceptance of food aid with GMO foods.

Discussion question:

- (i) *Why persistent toxic agrichemicals pesticides like DDT are being allowed to be used in Africa while Bt derived crops are restricted?*
- (ii) *Which of these regulated products have more harm to human health and adverse impact to non-targeted organisms?*

SECTION: 8

BIOSAFETY RISK MANAGEMENT AND COMMUNICATION

8.1 Biosafety Risk Management

8.1.1 Definition of Biosafety Risk Management

Biosafety risk assessment is defined as actions taken to regulate, manage and control risks identified in biosafety risk assessment. Biosafety risk management (BRM) is a series of procedures undertaken to ensure that biological agents that can have adverse effects on human health and safety are safely handled and contained. The same safety procedures are also accorded to the environmental safety. These procedures and practices are tools of biosafety regulatory mechanisms, which regulate use and research on potentially harmful biological organisms or the genetic materials.

Risk management practices include the following activities:

- Taking measures to reduce or minimize the adverse effects to acceptable level.
- Create regulatory measures of handling GMOs and other biological agents with potential adverse effects.
- Identify traits in living organisms or GMOs and designate appropriate management practices.
- Selection of appropriate prevention and control measures of risks identified under risk assessment procedures.
- Set containment levels or risk minimization measures.
- Measure the effectiveness of risk control measures.
- Monitoring the impact of GMOs released in environment.
- Control of transboundary movement of GMOs.
- Implement measures to manage uncertainties recognized in risk assessment.

It is important to know that where there is no option to minimize the risks or where risks outweigh the benefits. The risk can be judged to be unacceptable relative to benefits and potential mitigation measures.

8.1.2 Biosafety containment

The BRM principles and practices also cover the principle of containment as safe handling of biological material. The purpose of containment is to reduce the exposure of humans in research facilities or laboratories, and the environment to potential biological hazards associated with GMOS. The same principles are applied in microbiological and biomedical research. The containment is categorized into physical and biological.

(a) Physical Containment

This refers to use of physical facilities to limit the spread of of harmful organisms or GMOs and their genetic material. These facilities like:

- Containment barriers like biological safety cabinets class II, person protective gear.
- Containment equipment like biosafety cabinets.
- Special designed laboratory rooms and greenhouses with biosafety practice considerations.

(b) Biological Containment

This method refers to use of biological methods to ensure that neither the GMOs nor its genetic material is released into the environment. This is done by altering the reproductive portions of the GMO or its means of reproduction.

The main purpose of effecting biological containment is to protect the environment. It is done on animals and plants which are exotic or known to be pests, and it is also done to transgenic plants and animals which could be hazardous or pests. In most cases biosafety regulatory systems demand that this is done transgenic plants under field trial.

Containment level is also determined by the level of severity or scale of risk. The level march the risk levels assigned to the biological material under risk assessment. As stated before, this means those laboratories and other research facilities requiring containment of biohazards has to be designed

with specific containment requirements for the activities taking place within. They have to provide safety against risk levels they are designed for.

8.1.3 Biosafety confinement

These are measures or strategies to limit the unintentional spread of experimental animals or plants and their genetic materials within designated limits. It is done to isolate potentially hazardous organisms or GMOs from the environment, and sexually compatible organisms. This also exist in two categories of biological and physical confinement strategies.

(a) Physical confinement strategies:

- Geographical or special isolation.
- Use of physical barriers such as walls, fences, screens to keep away humans or animals or prevent movement of pollen.

(b) Biological confinement strategies:

- Reproductive isolation, this can be done in different ways. This includes keeping GMO animals or growing plants where there are sexually compatible organisms. In case of transgenic plants efforts should be made to prevent production of viable pollen. This can be achieved by having sterile male, producing transgenic plants with sterile seeds, growing plants with different flowering periods

8.1.4. Precautions to take under biosafety risk management

Risk management measures may not be sufficient to control the risk. Where GMOs are concern, strategies to manage risks have to be applied from product design to the level of testing the different use and interaction with the environment which receive them.

8.2 Biosafety Risk Communication

8.2.1 What is biosafety risk communication?

This is a process in biosafety risk analysis that involves explaining the benefits and risks of biotechnology products and applications. It involves the methods of understanding scientific and technological risks and how these risks are communicated within the social-political structure among individuals, group and institutions. As a tool of policy making of deciding and balancing benefits and risk, it requires that both risks and benefits of biotechnology are addressed during communication or information delivery to the public.

8.2.2 What is the purpose of risk communication in biosafety practices?

Policy makers, scientists and biosafety regulators need to know the functions and objectives of risk communication in biosafety practices. The procedures in biosafety risk communication include the following practices:

- To educate the public of potential hazards or risks associated with biological agents.
- Training of personnel handling biological agents of risks on safe practices.
- Insure availability of warning signs indicating sites with hazards
- Creating the practice of putting hazard labels on laboratory equipments or other facilities with potential of being contaminated.
- Create procedures of specifying hazard in the laboratory or any other environment with hazardous materials (biological, chemical and physical). This includes pontial hazards that may occur in facilities handling GMOs such as greenhouses and land with field trial of transgenic crops.

Generally risk communication serves the purpose of allowing the public to perceive the real and anticipated scientific risks from potentially hazardous biological agents as assessed under risk assessment processes. It serves to fill information vacuum.

8.2.3 Components of biosafety risk communication (Risk communication model)

- Identification of issues associated with risk and concerns
- Assessing risk and benefits
- Identifying and analyzing options
- Selecting the strategy
- Implementing the strategy
- Evaluating the results

8.2.4 How to achieve effective risk communication

- Use responsive consultation processes.
- Consultation processes should be interactive and involve all interested parties (government, industries, academia, media and consumer groups).
- The views of all interested parties should be sought and safety issues raised during consultations should be addressed in risk assessment and risk management processes.
- Risk communication should be done in a transparent manner, such that issues of concern raised during BRA and BRC processes are documented and be made available to public scrutiny.
- Communication must be done in a manner that safeguards the confidentiality of commercial and industrial information.
- Report on safety assessment and other aspects of decision making process should be available to all interested parties.
- Risk communication essentially has to take place during the whole process of risk analysis.
- Deliver information in a way that is culturally sensitive.
- Take concern of proper media coverage. Media can concentrate on sensational issues resulting in misconception and misinterpretation of risks and benefits of biotechnology.

8.2.5 Basic rules or guidelines for biosafety risk communication

- (i) Accept and involve the public or any legitimate partners in decision making. This paves way for the public to accept the

benefits, and be able to balance benefits and risks of biotechnology application.

- (ii) Provide information through credible or trusted sources. This also requires the identification of the means to channels information to the public. These channels could be academicians or religious leaders as they tend to command trusts from society.
- (iii) Be honest, frank and open in delivering information on benefits and risks. This can be achieved by having more communicators to make the public understand that no single person has all the answers on risks of biotechnology.
- (iv) Be proactive and provide information that balance issues of risk and benefits of biotechnology.

SECTION: 9

PERCEPTION AND MISCONCEPTION OF BENEFITS AND RISKS OF BIOTECHNOLOGY

9.1 Background

There is divergent approach on the definition and interpretation of the precautionary principle as it is stated under the UNCED and the Cartagena Protocol on Biosafety. The most clear and practical example is the difference in the interpretation between the USA and EU countries. This difference in opinion has significant impact on the perception of biotechnology risks and benefits in developing countries. It has created misconception on the benefits and risks of biotechnology application, particularly on transgenic crops and food relived from rDNA technology.

The difference in interpretation of the precautionary principle which is a policy tool of biosafety risk assessment and management of biotechnology has resulted in policy debate on application of biotechnology. Again this has strong impact on development of biotechnology and biosafety policies in developing countries. In some developing countries the policy debate has focus more on perceived risks with very little consideration on benefits of biotechnology that can solve numerous problems in developing countries. The main focus on perceived risks in policy debates has also created low acceptability of biotechnology by the public in these countries.

Given the promise of biotechnology in solving societal problems, its applications need to be known to the public in developing countries. The applications include solving problems related to diseases, environmental pollution, food security and energy in developing countries. There is an urgent need to create objective assessment of benefits and risks of biotechnology to abate the unscientific arguments on the perceived risks which create misperception and low acceptability. The specific factors contributing to misconception of biotechnology and means to abate it will be discussed in this section.

9.2 Factors Contributing to Misconception and Low Acceptability of Biotechnology Application

There are substantial benefits of biotechnology application, in solving numerous societal problems. There are also negative perceptions and misconceptions on biotechnology benefits and application. The result of these perceptions and misconceptions is low acceptability of biotechnology applications. As stated before the main are of resistance to biotechnology application is on production of GMOs. There cases of rejection of food aid in African countries because the food was derived from GM food crops. This is not a case for Africa only but a global issue at the moment.

Factors contributing to misconception and low acceptability of biotechnology applications include:

- (i) The process of producing and testing GMOs such as GM food crops and other products is complex beyond the understanding of most consumer and the general public. This makes it to appreciate the associated benefits. On the other hand this complex process combined with industrial secrecy involved with intellectual property right (IPR) issues increases the fear of unknown risk to health and environment. This also contributes to low acceptance of biotechnology foods.
- (ii) Many developing countries lack a policy on biotechnology application. This has made the public in these countries to be poorly informed on the potential benefits of this technology.
- (iii) There is a lot of ambiguous and sensational media coverage of GMO food and feed crops. This has contributed to rejection rather than reassurance on GM food safety.
- (iv) Negative media coverage of biotechnology products, mainly GM food crops has resulted in stigmatization of the public to fear their introduction being a risk to human health and environment.

MAIN CONCERNS RAISED BY MEDIA WHICH ARE APPLICATION OF TRANSGENIC FOOD CROPS AND MODERN BIOTECHNOLOGY

- Perceived risk to human health, mainly from *Bt*-crops which has an endotoxin protein pesticide.
- Perceived risk to the environment, mainly on harm to the biodiversity through gene flow from GM crops to wild relatives.
- Unknown long term consequences of GMOs
- The unnatural breeding process in animal and plants.
- Fear of GM crops replacing traditional crops in developing countries which will harm the economy of these countries.
- Use of patented seed from multinational companies poses a risk to small scale farmer who will have to buy seed always. This will have a cultural impact for people who are always used to preserve seeds.
- Biotechnology risks being linked to outbreak of new and emerging diseases like:
 - *Mad Cow Disease or Bovine spongiform encephalopathy (BSE) in case of food safety*
 - *Acute respiratory syndrome (SARS)*
 - *West Nile Fever Virus*
 - *Avian flue*

Potential risks raised by the media are not given scientific approach. At the same time the benefits of biotechnology which were a driving force to development and commercialization of GM crops are normally not advanced to the public.

9.3 Steps to Combat Misconception of Biotechnology Risks and Benefits

Harnessing the benefits of biotechnology requires combating factors which contribute to misconception and low acceptability of biotechnology application or products. This can be achieved through a number of initiatives that include:

- Create proper initiatives for communication and outreach to the public, policy-decision-makers to increase informed decision by those involved in policy making and assessment of biotechnology risks and benefits.
- Communicate to the public the driving forces behind the global trend on research and development in biotechnology application to solve the societal problems on food, health and environmental services.
- Promote public informed debates on risks and benefit of biotechnology based on scientific principles, while addressing ethical and social concerns. Creation of informed debate will lead to informed decision on acquisition of relevant biotechnology to meet the specific societal needs.
- The informed debate should involve the general public, scientists, policy maker and consumer groups of biotechnology products or any other civil society group.
- The communication of correct information should be achieved through use media, and source of information should come from competent institutions and individual experts.
- Cases of risk assessment under the application of the precautionary principle should be used to address the local risk concerns rather than global risk concerns. This will increase the public trust on biosafety risk assessment and promote product acceptability.
- The public need to know the risks associated with biotechnology application. At the same time they need to know who will be responsible for reliabilities associated with those risks.
- Building capacity in developing countries to enable them to undertake scientific, social and economic evaluation of different biotechnology applications.

9.4 Comparison of Risk Perception and Acceptance of Technologies: Biomedical, Industrial and Agricultural Biotechnologies

The public need to know how science and technology drive the social and economic development of any society. They also need to know that every technology has to be assessed of its potential impacts to the health, environment and social status of human beings where it is applied. The public need to engage in the discussions on what makes pharmaceutical and diagnostic biotechnology to be out of the anti-biotechnology movements. The regulatory processes used to other technologies, such as pesticide, X-ray use, electromagnetic and cellular phone radiations. They should be informed of factors which makes these technology applications to be easily acceptable. Factors like:

- Benefits of medical biotechnology are clearly seen by consumer while those of GM food crops it is difficult to realize their benefits.
- Pharmaceutical and vaccine products like recombinant insulin are accepted without reservation on process of production.
- Drug side effects are accepted when the benefit to the patients out weigh negative effects.
- Extensive use of pesticide to combat locust and pest birds in Africa, the benefits outweigh the environmental and human health effects.
- X-ray impacts are allowed also when they provide health benefits and solve health problems that outweigh side effects.
- Chlorination of water is still allowed because it eliminates potential pathogens, this outweighs the facts that it also creates potential carcinogenic compounds in water.

9.5 Consequences of Misconceptions on Biotechnology Application

While there are arguments that restrictive regulatory systems can prevent some countries to benefit from acquisition and safe application of biotechnology. Misconception is more of a problem in accepting and accessing biotechnology benefits to some countries, than the present biosafety regulatory systems based on restrictive precautionary principle approach. Some of these misconceptions are:

- In pest control measures, non-target insects are better-off with current pesticides than with Bt-crops.
- Use of chemical herbicides and pesticides is accepted as less environmentally damaging than pest resistant *Bt*-crops with herbicide resistance in combination with use of degradable and environmentally benign herbicides.
- Herbicide resistant crops are more harmful to the environment and soil fertility than heavy tillage of cultivated land or monoculture farming systems.
- In most cases environmental benefits are not weighed against potential risks, simply because the public debate focus only on the risks associated with biotechnology.
- There is also a misconception that advances in animal cloning will lead to human cloning, a factor which is still morally not acceptable.
- Some sited cases on risk assessment of GM plants are extrapolated to every environment rather than considering risk assessment to be a factor of specific organisms and environment where it is applied (The case of Monarch Butterfly).

The major consequence of these misconceptions on modern biotechnology application is the creation of fear among the public and decision makers on potential harm of some applications of biotechnology. The specific consequences are:

- (i) Research and development in biotechnology is being inhibited in developing countries by uninformed policy debates.
- (ii) In case of agriculture policies they are being decided in environmental forum and policies. This does not provide a chance for biotechnology to address specific needs of developing countries whose agricultural crops and systems are not of interests to multinational companies which mainly focus on crops of interests to rich farmers.
- (iii) The issued of current debates concentrating on the perceived risks of biotechnology also creates public rejection of biotechnology application mainly in plant and animal breeding.

9.6 What the Public should be told about Benefits of Biotechnology in Developing Countries.

The public needs to be informed of the proper information on societal problems in developing countries which biotechnology can offer solutions. There is a need to have informed population on issues related to the benefits and risks of biotechnology. These include issues like, where biotechnology can be used beneficially:

- (i) To reduce the level of nicotine in tobacco, keeping the demand of the cash crop.
- (ii) To eliminate toxins and allergens in foods like cyanide from cassava, aflatoxins in groundnuts making the food safe for human health.
- (iii) In production of drugs and vaccines for diseases like tuberculosis and HIV-AIDs.
- (iv) To combat loss of genetic biodiversity caused by intensive agriculture with low production in developing countries.
- (i) To reduce the use of chemical pesticides, this is a threat to non-target microorganisms and a cause of major loss of biodiversity.
- (ii) Use of biotechnology in the production of human and animal drugs, vaccines and diagnostics.

These beneficial biotechnology applications can be explained to the public through competent authorities and trusted channels to counter the misconceptions and promote acceptability of responsible use of biotechnology.

SECTION: 10

BIOETHICS: ETHICAL AND SOCIAL ISSUES ARISING FROM BIOTECHNOLOGY INNOVATION AND COMMERCIALIZATION

10.1 Background

Biotechnology applications have many concerns that are not necessarily scientific, and which need to be addressed before the benefits of the technology can be accepted. These concerns are also referred to as ethical, legal and social implications (ELSI) of biotechnology.

10.1.1 What is ethics?

Definition 1: Ethics refers to moral judgment of what is good or bad or harmful. It also refers to making a choice on what is good or bad or harmful. The judgments are influenced by cultural and religious beliefs.

Definition 2: Ethics can be defined to be “Evaluative studies of arguments about which action are right or wrong”.

From the discussions in previous sections of this book, it has come out clearly that acceptance of biotechnology and regulations that govern the procedures of ensuring safe use involve making choice of the good or benefits and the negative impact of biotechnology. This is what has developed into the discipline of “*bioethics*”.

10.1.2 What is bioethics

Bioethics is a discipline which has been in the past, a domain of medical science research and practices. It arose as an effort to change social practices in medicine and research. Of recent it has become a wide discipline covering the decision making processes in the applications of biotechnology. It is used policy maker and biosafety regulators in regulating practices of biotechnology research, application and commercialization. On the other

hand there are multiple patterns of linking ethics to biotechnology applications. This has resulted in different definitions of bioethics.

Definition of Bioethics

Definition 1: The study of ethical issues and decision making associated with using of living organisms.

Definition 2: The learning of how to balance different benefits, risks and duties when using living organisms.

Definition 3: Bioethics as applied to biotechnology can also be referred to as the arguments on balancing the benefits and risk of biotechnology to the society.

As a discipline, bioethics involves ethical analysis of issues to find out who would be affected by decision made in applying new science and technologies, medicine, biological and environmental sciences. It important to not that bioethics consideration is important in many policy issues such that many governments have bioethics policies. These policies include having regulatory systems and advisory bodies.

Discussion Questions:

1. What factors influences bioethics considerations and concerns on biotechnology?

10.2 Principles of Bioethics

The guiding principles in thinking and arguments on bioethical issues are centered on evaluation of actions being done in applying biotechnology.

These are adapted from medical ethics to environmental ethics as well. These principles are:

- (a) *Respect for autonomy*: Respect for individual to make choice of one's action.
- (b) *Beneficence*: Identify who benefits from your good action and in what ways the benefits are realized.
- (c) *Non-maleficence*: This is the principle of human obligation not to do any harm. Then if harm is done the following action must be taken:
 - Determine the parties that may be harmed by your action.
 - Determine the steps to be taken to minimize harm that may come from your actions.
 - Assess whether you have communicated risks involved in your action in a faithful and open manner.
 - In case disaster occurs because of your action, identify how to avert the harm caused by your action.
- (d) *Regard for Justice/Equity*: Principle of ensuring fair treatment and equity through reasonable resolution of dispute. To practice fairness the following actions are required:
 - Identify all the vulnerable groups that may be affected by your action.
 - Plan how to make your action equitable.

Discussion Question.

Describe practical examples that resulted in development of medical bioethics.

10.3 Theories of Bioethics

Bioethics as a concept can be viewed in three different ways which describe relationship between people in the society and their normal lives. The way bioethics is viewed is:

- (a) *Descriptive bioethics*: The way people view life, their interactions and responsibilities with living organisms in their life.
- (b) *Prescriptive bioethics*: This is the ethics of telling others of what is good or bad and what principles are most important in judging what is good or bad.
- (c) *Interactive bioethics*: This is the discussion or debates between people, groups within the society or communities about the descriptive and prescriptive bioethics. This is also the model of bioethics that increases communication and dialogue within the societies to clarify doubts and develop a universal acceptability of things. This can be said to be the bioethics model that lead to global convention on safe handling of biotechnology.

10.4 Cases of Application of Biotechnology in Medical Research and Practices with Bioethical Issues

Application of biotechnology in medical practices in many countries is subjected to ethical and biosafety regulations because they have social and safety concerns. The following are examples of such biotechnology applications with bioethics concerns:

- (i) *Human organ for transplant*: This is opposed by some people because of religion, while others oppose it as it could lead to trading in human organs. Some urge that the trade would benefit recipient patients in developed countries and cause harm to donors in poor developing countries. Bioethics regulatory systems require consent of the donor to provide the organ, and this should not cause harm to the donor.
- (ii) *Pharmaceutical drug development and trials*: There ethical concerns in development and clinical trials of drugs. The concerns arise from the facts that drugs have both therapeutically and toxic effects thus they have to be used with precaution to minimize potential adverse impact to the user. Bioethics regulations prohibit experimentation of medical and clinical drug trials to vulnerable people that could harm them. The consent of people to be used in the clinical trial is a requirement in good medical research practices. Information on the people used for clinical trial has to be confidential. They need to be

informed if the results are clinically useful. Avoid creating information that would create prejudice to group of people or race.

- (iii) Therapeutic human cloning
- (iv) Human Embryonic Stem Cell Research
- (v) Prenatal genetic screening and cases of therapeutic abortion
- (vi) Predictive gene testing
- (vii) Surrogacy and assisted reproduction
- (viii) Brain death
- (ix) Telling truth about terminal diseases
- (x) Gene therapy

10.5 Bioethical Issues in Biotechnology Research and Application

One of the global bioethical issues is the concerns on the impact of biotechnology to the environmental sustainability or biodiversity. This has lead to environmental biosafety policy at global level under “Precautionary Principle” approach to ensure safe use of biotechnology. This approach has resulted into the “*Convention of Biological Diversity - CBD*” and the “*Cartagena Protocol on Biosafety - CPB*” as ethics regulatory policies for ensuring human activities is done with less or no harm to the environment health.

10.6 Bioethical Issues on rDNA Technology Based on Reactive and Precautionary Risk Regulatory Approaches.

The divergence in interpretation of risk regulatory approaches has raised different arguments and ethical considerations used in evaluation the benefits and risks of biotechnology in decision making processes. This has an impact on policy development as well as ripping the benefits of biotechnology.

(a) Reactive ethics:

- Regulations of risk of technology should be done in a manner that, focus on risks that are foreseen from the past experience.

- Biotechnology like any other technology its beneficial application should be considered a desirable thing for the society.
- When balancing the benefits to the overall society over risks to few individuals. The benefits to the overall society should be given higher consideration.
- It is considered wrong to hold back benefits of technology for fear of risks.

(b) Precautionary ethics:

- Precautionary regulation approach assumes the lesson from the past should teach us not to be certain with the outcome of the new technology.
- Humans have no right to subject to the society and environment to unknown risks and dangers.
- Plays down the present human problems like diseases and hunger. Argues that solving these problems should not be the reason of subjecting the few members of the society and other living organisms in the environment to risks.
- More consideration is given to the wellbeing of the environment.

10.7 Other Scientific Research with Bioethics Considerations

- Research causing suffering to animal and which has no beneficial results directed to the animals.
- Gene and organism patenting under Intellectual Property Right (IPR) policies.
- Environmental ethics including gene pollution due to introduction to GMOs.
- Respecting the right of indigenous knowledge.
- Concern of food and feed derived from transgenic animals and plants with impact on social and cultural values of different societies.

Given the numerous ethical, legal and social implications (ELSI) of biotechnology and other biosciences, there has been strong pressure to regulate the technology to address these concerns. The trend in advances in biomedical and biotechnology applications has now necessitated the development of policies addressing both the scientific-based and ethics-

based application of biotechnology in an acceptable manner. These policies have been developed at both national and international level. These include those setting standards and procedure of ensuring bioethics policy on food and environment. This can be said to be a practical example of “Globalization of Biosafety and Bioethics Issues”

SECTION: 11

INTERNATION CONVENTIONS, TREATIES AND AGREEMENTS ON BIOSAFETY

11.1 Background

The worldwide concerns on safety of food and environment have raised a number of international treaties and conventions that address safe applications of biotechnology and biosafety in general. Many of these treaties and conventions have been formulated under the umbrella of the United Nations (UN) or its organs like that are involved with biosafety issues:

- Food and Agriculture Organization (FAO),
- World Health Organization (WHO)
- United Nations Environment Program (UNEP)
- International Center for Genetic Engineering and Biotechnology (ICGEB).
- United Nations Education, Scientific and Cultural Organization (UNESCO)
- United Nation Industrial Organization (UNIDO)
- Global Environmental Facility (GEF)

There more international and regional organizations other than those which are under the UN which deal with the governance of biotechnology and biosafety in different aspects. These include institutions addressing issues such as regulation of trade of GMO products.

11. 2 International Conventions

11.2.1 United Nations Convention on Environment and Development (UNCED) – 1992

This convention is also referred to as “*Rio Declaration on Environment and Development*”. It raised the issue of safe application of biotechnology and safeguarding the environment from impact of biotechnology. This form Principle 15.0 of this convention and is also referred to as “*Precautionary*”

Principle in Biosafety”. After this declaration the UN formed a specific institutions or organ to deal with global issues known as UNEP. This has been active in environmental policies and regulations in developing countries including building capacity in developing biosafety policies and regulatory systems.

11.2.2 Convention on Biological Diversity (CBD) – 1992

This is a convention on conserving biological diversity. Within this convention, Article 19.3 raises the concerns of potential impact of biotechnology application on biodiversity and describes the needs and precautions to be taken in safe handling of biotechnology products. The article has been the base for the international biosafety regulatory systems, through the Cartagena Protocol on Biosafety.

11.2.3 Cartagena Protocol on Biosafety – 2000/2003

The protocol was adopted in 2000 and entered into force in 2003. It used the precautionary principle to address risks posed by introduction of LMOs, mainly GM crops. It is used as a regulatory mechanism by a number of countries now to regulate transboundary movement of GMOs. It is also a regulatory device for trade and use of GM crops and derived foods. The main objective of this protocol is:

“ To contribute to ensuring an adequate level of protection in the field of safe transfer, handling and use of LMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risk to human health and especial focusing on transboundary trade”.

The Cartagena Protocol on Biosafety contains procedures on provisions of information during export and carrying out tests to assess the safety of GM crops.

The key component of the Cartagena Protocol on Biosafety is the use of the precautionary principle as a policy tool of risk management. It requires products to be proven safe before release to the market or into the environment. It emphasizes the need to take caution when dealing with complex issues like genetic modification. It has been used in enacting

regulation of labeling food containing GM products for people to make choice.

It is important to note that the use of precautionary principle under compliance with Cartagena Protocol on Biosafety has divergent views and interpretations. This has raised also a number of misconceptions and misinterpretation of biotechnology policies.

11.2.4 International Plant protection Convention (IPPC) – 1997

This convention has been developed through the initiative FAO, to emphasize the need of protecting and conserving genetic resources associated with food and plant crops. A special organ of FAO has been formed to ensure development of related policies in all member countries. This organ is known as “*The Commission on Genetic Resources for Food and Agriculture – CGFRA*”. Note that many developing countries including Tanzania has also a policy and a law on protecting plant genetic resources and has a gene bank of food crops in compliance with the global initiatives.

Discussion Question:

What is the importance of having gene banks for food crops to developing countries?

11. 3 International Treaties and agreements

11.3.1 International Treaty on Plant Genetic Resources for Food and Agriculture -2001

The aim of this treaty is to enhance policies on conservation and sustainable use of plant genetic resources, and ensure fair and equitable sharing of benefits derived from their use. Activities of this treaty includes establishment of modalities for access of genetic resources for various uses including the benefits to the farmers. This involves use of “Material Transfer

Agreement- MTA” which is an aspect related to intellectual property (IP) issues related to CBD.

11.3.2 European Union Directive on Deliberate Release into the Environment of GMOs -2001

This is legislation on GMOs used to restrict release in case the product derived from GMOs or LMOs have substantial evidence that it can cause risk to human health and the environment. This directive sets out regulatory measures such as:

- Following principles of risk assessment in evaluating safety.
- Mandatory post-market monitoring of long term effects that may arise from GMO.
- Mandatory information to the public on commercialized GMOs and derived products.
- Ensure that labeling and traceability of GMO at all stages of the market is done.

11.3.3 Codex Alimentarius Commission.

This is a joint commission formed by FAO/WHO experts to set standards, guidelines and procedures for risk analysis and assessment of food produced from transgenic food crops and microorganisms. The principle of risk analysis also follows the components of:

- Risk assessment to identify hazards
- Risk management
- Risk communication

The codex standards and guidelines consist of a collection of internationally adopted food quality standards to protect consumers. It also describes fair practices in the food trade. It mainly addresses food derived from modern biotechnology or rDNA technology. The detailed assessment procedures are as described under “Food Biosafety Risk Assessment” procedures.

11.3.4 Organization for Economic Cooperation and Development – (OECD)

This is one of the international organizations that deal with the promotion of biosafety issues. This is indicated by existence of two groups of experts who addresses the biotechnology regulation and safety. These are:

- Working Group on the Harmonization of Regulatory Oversight in Biotechnology – 1995.
- Task Force for Safety of Novel Food and Feeds - 1998.

11.3.5 International Centre for Genetic Engineering and Biotechnology – ICGEB.

This is one of the international institutions linked to UN which is in charge of building capacity in both biotechnology application and biosafety.

11.3.6 World Trade Organization – WTO.

Deals with trade policies including issues related to trade in GMOs. It handles also IPR matters related to trade including IPR issues on products derived from biotechnology.

11.3.7 The Agreement on Application of Sanitary and Phytosanitary Measures – SPS.

This agreement under WTO deals with regulating of the quality of foods and other goods which could harm life of human's health, animals and plant life. The agreement is also responsible for harmonizing international food and feed standards set by international regulatory systems like:

- Codex Alimentarius Commission
- International Plant Protection Convention
- Other WHO/FAO initiatives on food and human safety

11.3.8 The Agreement on Technical Barriers to Trade – TBT.

This agreement under WTO deals with trade regulatory issues which are not covered by SPS Agreement. This includes issues which could restrict trade in GMOs or the products derived from GMOs based on quality control and standards.

11.3.9 Regional organization in Africa that address the issues of biosafety policies and guidelines.

The African Union (AU) established an agreement of biosafety regulation known as, the “African Union Biosafety Model Law”. This requires also each member state to have national biosafety policies and guidelines. At regional level, Southern Africa Development Cooperation –SADC countries have an advisory committee on biotechnology and biosafety. The organization encourages member states to have biotechnology policies and biosafety regulatory system. These countries have a common policy on plant genetic resources.

SECTION: 12

BIOTECHNOLOGY AND INTELLECTUAL PROPERTY RIGHTS: ETHICAL AND SOCIAL ECONOMIC ISSUES.

12.1 Background

One has to understand that there is more to biotechnology than science and business, that it is why there are a lot of debates or discussions on the ethical, legal and social impact (ELSI) of biotechnology. Among these debatable issues is whether biotechnology can have benefits and solutions to problems in developing countries. The factors that put doubts on these countries being able to access the benefits of biotechnology can be put into the following categories:

- (i) Commercial interests and property right of private multinational companies: Access to technology which is increasingly becoming under the ownership of private sector and protected by Intellectual Property Right (IPR) regimes.
- (ii) Developing countries are constrained by lack of technology, resources and expertise required to have home grown R&D in biotechnology.
- (iii) Governance of biotechnology in developing countries. Many developing countries have no comprehensive policies on application and regulation of biotechnology. This is partly influenced by global debates on benefits and adverse impact of biotechnology.

In this section the issue of Intellectual Property (IP) and Intellectual Property Right (IPR) will be described as it is related to biotechnology impacts. This will be preceded by defining IP and IPR. The second and third factors will be discussed in Sections 13 and 14.

12.1.1 What is Intellectual Property?

Intellectual property refers to creations of the mind: inventions, literary and artistic works, and symbols, names, images, and designs used in commerce. It is divided into two categories:

Industrial property, which includes:

- inventions (patents),
- trademarks which include service marks commercial names and designs,
- industrial designs,
- geographic indications of source;

Copyright, which includes:

Literary and artistic works such as novels, poems and plays, films, musical works, artistic works such as drawings, paintings, photographs and sculptures, and architectural designs.

12.1.2 Patent

A patent is an exclusive right granted for an **invention**, which is a **product** or a **process** that provides, in general, a new way of doing something, or offers a new technical solution to a problem. In order to be patentable, the invention must fulfill certain conditions. The patent application has to specify the precise nature of protection. The owner of a patent, who can commercialize the information through products or granting right to use.

12.1.3 Kinds of inventions can be protected

An invention must, in general, fulfill the following conditions to be protected by a patent. It must be of **practical use**; it must show an element of **novelty**, that is, some **new characteristic** which is not known in the **body of existing knowledge** in its technical field. This body of existing knowledge is called "**prior art**". The invention must show an **inventive step** which could not be deduced by a person with average knowledge of the technical field. Finally, its subject matter must be accepted as "patentable" under law. In many countries, scientific theories, mathematical methods, plant or animal varieties, discoveries of natural substances, commercial

methods, or methods for medical treatment (as opposed to medical products) are generally not patentable.

12.1.4 Intellectual Property Right

The creator has the right of ownership. Intellectual property rights are the rights given to persons over the creations of their minds. They usually give the creator an exclusive right over the use of his/her creation for a certain period of time. The right of possession and use by others require the permission of the owner of IPR. Intellectual property right of Biotechnology innovations fall under the Industrial property can usefully be divided into two main areas. One area can be characterized as the protection of distinctive signs, in particular trademarks (which distinguish the goods or services of one undertaking from those of other undertakings) and geographical indications (which identify a good as originating in a place where a given characteristic of the good is essentially attributable to its geographical origin).

The protection of such distinctive signs aims to stimulate and ensure fair competition and to protect consumers, by enabling them to make informed choices between various goods and services. The protection may last indefinitely, provided the sign in question continues to be distinctive. Other types of industrial property are protected primarily to stimulate innovation, design and the creation of technology. In this category fall inventions (protected by patents), industrial designs and trade secrets. The social purpose is to provide protection for the results of investment in the development of new technology, thus giving the incentive and means to finance research and development activities.

A functioning intellectual property regime should also facilitate the transfer of technology in the form of foreign direct investment, joint ventures and licensing. The protection is usually given for a finite term (typically 20 years in the case of patents). While the basic social objectives of intellectual property protection are as outlined above, it should also be noted that the exclusive rights given are generally subject to a number of limitations and exceptions, aimed at fine-tuning the balance that has to be found between the legitimate interests of right holders and of users.

12.2 Intellectual Property Right (IPR) as Applied to Biotechnology Applications

IPR is known to be a key in promoting investment in technology R&D to develop new products. This is also applicable to biotechnology R&D, as it allows the investors to recover the investments and stimulate innovations. This topic will be discussed from two approaches:

- (a) Importance of patenting in biotechnology development and application.
- (b) Concerns on the issue of patenting biotechnology innovations.

Is generally now acceptable that patents in biotechnology application, especially in rDNA technology is necessary to stimulate investment in R&D on new products and processes with commercial utilizations and beneficial to the public. The innovation which has benefited the public includes those in medicine, agriculture, and pharmaceutical industry, many industrial processing and environmental remediation. It is also important to note that what is patentable and process of patenting lies in the national laws and differs between countries.

12.3 Historical Trends in Patenting of Biotechnology Innovations.

At the moment there many thousands of patents related to biotechnology innovations which have been granted to researchers in public and private sectors. Many of these have been granted to assert rights of innovations associated with DNA sequences. This is because current patenting systems regard DNA sequences as eligible for patenting. The application of IPR systems to biotechnology can best be understood by looking at some historical trends in patenting of some biotechnology innovations (Table below).

Many more patents on biotechnology products and innovations are in place today. The issues in biotechnology which has created the rise in patentable gene-technology inventions can be listed as follows:

- Ability to sequence genes
- Identification of gene function and mutations

- Method to create selective expression of specific genes
- Regulating and silencing genes
- Method of predicting protein structure and expression
- Mapping influence of genetic make-up on metabolism of organisms
- Ability to create huge amount of genetic data and means of analyzing it (Genomic Data and Bioinformatics).

Improvement in biotechnology tools of research has resulted in development of a wide range of commercially valuable and useful products in medicine, agriculture and industry. This has resulted in patentability of biological materials, processes and forms of transgenic life.

Historical Trends in Patenting of Some Biotechnology Innovations

1972: Chakrabarty filed a patent application for a genetically engineered bacterium that breaks crude oil. The application was rejected based on the ground that microorganisms are “Products” of nature and as living organisms are not eligible for patenting or not patentable.

1973: Patenting of Cohen and Boyer perfected genetic engineering techniques in the USA.

1980: Patenting of genetically engineered *Pseudomonas* bacteria for breaking down crude oils. (Diamond and Chakrabarty).

1981: USA Supreme Court holds that patent protection is not available for “laws of nature, natural phenomenon, and abstract ideas”.

1987: USA Patent Department accepts that oysters which have been artificially treated to alter the number of chromosomes are patentable subjects.

1988: Patenting of transgenic mouse with breast cancer susceptibility gene which made the mouse highly sensitive or susceptible to carcinogenic chemicals. The mouse was used to test anti-cancer drugs and determination of environmental pollutant in cancer development.

1997: 1st patent granted for purified DNA sequence encoding a gene-related product and method for identifying the sequences to Forsyth Dental, Boston, USA.

1997: Patent granted on expressed sequence tags (ESTs), which is a short chain of cDNA for production of human protein kinase homologues.

12.4 Characteristics of Patentable Biotechnology Innovations

This section describes categories of patentable and non-patentable biotechnology innovations or creativity. These innovations fall into three categories:

- Products or composition of matter;
- Methods of use; and
- Manufacturing processes which may include use of biochemical or microbiological processes.

Just like in general regulations of patentability, these innovations in biotechnology have to meet certain criteria to be patentable. These criteria are:

- The invention claimed must be new or novel.
- It has to have tangible application or useful industrial application. It could be also ideas which can be put into practice.
- The invention has to be genuinely useful for the benefits claimed in the patent application.
- It has to be based on obvious knowledge which is available, to determine the scope of patent claim of invention.
- It has to have a description of the nature of invention which needs protection.
- The patent application has to have detailed description of indispensable steps or instructions for construction of the invention that can be used by a skilled person to perform or produce the invention.
- The invention must be eligible for patenting, which means it should not be contrary to morality or public order. This means exploitation of your patent should not be harmful to the environment, humans, animals and plants.

Depending on the law of the country these criteria can have different interpretations and therefore difference in eligibility and patentable innovations. In some countries certain innovations cannot be granted patents. This has been agreed upon by WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). In this Agreement some innovations achieved through biotechnological techniques or tools may not be eligible

for patenting, depending on country specific laws. It allows countries to exclude from patenting inventions related to diagnostic, therapeutic and surgical methods of treatment of humans, animals and plants.

In case of EU, ineligible inventions may include:

- (a) Process of cloning human being
- (b) Process of modifying the germ line genetic identity of human being.
- (c) Use of human embryos for industrial or commercial purpose
- (d) Process of modifying genetic identity of animals which can cause them suffering without any substantial medical benefits to man or animal, and also animals resulting from such processes.

The type of biotechnology innovations which seem to be excluded from patenting seem to be mainly associated with animals. This is attributed to ethical concerns.

Discussion question

What do you consider to be the cause of TRIPS allowing countries to exclude from patenting inventions related to diagnostic, therapeutic and surgical methods of treatment of humans, animals and plants?

12.5 Concerns of Patenting Biotechnology Innovations

IPR issues have raised a number of social and ethical concerns on patenting biotechnology inventions. These concerns include issues such as: (a) affordability of biotechnology products to the needy; (b) equality in access to the technology and product by marginalized communities; (c) “Genomic divide” which is also referred to as biotechnology dependence. The general concern is whether patenting of biotechnological innovations is socially beneficial.

Specific concerns on patenting of innovation based on DNA sequences have been raised. Such patents may have the following negative impacts of:

- Preventing and hindering development of new or improved medicines and treatment, by impeding access to genetic information and materials necessary to perform biological research.
- Limiting access to availability of products derived from biotechnology research and development
- Exploiting information and materials and inhibiting the free exchange between researchers
- Involving parties in extensive and costly legal battles over patent infringement.

The ethical reasons advanced by opponents of patenting of DNA based inventions include:

- Genetic material as common heritage of humanity and should be public property only and therefore not eligible for use in patentable innovations.
- Genes or DNA as “nature identical material” and claimed innovations are mere discoveries.
- Where applied to human gene sequence, ownership of patent is equated to slavery.

Opponents of patenting of DNA argue that, IPR restrict access and control of breeding of patented GM seeds. This in turn scare poor farmers from biotechnology derived improved seed that they have to buy seeds every time they have to plant new crops. It is argued that, patenting has hampered the delivery of “golden rice” to needy. This is considered to be ethically a wrong practice.

IPR issues also raise the fear of the “terminator gene technology” which can be used by profit driven multinational companies to sterilize the seed product produced. The scare is creation of dependence of seed source by farmers who are used to save their own seeds. It this concern that lead to creation of “Plant Breeders Right” concept. In this case, proprietary process of biotechnology derived crops has to recognize the farmer’s right who have been breeding the transformed or GM crop.

Under the current IP regimes there is a need of showing who owns the IP of the GM crop in terms of gene, promoter and plant or crop variety. It is also

accepted in many countries and under TRIPS, in considering patent applications, the ethical and social concerns be taken into consideration.

12. 6 Intellectual Property on Plant Variety Protect

Although patents are the most commonly recognized forms of IP assets, the other forms of IP that are relevant to protection of biotechnology and biological material in general. One of these other forms of IP is the plant variety protection (PVP) under the *sui generis* rights system. This kind of IP protecting plant varieties exists in laws of many countries, and has its origin from the international treaties known as *International Plant Protection Convention (IPPC)*, *International Union for the Protection of New Varieties of Plants (UPOV)*, and many more treaties which will be discussed later under this topic.

12.7 Protection of Undisclosed Traditional Knowledge and Biodiversity with Biotechnological Applications

It is known that different communities in the world harbors a lot of information on medicinal value, plant and animal breeding, food processing and bio-fungicides which may lead to new innovation in biotechnology. This information is not documented in many places and cannot meet the patenting processes and procedures. This king of information held under traditional knowledge needs also IP protection under the *sui generis* rights system.

To protect this valuable knowledge from bio-piracy, efforts should be made to raise the awareness of communities and scientists, with support of policy makers to bring this traditional knowledge to formal bioscience expertise and patent it. This should also apply to protection of national or community genetic wealth in form of biodiversity.

Protection of biodiversity from bio-piracy requires documentation of biodiversity, geographical indication on origin, undisclosed information use and of bio-forms materials. Through international initiatives such as the CBD, these efforts on IP protection on biodiversity for use in biotechnology as common heritage have been affected. There are a number of management instruments which have been put in place to regulate this ownership of

biodiversity. This includes the use of “*Material Transfer Agreement - MTA*” to exchange biological material which can be used in inventions.

12.8 International Framework for Protection of Intellectual Property at International Level

The issue of protection of IPR is an integral part of international trade, but it is also part of global ethical issues of concerns which call for harmonization of management and regulation of IPRs. Issues of global concerns on protection of IPR are like:

- Ownership of biodiversity and genetic resources
- Creation of monopoly in the interests of multinational companies
- Blocking access to technology for developing countries
- Inhibiting flow of valuable information to researchers
- Forcing high prices of essential commodities like pharmaceuticals making them unobtainable
- Putting private rights over collective or community interest
- Overruling ethical and environmental concerns

There also views that IPR should not be obstacle to trade or transfer of technology or fair competition in trade. Though these concerns are general to IPR, the balancing of advantage and concerns of IPR in biotechnology are addressed by a number of international treaties and agreements. These form global policies which affect also development of biotechnology policies in different countries. The international treaties relevant to IP protection of biotechnology are listed in three categories.

(1) The key international treaties relevant to IP protection of biotechnology

- WTO Agreement on Trade-Related Aspect of Intellectual Property Rights (TRIPS) - 1994. This agreement covers patents, plant breeder's rights, trade secrets, trade marks, copyright, designs and integrated circuits, enforcing patenting rules and dispute settlement.
- The Paris Convention for Protection of Industrial Property – 1883, which provides rules on patents, trademarks, designs and unfair competition.

- The Patent Cooperation Treaty (PCT) – 1970, which provides a streamlined process for making an international patent application with effect or reserving rights in many countries at once.
- Budapest Treaty on the International Recognition of Deposit of Microorganisms for the Purpose of Patent Procedure (referred as Budapest Treaty) - 1977. This treaty provides an easy way for patents applicants to refer to microorganisms in the description of their inventions.
- The Strasbourg Agreement Concerning the International Patent Classification (IPC) – 1971. The agreement sets up the system of technological classifications, facilitating patent searching.
- The International Convention for the Protection of New Varieties of Plant (UPOV) – 1961. Provides international standards in relation to the protection of new varieties of plants.

(2) International agreements with implication for biotechnology

- The Convention on Biological Diversity - 1992.
- The Food and Agriculture Organization (FAO) International Treaty on Plant Genetic Resources for Food and Agriculture -Adopted -2001

(3) Other important treaties concerning other aspects of IP which has no direct implication on biotechnology

- The World Intellectual Property Organization (WIPO) is a UN agency responsible for administration of international IP issues.

12.9 Conclusion

It important to develop IP policies and laws which promote linkage of ownership of knowledge on utilization of biological material and processes to generate wealth in developing countries. This will ensure use of biodiversity as the feedstock of biotechnology and source of wealth. This should include undertakings like:

- The maintenance of culture collection of useful microorganisms has been recommended by the report on biological diversity published in 1998 (URT, 1998).
- Formulating a national policy on intellectual property rights (IPR) in Tanzania, and particularly on biotechnology innovations arising from use of biological genetic resources. At the moment, IPR issues are mentioned in some sectoral policies despite having IPR legislations related to Trade Policy.
- Creating guideline or legislation governing exchange of genetic resources such as Material Transfer Agreement (MTA) to facilitate exchange and accessibility of genetic resources, which could be held in microbial genetic resource centers.
- The Commission for Science and Technology (COSTECH) has been undertaking initiatives to create awareness in scientific research institutions on matters related to IPR policy especially at institution level.
- Creating institutional IPR regimes supported by clear national legal framework on IPR that will ensure of development biotechnology in a manner that will ensure fair and equitable sharing of benefits arising out of utilizing of genetic resources by potential industries.

SECTION: 13

BIOTECHNOLOGY POLICY (BIOPOLICY) DEVELOPMENT: THE CASE OF DEVELOPING COUNTRIES

13.1 Background

It is important to understand the policy context of biotechnology and biosafety in developing countries. Biotechnology like any other technology is a tool of delivering products and services to humans and environment. It has developed with time to offer a lot of promises to the social and economic development of human being. Modern biotechnology especially is considered under the UNCED/CBD to be a key in developing sustainable production of food, feed, improved medical application, and new ways of environmental protection. Many more of these benefits have been described in the introduction sections.

Developments in biotechnology should be taken to be a strong driving force of the livelihood, economy and social development in developed countries. This is due to the contribution the technology has on meeting various societal demands. Developing countries also are looking into acquiring the technology to improve the livelihood of their people. Just like any other technology, biotechnology development is also considered to have a significant impact on local and global environment including climate. This could be in terms of benefits and negative impacts to the environment which could have also negative impacts to human health and livelihood in general.

It is also a fact that the science and technology development affects the social choice we make. This includes the type of research and developments objectives we make.

13.2 Challenges in Biotechnology Development

Biotechnology has a lot of challenges when it comes to application in solving different societal problems. This is because it is a technology that has strong social and political characters, that creates new and specific economic, social and legal challenges. The challenges include:

- (a) The controversies and concerns of biotechnology application
- (b) Meeting the global governance of biotechnology
- (c) Global political economy issues
- (d) Security concerns on misuse (biological weapons, biosecurity issues)

13.3 Need for Biotechnology Development Guidance: Biotechnology Policy

To meet the challenges, biotechnology development requires having a policy which will promote its acquisition and safe used. The policy should also ensure that the benefits to the public and potential negative impacts are regulated.

13.4 Features of Biotechnology Policy

To have an effective biotechnology policy in any country, the policy has to have the following features:

- Embrace biotechnology revolution.
- Promote the use of economic benefits of biotechnology to improve public livelihood. This includes the linking of research and development to meet societal demands.
- Incorporate the ability of the society to use ethical consideration into biotechnology regulatory systems.
- Identify the key stakeholders will be part of biotechnology development process and regulation.
- Set clear goals of biotechnology applications and adoption.
- The policy has to be linked to national and global developmental policies.

13.5 Process of Making Biotechnology Policy

To develop an effective biotechnology policy in the country, the following process has to be followed:

- (i) Identification of scientists and institutions to be involved in making scientific policy.
 - Scientists and their institution.
 - Industries involved in research and commercialization of biotechnology products.
 - Government regulatory and research funding agencies.
 - Public through their concerns (issues that lead to necessity of information and risk analysis policies).
- (ii) Determine at what point in technology development the biotechnology policy and related policies are to be made.
- (iii) Last there is need establish factors to be considered in policy formulation such as:
 - Set clear goals to be achieved.
 - Defining clear problems to be solved by biotechnology application.
 - Evaluate relevant experiences and options to be used to achieve the objectives.
 - Define means of selecting partners to be involved in decision making.
 - Identifying institutions to promote R&D in biotechnology and those responsible for management the risks.
- (iv) Build the process of making decision.
- (v) Create plans for biotechnology capacity building.

13.6 Linkage of Biotechnology Policy to Other National and Global Policies

Biotechnology as a tool of producing products and services has many potentials of enhancing the implementation of many developmental policies. The development of biotechnology policy also requires the existence of other policies. These policies may vary between countries, but a set of policies which are common in many countries include:

- Science and technology policies
- Agriculture and food security
- Food laws and regulations
- Environmental policies
- Industrial development
- Trade
- Health
- Renewable energy
- Biosafety policies
- Technology transfer
- Intellectual property right
- Occupational Health
- National Security
- Conservation
- Research and development
- Sustainable development

13.7 Conclusion

Biotechnology policy should be considered to be guidance on the development of biotechnology and safe application. It is influenced by societal demands and market forces. To make this policy effective, the government strategies should take the following actions:

- Setting up advisory bodies and task forces to advice on means of developing and implementing the biotechnology policy.
- Evaluating impact on ethical and social issues, economic development, as well as environmental sustainability. This also requires biosafety and bioethics advisory committees to the government.

SECTION: 14

OVERVIEW OF GOVERNANCE OF BIOTECHNOLOGY: IMPLEMENTATION OF BIOSAFETY REGULATORY SYSTEMS.

14.1 Developing National Biosafety Policy and Regulatory System: National Biosafety Framework.

Under the UNCED/CBD promotion of application of biotechnology has been proposed as means of achieving sustainable development in both developed and developing countries. It was also emphasized that the application of biotechnology should be done with the precaution that biotechnology dose not create harm to the environment and human health. Undertaking these precautions makes biosafety principles and practices as part of a sustainable development strategy. This has resulted in international biosafety policies, agreements and treaties which have been discussed.

The last part of this book, the discussion on focuses on the application of biosafety, bioethics and biopolicy issues in developing “*National Biosafety Framework*”. It is important to note that countries with functioning biosafety regulatory systems have developed them gradually. They usually begin with voluntary guidelines and standards developed cooperatively by stakeholders in academia, industry, and government. Also effective national biosafety systems are important as they allow countries to make effective decisions on utilizing biotechnology and complying with international standards that impact trade and other issues.

What is a National Biosafety Framework?

This is a combination of policy, legal and technical instruments that is developed to address safety issues with respect to environment and human health in the context of developing and applying modern biotechnology or other biohazardous biological agents.

14.2 Special Consideration on Developing National Biosafety Framework in Developing Countries.

The last discussion of biotechnology governance will focus on development of biosafety systems in developing countries which need special approach as compared to developing biosafety systems in developed countries. The special consideration is on the level of application of biotechnology in these countries which is characterized by the following features which impact development and implementation of biosafety regulatory systems. These features are:

- Lack of human capacity in biotechnology.
- Lack of infrastructure to support biotechnology research and development (R&D). The infrastructure refers to biotechnology or science and technology (S&T) policy, funding, appropriate research equipment.
- Lack of local expertise to undertake risk assessment and management.
- Lack of scientific evidence of nature and behavior of GMOs in local environment.

14.3 Approaches or Models Used in Development of National Biosafety Frameworks.

The approaches or models used to development of biosafety systems vary from country to country. The main two approaches used include:

- (I) Incorporating the biosafety regulatory system into existing laws and legislations such as those covering food and agricultural product to cover the GMO crops and derived foods.
- (II) Creating new laws dealing specifically with handling of biotechnology research, products and applications.

As international biosafety policies and regulatory systems continue to evolve, the national systems will also continue to change with the new developments and international regimes.

14.4 Process and Procedures for Developing National Biosafety Systems: The Case of Developing Countries.

For countries developing national biosafety systems, there are issues which they have to consider in the process of developing the systems and implementing them. These issues are briefly discussed below.

14.4.1 Taking inventory and evaluation of development priorities, policies and regulatory systems which need biotechnology application. These include:

- a. Agricultural policies.
- b. Existing regulatory regimes relevant to biosafety such as biomedical biosafety and bioethics, phytosanitary regulatory systems.
- c. National technical capacity relevant to biosafety practices and biotechnology application.

This information provides a means to identify and characterize available resources and regulatory infrastructures, assess their adequacy for supporting intended biosafety system, and identify gaps where capacities need to be strengthened.

14.4.2 Describe the goals and objectives of biosafety frameworks and how they will be linked to other developmental strategies and policies.

For examples this must include the extent to which social, ethical, and economic factors should be considered, the social acceptability of biotechnology and its products, and linkages with other national policies on environment, human health, medical practices, food, agriculture, and economic development.

14.4.4 Assess the national capacity in terms of scientific knowledge and skills required to support the development and implementation of biosafety system. As stated before this is a key issue for developing countries that lack trained human resources. These countries need to create a strong base of scientific knowledge in support of the regulatory system, and development of core competencies in biotechnology product evaluation. The skills allow an improved scientific basis for assessments of potential risks and/or benefits, and they strengthen the scientific capabilities for risk management,

inspection, and monitoring. This will create the trust for safety of biotechnology application where it is missing.

14.4.5 Developing national biosafety regulatory framework.

This should be done through consultation with the public and key stakeholders. The formation of regulation should draw from information provided by steps of inventory and evaluation of needs, priorities and developmental strategies (Section a). This step and procedure is important in case where non-safety issues are to be included in the decision making process. The features of effective National Biosafety Framework will be discussed below.

14.4.6 Biosafety regulatory system implementation steps. This includes the process of establishment of appropriate mechanisms for risk assessment, risk management, and risk communication within existing financial, technical, and human resource constraints. It has to consider how decisions made during the implementation phase directly affect the costs associated with assessing and managing risks and ensuring compliance with regulations.

14.4.7 Looking at cross cutting issues.

Cross cutting issues are those that are common to each of the five preceding elements and they are often the most challenging factors to address and resolve. They are, however, the issues that will ultimately dictate the scope of a national policy on biosafety, and the conversion of policy into practice. Cross cutting issues affect the implementation of the biosafety system to assess risks, and perhaps more importantly, those non-scientific factors that are crucial to public acceptance and confidence in the decisions that are made by government on behalf of the people.

The twin issues of public information and participation have to do with the degree of transparency in a regulatory system, and the degree to which the public has input either into the formulation of regulatory policy or into specific regulatory decisions. Transparency refers to the extent to which

governments provide information on why and how certain products are regulated, how risk assessments are performed and decisions made, and as well, the conclusions and decisions that have been reached. Transparency can also involve the perceived independence and objectivity of the regulatory decision-makers.

Human, financial and infrastructure resources largely determine the scientific and administrative capacity of any country; they obviously influence any biosafety related policy or program. Funds must be available to develop and implement a national biosafety system; to support the infrastructure required, such as buildings, labs, equipment, and computers; to facilitate communication and public participation; to train scientific and regulatory personnel; and to foster the research required to assure that risk assessments are sound.

14.5 Elements of a National Biosafety Framework (NBF)

To support research and development in biotechnology and ensure product delivery to solve societal problems and meet the needs requires a good NBF. An effective NBF should have the following elements to ensure implementation and compliance.

- (a) *Regulatory system*: Consisting of legally binding regulations and non-binding guidelines. These should include procedures for GMOs release, biosafety review system, risk assessment and management, and feedback mechanisms.
- (b) *Means of implementing the regulatory systems*: These should be based on scientific expertise.
- (c) *Decision-making system*: This should include capability to conduct risk assessment of different impacts.
- (d) *Information communication system*: This is required, both to maintain public acceptance of the biosafety regulation system and ensuring that the decisions are made based on knowledge.
- (e) *Means of enforcing the compliance*: It is required for any decision made and to allow the monitoring of GMOs after accepting the release.
- (f) *Means of validation of presence and concentration of GMOs in the environment or products*. This including having competent scientists and institutions to make analysis of contested products to verify the presence and concentrations of GM products.

14.6 Institutional Component of Nation Biosafety Regulatory Framework

The requirement of decision making process and ensuring compliance of biosafety regulations requires a number of institutions and mechanisms to regulatory process. The main components include:

- i) National Biosafety Decision Making Body (National Biosafety Committee (NBC))
- ii) National Biosafety Administrative Office
- iii) Science Advisory Committee(s)
- iv) Institutional Biosafety Committees (IBC)
- v) Pool of Scientists for Reviewing Applications of releasing GMOs
- vi) Public Consultation Process
- vii) Appeal Process
- viii) Inspection Monitoring Body

14.7 Conclusions

The development of an effective national biosafety system is important to encourage the growth of domestic biotechnologies; to ensure safe access to novel products and technologies developed elsewhere; and to build public confidence that biotechnology products which are produced and regulated condition are safe. The presence of a suitable framework affects the ability of the public and private sectors to invest in biotechnology and to make the products of biotechnology available so that the benefits they afford can be realized.

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