



॥ सरस्वती नः सुभगा मयस्कन्तु ॥

Uttar Pradesh Rajarshi Tandon
Open University

PGBCH-116

Biosafety and IPR

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COURSE INTRODUCTION

The objective of this course is to provide knowledge of Biosafety and IPR. Biosafety and IPR is refers to the study of awareness about the value of IPR in our lives and fosters a better understanding of the rights associated with IPR such as copyright, patent, trademarks, industrial designs, agreements, gene flow and geographical indications etc. This course covers the biosafety, convention, gene, GMO, patent and agreements which are written in an easy-to-understand manner for post graduate students and early career researchers interested in the opportunities and challenges associated with advances in biochemistry. The course is organized into following blocks:

Block-1 covers the bio-safety, health aspects convention and ecolabelling.

Block-2 deals the Gene and GMO which covers the gene flow, risk management, GMO and human health.

Block-3 describes in brief of patent and agreements, which deals the ethical, legal and social implications of living being.



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BLOCK

1

BIOSAFETY AND CONVENTION

UNIT-1

Biosafety and health aspect

UNIT-2

Convention and Ecolabelling

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BLOCK INTRODUCTION

This is the first block of biosafety and IPR, covers biosafety and convention. The block first consists of following two units:

Unit-1 : This unit covers the bio-safety and convention. In this unit the objectives of bio-safety, risk assessment and its regulatory framework is mentioned in briefly. The national policies and law on biosafety that regulate the process of bio-safety deeply discuss in this unit. Here the general principles for the laboratory and environmental biosafety; healthy aspects; toxicology, allergen city and antibiotic resistance etc. is also cover in this unit.

Unit-2 : Under second unit of convention and bio-safety. There is a brief description about principle of convention on biological diversity and other some important related terms. There are several convention such as Berne and Paris convention etc are briefly discuss under the convention on biological diversity. Apart from convention the government policy and guides line on the patent, ecolabelling ecomark, and geographical indications are also cover in this unit.

UNIT-1 BIOSAFETY AND HEALTH ASPECTS

Structure

- 1.1 Introduction
 - Objectives
- 1.2 Biosafety
- 1.3 Biosafety Guidelines
- 1.4 Classification of pathogenic microorganisms
- 1.5 Biosafety Levels
- 1.6 Risk Assessment
- 1.7 Risk Regulation
- 1.8 National Biosafety Policies and Laws
- 1.9 The Cartagena protocol on Biosafety
- 1.10 Biosafety Principles
- 1.11 Summary
- 1.12 Self assessment questions
- 1.13 Further readings

1.1. INTRODUCTION

Safety culture is a part of organizational culture and is often described by the phrase “the way we do things around here”. According to the American Chemical Society, safety culture at an academic institution is a “reflection of the actions, attitudes, and behaviors” demonstrated by the faculty, staff and students concerning safety”. In addition, safety is viewed as an operational priority, because of the benefits thoughtful, safe procedures and attitudes bring to research. Biosafety is the prevention of large-scale loss of biological integrity, focusing both on ecology and human health. These prevention mechanisms include conduction of regular reviews of the biosafety in laboratory settings, as well as strict guidelines to follow. Biosafety is used to protect from harmful incidents. Many laboratories handling biohazards employ an ongoing risk management assessment and enforcement process for biosafety. However, Biosafety is defined as, “The

discipline addressing the safe handling and containment of infectious microorganisms and hazardous biological materials. Biosafety is used to protect from harmful incidents. Biosafety guidelines are a set of policies, rules, and procedures, necessary to observe by personnel working in various facilities handling microbiological agents such as bacteria, viruses, parasites, fungi, prions, and other related agents and microbiological products.

Objectives:

- To discuss the bio-related research activities that involves in manipulation of microbial, animal or plant cells.
- To discuss risks associated with different activities arise from the samples and /or the procedural requirements.
- To discuss the adherence to standard microbiological techniques and using facilities suitable to the risk level of the pathogen helps to protect the researcher from laboratory-acquired infections.

1.2. BIOSAFETY OVERVIEW

Biosafety is the prevention of large scale loss of biological integrity, focusing on both ecology and human health. These prevention mechanisms include conduction of regular reviews of the biosafety in laboratory as well as strict guidelines to follow. Biosafety is used to protect from harmful incidents.

Many laboratories handling biohazards employ an ongoing risk management assessment and enforcement process for biosafety. Failures to follow such protocols can lead to increased risk of exposure to biohazards or pathogens. Human error and poor technique contribute to unnecessary exposure and compromise the best safeguards set into place for protection. Typically, institutions that experiment with or create potentially harmful biological material will have a committee or board of supervisors that is in charge of the institution's biosafety. They create and monitor the biosafety standards that must be met by labs in order to prevent the accidental release of potentially destructive biological material.

1.3. BIOSAFETY GUIDELINES

Biohazardous material requires special safety precautions and procedures. Biosafety guidelines are a set of policies, rules, and procedures necessary to observe by personnel working in various facilities handling microbiological agents such as bacteria, viruses, parasites, fungi, prions, and other related agents and microbiological products. Institutions requiring strict adherence to these biosafety guidelines include clinical and microbiological laboratories, biomedical research facilities, teaching and

training laboratories and other healthcare institutions (e.g., clinics, health centers, hospital facilities). These guidelines are intended to provide proper management and regulation of biosafety programs and practices implemented at all levels of the organization.

Essential components of the biosafety guidelines contain some or all the following, depending on the facility: microbiological risk assessment and identification; specific biosafety measures, which cover the code of practice, physical plant such as laboratory design and facilities, equipment acquisition and maintenance, medical surveillance, staff training, safe handling of chemicals, with fire, radiation and electricity safety, among others. Additional components may be included such as commissioning and certification guidelines for the facilities.

1.3.1 Need for Biosafety Guidelines

It was feared that the GMOs (GMO means any living organism that contains a novel combination of genetic material obtained through the use of recombinant DNA technology) may disturb the ecosystem and its processes in following ways-

- When introduced, GMOs may rapidly multiply and out-compete the native microbes.
- They may also transfer genes related to virulence into native bacterial population.
- Production of toxic or allergic metabolites.
- They may generate unexpected susceptibilities to pathogens.
- Transmission of new traits to weeds may occur.
- Ecosystem may be disturbed by altered reaction to parasites, symbionts or competitors.

1.3.2 Objectives of Biosafety Guidelines

- Biosafety guidelines are applicable to all research and development activities of modern biotechnology conducted in laboratories of the government research institutes, state enterprises, universities and private companies.
- It applies to lab experiments and field trials, transboundary movements, transit, handling and use of all GMOs that may have adverse effects on the conservation and sustainable use of biodiversity and also to human health.

1.3.3 Guidelines to Follow While Working With Infectious Agents

1.3.3.1 Personal Hygiene Guidelines

Wash your hands thoroughly, as indicated below:

- After working with any biohazard
- After removing gloves, laboratory coat, and other contaminated protective clothing
- Before eating, drinking, smoking, or applying cosmetics
- Before leaving the laboratory area
- Do not touch your face when handling biological material.
- Never eat, drink, smoke, or apply cosmetics in the work area.

1.3.3.2 Clothing Guidelines

- Always wear a wrap-around gown or scrub suit, gloves, and a surgical mask when working with infectious agents or infected animals.
- Wear gloves over gown cuffs.
- Never wear contact lenses around infectious agents.
- Do not wear potentially contaminated clothing outside the laboratory area.

1.3.3.3 Handling Procedures

- Use mechanical pipetting devices.
- Minimize aerosol production.
- Add disinfectant to water baths for infectious substances.
- Use trunnion cups with screw caps for centrifuging procedures. Inspect the tubes before use.
- Use secondary leak-proof containers when transporting samples, cultures, inoculated petri dishes, and other containers of biohazardous materials.

1.3.3.4 Syringes

Avoid using syringes and needles whenever possible. If a syringe is necessary, minimize your chances of exposure by following these guidelines:

- Use a needle-locking or disposable needle unit.
- Take care not to touch yourself with a used needle.
- Place used syringes into a pan of disinfectant without removing the needles.
- Do not place used syringes in pans containing pipets or other glassware that require sorting.

- Do not recap used needles.
- Dispose of needles in an approved sharps container.

1.3.3.5 Work Area

- Keep laboratory doors shut when experiments are in progress.
- Limit access to laboratory areas when experiments involve biohazardous agents.
- Ensure that warning signs are posted on laboratory doors. These signs should include the universal biohazard symbol and the approved biosafety level for the laboratory.
- Ensure that vacuum lines have a suitable filter trap.
- Decontaminate work surfaces daily and after each spill.
- Decontaminate all potentially contaminated equipment.

1.3.3.6 Universal Precautions

Clinical and diagnostic laboratories often handle specimens without full knowledge of the material's diagnosis; these specimens may contain infectious agents. To minimize exposure, observe universal precautions when handling any biological specimen. Consider all specimens to be infectious and treat these materials as potentially hazardous.

1.4. CLASSIFICATION OF PATHOGENIC MICROORGANISMS

1.4.1 Risk group I- A pathogen that is unlikely to cause any disease in humans or animals. All bacterial, fungal and parasitic agents not included in higher groups.

1.4.2 Risk group II- A pathogen that can cause disease in humans or animals but is unlikely to be a serious hazard. Effective treatment and preventive measures are available and the risk of spread of infection is limited. Bacterial- *Vibrio cholera*, Fungal- *Aspergillus fumigates* and Actinomycetes, Parasitic - *Plasmodium falciparum* and *Plasmodium theileri*, Viral and Rickettsial - Vole rickettsia and Mumps virus.

1.4.3 Risk group III- A pathogen that can cause serious human or animal disease, but does not ordinarily spread from one infected person to another. Effective treatment and preventive measures are available. Bacterial- *Clostridium botulium* and *Francisella tularensis*, Fungal - *Coccidioides immitis* and *Histoplasma capsulatum*, Parasitic- *Schistosoma mansoni*, Viral and Rickettsial - Foot-and- Mouth disease virus.

1.4.4 Risk group IV- A pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available. Korean hemorrhagic fever, Omsk hemorrhagic fever and Central European Encephalitis viruses.

1.5. BIOSAFETY LEVELS

A biosafety level is a set of biocontainment precautions required to isolate dangerous biological agents in an enclosed laboratory facility. The levels of containment range from the lowest biosafety level 1 (BSL-1) to the highest at level 4 (BSL-4).

Biosafety level refers to the stringency of biocontainment precautions deemed necessary by the Centers for Disease Control and Prevention (CDC) for laboratory work with infectious materials. It consists of a combination of laboratory practices and techniques, safety equipment and laboratory facilities appropriate for the operations performed and the hazard posed by the infectious agents.

At the lowest level of biosafety, precautions may consist of regular hand-washing and minimal protective equipment. At higher biosafety levels, precautions may include airflow systems, multiple containment rooms, sealed containers, positive pressure personnel suits, established protocols for all procedures, extensive personnel training, and high levels of security to control access to the facility.

These levels and the appropriate conditions are enumerated as follows:

1.5.1 Biosafety Level 1

These practices, safety equipments and facilities are appropriate for undergraduate and secondary educational training and teaching laboratories and for other facilities in which work is done with defined and characterised strains of viable microorganisms not known to cause disease in healthy adult human. No special accommodation or equipment is required but the laboratory personnel are required to have specific training and to be supervised by a scientist with general training in biochemistry or a related science. However, eating and drinking are generally prohibited in laboratory areas. Potentially infectious material must be decontaminated before disposal, either by adding a chemical such as bleach or isopropanol or by packaging for decontamination elsewhere. Personal protective equipment is only required for circumstances where personnel might be exposed to hazardous material. BSL-1 laboratories must have a door which can be locked to limit access to the lab. However, it is not necessary for BSL-1 labs to be isolated from the general building.

1.5.2 Biosafety Level 2

These practices, safety equipment and facilities are applicable in

clinical, diagnostic, teaching and other facilities in which work is done with the broad spectrum of indigenous moderate-risk agents present in the community and associated with human disease of varying severity. Laboratory workers are required to have specific training in handling pathogenic agents and to be supervised by competent scientists. Accommodation and facilities including safety cabinets are prescribed, especially for handling large volume are high concentrations of agents when aerosols are likely to be created. Access to the laboratory is controlled.

1.5.3 Biosafety Level 3

These practices, safety equipment and facilities are applicable to clinical, diagnostic, teaching research or production facilities in which work is done with indigenous or exotic agents where the potential for infection by aerosols is real and the disease may have serious or lethal consequences. Personnel are required to have specific training in work with these agents and to be supervised by scientists experienced in this kind of microbiology. Specially designed laboratories and precautions including the use of safety cabinets are prescribed and the access is strictly controlled. In addition, the facility which houses the BSL-3 laboratory must have certain features to ensure appropriate containment. The entrance to the laboratory must be separated from areas of the building with unrestricted traffic flow. Additionally, the laboratory must be behind two sets of self-closing doors (to reduce the risk of aerosols escaping). The construction of the laboratory is such that it can be easily cleaned. Carpets are not permitted, and any seams in the floors, walls, and ceilings are sealed to allow for easy cleaning and decontamination. Additionally, windows must be sealed, and a ventilation system installed which forces air to flow from the "clean" areas of the lab to the areas where infectious agents are handled. Air from the laboratory must be filtered before it can be recirculated.

1.5.4 Biosafety Level 4

These practices, safety equipment and facilities are applicable to work with dangerous and exotic agents which pose a high individual risk of life-threatening disease. Strict training and supervision are required and the work is done in specially designed laboratories under stringent safety conditions, including the use of safety cabinets and positive pressure personnel suits. Access is strictly limited. A specially designed suit area may be provided in the facility. Personnel who enter this area wear a one-piece positive pressure suit that is ventilated by a life support system. The life support system is provided with alarms and emergency break-up breathing air tanks. Entry to this area is through an airlock fitted with air tight doors. A chemical shower is provided to decontaminate the surface of the suit before the worker leaves the area. The exhaust air from the suit area is filtered by two sets of HEPA filters installed in the series. A duplicate filtration unit, exhaust fan and an automatically starting emergency power source are provided. The air pressure within the suit

area is lower than that of any adjacent area. Emergency lighting and communication systems are provided. All penetrations into the inner shell of the suit area are sealed. A double door autoclave is provided for decontamination of disposable waste materials from the suit area.

Biosafety level 4 laboratories are used for diagnostic work and research on easily transmitted pathogens which can cause fatal disease. These include a number of viruses known to cause viral hemorrhagic fever such as Marburg virus, Ebola virus, Lassa virus, Crimean-Congo hemorrhagic fever. Other pathogens handled at BSL-4 include Hendra virus, Nipah virus, and some flaviviruses. Additionally, poorly characterized pathogens which appear closely related to dangerous pathogens are often handled at this level until sufficient data are obtained either to confirm continued work at this level, or to permit working with them at a lower level. This level is also used for work with Variola virus, the causative agent of smallpox, though this work can only be done at the World Health Organization approved facilities at the Centers for Disease Control and Prevention in Atlanta, United States, as well as the State Research Center of Virology and Biotechnology in Koltsovo, Russia.

1.6. RISK ASSESSMENT

Risk assessment is a process of evaluation including the identification of the attendant uncertainties and severity of adverse effects occurring to man or the environment, on exposure to a risk source. It involves determination of the potential and anticipated adverse effects of the recombinant DNA research to the concerned workers, human health and on the environment.

Risk assessment consists of hazard identification, hazard analysis, consequence analysis, risk determination and risk evaluation. This approach can not be applied to the cases where risk is very low or minimal. A risk assessment is the best method for determining the proper biosafety level and safety practices for work. Risk assessment should be performed by the individuals familiar with- i) the organisms used, ii) the equipments and procedures to be employed, iii) animal models that may be used and iv) the containment equipment and facilities available.

1.6.1. Types of Risk Assessments

- Microbiological risk assessment
- Risk assessments in animal biosafety
- Risk assessments of Genetically Modified Plants
- Risk assessments of Genetically Modified Organisms (GMOs)

1.6.1.1 Microbiological Risk Assessment

First, determine the risk group of agents with which you are working. On the basis of-

- Pathogenicity/ Virulence- Is the agent able to infect and what is the degree of disease severity.
- Route of infection i.e., ingestion, inhalation, mucous membrane, subcutaneous, genitourinary.
- Mode of transmission (direct contact, indirect contact, aerosolized droplet, vectors, intermediate host, etc.)

1.6.1.2 Risk Assessments In Animal Biosafety

For selection of model animals:

- Known animal species should be allowed in the labs.
- The nature of animal i.e., aggressiveness and tendency to bite and scratch should be known.
- Risks like route of exposure, signs of infection, etc should be known.
- Medical surveillance programme for the staff must be available.
- Biohazard warning signs should be posted.
- Heating, ventilation and lighting of room with cages must be adequate.
- Arthropod and rodent control programme.

1.6.1.3 Risk Assessments of Genetically Modified Plants

It includes hazard identification, hazard characterization, exposure characterization, risk characterization, risk management strategies and an overall risk evaluation. Following considerations are as follows:

- Persistence and invasiveness of GM plants.
- Plant to microorganism gene transfer.
- Interaction of GM Plant with target organisms.
- Interaction of GM Plant with non-target organisms.
- Impact of cultivation, management and harvesting techniques on production and environment.
- Effect on biogeochemical processes, human and animal health.

1.6.1.4 Risk Assessments Of Genetically Modified Organisms (GMOS)

The pre-market safety assessment should be undertaken.

- It comprises hazard identification, hazard characterization, and exposure assessment and risk characterization. These steps identify

characteristics which may cause adverse effects, evaluate their potential consequences; assess the likelihood of occurrence and the risk posed.

- Safety assessment of GMOs include 2 steps- i) Comparative analysis of GM with their non-GM counterparts to identify differences. ii) An assessment of the environmental and food safety impact of identified differences.
- Hazards arising from the alteration of existing pathogenic traits.

1.7. RISK REGULATION

Procedures, assays, biological agents, equipments and working designs are developed subsequent to the risk assessment to minimize the risk; this is termed as risk regulation. Risk regulation can be either Reactive or Proactive. Reactive risk regulation develops gradually and is designed to prevent the proven adverse effects shown by earlier products. The assays for toxicity, mutagenicity etc are considered as a part of such regulation. They are designed due to realized hazards in the past and not on the basis of expected risks. But proactive risk regulation is developed to avoid potential hazards that are predicted. Assays and trials are then designed to evaluate the safety of the product. A proactive approach is far more desirable than a reactive approach of risk regulation.

1.8 NATIONAL BIOSAFETY POLICIES AND LAWS

Under Biosafety Research programme main emphasis is given to facilitate the implementation of biosafety procedures, rules and guidelines under Environment (Protection) Act 1986 and Rules 1989 to ensure safety from the use of Genetically Modified Organisms (GMOs) and products thereof in research and application to the users as well as to the environment. A three tier mechanism comprising **Institutional Biosafety Committees (IBSC)** at the Institute/ company; the Review Committee on Genetic Manipulation (RCGM) in the Department of Biotechnology; and the Genetic Engineering Approval Committee (GEAC) in the Ministry of Environment & Forests (MoE&F) for granting approval for research and development activities on recombinant DNA products, environmental release of genetically engineered (GE) crops and monitoring and evaluation of research activities involving recombinant DNA technology has been established. Applications in pharma/ agriculture sectors for import/ export/ transfer / exchange of GE materials including GE seeds, conduct of pre-clinical toxicity studies, evaluation of pre-clinical study reports and recommendations to DCGI for appropriate phase of clinical trials of new drug(s) or similar biologics, confined field trials on GE crops, etc., were examined by the RCGM and appropriate decisions were taken.

RCGM has taken several policy decisions on biosafety research on agricultural/ bio-pharmaceuticals / industrial products.

In exercise of the powers conferred by sections 6, 8 and 25 of the Environment (Protection) Act, 1986 (29 of 1986) and with a view to protecting the environment, nature and health, in connection with the application of gene technology and micro-organisms, the Central Government hereby makes the following rules, namely:-

1. Rules for the Manufacture, Use, Import, Export and Storage of Hazardous micro-organisms genetically engineered organisms or cells.

2. Applications

- 1) These rules are applicable to the manufacture, import and storage of micro-organisms and Gene-Technological products.
- 2) These shall apply to genetically engineered organisms micro-organisms and cells and correspondingly to any substances and products and food stuffs derived from GMOs.
- 3) These rules shall apply to organisms/micro-organisms and cells generated by the utilization of gene-technologies and to substances and products of which such organisms and cells form part.
- 4) These rules shall be applicable to the whole of India.

3. Definition

In these rules unless the context requires,

- i. **Biotechnology**" means the application of scientific and engineering principles to the processing of materials by biological agents to produce goods and services;
- ii. **"Cell hybridisation"** means the formation of live cells with new combinations of genetic material through the fusion of two or more cells by means of methods which do not occur naturally;
- iii. **"Gene Technology"** means the application of the gene technique called genetic engineering, include self-cloning and deletion as well as cell hybridisation;
- iv. **"Genetic engineering"** means the technique by which heritable material, which does not usually occur or will not occur naturally in the organism or cell concerned, generated outside the organism or the cell is inserted into said cell or organism. It shall also mean the formation of new combinations of genetic material by incorporation of a cell into a host cell, where they occur naturally (self cloning) as

well as modification of an organism or in a cell by deletion and removal of parts of the heritable material;

- v. "**Microorganisms**" shall include all the bacteria, viruses, fungi, mycoplasma, cells lines, algae, protodones and nematotes indicated in the schedule and those that have not been presently known to exist in the country or not have been discovered so far.

4. Competent Authorities

The Rules 1989 are broad in scope and covers area of research as well as large scale handling of hazardous microorganisms, GE organisms or cells and products thereof. In order to implement the Rules in the entire country, six competent authorities and their roles have been notified for: i. Regulation and control of contained research activities with hazardous microorganisms, and GE organisms. ii. Regulation and control of large scale use of GE organisms in production activity. iii. Import, export and transfer of hazardous microorganisms, GE organisms and products thereof. iv. Release of GE organisms and products thereof in environmental applications under statutory provisions.

- (1) **Recombinant DNA Advisory Committee (RDAC):** This committee functions in the Department of Biotechnology with a role to:

- I. Review developments in Biotechnology at national and international levels.
- II. Shall recommend suitable and appropriate safety regulations for India in recombinant research, use and applications from time to time.
- III. Evolve long term policy for research and development in Recombinant DNA research.

- (2) **Review Committee on Genetic Manipulation (RCGM):** This committee functions from the Department of Biotechnology to monitor the safety related aspect in respect of on-going research projects or activities involving hazardous microorganisms, GE organisms and cells and products thereof. The RCGM includes representatives of (a) Department of Biotechnology (b) Indian Council of Medical Research (c) Indian Council of Agricultural Research (d) Council of Scientific and Industrial Research (e) other experts in their individual capacity. RCGM may appoint sub groups to assist RCGM on matters related to risk(s) assessment, in reviewing of existing and preparing new guidelines. RCGM is mandated to bring out manuals of guidelines specifying procedure for regulatory process with respect to activities involving GE

organisms in research use as well as industrial and environmental applications with a view to ensure human health and environmental safety. All ongoing research projects involving hazardous microorganisms, GE organisms or cells and products thereof shall be reviewed to ensure that adequate precautions and containment conditions are being met. RCGM lays down procedures restricting or prohibiting production, sale, importation and use of such hazardous microorganisms, GE organisms or cells.

- (3) **Institutional Biosafety Committee (IBSC):** This committee is constituted by all institutions handling hazardous microorganisms and/or GE organisms. The committee is the nodal point for implementation of the biosafety guidelines and for the interactions within the institution. The committee comprises of the Head of the Institution, Scientists engaged in the recombinant DNA work, a medical doctor and a nominee of the Department of Biotechnology. Institutions handling risk-inherent microorganisms or GE organisms shall prepare, with the assistance of the Institutional Biosafety Committee (IBSC), on-site emergency plan and update from time to time according to the manuals/guidelines of the RCGM and make available as required copies to the District Level Committee/State Biotechnology Co-ordination Committee and the Genetic Engineering Appraisal Committee.
- (4) **Genetic Engineering Appraisal Committee (GEAC):** Genetic Engineering Appraisal Committee (GEAC) [formerly known as Genetic Engineering Approval Committee (GEAC); name changed through Gazette notification, G.S.R No. 613 dated 16th July 2010], has been established under the Ministry of Environment, Forest and Climate Change (MoEF&CC). The major functions of GEAC as prescribed in the Rules 1989 are: i. to appraise activities involving large scale use of hazardous microorganisms GE organisms or cells in research and industrial production from the environmental angle. To appraise proposals relating to release of GE organisms and products into the environment including experimental field trials.iii. The committee or any persons authorized by it has powers to take punitive action under the Environment (Protection) Act, 1986.
- (5) **State Biotechnology Co-Ordination Committee (SBCC):** The State Biotechnology Co-ordination Committee (SBCC) is a monitoring committee at State level. It shall have powers: i. To inspect, investigate and to take punitive action in case of violations of statutory provisions through the State Pollution Control Board (SPCB) or the Directorate of Health etc. ii. To review periodically the safety and control measures established at various institutions handling GE organisms. iii. To act as nodal agency at the State level to assess the damage, if any, due to release of GE organisms and to take on site control measures.

(6) **District Level Committee (DLC):** There shall be a District Level Biotechnology Committee (DLC) in the districts wherever necessary under the District Collectors to monitor the safety regulations in installations engaged in the use of genetically modified organisms/ hazardous microorganisms and its applications in the environment. The District Level Committee/or any other person/s authorized in this behalf shall visit the installation engaged in activity involving hazardous microorganisms, GE organisms or cells, and , formulate information chart, find out hazards and risk(s) associated with each of these installations and coordinate activities with a view to meeting any emergency. They shall also prepare an off-site emergency plan.

(7) **Classification of microorganisms or genetically engineered product**

(1) For the purpose of these rules, microorganisms or genetically engineered organisms, products or cells shall be dealt with fewer than two major heads; animal, pathogens and plant pests and these shall be classified in the manner specified in the Schedule.

(2) If any of the microorganisms, genetically engineered organism or cell falls within the limits of more than one risk class as specified in the Schedule, it shall be deemed to belong exclusively to the last in number of such classes.

(8) **Microorganisms laid down in the Schedule are divided into the following:-**

(i) Bacterial Agents; (ii) Fungal Agents; (iii) Parasitic Agents; (iv) Viral, Rickettsial and Chlamydial Agents; and (v) Special Category.

(9) **Approval and Prohibitions etc.**

1. No person shall import, export, transport, manufacture, process, use or sell any hazardous microorganisms of genetically engineered organisms/substances or cells except with the approval of the Genetic Engineering Approval Committee.

2. Use of pathogenic microorganisms or any genetically engineered organisms or cells for the purpose of research shall only be allowed in laboratories or inside laboratory area notified by the Ministry of Environment and Forests for this purpose under the Environment (Protection) Act, 1986.

3. The Genetic Engineering Approval Committee shall give directions to the occupier to determine or take measures concerning the discharge of microorganisms/genetically engineered organisms or cells mentioned in the Schedule from the

laboratories, hospitals and other areas including prohibition of such discharges and laying down measures to be taken to prevent such discharges.

4. Any person operating or using genetically engineered organisms/microorganisms mentioned in the schedule for scale up or pilot operations shall have to obtain licence issued by the Genetic Engineering Approval Committee for any such activity. The possessor shall have to apply for licence in prescribed proforma.
5. Certain experiments for the purpose of education within the field of gene technology or microorganism may be carried out outside the laboratories and laboratory areas mentioned in sub-rule (2) and will be looked after by the Institutional Biosafety Committee.

8. Production

Production in which genetically engineered organisms or cells or micro- organisms are generated or used shall not be commenced except with the consent of Genetic Engineering Approval Committee with respect of discharge of genetically engineered organisms or cells into the environment. This shall also apply to production taking place in connection with development, testing and experiments where such production, etc., is not subject to rule 7.

9. Deliberate or unintentional release

- (1) Deliberate or unintentional release of genetically engineered organisms/hazardous microorganisms or cells, including deliberate release for the purpose of experiment shall not be allowed. **Note:** Deliberate release shall mean any intentional transfer of genetically engineered organisms/hazardous, microorganisms or cells to the environment or nature, irrespective of the way in which it is done.
- (2) The Genetic Engineering Approval Committee may in special cases give approval of deliberate release.

10. Permission and approval for certain substances

Substances and products, which contain genetically engineered organisms or cells or microorganisms shall not be produced, sold, imported or used except with the approval of Genetic Engineering Approval Committee.

11. Permission and approval for food stuffs

Food stuffs, ingredients in food stuffs and additives including processing and containing or consisting of genetically engineered organisms or cells, shall not be produced, sold, imported or used except with the approval of the Genetic Engineering Approval Committee.

12. Guidelines

- (1) Any person who applies for approval under rules 8-11 shall, as determined by the Genetic Engineering Approval Committee submit information and make examinations or cause examinations to be made to eradicate the case, including examinations according to specific directions and at specific laboratories. He shall also make available an on-site emergency plan to GEAC before obtaining the approval. If the authority makes examination itself, it may order the applicant to delay the expenses incurred by it in so doing.
- (2) Any person to whom an approval has been granted under rules 8-11 above shall notify the Genetic Engineering Approval Committee of any change in or addition to the information already submitted

13. Grant of approval

- (1) In connection with the granting of approval under rules 8 to 11 above, terms and conditions shall be stipulated, including terms and conditions as to the control to be exercised by the applicant, supervision, restriction on use, the layout of the enterprise and as to the submission of information to the State Biotechnology Co-ordination Committee or to the District Level Committee.
- (2) All approvals of the Genetic Engineering Approval Committee shall be for a specific period not exceeding four year at the first instance renewable for 2 years at a time. The Genetic Engineering Approval Committee shall have powers to revoke such approval in the following situations:-
 - (a) If there is any new information as to the harmful effects of the genetically engineered organisms or cells.
 - (b) If the genetically engineered organisms or cells cause such damage to the environment, nature or health as could not be envisaged when the approval was given, or
 - (c) Non compliance of any condition stipulated by Genetic Engineering Approval Committee.

14. Supervision

- (1) The Genetic Engineering Approval Committee may supervise the implementation of the terms and conditions laid down in connection with the approvals accorded by it.
- (2) The Genetic Engineering Approval Committee may carry out this supervision through the State Biotechnology Coordination Committee or the State Pollution Control Boards/District Level Committee or through any person

authorized in this behalf.

15. Penalties

- (1) If an order is not complied with, the District Level Committee or State Biotechnology Co-ordination Committee may take measures at the expense of the person who is responsible.
- (2) In case where immediate intervention is required in order to prevent any damage to the environment, nature or health, the District level Committee or State Biotechnology Coordination Committee may take the necessary steps without issuing any order or notice. The expenses incurred for this purpose will be repayable by the person responsible for such damage.
- (3) The State Biotechnology Co-ordination Committee/District Level Committee may take samples for a more detailed examination of organisms and cells.
- (4) The State Biotechnology Co-ordination Committee/District Level Committee shall be competent to ask for assistance from any other government authority to carry out its instructions.

16. Responsibility to notify interruptions or accidents

- (1) Any person who under rule 7-11 is responsible for conditions or arrangements shall immediately notify the District Level Committee/State Biotechnology Co-ordination Committee and the state medical officer of any interruption of operations or accidents that may lead to discharges of genetically engineered organisms or cells which may be harmful to the environment, nature or health or involve any danger thereto.
- (2) Any notice given under sub-rule (I) above shall not lessen the duty of the person who is responsible to try effectively to minimize or prevent the effects of interruptions of operations or accidents.

17. Preparation Off-site emergency Plan by the DLC

- (1) It shall be the duty of the DLC to prepare an off-site emergency plan detailing how emergencies relating to a possible major accident at a site will be dealt with and in preparing the plan, the DLC shall consult the occupier and such other person as it may deem necessary.
- (2) For the purpose of enabling the DLC- to prepare the emergency plan required under sub-rule (1), the occupier shall provide the DLC with such information relating to the handling of hazardous microorganisms/ genetically engineered organisms under his control as the DLC may

required including the nature, extent and likely off-site affects of a possible major accident and the DLC shall provide the occupier with any information from the off-site emergency plan which relates to his duties under rule 16.

18. Inspections and information regarding finance

- (1) The State Biotechnology Co-ordination Committee or the Genetic Engineering Approval Committee/the DLC or any person with special knowledge duly authorized by the State Biotechnology Co-ordination Committee or the Genetic Engineering Approval Committee or the DLC where it is deemed necessary, at any time on due production of identity be admitted to public as well as to private premises and localities for the purpose of carrying out supervision.
- (2) Any person who is responsible for activities subject to rules 7-11 above shall at the request of District level Committee or State Biotechnology Coordination Committee or the GEAC submit all such information including information relating to financial conditions and accounts, as is essential to the authority's administration under these rules He shall also allow supervision or inspection by the authorities or persons indicated in sub-rule (1).
- (3) The Genetic Engineering Approval Committee may fix fees to cover, in whole or in part, the expenses incurred by the authorities in connection with approvals, examinations, supervisions and control.

19. Appeal

Any person aggrieved by a decision made by Genetic Engineering Approval Committee/State Biotechnology Co-ordination Committee in pursuance of these rules may within thirty days from the date on which the decision is communicated to him, prefer an appeal to such authority as may be appointed by Ministry of Environment and Forests provided that the appellate authority may entertain the appeal after the expiry of the said period of thirty days if such authority is satisfied that the appellant was prevented by sufficient cause from filing the appeal in time.

20. Exemption

The Ministry of Environment and Forests shall, wherever necessary, exempt an occupier handling a particular microorganism/genetically engineered organism from rule 7-11.

1.9 THE CARTAGENA PROTOCOL ON BIOSAFETY

The *Cartagena Protocol on Biosafety to the Convention on Biological Diversity* is an international agreement which aims to ensure the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health. It was adopted on 29 January 2000 and entered into force on 11 September 2003.

1.9.1 Introduction

On 29th January 2000, the Conference of the Parties to the Convention on Biological Diversity adopted a supplementary agreement to the Convention known as the Cartagena Protocol on Biosafety. The Protocol seeks to protect biological diversity from the potential risks posed by living modified organisms resulting from modern biotechnology. It establishes an advance informed agreement (AIA) procedure for ensuring that countries are provided with the information necessary to make informed decisions before agreeing to the import of such organisms into their territory. The Protocol contains reference to a precautionary approach and reaffirms the precaution language in Principle 15 of the Rio Declaration on Environment and Development. The Protocol also establishes a Biosafety Clearing-House to facilitate the exchange of information on living modified organisms and to assist countries in the implementation of the Protocol.

1.9.2 History

Pursuant to Article 19, paragraph 3, of the Convention on Biological Diversity, the Conference of the Parties, by its decision II/5, established an Open-ended Ad Hoc Working Group on Biosafety to develop a draft protocol on biosafety, specifically focusing on transboundary movement of any living modified organism resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

Timeline of the Cartagena Protocol on Biosafety

1993		<i>The Convention on Biological Diversity enters into force on 29 December 1993</i>
1995	COP2	Second meeting of the Conference of the Parties - Consideration of the need for and modalities of a protocol for the safe transfer, handling and use of living modified organisms. <i>Jakarta, Indonesia, 6 - 17 November 1995</i>
1996	COP3	Third meeting of the Conference of the Parties - Issues related to biosafety. <i>Buenos Aires, Argentina, 4 - 15 November 1996</i>

1996	BSWG1	First meeting of the Open-Ended <i>Ad Hoc</i> working Group on Biosafety. <i>Aarhus, Denmark, 22 - 26 July 1996</i>
1997	BSWG2	Second meeting of the Open-Ended <i>Ad Hoc</i> working Group on Biosafety. <i>Montreal, Canada, 12 - 16 May 1997</i>
1997	BSWG3	Third meeting of the Open-Ended <i>Ad Hoc</i> working Group on Biosafety. <i>Montreal, Canada, 13 - 17 October 1997</i>
1998	BSWG4	Fourth meeting of the Open-Ended <i>Ad Hoc</i> working Group on Biosafety. <i>Montreal, Canada, 5 - 13 February 1998</i>
1998	COP4	Fourth meeting of the Conference of the Parties - Issues related to biosafety. <i>Bratislava, Slovakia, 4 - 15 May 1998</i>
1998	BSWG5	Fifth meeting of the Open-Ended <i>Ad Hoc</i> working Group on Biosafety. <i>Montreal, Canada, 17 - 28 August 1998</i>
1999	BSWG6	Sixth meeting of the Open-Ended <i>Ad Hoc</i> working Group on Biosafety. <i>Cartagena, Colombia, 14 - 19 February 1999</i>
1999	BSIC1	Informal Consultation on the process to resume the Extraordinary Meeting of COP to adopt a protocol on Biosafety. <i>Montreal, Canada, 1 July 1999</i>
1999	BSIC2	Second Informal Consultation on the process to resume the Extraordinary Meeting of COP to adopt a protocol on Biosafety. <i>Vienna, Austria, 15 - 19 September 1999</i>
1999 - 2000	EXCOP1	First Extraordinary Meeting of the Conference of the Parties - Decisions on the continuation of the first extraordinary meeting of the Conference of the Parties to the Convention on Biological Diversity, <i>adoption of the Cartagena Protocol</i> and interim arrangements. <i>Cartagena, Colombia 22 - 23 February 1999 and Montreal, Canada, 24</i>

		- 28 January 2000
2000	COP5	<i>The Cartagena Protocol on Biosafety is opened for signature.</i> Fifth meeting of the Conference of the Parties - Work plan of the Intergovernmental Committee for the Cartagena Protocol on Biosafety. <i>Nairobi, Kenya, 15 - 26 May 2000</i>
2000	ICCP1	First meeting of the Intergovernmental Committee for the Cartagena Protocol on Biosafety. <i>Montpellier, France, 11 - 15 December 2000</i>
2001	ICCP2	Second meeting of the Intergovernmental Committee for the Cartagena Protocol on Biosafety. <i>Nairobi, Kenya, 1 - 5 October 2001</i>
2002	COP6	Sixth meeting of the Conference of the Parties - Intergovernmental Committee for the Cartagena Protocol on Biosafety. <i>The Hague, Netherlands, 7 - 19 April 2002</i>
2002	ICCP3	Third meeting of the Intergovernmental Committee for the Cartagena Protocol on Biosafety. <i>The Hague, The Netherlands, 22 - 26 April 2002</i>
2003	<i>The Cartagena Protocol on Biosafety enters into force on 11 September 2003</i>	

1.9.3 The ICCP Process

The Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP) was established in decision EM-I/3 adopting the Cartagena Protocol on Biosafety, to undertake the preparations necessary for the first meeting of the Parties to the Protocol.

Following its establishment, the ICCP convened an organizational meeting on 29th January 2000, chaired by Ambassador Yang of Cameroon, and elected a Bureau to oversee its activities. The members elected to the Bureau were: Cameroon (Chair), Denmark, India, Islamic Republic of Iran, Peru, Poland, Saint Kitts and Nevis, South Africa, Switzerland and Ukraine. At the first meeting of the ICCP, Denmark was replaced by France. The first task of the Bureau was to develop a work plan for the ICCP which was submitted, to and endorsed by, the fifth meeting of the Conference of the Parties in May 2000.

The ICCP Bureau held more than 10 oversight meetings over a period of four years of its existence. The ICCP submitted its final report to the first meeting of the Parties to the Protocol which was held 23-27 February 2004 in Kuala Lumpur, Malaysia.

1.9.4 Entry into force

The Protocol entered into force on 11th September 2003, ninety days after the deposit of the fiftieth instrument of ratification. In accordance with Article 29, paragraph 1, of the Protocol, the COP to the Convention serves as the meeting of the Parties to the Protocol (COP-MOP), the governing body of the Protocol.

1. This Protocol shall enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Convention.
2. This Protocol shall enter into force for a State or regional economic integration organization that ratifies, accepts or approves this Protocol or accedes thereto after its entry into force pursuant to paragraph 1 above, on the ninetieth day after the date on which that State or regional economic integration organization deposits its instrument of ratification, acceptance, approval or accession, or on the date on which the Convention enters into force for that State or regional economic integration organization, whichever shall be the later.
3. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.

1.10 Biosafety Principles

The primary principle of biological safety (i.e., biosafety) is containment. The term containment refers to a series of safe methods for managing infectious agents in the laboratory. The purpose of containment is to reduce or eliminate human and environmental exposure to potentially harmful agents.

Containment

The term "Containment" is used in describing the safe methods for managing infectious agents in the laboratory environment where they are being handled or maintained. There are 2 Types of containment:

1. **Biological containment (BC):** In consideration of biological containment, the vector (plasmid, organelle, or virus) for the recombinant DNA and the host (bacterial, plant, or animal cell) in which the vector is propagated in the laboratory will be considered

together. Any combination of vector and host must be chosen to limit the infectivity of vector to specific hosts and control the host-vector survival in the environment.

Physical Containment (PC): The objective of physical containment is to confine recombinant organisms thereby preventing the exposure of the researcher and the environment to the harmful agents. Physical containment is achieved through the use of i) Laboratory Practice, ii) Containment Equipment, and iii) Special Laboratory Design. The protection of the environment external to the laboratory from exposure to infectious materials, is provided by a combination of facility design and operational practices.

Elements of Containment: The three elements of containment include laboratory practice and technique, safety equipment and facility design.

i) Laboratory practice and technique:

- Strict adherence to standard microbiological practices and techniques
- Awareness of potential hazards
- Providing/arranging for appropriate training of personnel
- Selection of safety practices in addition to standard laboratory practices if required
- Developing of adopting a biosafety or operations manual which identifies the hazards

ii) Safety equipment (*primary barriers*): Safety equipment includes biological safety cabinets and a variety of enclosed containers (e.g. safety centrifuge cup). The biological safety cabinet (BSC) is the principal device used to provide containment of infectious aerosols generated by many microbiological procedures. Three types of BSCs (Class I, II, III) are used in microbiological laboratories. Safety equipment also includes items for personal protection such as gloves, coats, gowns, shoe covers, boots, respirators, face shields and safety glasses, etc.

iii) Facility Design (*Secondary barriers*): The design of the facility is important in providing a barrier to protect persons working in the facility but outside of the laboratory and those in the community from infectious agents which may be accidentally released from the laboratory. There are three types of facility designs: viz, the Basic Laboratory (for Risk Group I and II), the Containment Laboratory (for Risk Group III) and the Maximum Containment Laboratory (for Risk Group IV).

1.10.1 Laboratory Monitoring

Laboratory monitoring is a systematic, regular and preventive activity designed for corrective actions, if required. It is the responsibility of the Head of the Institution to ensure:

- i. Prevention of any unauthorized entry in the laboratory. Entry and exit procedures must cover:
 - Authorization for laboratory staff, visitors, maintenance, visiting scholars.
 - Entry/exit log or other method to monitor authorized entry.
 - Required personal protective equipment.
 - Escort requirements.
 - Removal of interfering objects and viable culture
 - Disinfection procedure prior to entry and maintenance.
 - Disinfection procedure for exiting
- ii. Allow entry of person having proper training in laboratory safety and immunization, if required (For handling RG 3 and above organisms). Personnel training in biosafety is the key for prevention of laboratory-acquired infections, incidents and accidents ensuring success of any containment strategy. Based on the organism to be handled and the nature of work, training program to be developed and laboratory in charge must play the key role in training of laboratory staff. A training program must include information on safe handling of organisms of different risk groups that are commonly encountered by all laboratory personnel, involving any possible exposure scenarios and decontamination and emergency plan strategies. Training should involve class room work as well as significant one-on-one mentoring in the lab before an individual is allowed to work alone. It may include:
 - Inhalation risk(s) (i.e. aerosol production), such as using loops, streaking agar plates, pipetting, making smears, opening cultures, taking blood/serum samples, centrifugation etc.
 - Ingestion risks, such as handling specimens, smears and cultures.
 - Risk(s) of percutaneous exposures, through the use of syringe and needle techniques.

1.10.2 Health Aspects

The antibiotic resistance marker genes generally used for the screening purposes of transgenic plants and organisms. But their effect on

human health should also be ascertained beforehand to assure the critical level. However health benefits can also not be ignored, especially when we talk about reduced pesticide consumption in residual form in the food products. Some of the health benefits have been obtained in the form of biofortification i.e. augmented specific nutrients. One example is Golden rice with increased the availability of vitamin A6. But still many gaps exist even at the cellular level because of the incomplete knowledge of how genes govern their expression. Transgenic soybean expressing allergenic seed storage protein from Brazil nut was reported to retain the allergenicity. The issue was so intense that it was withdrawn from release subsequently. Another example includes development of a genetically engineered pea expressing the “ α -amylase inhibitor-1” protein from beans. It was also found to contain protein that could invoke an immune response. Hence no guarantees can be provide from scientists and plant researchers that a variety produced using GM process will be of completely free from all the negative impacts on environment or human health. Therefore, the expression of the recombinant protein needs to be critically and carefully assessed by all means and from each aspect including the most important ones like health, allergenicity, toxicity etc.

1.10.3 Allergenicity

Allergic sensitization is the process of specific immunological priming through which heightened sensitivity (sensitization) to food proteins is acquired. Allergenicity or allergenic potential is the potential of a material to cause sensitization and allergic reactions, frequently associated with IgE antibody. Allergies and chemical sensitivities are a perennial threat to scientists who spend most of their time in the lab. Laboratory animal allergy is an occupational disease of laboratory animal technicians and scientists. It manifests as an allergic response to animal urine and can lead to the development of asthma. Globally the prevalence among at risk workers is estimated between 11 and 30%. Animals are not the only potential health issue in a laboratory. Chemicals and other materials can cause allergies or sensitivity. For example, 8–12% of health-care workers are allergic to latex, according to the US National Institute for Occupational Safety and Health (NIOSH).

According to the National Institutes of Health, prevention of animal allergy depends on the control of allergens in the work environment. This involves a combination of measures to eliminate or control allergen exposure, including engineering controls, administrative controls and personal protective equipment.

1.10.4 Antibiotic Resistance

Horizontal gene transfer (HGT) is quite rare, though documentation through evolutionary timescale gives evidences of HGT. However, even its chance occurrence may have significant health and ecological impacts thus a focus of attention for biosafety considerationis

the possible consequences of horizontal gene transfer. The possibility of HGT between bacteria and plants in either the soil or gut has been seen as a hazard associated with transgenic plants, particularly when this is related to the possible transfer of genes encoding antibiotic resistance. The thus the level of significance of this concern as a risk depends on the likelihood of horizontal gene transfer and the magnitude of associated adverse outcome.

1.10.5 Medical Surveillance

The objectives of the health and medical surveillance of laboratory personnel are:

- Prevent individual from acquiring infection during the work
- Provide for early detection of laboratory-acquired infection.
- Provide for assessing the efficacy of protective equipment and procedures.
- Provide for prophylactic vaccinations where needed and monitor booster regimens and assessment of sero conversion, in applicable cases.

It is the responsibility of the employing authority and/or the facility in-charge to ensure that health and medical surveillance of laboratory personnel is carried out.

1.11 SUMMARY

Bio-related research activities may involve manipulation of microbial, animal or plant cells. The risks associated with these activities arise from the samples and /or the procedural requirements. Adherence to standard microbiological techniques and using facilities suitable to the risk level of the pathogen helps to protect the researcher from laboratory-acquired infections. Biosafety levels are a set of biocontainment precautions required to isolate dangerous biological agents in an enclosed laboratory facility. There are four biosafety levels according to the risk group associated with the microorganisms. Risk assessment consists of hazard identification, hazard analysis, consequence analysis, risk determination and risk evaluation. Procedures, assays, biological agents, equipments and working designs are developed subsequent to the risk assessment to minimize the risk; this is termed as risk regulation. There are National policies and laws with main emphasis to facilitate the implementation of biosafety procedures, rules and guidelines under Environment (Protection) Act 1986 and Rules 1989 to ensure safety from the use of Genetically Modified Organisms (GMOs) and products thereof in research and application to the users as well as to the environment. The primary principle of biosafety is containment. The purpose of containment is to reduce or eliminate human and environmental exposure to potentially

harmful agents. The *Cartagena Protocol on Biosafety to the Convention on Biological Diversity* is an international agreement which aims to ensure the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health.

1.12. SELF ASSESSMENT QUESTIONS

Q.1. Explain the concept of risk assessment relevant to recombinant DNA technology with special reference to laboratory experiments.

Answer:-----

Q.2. Briefly explain the concept of containment during recombinant DNA research.

Answer:-----

Q.3. Write short note on the following: (i) genetically modified organisms (ii) containment (iii) risk assessment (iv) biosafety (v) risk groups (vi) risk regulation (vii) biosafety levels.

Answer:-----

Q.4. Discuss the biosafety and its levels.

Answer:-----

Q.5. What are some potential risks of biotechnology?

Answer:-----

Q.6. What does the Cartagena protocol cover?

Answer:-----

1.13. FURTHER READINGS

1. Principles of Biochemistry: Lehninger, Nelson and Cox. Student Edition, CBS 1439 Publishers and Distributors, Delhi.

2. Biochemistry: Lubert Stryer, published by W. H. Freeman
3. Biochemistry: U Satyanarayana, published by Elsevier, India
4. Fundamentals of Biochemistry: Dr J L Jain, S. Chand and Company
5. Fundamentals of Cognitive psychology by R. Reed Hunt and Henry C. Ellis
6. An Introduction to Applied Cognitive Psychology: A Esgate and David Groom, TMH
7. Biotechnology: B.D Singh, Expanding Horizons. Kalyani, 2007.

UNIT-2 CONVENTION AND ECOLABELLING

Structure

- 2.1. Introduction
 - Objectives
- 2.2. Convention on biological diversity
- 2.3. The Paris Convention of 1883
- 2.4. Berne convention
- 2.5. Government use of patent
- 2.6. Ecolabelling
- 2.7. Ecomark
- 2.8. Geographical Indications
- 2.9. Summary
- 2.10. Terminal Questions
- 2.11. Further readings

2.1. INTRODUCTION

The Paris convention is an international treaty that is currently administered by the World Intellectual Property Organization (WIPO), origin of the treaty and the substantive provisions of the convocation are explained. Some terms such as patents, marks, trade names, source indications and unfair competition are very necessary for proper concept. Berne convention, its principles, copyright terms, limitations and implementation are also discussed in brief. The government use of patents, term of patent, Indian patent act and compulsory licenses are very important tools for its proper understanding. Ecolabelling, types of labels, its objectives, guiding principles and key steps are given. Ecomark, its objectives, function of BIS and criteria for awarding eco-mark are described.

Objectives

- To discuss the convention on biological diversity (CBD)
- To discuss the various convention such as Paris and Berne convention etc. on CBD
- To briefly discuss about government use of patent, ecolabelling and ecomark

2.2 CONVENTION ON BIOLOGICAL DIVERSITY (CBD)

CBD, known informally as the Biodiversity Convention, is a multilateral treaty. Its objective is to develop national strategies for the conservation and sustainable use of biological diversity. It is often seen as the key document regarding sustainable development. The Convention was opened for signature at the Earth Summit in Rio de Janeiro on 5th June 1992 and entered into force on 29th December 1993. CBD has two supplementary agreements- Cartagena protocol and Nagoya Protocol.

The Cartagena protocol on Biosafety to the Convention on Biological Diversity is an international treaty governing the movements of living modified organisms (LMOs) resulting from modern biotechnology from one country to another. It was adopted on 29th January 2000 as a supplementary agreement to the Convention on Biological Diversity and entered into force on 11th September 2003.

The Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization (ABS) to the convention on Biological Diversity is a supplementary agreement to the Convention on Biological Diversity. It provides a transparent legal framework for the effective implementation of one of the three objectives of the CBD: the fair and equitable sharing of benefits arising out of the utilization of genetic resources. The Nagoya Protocol on ABS was adopted on 29th October 2010 in Nagoya, Japan, and entered into force on 12th October 2014, 90 days after the deposit of fiftieth instrument of ratification. Its objective is the fair and equitable sharing of benefits arising from the utilization of genetics resources, thereby contributing to the conservation and sustainable use of biodiversity.

The Convention was opened for signature at the United Nations Conference on Environment and Development, the "Earth Summit", in Rio de Janeiro (Brazil) on 5th June 1992. The Convention entered into force on 29th December 1993, 90 days after the 30th ratification, as stated in its article 36. It has now been ratified by 190 parties (189 countries and the European Community). The Convention on Biological Diversity (CBD) entered into force on 29th December 1993. It has 3 main objectives:

1. The conservation of biological diversity
2. The sustainable use of the components of biological diversity
3. The fair and equitable sharing of the benefits arising out of the utilization of genetic resources

Principle :

States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the

responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.

Use of Terms :

For the purposes of this Convention:

Biological diversity means the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.

Biological resources includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.

Biotechnology means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

Country of origin of genetic resources" means the country which possesses those genetic resources in in-situ conditions.

Country providing genetic resources" means the country supplying genetic resources collected from in-situ sources, including populations of both wild and domesticated species, or taken from ex-situ sources, which may or may not have originated in that country.

Domesticated or cultivated species" means species in which the evolutionary process has been influenced by humans to meet their needs.

Ecosystem" means a dynamic complex of plant, animal and micro-organism communities and their non-living environment interacting as a functional unit.

Ex-situ conservation" means the conservation of components of biological diversity outside their natural habitats.

Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity.

Genetic resources" means genetic material of actual or potential value.

Habitat means the place or type of site where an organism or population naturally occurs.

In-situ conditions means conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.

In-situ conservation means the conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surroundings and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.

Protected area means a geographically defined area which is designated or regulated and managed to achieve specific conservation objectives. **Regional economic integration organization**" means an organization constituted by sovereign States of a given region, to which its member States have transferred competence in respect of matters governed by this Convention and which has been duly authorized, in accordance with its internal procedures, to sign, ratify, accept, approve or accede to it.

Sustainable use means the use of components of biological diversity in a way and at a rate that does not lead to the long-term decline of biological diversity, thereby maintaining its potential to meet the needs and aspirations of present and future generations.

Technology includes biotechnology.

Cooperation :

Each Contracting Party shall, as far as possible and as appropriate, cooperate with other Contracting Parties, directly or, where appropriate, through competent international organizations, in respect of areas beyond national jurisdiction and on other matters of mutual interest, for the conservation and sustainable use of biological diversity.

General Measures for Conservation and Sustainable Use :

Each Contracting Party shall, in accordance with its particular conditions and capabilities:

- a. Develop national strategies, plans or programmes for the conservation and sustainable use of biological diversity or adapt for this purpose existing strategies, plans or programmes which shall reflect, inter alia, the measures set out in this Convention relevant to the Contracting Party concerned; and
- b. Integrate the conservation and sustainable use of biological diversity into relevant sectoral or cross-sectoral plans, programmes and policies.

The CBD was negotiated under the guidance of the United Nations. It was signed by more than 150 government leaders at the Rio Earth Summit (which official denomination is the 'United Nations Conference on Environment and Development'). The Convention is now one of the most widely ratified international treaties on environmental issues, with 194 member countries. Unlike other international agreements that set compulsory targets and obligations, the CBD takes a flexible approach to implementation. It identifies general goals and policies, and countries are free to determine how they want to implement them. One of the CBD's greatest achievements so far has been to generate an enormous amount of interest in biodiversity, both in developed and developing countries. Biodiversity is now seen as a critically important environment and development issue.

Identification and Monitoring :

Each Contracting Party shall, as far as possible and as appropriate:

- (a) Identify components of biological diversity important for its conservation and sustainable use;
- (b) Monitor, through sampling and other techniques, the components of biological diversity identified pursuant to: (a) paying particular attention to those requiring urgent conservation measures and (b) those which offer the greatest potential for sustainable use; (c) Identify processes and categories of activities which have or are likely to have significant adverse impacts on the conservation and sustainable use of biological diversity, and monitor their effects through sampling and other techniques; and (d) Maintain and organize, by any mechanism data, derived from identification and monitoring activities pursuant to subparagraphs (a), (b) and (c) above.

In-situ Conservation:

Each Contracting Party shall, as far as possible and as appropriate:

- a. Establish a system of protected areas or areas where special measures need to be taken to conserve biological diversity;
- b. Develop, where necessary, guidelines for the selection, establishment and management of protected areas or areas where special measures need to be taken to conserve biological diversity;
- c. Regulate or manage biological resources important for the conservation of biological diversity whether within or outside protected areas, with a view to ensuring their conservation and sustainable use;
- d. Promote the protection of ecosystems, natural habitats and the maintenance of viable populations of species in natural surroundings;
- e. Promote environmentally sound and sustainable development in areas adjacent to protected areas with a view to furthering protection of these areas;
- f. Rehabilitate and restore degraded ecosystems and promote the recovery of threatened species, inter alia, through the development and implementation of plans or other management strategies;

Ex-situ Conservation:

Each Contracting Party shall, as far as possible and as appropriate, and predominantly for the purpose of complementing in-situ measures:

- (a) Adopt measures for the ex-situ conservation of components of biological diversity, preferably in the country of origin of such components;

- (b) Establish and maintain facilities for ex-situ conservation of and research on plants, animals and micro-organisms, preferably in the country of origin of genetic resources;
- (c) Adopt measures for the recovery and rehabilitation of threatened species and for their reintroduction into their natural habitats under appropriate conditions;

Sustainable Use of Components of Biological Diversity:

Each Contracting Party shall, as far as possible and as appropriate:

- (a) Integrate consideration of the conservation and sustainable use of biological resources into national decision-making;
- (b) Adopt measures relating to the use of biological resources to avoid or minimize adverse impacts on biological diversity;
- (c) Protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements;
- (d) Support local populations to develop and implement remedial action in degraded areas where biological diversity has been reduced.

Research and Training:

The Contracting Parties, taking into account the special needs of developing countries, shall:

- (a) Establish and maintain programmes for scientific and technical education and training in measures for the identification, conservation and sustainable use of biological diversity and its components and provide support for such education and training for the specific needs of developing countries;
- (b) Promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, inter alia, in accordance with decisions of the Conference of the Parties taken in consequence of recommendations of the Subsidiary Body on Scientific, Technical and Technological Advice; and
- (c) In keeping with the provisions of Articles 16, 18 and 20, promote and cooperate in the use of scientific advances in biological diversity research in developing methods for conservation and sustainable use of biological resources.

Public Education and Awareness :

The Contracting Parties shall :

- (a) Promote and encourage understanding of the importance of, and the measures required for, the conservation of biological diversity,

as well as its propagation through media, and the inclusion of these topics in educational programmes; and

- (b) Cooperate, as appropriate, with other States and international organizations in developing educational and public awareness programmes, with respect to conservation and sustainable use of biological diversity.

Impact Assessment and Minimizing Adverse Impacts:

1. Each Contracting Party, as far as possible and as appropriate, shall:
 - a. Introduce appropriate procedures requiring environmental impact assessment of its proposed projects that are likely to have significant adverse effects on biological diversity with a view to avoiding or minimizing such effects and, where appropriate, allow for public participation in such procedures;
 - b. Introduce appropriate arrangements to ensure that the environmental consequences of its programmes and policies that are likely to have significant adverse impacts on biological diversity are duly taken into account;
 - c. Promote, on the basis of reciprocity, notification, exchange of information and consultation on activities under their jurisdiction or control which are likely to significantly affect adversely the biological diversity of other States or areas beyond the limits of national jurisdiction, by encouraging the conclusion of bilateral, regional or multilateral arrangements, as appropriate;
 - d. In the case of imminent or grave danger or damage, originating under its jurisdiction or control, to biological diversity within the area under jurisdiction of other States or in areas beyond the limits of national jurisdiction, notify immediately the potentially affected States of such danger or damage, as well as initiate action to prevent or minimize such danger or damage; and
2. The Conference of the Parties shall examine, on the basis of studies to be carried out, the issue of liability and redress, including restoration and compensation, for damage to biological diversity, except where such liability is a purely internal matter.

Access to Genetic Resources:

- 1) Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.
- 2) Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound

uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.

- 3) For the purpose of this Convention, the genetic resources being provided by a Contracting Party are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.
- 4) Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.
- 5) Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.

Access to and Transfer of technology:

- i. Each Contracting Party, recognizing that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention, undertakes subject to the provisions of this Article to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment.
- ii. Access to and transfer of technology referred to in paragraph 1 above to developing countries shall be provided and/or facilitated under fair and most favorable terms, including on concessional and preferential terms where mutually agreed, and, where necessary. In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights.
- iii. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that are developing countries, which provide genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights, where necessary, and in accordance with international law and consistent with paragraphs 4 and 5 below.
- iv. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that the private sector facilitates access to, joint development and transfer of technology referred to in paragraph 1 above for the benefit of both governmental institutions and the private sector of developing

countries and in this regard shall abide by the obligations included in paragraphs 1, 2 and 3 above.

Exchange of Information:

1. The Contracting Parties shall facilitate the exchange of information, from all publicly available sources, relevant to the conservation and sustainable use of biological diversity, taking into account the special needs of developing countries.
2. Such exchange of information shall include exchange of results of technical, scientific and socio-economic research, as well as information on training and surveying programmes, specialized knowledge, indigenous and traditional knowledge as such and in combination with the technologies referred to in Article 16, paragraph 1. It shall also, where feasible, include repatriation of information.

Technical and Scientific Cooperation:

1. The Contracting Parties shall promote international technical and scientific cooperation in the field of conservation and sustainable use of biological diversity, where necessary, through the appropriate international and national institutions.
2. Each Contracting Party shall promote technical and scientific cooperation with other Contracting Parties, in particular developing countries, in implementing this Convention, inter alia, through the development and implementation of national policies.
3. The Conference of the Parties, at its first meeting, shall determine how to establish a clearing-house mechanism to promote and facilitate technical and scientific cooperation.
4. The Contracting Parties shall, in accordance with national legislation and policies, encourage and develop methods of cooperation for the development and use of technologies, including indigenous and traditional technologies.
5. The Contracting Parties shall, subject to mutual agreement, promote the establishment of joint research programmes and joint ventures for the development of technologies relevant to the objectives of this Convention.

Handling of Biotechnology and Distribution of its Benefits:

1. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and where feasible in such Contracting Parties.
2. Each Contracting Party shall take all practicable measures to

promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. Such access shall be on mutually agreed terms.

3. The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.
4. Each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in paragraph 3 above, provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced.

Financial Resources :

1. Each Contracting Party undertakes to provide, in accordance with its capabilities, financial support and incentives in respect of those national activities which are intended to achieve the objectives of this Convention, in accordance with its national plans, priorities and programmes.
2. The developed country Parties shall provide new and additional financial resources to enable developing country Parties to meet the agreed full incremental costs to them of implementing measures which fulfil the obligations of this Convention and to benefit from its provisions and which costs are agreed between a developing country Party and the institutional structure referred to in Article 21, in accordance with policy, strategy, programme priorities and eligibility criteria and an indicative list of incremental costs established by the Conference of the Parties.
3. The developed country Parties may also provide, and developing country Parties avail themselves of, financial resources related to the implementation of this Convention through bilateral, regional and other multilateral channels.
4. The extent to which developing country Parties will effectively implement their commitments under this Convention will depend on the effective implementation by developed country Parties of their commitments under this Convention related to financial resources and transfer of technology and will take fully into account the fact that economic and social development and

eradication of poverty are the first and overriding priorities of the developing country Parties.

5. The Parties shall take full account of the specific needs and special situation of least developed countries in their actions with regard to funding and transfer of technology.

Relationship with Other International Conventions:

1. The provisions of this Convention shall not affect the rights and obligations of any Contracting Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity.
2. Contracting Parties shall implement this Convention with respect to the marine environment consistently with the rights and obligations of States under the law of the sea.

Conference of the Parties :

1. A Conference of the Parties is hereby established. The first meeting of the Conference of the Parties shall be convened by the Executive Director of the United Nations Environment Programme not later than one year after the entry into force of this Convention. Thereafter, ordinary meetings of the Conference of the Parties shall be held at regular intervals to be determined by the Conference at its first meeting.
2. Extraordinary meetings of the Conference of the Parties shall be held at such other times as may be deemed necessary by the Conference, or at the written request of any Party, provided that, within six months of the request being communicated to them by the Secretariat, it is supported by at least one third of the Parties.
3. The Conference of the Parties shall by consensus agree upon and adopt rules of procedure for itself and for any subsidiary body it may establish, as well as financial rules governing the funding of the Secretariat. At each ordinary meeting, it shall adopt a budget for the financial period until the next ordinary meeting.
4. The Conference of the Parties shall keep under review the implementation of this Convention, and, for this purpose, shall:
 - (a) Establish the form and the intervals for transmitting the information to be submitted and consider such information as well as reports submitted by any subsidiary body;
 - (b) Review scientific, technical and technological advice on biological diversity provided;
 - (c) Consider and adopt, as required, protocols;
 - (d) Consider and adopt, as required, amendments to this Convention and its annexes;

Secretariat :

1. A secretariat is hereby established. Its functions shall be:
 - (a) To arrange for and service meetings of the Conference of the Parties;
 - (b) To perform the functions assigned to it by any protocol;
 - (c) To prepare reports on the execution of its functions under this Convention and present them to the Conference of the Parties;
 - (d) To coordinate with other relevant international bodies and, in particular to enter into such administrative and contractual arrangements as may be required for the effective discharge of its functions; and
 - (e) To perform such other functions as may be determined by the Conference of the Parties.
2. At its first ordinary meeting, the Conference of the Parties shall designate the secretariat from amongst those existing competent international organizations which have signified their willingness to carry out the secretariat functions under this Convention.

Reports :

Each Contracting Party shall, at intervals to be determined by the Conference of the Parties, present to the Conference of the Parties, reports on measures which it has taken for the implementation of the provisions of this Convention and their effectiveness in meeting the objectives of this Convention.

Settlement of Disputes :

1. In the event of a dispute between Contracting Parties concerning the interpretation or application of this Convention, the parties concerned shall seek solution by negotiation.
2. If the parties concerned cannot reach agreement by negotiation, they may jointly seek the good offices of, or request mediation by, a third party.
3. When ratifying, accepting, approving or acceding to this Convention, or at any time thereafter, a State or regional economic integration organization may declare in writing to the Depositary that for a dispute not resolved in accordance with paragraph 1 or paragraph 2 above, it accepts one or both of the following means of dispute settlement as compulsory :
 - (a) Arbitration in accordance with the procedure laid down in Part 1 of Annex II;

- (b) Submission of the dispute to the International Court of Justice.
4. If the parties to the dispute have not, in accordance with paragraph 3 above, accepted the same or any procedure, the dispute shall be submitted to conciliation in accordance with Part 2 of Annex II unless the parties otherwise agree.
 5. The provisions of this Article shall apply with respect to any protocol except as otherwise provided in the protocol concerned.

Adoption of Protocols :

1. The Contracting Parties shall cooperate in the formulation and adoption of protocols to this Convention.
2. Protocols shall be adopted at a meeting of the Conference of the Parties.
3. The text of any proposed protocol shall be communicated to the Contracting Parties by the Secretariat at least six months before such a meeting.

Right to Vote :

1. Except as provided for in paragraph 2 below, each Contracting Party to this Convention or to any protocol shall have one vote.
2. Regional economic integration organizations, in matters within their competence, shall exercise their right to vote with a number of votes equal to the number of their member States which are Contracting Parties to this Convention or the relevant protocol. Such organizations shall not exercise their right to vote if their member States exercise theirs, and vice versa.

Withdrawals :

1. At any time after two years from the date on which this Convention has entered into force for a Contracting Party, the Party may withdraw from the Convention by giving written notification to the Depositary.
2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal.
3. Any Contracting Party which withdraws from this Convention shall be considered as also having withdrawn from any protocol to which it is party.

Issues :

Some of the many issues dealt with under the convention include:

- Measures the incentives for the conservation and sustainable use of biological diversity.

- Regulated access to genetic resources and traditional knowledge, including prior informed consent of party providing resources.
- Sharing, in a fair and equitable way, the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the contracting party providing such resources (government/ local communities that provided the traditional knowledge or biodiversity resources utilized).
- Access to and transfer of technology, including biotechnology, to the governments and/or local communities that provided traditional knowledge and/or biodiversity resources.

2.3. THE PARIS CONVENTION OF 1883

The Paris Convention is an international treaty that is currently administered by the World Intellectual Property Organization (WIPO) and based in Geneva Switzerland. The treaty was signed into effect on March 20, 1883 and was a milestone for international patent law because it paved the way for international patents and helped to enforce them for the first time.

Origin of the Treaty :

The Paris Convention was conceived to eliminate the threat of an inventor's work being stolen and used in another country where they would be free of any national patent laws protecting the invention. Inventors from around the world were reluctant to attend world fairs to display their new strides in technology. In 1873, world leaders took notice that inventors did not attend the International Exhibition of Inventions in Vienna for fear that their work would be exploited. It was not long before diplomatic leaders met in Paris in 1880 to discuss this problem and likely ways to resolve it. They came up with international patent law and other intellectual property guidelines and three years later, it was signed into effect as the Paris Convention.

Content :

The Treaty also stresses the importance of priority for inventors. When a person within a contracting State files and successfully receives a patent for their invention, the inventor will be given "priority" over other inventors when perusing international patents. This is a period of six or twelve months (depending on the nature of the patent) in which the inventor must prepare patent applications to other countries.

Once patent applications are submitted to other countries within the limited time period, the filing date is handled as the original filing date of the initial patent the inventor received in his home country. This is important in international patent law because it gives an inventor ample

time to prepare patents for submission in other countries, while giving the inventor an edge over other inventors in foreign countries.

The substantive provisions of the Convention :

The substantive provisions of the Convention fall into three main categories:

- National treatment,
 - Right of priority and
 - Common rules.
- (1) Under the provisions on **national treatment**, the Convention provides that, as regards the protection of industrial property, each Contracting State must grant the **same** protection to nationals of other Contracting States that it grants to its own nationals. Nationals of non-Contracting States are also entitled to national treatment under the Convention if they are domiciled or have a real and effective industrial or commercial establishment in a Contracting State.
 - (2) The Convention provides for the **right of priority** in the case of patents (and utility models where they exist), marks and industrial designs. This right means that, on the basis of a regular first application filed **in one** of the Contracting States, the applicant may, within a certain period of time (12 months for patents and utility models; 6 months for industrial designs and marks), apply for protection **in any of the other** Contracting States. These subsequent applications will be regarded as if they had been filed on the same day as the first application.
 - (3) The Convention lays down a few **common rules** that all Contracting States must follow. The most important are:
 - (a) **Patents**
 - Patents granted in different Contracting States for the same invention are **independent of each other**. The granting of a patent in one Contracting State does not oblige other Contracting States to grant a patent; a patent cannot be refused, annulled or terminated in any Contracting State on the ground that it has been refused or annulled or has terminated in any other Contracting State.
 - The inventor has **the right to be named** as such in the patent.
 - The grant of a patent may not be refused, and a patent may not be invalidated, on the ground that the sale of the patented product, or of a product obtained by means of the patented process, is subject to restrictions or limitations resulting from the domestic law.

- Each Contracting State that takes legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exclusive rights conferred by a patent may do so only under **certain conditions**. A compulsory license (a license not granted by the owner of the patent but by a public authority of the State concerned), based on failure to work or insufficient working of the patented invention, may only be granted pursuant to a request filed after three years from the grant of the patent or four years from the filing date of the patent application, and it must be refused if the patentee gives legitimate reasons to justify this inaction.

(b) Marks

- The Paris Convention does not regulate the conditions for the **filing and registration of marks** which are determined in each Contracting State by domestic law. Consequently, no application for the registration of a mark filed by a national of a Contracting State may be refused, nor may a registration be invalidated, on the ground that filing, registration or renewal **has not been affected in the country of origin**.
- Where a mark has been **duly registered in the country of origin**, it must, on request, be accepted for filing and protected in its original form in the other Contracting States. Nevertheless, registration may be refused in well-defined cases, such as where the mark would infringe the acquired rights of third parties; where it is devoid of distinctive character; where it is contrary to morality or public order; or where it is of such a nature as to be liable to deceive the public.
- If, in any Contracting State, the use of a registered mark is compulsory, the registration cannot be canceled for non-use until after a reasonable period, and then only if the owner cannot justify this inaction.
- **Collective marks** must be granted protection.

Industrial Designs:

Industrial designs must be protected in each Contracting State, and protection may not be forfeited on the ground that articles incorporating the design are not manufactured in that State.

(d) Trade Names

Protection must be granted to trade names in each Contracting State without there being an obligation to file or register the names.

(e) **Indications of Source**

Measures must be taken by each Contracting State against direct or indirect use of a false indication of the source of goods or the identity of their producer, manufacturer or trader.

(f) **Unfair competition**

Each Contracting State must provide for effective protection against unfair competition.

Implications on International Patent Law:

The Paris Convention was the first successful international intellectual property treaty to emerge. It demonstrated that patents, which were a part of local laws for hundreds of years, needed an international standard so that protection could be granted on a global scale. It also proved to be an essential part of intellectual property law because it allowed innovative thinkers and creators to spread new ideas and inspire others, without the threat of having their work stolen and used in other countries.

It also benefited inventors by allowing them access for their work into foreign markets. In addition, the Paris Convention has become one of the largest international treaties in the world, enlisting 173 countries under its guidelines. This is a testament to its importance in intellectual property to protect the natural right to have exclusive rights to one's own work and for the growth of new ideas through inspiration.

2.4. BERNE CONVENTION

The Berne Convention for the Protection of Literary and Artistic Works, usually known as the Berne Convention, is an international agreement governing copyright, which was first accepted in Berne, Switzerland, in 1886.

The Berne Convention formally mandated several aspects of modern copyright law; it introduced the concept that a copyright exists the moment a work is "fixed", rather than requiring registration. It also enforces a requirement that countries recognize copyrights held by the citizens of all other parties to the convention.

The Berne Convention requires its parties to treat the copyright of works of authors from other parties to the convention (known as members of the Berne Union) at least as well as those of its own nationals. For example, French copyright law applies to anything published or performed in France, regardless of where it was originally created. In addition to establishing a system of equal treatment that harmonized copyright amongst parties, the agreement also required member states to provide strong minimum standards for copyright law.

Copyright under the Berne Convention must be automatic; it is prohibited to require formal registration. However, when the United States joined the Convention on 1 March 1989, it continued to make statutory damages and attorney's fees only available for registered works. However, in *Moberg v Leygues*, a 2009 decision of a Delaware Federal District Court, decided that the protections of the Berne Convention are supposed to essentially be "frictionless," meaning no registration requirements can be imposed on a work from a different Berne member country. This means Berne member countries can require works originating in their own country to be registered and/or deposited, but cannot require these formalities of works from other Berne member countries.

Applicability

Under Article 3, the protection of the Convention applies to nationals and residents of countries that are party to the convention, and to works first published or simultaneously published (under Article 3(4), "simultaneously" is defined as "within 30 days") in a country that is party to the convention. Under Article 4, it also applies to cinematic works by persons who have their headquarters or habitual residence in a party country, and to architectural works situated in a party country.

Country of origin

The Convention relies on the concept of "country of origin". Often determining the country of origin is straightforward: when a work is published in a party country and nowhere else, this is the country of origin. However, under Article 5(4), when a work is published simultaneously in several party countries (under Article 3(4), "simultaneously" is defined as "within 30 days"), the country with the shortest term of protection is defined as the country of origin.

For works simultaneously published in a party country and one or more non-parties, the party country is the country of origin. For unpublished works or works first published in a non-party country (without publication within 30 days in a party country), the author's nationality usually provides the country of origin, if a national of a party country. In the Internet age, unrestricted publication online may be considered publication in every sufficiently internet-connected jurisdiction in the world. It is not clear what this may mean for determining "country of origin". In *Kernel v. Mosley* (2011), a U.S. court "concluded that a work created outside of the United States, uploaded in Australia and owned by a company registered in Finland was nonetheless a U.S. work by virtue of its being published online". However, the matter of determining the country of origin for digital publication remains a topic of controversy among law academics as well.

Principles of the Berne Convention

The Berne Convention deals with the protection of works and the rights of their authors. It is based on **three basic principles** and contains a

series of provisions determining the **minimum protection** to be granted, as well as special provisions available to **developing countries** that want to make use of them.

The **three basic principles** are the following:

- (a) Works originating in one of the Contracting States (that is, works the author of which is a national of such a State or works first published in such a State) must be given the same protection in each of the other Contracting States as the latter grants to the works of its own nationals (principle of "national treatment").
- (b) Protection must not be conditional upon compliance with any formality (principle of "automatic" protection).
- (c) Protection is independent of the existence of protection in the country of origin of the work (principle of "independence" of protection). If, however, a Contracting State provides for a longer term of protection than the minimum prescribed by the Convention and the work ceases to be protected in the country of origin, protection may be denied once protection in the country of origin ceases.

Copyright terms

The **minimum standards** of protection relate to the works and rights to be protected, and to the duration of protection:

- (a) As to works, protection must include "every production in the literary, scientific and artistic domain, whatever the mode or form of its expression".
- (b) Subject to certain allowed reservations, limitations or exceptions, the following are among the **rights** that must be recognized as exclusive rights of authorization:
 - **the right to translate,**
 - **the right to make adaptations and arrangements** of the work,
 - **the right to perform in public** dramatic, dramatico-musical and musical works,
 - **the right to recite** literary works in **public,**
 - **the right to communicate to the public** the performance of such works,
 - **the right to broadcast** (with the possibility that a Contracting State may provide for a mere right to equitable remuneration instead of a right of authorization),
 - **the right to make reproductions** in any manner or form (with the possibility that a Contracting State may permit, in

certain special cases, reproduction without authorization, provided that the reproduction does not conflict with the normal exploitation of the work and does not unreasonably prejudice the legitimate interests of the author; and the possibility that a Contracting State may provide, in the case of sound recordings of musical works, for a right to equitable remuneration).

- **The right to use the work as a basis for an audiovisual work**, and the right to reproduce, distribute, perform in public or communicate to the public that audiovisual works.

The Convention also provides for "**moral rights**", that is, the right to claim authorship of the work and the right to object to any mutilation, deformation or other modification of, or other derogatory action in relation to, the work that would be prejudicial to the author's honor or reputation.

- (c) As to the **duration** of protection, the general rule is that protection must be granted until the expiration of the 50th year after the author's death. There are, however, exceptions to this general rule. In the case of anonymous or pseudonymous works, the term of protection expires 50 years after the work has been lawfully made available to the public, except if the pseudonym leaves no doubt as to the author's identity or if the author discloses his or her identity during that period; in the latter case, the general rule applies.

Limitations and exceptions

The Berne Convention allows certain limitations and exceptions on economic rights, that is, cases in which protected works may be used without the authorization of the owner of the copyright, and without payment of compensation. These limitations are commonly referred to as "free uses" of protected works, and are set forth in Articles 9(2) (reproduction in certain special cases), 10 (quotations and use of works by way of illustration for teaching purposes), 10*bis* (reproduction of newspaper or similar articles and use of works for the purpose of reporting current events) and 11 *bis*(3) (ephemeral recordings for broadcasting purposes).

The Appendix to the Paris Act of the Convention also permits developing countries to implement non-voluntary licenses for translation and reproduction of works in certain cases, in connection with educational activities. In these cases, the described use is allowed without the authorization of the right holder, subject to the payment of remuneration to be fixed by the law.

Adoption and implementation

The first version of the Berne Convention treaty was signed on 9 September 1886, by Belgium, France, Germany, Haiti, Italy, Liberia, Spain, Switzerland, Tunisia, and the United Kingdom. They ratified it on 5 September 1887. Although the United Kingdom ratified the convention in

1887, it did not implement large parts of it until 100 years later with the passage of the Copyright, Designs and Patents Act 1988.

The United States acceded to the convention on 16 November 1988, and the convention entered into force for the United States on 1 March 1989. The United States initially refused to become a party to the Convention, since that would have required major changes in its copyright law, particularly with regard to moral rights, removal of the general requirement for registration of copyright works and elimination of mandatory copyright notice. This led first to the U.S. ratifying the Buenos Aires Convention (BAC) in 1910, and later the Universal Copyright Convention (UCC) in 1952 to accommodate the wishes of other countries. With the WIPO's Berne revision on Paris 1971, many other countries joined the treaty, as expressed by Brazil federal law of 1975.

2.5. GOVERNMENT USE OF PATENT

Patent:

Patent is a monopoly granted by statute of a country for a limited time. Patent is granted for new and useful invention that involves inventive step. Invention may either product or process of industrial application. Invention includes any new and valuable art, process, method or manner of manufacture; machine apparatus or other Articles; substance produced by manufacture, and includes any new and useful improvement of any of them, and an alleged invention. It empowers the owner of an invention to prevent others from manufacturing, using, importing or selling the patented invention. Patent Act, 1970 as amended in the years 1998 and 1999 along with Patent Rules, 1972 govern patents in India. Registration is a prerequisite for patent protection and the protection granted is territorial in nature i.e., patent granted in a country will give the owner of the patent right only within that country.

Term of Patent:

Normally a patent remains in force for a period of 14 years from the date of application subject to the payment of the stipulated renewal fees. But the term differs, when it is related to food, medicine or drug i.e., it is 5 years from the date of selling of patent or it is 7 years from the date of patent whichever period is shorter.

Indian Patent Act:

Section 48 of the Indian Patents Act provides the rights of patentee under the act. The section confers upon the patentee the exclusive right to prevent third parties from the act of making, using, selling or importing that product in India if the subject matter of the patent is a product. Similarly, if the subject matter of the patent is a process, the patentee has the exclusive right to prevent third parties from the act of using the process for sale, selling the product obtained directly by that process in India.

These rights of patentee are subject to certain conditions specified in the Act. **Section 47** provides certain conditions where exclusive rights of patentee are limited by certain specific acts:

1. Any machine, apparatus, or other article which is granted a patent or any patented article may be imported or made by the Government for the purpose merely of its own use;
2. Any process in respect of which the patent is granted may be used by or on behalf of the Government for the purpose merely of its own use;
3. Any machine, apparatus or other article in respect of which the patent is granted, may be made or used, and any process in respect of which the patent is granted may be used, by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils; and
4. In the case of a patent in respect of any medicine or drug, the medicine or drug may be imported by the Government for the purpose merely of its own use or for distribution in any dispensary, hospital or other medical institution maintained by or on behalf of the Government or any other dispensary, hospital or other medical institution which the Central Government may, having regard to the public service that such dispensary, hospital or medical institution renders, specify in this behalf by notification in the official Gazette.

There are certain other provisions in the act for the interest of general public:

Bolar-like provision and Parallel import provision :

Some countries allow manufacturers of generic drugs to use the patented inventions for development and submission of information required under law- for example from public health authorities - without the patent owner's permission and before the patent protection expires. The generic producers can then market their version as soon as the patent expires. This provision is called "Bolar-like provision" or "regulatory exception". Indian Patents Act provides such a provision under Section 107A (a).

Parallel Import:

Parallel import provisions are provided in **Section 107A (b)**, which says that importation of patented products by any person authorized by the Patentee will not be considered as an infringement. Therefore, it is possible to import the patented products from the licensee of the patentee in any country without the permission of the Patentee. The purpose of Parallel import is to check the abuse of patent rights and meant to control the price of patented product.

Working of patented invention:

Section 83 of the Act clearly mentions that the Patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay. Patents are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article.

Statement regarding working of patent:

Patents granted do not in any way prohibit Central Government in taking measures to protect public health. For this purpose, government mandates every patentee to submit a statement regarding working of the invention for every calendar year. Every patentee or his assignee is required by the government, to submit annually, a statement to show the extent to which the patented invention has been commercially worked in India. If this statement is not submitted within 3 months of the end of each calendar year, then the patentee is liable for a penalty. Non-submission of such information annually, leads to the possibility of grant of compulsory license on the patented invention to other persons to commercially exploit the patent.

Compulsory Licenses:

Under **Section 84(1) of the Act** - at any time after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the controller for grant of compulsory licence on patent on any of the following grounds:

- (a) The reasonable requirements of the public with respect to the patented invention have not been satisfied.
- (b) The patented invention is not available to the public at a reasonably affordable price, or
- (c) The patented invention is not worked in the territory of India.

2.6. ECOLABELLING

"Ecolabelling" is a voluntary method of environmental performance certification and labelling that is practiced around the world. An ecolabel identifies products or services proven environmentally preferable overall, within a specific product or service category.

The roots of ecolabelling are found in the growing global concern for environmental protection on the part of governments, businesses and the public. As businesses have come to recognize that environmental concerns may be translated into a market advantage for certain products and services, various environmental declarations, claims and labels have emerged, such as natural, recyclable, eco-friendly, low energy, recycled content, etc. These have attracted consumers looking for ways to reduce environmental impacts through their purchasing choices, but they have also led to some confusion and skepticism. Unproven or irrelevant claims have been branded greenwash.

Types of labels:

The International Organization for Standardisation (ISO) has identified three broad types of voluntary labels, with ecolabelling fitting under the strongest Type 1 designation.

TYPE-I : a voluntary, multiple-criteria based, *third party* programme that awards a license that authorises the use of environmental labels on products indicating overall environmental preferability of a product within a particular product category based on life cycle considerations

TYPE-II: Informative environmental *self-declaration* claims

TYPE-III: voluntary programmes that provide quantified environmental data of a product, under pre-set categories of parameters set by a qualified third party and based on life cycle assessment, and verified by that or another qualified third party.

Ecolabelling Objectives:

Ecolabelling has become a useful tool for governments in encouraging sound environmental practices, and for businesses in identifying and establishing markets (i.e. domestic and sometimes international) for their environmentally preferable products. Many countries now have some form of ecolabelling in place, while others are considering program development. Three core objectives are generally established and pursued:

- 1. Protecting the environment-** Specific environmental objectives may include :
 - encouraging the efficient management of renewable resources to ensure their availability to future generations;
 - promoting the efficient use of non-renewable resources, including fossil fuels;
 - facilitating the reduction, reuse and recycling of industrial, commercial and consumer waste;
 - encouraging the protection of ecosystems and species diversity; and
 - Encouraging the proper management of chemicals in products.
- 2. Encouraging environmentally sound innovation and leadership-** Ecolabelling programs, through the awarding and promotion of an ecolabel, offer a market incentive to environmentally innovative and progressive businesses. Generally, ecolabelling criteria are set to reward only the top environmental performers in a product category. Most programs gradually and incrementally raise standards to encourage producers and service providers to keep pace with new and emerging performance improvement opportunities and market shifts.

- 3. Building consumer awareness of environmental issues-** Ecolabelling programs can also serve to heighten consumer awareness of environmental issues and of the implications of their choices. In countries where consumers are not as highly motivated by environmental concerns, ecolabelling can be used to promote environmentally beneficial actions.

Guiding Principles for Ecolabelling:

Based on the experiences of successful ecolabelling programs and pertinent ISO work, a series of principles can be identified as being critical to an effective and credible program:

- 1. Voluntary participation-** The decisions of manufacturers, importers, service providers and other businesses to participate in an ecolabelling program must be voluntary.
- 2. Consideration of "fitness for purpose" and level of overall performance-** Besides legislative compliance, it is also important to address the quality and performance of a product that is to be considered for ecolabelling.
- 3. Based on sound scientific and engineering principles-** Maintenance of stringent technical requirements based on good ecological science assures consumers that they can trust the ecolabel and licensing applicants that they will be treated fairly.
- 4. Criteria must be credible, relevant, attainable, and measurable/verifiable**
- 5. Independence-** A credible ecolabelling program should be operated by an organisation independent of vested commercial or other interests.
- 6. Open and accountable process-** A credible program must be based on an open and accountable process that can be observed, monitored and questioned at any time.
- 7. Flexibility-** In order to be credible and effective, programs must operate in a business-like and cost-effective manner consistent with market forces and requirements.
- 8. Consistency with ISO 14020 and ISO 14024 guiding principles (or other appropriate documents) -** It may prove advantageous for ecolabelling programs to demonstrate consistency with the guiding principles contained in the relevant ISO environmental labelling standards.

Major Participants:

Multiple stakeholder participation in any ecolabelling initiative is important to its overall impact and success. While no two programs are identical, most involve the participation of the following groups:

- **Government-** Many programs are initiated and funded by government departments or agencies. Besides providing input (directly and/or indirectly) in program development, management and delivery areas, government at different levels can exert significant influence and demand through its procurement initiatives and activities.
- **Program management authority (i.e. Program Managers)-** An independent body typically oversees and directs the program delivery activities (e.g. technical, marketing, and administrative aspects).
- **Industry and commercial associations, retailers and companies-** Industry and commercial sector awareness, interest and direct involvement are essential to program success.
- **Consumers-** Consumer demand whether in households, institutions or corporations generates market impact. Consumer requirements and preferences must be determined, recognized and reflected in various program initiatives and outputs.
- **Interested parties -** The credibility of a program can be enhanced through the involvement and support of various organizations, groups and individuals with no direct commercial interest in ecolabelling. Conversely, omission of such groups can jeopardize public confidence and acceptance. Eg. Media and international communities.

Key Steps:

Assuming program management officials have acquired a general knowledge and understanding of environmental priorities to be considered and addressed through their ecolabelling program, program delivery generally involves three basic steps:

1. Selection and determination of product categories;
2. Development and adoption of appropriate criteria, standards or guidelines(including: development, public review, and finalization/announcement); and
3. Certification and licensing (including: application, testing and verification, and license issuing).

2.7. ECO MARK

- The Government of India has instituted a scheme for labeling of environment friendly products to be known as ECO Mark.
- The scheme is being administered by the Bureau of Indian Standards (BIS).

- So far the following product categories have been identified for coverage under this scheme: a) Soaps and Detergents; b) Paints c) Paper d) Plastics e) Cosmetics f) Textiles g) Batteries h) Wood Substitutes j) Propellants and Aerosols k) Food Items (edible oils – including Vanaspati, Tea and Coffee) m) Electrical and Electronics Goods n) Packing/Packaging Materials p) Lubricating/Specialty Oils q) Drugs r) Foods Preservatives and Additives s) Pesticides t) Leather.
- The Scheme is being operated on a national basis and provides certification and labeling for house-hold and other consumer products which meet certain environmental criteria along with quality requirements prescribed in relevant Indian Standards for the product.

The objectives of the Eco Mark Scheme:

- Encourage all citizens to use and buy products which are environment friendly.
- Reward and promote genuine initiatives by companies to reduce the adverse environmental impact on their products.
- Provide incentive for manufacturers and importers to control the ill effects of their products on the environment.
- Improve the overall quality of the environment and promote sustainable management of resources in India.

Functions of BIS:

For the implementation of the scheme, BIS is responsible for the following functions:

- i. Assessment of the product for ECO Mark, certification of the product for award of ECO Mark.
- ii. Renewal, suspension and cancellation of the license.
- iii. Products certified as eligible for the ECO Mark shall also carry the ISI Mark (except for leather) for quality, safety and performance of the product and shall be licensed to carry the ECO Mark for a prescribed time period after which it shall be reassessed.
- iv. Undertaking inspections and taking samples for analysis of any material or substance in relation to which the BIS – ECO Mark has been used as may be necessary for proper implementation of ECO Mark. For this purpose the Standard Mark of Bureau would be a single mark having a combination of the ISI Mark and the ECO Logo.

To operate the scheme, BIS has included additional requirements for ECO Mark in the concerned Indian Standards. The terms and conditions governing operation of the licences including fees shall be as

per the Bureau of Indian Standards Act, Rules and Regulations framed there under. Marking fee would be separate – one with and the other without ECO Mark requirements. Similarly two types of schemes of testing and inspection have been prepared, one incorporating the additional requirements of the ECO Mark and the other for BIS Certification against Indian Standards.

Criteria for awarding Eco-Mark:

The products which get the Eco-Mark need to strictly follow the environmental requirements and also pass stringent quality control tests to keep their certifications valid. The following conditions are evaluated before awarding the Eco Mark certification to a product:

- Substantially less potential for pollution in production, usage and disposal;
- Recycled, recyclable, made from recycled or biodegradable products;
- Make significant contribution in saving non-renewable resources and natural resources;
- Production process including source of raw material;

2.8. GEOGRAPHICAL INDICATIONS

A geographical indication (GI) is a sign used on products that have a specific geographical origin and possess qualities or a reputation that are due to that origin. In order to function as a GI, a sign must identify a product as originating in a given place. In addition, the qualities, characteristics or reputation of the product should be essentially due to the place of origin. Since the qualities depend on the geographical place of production, there is a clear link between the product and its original place of production.

The agreement contains a general obligation that parties shall provide the legal means for interested parties to prevent the use of any means in the designation or presentation of a good that indicates or suggests that the good in question originates in a geographical area other than the true place of origin in a manner which misleads the public as to the geographical origin of the goods. There is no obligation under the Agreement to protect geographical indications which are not protected in their country or origin or which have fallen into disuse in that country. A new law for the protection of geographical indications, viz. the Geographical Indications of Goods (Registration and the Protection) Act, 1999 has also been passed by the Parliament and notified on 30.12.1999 and the rules made there under notified on 8-3-2002.

Rights provided by geographical indication:

A geographical indication right enables those who have the right to use the indication to prevent its use by a third party whose product does

not conform to the applicable standards. For example, in the jurisdictions in which the Darjeeling geographical indication is protected, producers of Darjeeling tea can exclude use of the term “Darjeeling” for tea not grown in their tea gardens or not produced according to the standards set out in the code of practice for the geographical indication.

However, a protected geographical indication does not enable the holder to prevent someone from making a product using the same techniques as those set out in the standards for that indication. Protection for a geographical indication is usually obtained by acquiring a right over the sign that constitutes the indication.

Type of products under geographical indications:

Geographical indications are typically used for agricultural products, foodstuffs, wine and spirit drinks, handicrafts, and industrial products.

How are geographical indications protected?

There are three main ways to protect a geographical indication:

- so-called *sui generis* systems (i.e. special regimes of protection);
- using collective or certification marks; and
- Methods focusing on business practices, including administrative product approval schemes.

These approaches involve differences with respect to important questions, such as the conditions for protection or the scope of protection. On the other hand, two of the modes of protection — namely *sui generis* systems and collective or certification mark systems -share some common features, such as the fact that they set up rights for collective use by those who comply with defined standards.

Broadly speaking geographical indications are protected in different countries and regional systems through a wide variety of approaches and often using a combination of two or more of the approaches outlined above. These approaches have been developed in accordance with different legal traditions and within a framework of individual historical and economic conditions.

2.9. SUMMARY

Biodiversity Convention is a multilateral treaty. Its objective is to develop national strategies for the conservation and sustainable use of biological diversity. The Paris Convention is an international treaty that is currently administered by the World Intellectual Property Organization (WIPO). It paved the way for international patents and helped to enforce them for the first time. The Paris Convention was conceived to eliminate the threat of an inventor's work being stolen and used in another country where they would be free of any national patent laws protecting the

invention. The Berne Convention for the Protection of Literary and Artistic Works, usually known as the Berne Convention, is an international agreement governing copyright, which was first accepted in Berne, Switzerland, in 1886. The patent right is not an absolute right. Along with giving protection to the right-holder for his invention, the Act is also aware of the interest of public; the main purpose of Act being encouragement of the development of technology and innovation. Under certain conditions the rights of the patentee may be limited. Any apparatus or process in respect of which the patent is granted may be used by or on behalf of the Government for the purpose merely of its own use. Ecolabelling is a method of environmental performance certification and labelling that is practised around the world. An ecolabel identifies products or services proven environmentally preferable overall, within a specific product or service category. The Government of India has instituted a scheme for labeling of environment friendly products to be known as ECO Mark. It improves the overall quality of the environment and promotes sustainable management of resources in India. A geographical indication is a sign used on products that have a specific geographical origin and possess qualities or a reputation that are due to that origin. In order to function as a GI, a sign must identify a product as originating in a given place.

2.10. TERMINAL QUESTIONS

Q.1. What is the convention of biological diversity? Explain its objective, principles and general measures for Conservation and Sustainable Use of biodiversity.

Answer:-----

Q.2. How does the Convention on Biological diversity work?

Answer: -----

Q.3. What does the Berne Convention protect?

Answer:-----

Q.4. What is the Berne Convention and why is it important to copyright?

Answer:-----

Q.5. What do you mean by the government use of patent? Can the government take your patent?

Answer:-----

Q.6. Explain Ecolabelling? What does an Ecolabelling mean?

Answer:-----

2.11. FURTHER READINGS

1. Biochemistry: Lubert Stryer, published by W. H. Freeman
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6. Biotechnology: B.D Singh, Expanding Horizons. Kalyani, 2007.



॥ सरस्वती नः सुभगा मयस्कृत ॥

**Uttar Pradesh Rajarshi Tandon
Open University**

PGBCH-116

Biosafety and IPR

BLOCK

2

GENE AND GMO

UNIT-3

Gene flow and Risk Management

UNIT-4

GMO and Human Health

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BLOCK INTRODUCTION

This is the second block of biosafety and IPR, which cover Gene and GMO. This block consists of following two units:

- Unit-3:** This unit covers the Gene and its roles in genetically modified organism. Gene flow in natural and artificial ecology, and gene escape and tolerance of target organisms briefly cover here. The Cross border movement of germplasm and issues regarding risk management is discussed in this unit. Apart from that the creation of super-weeds/super viruses etc. are also mentioned here.
- Unit-4:** This unit covers the GMO and human health. The ecological aspects of GMOs, monitoring and methods for detecting transgenic are briefly discussed. The role and the benefits of transgenic in human health society and the environment mentioned here. Apart from that the radiation safety, non-isotopic procedures is also discussed briefly.

UNIT-3 GENE FLOW AND RISK MANAGEMENT

Structure

- 3.1. Introduction
 - Objectives
- 3.2. DNA
 - 3.2.1.1. Discovery of DNA
 - 3.2.1.2. Structure of DNA
- 3.3. Gene
 - 3.3.1.1. Structure of gene
 - 3.3.1.2. Gene Flow
- 3.4. Germplasm
 - 3.4.1.1. Germplasm conservation
- 3.5. Cryoconservation of animal genetic resources
- 3.6. Cryopreservation
- 3.7. Risk management issues
- 3.8. Competition with natural species
- 3.9. Ethical concerns
- 3.10. Risk assessment
- 3.11. Gene escapes
- 3.12. Target organisms
- 3.13. Tolerance
- 3.14. Super-weeds
 - 3.14.1.1. Virus and evolution/super virus
 - 3.14.1.2. Killing dangerous super viruses with cold plasma
- 3.15. Summary
- 3.16. Terminal Questions
- 3.17. Further Readings

3.1. INTRODUCTION

Gene flow, also called **gene migration**, the introduction of genetic material (by interbreeding) from one population of a species to another,

thereby changing the composition of the gene pool of the receiving population. The introduction of new alleles through gene flow increases variability within the population and makes possible new combinations of traits. In humans gene flow usually comes about through the actual migration of human populations, either voluntary or forced. Although gene flow does not change allele frequencies for a species as a whole, it can alter allele frequencies in local populations. In the case of migration, the greater the difference in allele frequencies between the resident and the migrant individuals, and the larger the number of migrants, the greater the effect the migrants have in changing the genetic constitution of the resident population.

If there are wild populations related to the transgenic crop then hybridization and eventually introgression in the wild may occur, as it has for herbicide resistant transgenic oilseed rape (*Brassica napus*). Tools to measure the amount of gene flow, experimental data measuring the distance of pollen dispersal, and experiments measuring hybridization and seed survivability are discussed in this review.

Objectives

- To discuss the about genitally modified organism.
- To discuss the role of gene in GMO.
- To discuss about the cryo-conservation of animal genetic resources.
- To cover the risk management issues and risk assessment.

3.2. DEOXYRIBONUCLEIC ACID (DNA)

Deoxyribonucleic acid is a molecule composed of two chains that coil around each other to form a double helix carrying genetic instructions for the development, functioning, growth and reproduction of all known organisms and many viruses. DNA and ribonucleic acid (RNA) are nucleic acids; alongside proteins, lipids and complex carbohydrates (polysaccharides), nucleic acids are one of the four major types of macromolecules that are essential for all known forms of life.

The two DNA strands are also known as polynucleotides as they are composed of simpler monomeric units called nucleotides. Each nucleotide is composed of one of four nitrogen-containing nucleobases (cytosine [C], guanine [G], adenine [A] or thymine [T]), a sugar called deoxyribose, and a phosphate group. The nucleotides are joined to one another in a chain by covalent bonds between the sugar of one nucleotide and the phosphate of the next, resulting in an alternating sugar-phosphate backbone. The nitrogenous bases of the two separate polynucleotide strands are bound together, according to base pairing rules (A with T and C with G), with hydrogen bonds to make double-stranded DNA. The complementary nitrogenous bases are divided

into two groups, pyrimidines and purines. In DNA, the pyrimidines are thymine and cytosine; the purines are adenine and guanine.

Both strands of double-stranded DNA store the same biological information. This information is replicated as and when the two strands separate. A large part of DNA (more than 98% for humans) is non-coding, meaning that these sections do not serve as patterns for protein sequences. The two strands of DNA run in opposite directions to each other and are thus antiparallel. Attached to each sugar is one of four types of nucleobases (informally, *bases*). It is the sequence of these four nucleobases along the backbone that encodes genetic information. RNA strands are created using DNA strands as a template in a process called transcription, where DNA bases are exchanged for their corresponding bases except in the case of thymine (T), which RNA substitutes for uracil (U). Under the genetic code, these RNA strands specify the sequence of amino acids within proteins in a process called translation.

Within eukaryotic cells, DNA is organized into long structures called chromosomes. Before typical cell division, these chromosomes are duplicated in the process of DNA replication, providing a complete set of chromosomes for each daughter cell. Eukaryotic organisms (animals, plants, fungi and protists) store most of their DNA inside the cell nucleus as nuclear DNA, and some in the mitochondria as mitochondrial DNA or in chloroplasts as chloroplast DNA. In contrast, prokaryotes (bacteria and archaea) store their DNA only in the cytoplasm, in circular chromosomes. Within eukaryotic chromosomes, chromatin proteins, such as histones, compact and organize DNA. These compacting structures guide the interactions between DNA and other proteins, helping control which parts of the DNA are transcribed.

DNA was first isolated by Friedrich Miescher in 1869. Its molecular structure was first identified by Francis Crick and James Watson at the Cavendish Laboratory within the University of Cambridge in 1953, whose model-building efforts were guided by X-ray diffraction data acquired by Raymond Gosling, who was a post-graduate student of Rosalind Franklin. DNA is used by researchers as a molecular tool to explore physical laws and theories, such as the ergodic theorem and the theory of elasticity. The unique material properties of DNA have made it an attractive molecule for material scientists and engineers interested in micro- and nano-fabrication. Among notable advances in this field are DNA origami and DNA-based hybrid materials.

3.2.1. DISCOVERY OF DNA

Advances in understanding genes and inheritance continued throughout the 20th century. Deoxyribonucleic acid (DNA) was shown to be the molecular repository of genetic information by experiments in the 1940s to 1950s. The structure of DNA was studied by Rosalind Franklin and Maurice Wilkins using X-ray crystallography, which led James D. Watson and Francis Crick to publish a model of the double-

stranded DNA molecule whose paired nucleotide bases indicated a compelling hypothesis for the mechanism of genetic replication.

In the early 1950s the prevailing view was that the genes in a chromosome acted like discrete entities, indivisible by recombination and arranged like beads on a string. The experiments of Benzer using mutants defective in the rII region of bacteriophage T4 showed that individual genes have a simple linear structure and are likely to be equivalent to a linear section of DNA. Collectively, this body of research established the central dogma of molecular biology, which states that proteins are translated from RNA, which is transcribed from DNA. This dogma has since been shown to have exceptions, such as reverse transcription in retroviruses. The modern study of genetics at the level of DNA is known as molecular genetics.

In 1972, Walter Fiers and his team were the first to determine the sequence of a gene: that of Bacteriophage MS2 coat protein. The subsequent development of chain-termination DNA sequencing in 1977 by Frederick Sanger improved the efficiency of sequencing and turned it into a routine laboratory tool. An automated version of the Sanger method was used in early phases of the Human Genome Project.

3.2.2 Structure of DNA

The vast majority of organisms encode their genes in long strands of DNA (deoxyribonucleic acid). DNA consists of a chain made from four types of nucleotide subunits, each composed of: a five-carbon sugar (2-deoxyribose), a phosphate group, and one of the four bases adenine, cytosine, guanine, and thymine. Two chains of DNA twist around each other to form a DNA double helix with the phosphate-sugar backbone spiralling around the outside, and the bases pointing inwards with adenine base pairing to thymine and guanine to cytosine. The specificity of base pairing occurs because adenine and thymine align to form two hydrogen bonds, whereas cytosine and guanine form three hydrogen bonds.

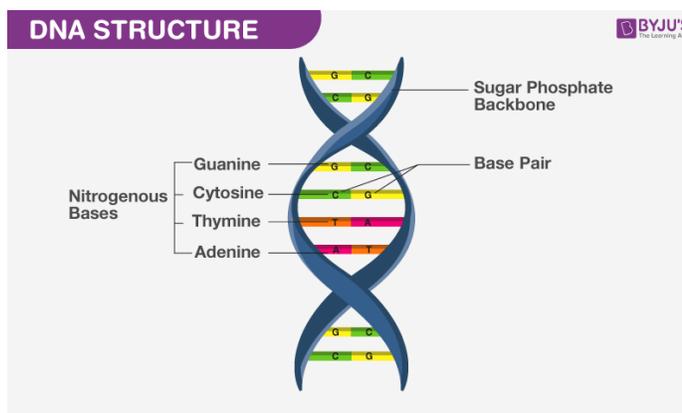


Fig. 1 Structure of DNA

The two strands in a double helix must therefore be complementary, with their sequence of bases matching such that the adenines of one strand

are paired with the thymines of the other strand, and so on. Due to the chemical composition of the pentose residues of the bases, DNA strands have directionality. One end of a DNA polymer contains an exposed hydroxyl group on the deoxyribose; this is known as the 3' end of the molecule. The other end contains an exposed phosphate group; this is the 5' end. The two strands of a double-helix run in opposite directions. Nucleic acid synthesis, including DNA replication and transcription occurs in the 5'→3' direction, because new nucleotides are added via a dehydration reaction that uses the exposed 3' hydroxyl as a nucleophile.

The expression of genes encoded in DNA begins by transcribing the gene into RNA, a second type of nucleic acid that is very similar to DNA, but whose monomers contain the sugar ribose rather than deoxyribose. RNA also contains the base uracil in place of thymine. RNA molecules are less stable than DNA and are typically single-stranded. Genes that encode proteins are composed of a series of three-nucleotide sequences called codons, which serve as the "words" in the genetic "language". The genetic code specifies the correspondence during protein translation between codons and amino acids. The genetic code is nearly the same for all known organisms.

3.3. GENE

In biology, a **gene** is a sequence of nucleotides in DNA or RNA that encodes the synthesis of a gene product, either RNA or protein. During gene expression, the DNA is first copied into RNA. The RNA can be directly functional or be the intermediate template for a protein that performs a function. The transmission of genes to an organism's offspring is the basis of the inheritance of phenotypic trait. These genes make up different DNA sequences called genotypes. Genotypes along with environmental and developmental factors determine what the phenotypes will be. Most biological traits are under the influence of polygenes (many different genes) as well as gene–environment interactions. Some genetic traits are instantly visible, such as eye color or the number of limbs, and some are not, such as blood type, risk for specific diseases, or the thousands of basic biochemical processes that constitute life.

Genes can acquire mutations in their sequence, leading to different variants, known as alleles, in the population. These alleles encode slightly different versions of a protein, which cause different phenotypical traits. Usage of the term "having a gene" (e.g., "good genes," "hair colour gene") typically refers to containing a different allele of the same, shared gene. Genes evolve due to natural selection / survival of the fittest and genetic drift of the alleles. The concept of a gene continues to be refined as new phenomena are discovered. For example, regulatory regions of a gene can be far removed from its coding regions, and coding regions can be split into several exons.

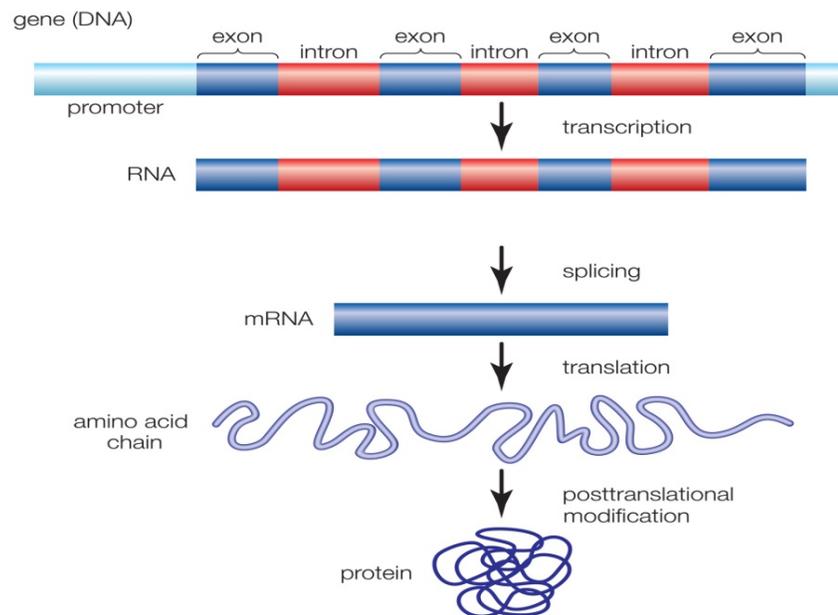
Some viruses store their genome in RNA instead of DNA and

some gene products are functional non-coding RNAs. Therefore, a broad, modern working definition of a gene is any discrete locus of heritable, genomic sequence which affect an organism's traits by being expressed as a functional product or by regulation of gene expression. The term *gene* was introduced by Danish botanist, plant physiologist and geneticist Wilhelm Johannsen in 1909.

3.3.1 Structure of Gene

The structure of a gene consists of many elements of which the actual protein coding sequence is often only a small part. These include DNA regions that are not transcribed as well as untranslated regions of the RNA. Flanking the open reading frame, genes contain a regulatory sequence that is required for their expression. First, genes require a promoter sequence. The promoter is recognized and bound by transcription factors that recruit and help RNA polymerase bind to the region to initiate transcription.

The recognition typically occurs as a consensus sequence like the TATA box. A gene can have more than one promoter, resulting in messenger RNAs (mRNA) that differ in how far they extend in the 5' end. Highly transcribed genes have "strong" promoter sequences that form strong associations with transcription factors, thereby initiating transcription at a high rate. Others genes have "weak" promoters that form weak associations with transcription factors and initiate transcription less frequently. Eukaryotic promoter regions are much more complex and difficult to identify than prokaryotic promoters.



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Fig. 2 Structure of gene

3.2.2 Gene Flow

In population genetics, gene flow (also known as gene migration or allele flow) is the transfer of genetic variation from one population to another. If the rate of gene flow is high enough, then two populations are considered to have equivalent allele frequencies and therefore effectively be a single population. It has been shown that it takes only "One migrant per generation" to prevent populations from diverging due to drift. Gene flow is an important mechanism for transferring genetic diversity among populations. Migrants change the distribution of genetic diversity within the populations, by modifying the allele frequencies (the proportion of members carrying a particular variant of a gene). High rates of gene flow can reduce the genetic differentiation between the two groups, increasing homogeneity. For this reason, gene flow has been thought to constrain speciation by combining the gene pools of the groups, thus preventing the development of differences in genetic variation that would have led to full speciation. In some cases migration may also result in the addition of novel genetic variants to the gene pool of a species or population.

There are a number of factors that affect the rate of gene flow between different populations. Gene flow is expected to be lower in species that have low dispersal or mobility, that occur in fragmented habitats, where there is long distances between populations, and when there are small population sizes. Mobility plays an important role in the migration rate, as highly mobile individuals tend to have greater migratory prospects. Although animals are thought to be more mobile than plants, pollen and seeds may be carried great distances by animals or wind. When gene flow is impeded, there can be an increase in inbreeding, measured by the inbreeding coefficient (F) within a population. For example, many island populations have low rates of gene flow due to geographic isolation and small population sizes. The Black Footed Rock Wallaby has several inbred populations that live on various islands off the coast of Australia.

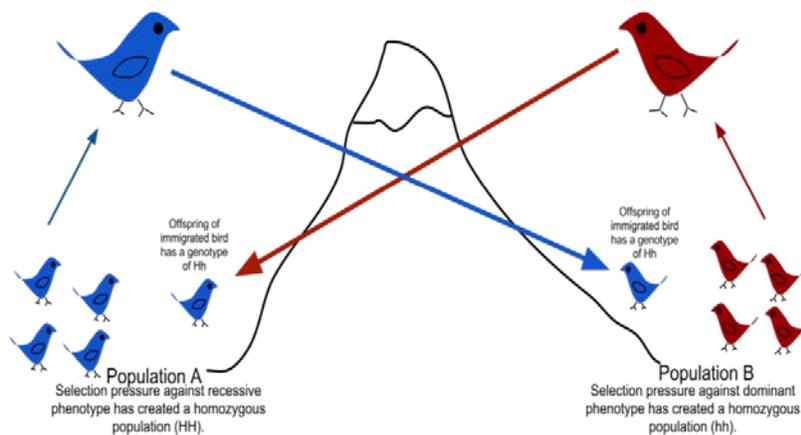


Fig. 3 Gene flow is the transfer of alleles from one population to another population through immigration of individuals.

3.4. GERMPLASM

Germplasm is living tissue from which new plants can be grown. It can be a seed or another plant part- a leaf, a piece of stem, pollen or even just a few cells that can be turned into a whole plant. Germplasm contains the information for a species' genetic makeup, a valuable natural resource of plant diversity. Agriculture benefits from uniformity among crop plants within a variety, which ensures consistent yields and make management easier. However, genetic uniformity leaves crops especially vulnerable to new pests and stresses.

Genetic diversity of germplasm gives plant breeders the sustained ability to develop new high yielding, high quality varieties that can resist constantly evolving pests, diseases and environmental stresses. Sexually compatible wild species and landraces – ancestral varieties of crop species- are the key to genetic diversity, but the amount of land where plants grow wild continues to shrink and many plant species and varieties are disappearing. Therefore the plant science community has developed conservation programs to gather, preserve, evaluate, catalogue and distribute germplasm for people all over the world to use.

Farming could be considered the original biological technology (biotechnology) when, some 10,000 years ago, humans began to cultivate and harvest specific plants to produce food. With increasing knowledge of genetics, plant breeders have accelerated the selection process, steadily increasing crop yields and enhancing quality. Some of the new technologies include: genomics, the study of the genome of organisms; genotyping, the process of determining the genotype; induced mutation, an externally generated change in the structure of DNA or chromosomes often resulting in a visible or detectable trait alteration; phenomics, a field of study concerned with the characterization of phenotypes; and proteomics, the large-scale study of proteins, particularly their structures and functions.

3.4.1. Germplasm Conservation

Germplasm conservation is the most successful method to conserve the genetic traits of endangered and commercially valuable species. Germplasm is a live information source for all the genes present in the respective plant, which can be conserved for long periods and regenerated whenever it is required in the future. Different plants' genetic diversity is also preserved and this in turn creates a pool of different genes that acts as resource house (gene bank/library) for new or unidentified species. This gene bank also assists the *in vitro* testing of germplasms for their genetic alterations (transgene) and to screen the elite germplasms among them.

Genetic variation leads to the loss of genetic information of earlier generations, which makes germplasm conservation an important aspect to

preserve this information regarding endangered, primitive, or even any existing species. The International Board of Plant Genetic Resources (IBPGR) is a global organization that has been recognized for germplasm conservation and provides essential support for collection, conservation, and utilization of plant genetic resources throughout the world. Germplasm conservation includes the following.

- Breeding lines
- Cultivated species
- Commercial varieties
- Special genetic stocks
- Landraces
- Wild species (for direct use (crop species) and indirect use (as root stocks)).

In-situ conservation

On-site conservation is called as *in-situ* conservation, which means conservation of genetic resources in the form of natural populations by establishing biosphere reserves such as national parks and sanctuaries. Practices like horticulture and floriculture also preserve plants in a natural habitat.

Ex-situ conservation

Off-site conservation is called as *ex-situ* conservation, which deals with conservation of an endangered species outside its natural habitat. In this method genetic information of cultivated and wild plant species is preserved in the form of *in vitro* cultures and seeds, which are stored as gene banks for long-term use. This type of conservation creates a bank of genes/DNA, seeds, and germplasms and forms a genetic information library (e.g., common garden archives) for endangered, primitive, and commercially valuable species. It also includes certain preservation (cryopreservation) and gene transformation techniques for the incorporation of disease, pest and stress tolerance traits, and environmental restoration of endangered plant species.

Genetic resources are used for a variety of reasons such as genetic improvement, conservation of biodiversity, mechanistic studies of adaptation, systematics and taxonomy, environmental monitoring, epidemiology, and forensics. One of the main strategies behind germplasm conservation is to maintain the biological integrity and provide germplasms with validated phenotypic and genetic descriptions. Gene banks are represented as *in vivo* and *in vitro* gene banks. Banks in which genetic resources are preserved by conventional methods, for example, seeds, vegetative propagules, etc., are called *in vivo* gene banks, whereas banks in which the genetic resources are preserved by nonconventional methods such as cell and tissue culture methods are

called *in vitro* gene banks. Both these ensure the availability of valuable germplasm to a breeder to develop new and improved varieties.

3.5. CRYOCONSERVATION OF ANIMAL GENETIC RESOURCES

Animal genetic resources, as defined by the Food and Agriculture Organization of the United Nations, are "those animal species that are used, or may be used, for the production of food and agriculture, and the populations within each of them. These populations within each species can be classified as wild and feral populations, landraces and primary populations, standardized breeds, selected lines, varieties, strains and any conserved genetic material; all of which are currently categorized as Breeds. Genetic materials that are typically cryogenically preserved include sperm, oocytes, embryos and somatic cells.

Cryogenic facilities are called gene banks and can vary greatly in size usually according to the economic resources available. They must be able to facilitate germplasm collection, processing, freezing, and long term storage, all in a hygienic and organized manner. Gene banks must maintain a precise database and make information and genetic resources accessible to properly facilitate cryoconservation. Cryoconservation is an *ex situ* conservation strategy that often coexists alongside *in situ* conservation to protect and preserve livestock genetics.

Cryoconservation of livestock genetic resources is primarily done in order to preserve the genetics of populations of interest, such as indigenous breeds, also known as local or minor breeds. Material may be stored because individuals shared specific genes and phenotypes that may be of value or have potential value for researchers or breeders. Therefore, one of the main goals remains preserving the gene pool of local breeds that may be threatened. Indigenous livestock genetics are commonly threatened by factors such as globalization, modernization, changes in production systems, inappropriate introduction of major breeds, genetic drift, inbreeding, crossbreeding, climate change, natural disasters, disease, cultural changes, and urbanization.

Indigenous livestock are critical to sustainable agricultural development

and food security, due to their: adaptation to environment and endemic diseases, indispensable part in local production systems, social and cultural significance, and importance to local rural economies. The genetic resources of minor breeds have value to the local farmers, consumers of the products, private companies and investors interested in crossbreeding, breed associations, governments, those conducting research and development, and non-governmental organizations.

Therefore, efforts have been made by national governments and non-governmental organizations, such as the Livestock Conservancy, to encourage conservation of livestock genetics through cryoconservation, as

well as through other *ex situ* and *in situ* strategies. Cryogenic specimens of livestock genetic resources can be preserved and used for extended periods of time. This advantage makes cryoconservation beneficial particularly for threatened breeds that have low breed populations. Cryogenically preserved specimens can be used to revive breeds that are endangered or extinct, for breed improvement, crossbreeding, research and development. However, cryoconservation can be an expensive strategy and requires long term hygienic and economic commitment for germplasms to remain viable. Cryoconservation can also face unique challenges based on the species, as some species have a reduced survival rate of frozen germplasm.

3.6. CRYOPRESERVATION

Cryopreservation is the use of very low temperatures to preserve structurally intact living cells and tissues. Unprotected freezing is normally lethal and this chapter seeks to analyze some of the mechanisms involved and to show how cooling can be used to produce stable conditions that preserve life. It requires equipment to collect biological material and test tubes for storage. Price is highly variable based on the quality of the collection and storage materials. The life expectancy of tools should be considered when determining costs. In addition to traditional laboratory equipment, the FAO also suggests the following:

- Disposable coveralls
- Portable incubator
- Haemocytometer
- Semen straws and filling/sealing equipment
- Liquid nitrogen storage tank
- Liquid nitrogen
- Liquid nitrogen dry-shipper
- Equipment for determining sperm concentration
- Spectrophotometer (fixed or portable)
- Makler counter chamber or disposable counting chamber
- Haemocytometer
- Straw filling and sealing equipments
- Freezing equipments
- Carbon dioxide incubator (for embryos)
- Laminar flow benches (for embryos)
- Dry liquid nitrogen shipping tanks

- Long-term liquid nitrogen storage tanks.

3.7. RISK MANAGEMENT ISSUES

Modern biotechnology has allowed the movement of genetic material across unrelated species, something impossible with the traditional breeding methods. This intentional transfer of genetic material has in turn brought biotechnology out from the laboratory to the field. Genetically modified organisms (GMOs) are organisms whose genetic material has been artificially modified to change their characteristics in some way or another. In essence, “genetic modification” or “genetic engineering” techniques enable scientists to find individual genes that control particular characteristics, separate them from the original source, and transfer them directly into the cells of an animal, plant, bacterium, or virus. This technology has many potential applications. These new opportunities bring along greater public scrutiny and government regulation. Risk assessment is a common regulatory tool used in the decision-making process for a proposed commercial release of a GMO into the environment.

Environmental applications of microorganisms are wide and varied, ranging from bioremediation, biopesticides, nitrogen fixation, plant growth promoter, to biocontrol of plant diseases, and other such agricultural practices. The sensible application of recombinant DNA techniques has shown the potential for genetically improved microorganisms to be used as soil or seed inoculants. However, when introduced into the environment, they could have unintended environmental consequences and may play more pronounced ecological roles than the wild types.

Genetically improved microorganisms are able to reproduce and establish themselves as persistent populations and may have subtle and long-term effects on biological communities and natural ecosystems. Results of DNA modification may not be limited only to the particular characteristics of the replaced gene. It is therefore important to ensure that when these organisms are released into nature they do not harm the environment or human health. Such concerns have led to broader interests in the theme of risk assessment in the release of GMOs. A cautious approach is necessary to assess environmental risks which may occur due to introduction of recombinant organisms in the natural environment.

Risks related to the use of genetically modified organisms ecological stability of the GMO

The application of genetic modification allows genetic material to be transferred from any species into plants or other organisms. The introduction of a gene into different cells can result in different outcomes, and the overall pattern of gene expression can be altered by the introduction of a single gene. The sequence of the gene and its role in the donor organism may have a relatively well-characterized function in the

organism from which it is isolated. However, this apparent “precision” in the understanding of a gene does not mean that the consequences of the transfer are known or can be predicted. Copies of a gene may be integrated, additional fragments inserted, and gene sequences rearranged and deleted- which may result in lack of operation of the genes instability or interference with other gene functions possibly cause some potential risks.

Therefore, there could be a number of predictable and unpredictable risks related to release of GMOs in the open environment. The report prepared by the Law Centre of IUCN, the World Conservation Union (2004), enlists numerous environmental risks likely to occur by the use of GMOs in the field. These risks are as follows. Each gene may control several different traits in a single organism. Even the insertion of a single gene can impact the entire genome of the host resulting in unintended side effects, all of which may not be recognizable at the same time. It is difficult to predict this type of risk.

Genetic contamination/ interbreeding

Introduced GMOs may interbreed with the wild-type or sexually compatible relatives. The novel trait may disappear in wild types unless it confers a selective advantage to the recipient. However, tolerance abilities of wild types may also develop, thus altering the native species’ ecological relationship and behavior.

3.8. COMPETITION WITH NATURAL SPECIES

Faster growth of GMOs can enable them to have a competitive advantage over the native organisms. This may allow them to become invasive, to spread into new habitats, and cause ecological and economic damage.

Increased selection pressure on target and nontarget organisms

Pressure may increase on target and nontarget species to adapt to the introduced changes as if to a geological change or a natural selection pressure causing them to evolve distinct resistant populations.

Ecosystem impacts

The effects of changes in a single species may extend well beyond to the ecosystem. Single impacts are always joined by the risk of ecosystem damage and destruction.

3.9. ETHICAL CONCERNS

Various ethical issues associated with HGT from GMOs have been raised including perceived threats to the integrity and intrinsic value of the organisms involved, to the concept of natural order and integrity of species, and to the integrity of the ecosystems in which the genetically

modified organism occurs. Several scientific evidence that has emerged on GMOs over the last couple of years shows that there are several clear risks to human health and the environment. When genetic engineers create GMO or transgenic plants, they have no means of inserting the gene in a particular position. The gene ends up in a random location in the genetic material, and its position is not usually identified.

There are already several examples of such undesired effects being identified in the US after approval (e.g., GM cotton with deformed cotton bolls; increased lignin in GM soya, etc.). Releasing genetically modified plants or crop into the environment may have direct effects, including gene transfer to wild relatives or conventional crops, weediness, trait effects on nontarget species, and other unintended effects. It is widely accepted that the gene flow from GM crops is possible through pollen, from open-pollinated varieties crossing with local crops or wild relatives.

Because gene flow has happened for millennia between land races and conventionally bred crops, it is reasonable to expect that it could also happen with transgenic crops. Transgenic crops vary in their tendency to outcross, and the ability to outcross depends on the presence of sexually compatible wild relatives or crops, which varies according to location. However, some lines of evidence suggested that whether or not gene flow between transgenic crops and wild relatives matters, in and of itself. If a resulting transgenic/wild hybrid had some competitive advantage over the wild population, it could persist in the environment and potentially disrupt the ecosystem.

3.10. RISK ASSESSMENT

Risk is ubiquitous and unavoidable. To a great extent, therefore, our modus operandi involves assessment and management of risk. Directly observable risks are assessed and managed through heuristic processes. This direct observation may sometimes be insufficient to establish the nature and extent of risk. In such cases, we rely on other institutions, especially reputation and the rule of law. Biosafety issues pertaining to the marketing of GMOs have received increasing attention by national and international agencies and regulatory bodies worldwide. These are based on a common set of principles built on the accumulation of experience and scientific knowledge over the past decades.

Risk assessment intends to quantify risks and evaluate the probabilities of possible outcomes on the basis of scientific data. It is a fundamental part of improving quality, being the quality of products or the quality of life, and plays a central role in the innovation required to maximize benefits. A critical step in risk assessment is identification of circumstances that may give rise to an adverse effect(s). The level of risk is then estimated from both the likelihood and severity/consequences associated with the circumstances of concern. This is then followed by characterization of the risk based on evaluation of likelihood and

consequences of the identified adverse effects being realized. The international agreements such as Cartagena Protocol on Biosafety, Convention on Biological Diversity (CBD), and the International Plant Protection Convention (IPPC) address the environmental aspects of GMOs. The Article 15 of the Cartagena Protocol on Biosafety (CBD 2000) implies risk assessment to be in compliance with criteria of science and transparency using already existing and recognized techniques. The characterization process should adopt a multidisciplinary approach as given below.

- Analyses methodologies in statistics.
- Considers the individual components employed to produce the GMOs (such as characteristics of the donor organism, vector, and inserted DNA).
- Evaluates the final result in its totality (characteristics of the organism with new traits, information related to intended use, and characteristics of the potential receiving environment).
- Considers relevant information produced from both public and private research institutes and from international agencies.

Environmental risk assessment

Environmental risk assessment (ERA) considers the impact of introducing a GM plant into a given environment. The ERA is concerned with evaluating the potential for harm to ecosystem components given that there is exposure to the GM plant. Importantly, the focus and degree of emphasis on elements of the ERA will change during the development process for the GM plant as the scope of environmental release ranges from confined field trials of limited extent through to larger-scale trials and seed increases in more environments, and to the final unconfined commercial release.

Public awareness/access to information

Public access to information is an important cornerstone of public participation and is one of the tools that could help to realize the benefits and avoid the risks of modern biotechnology. This concept is well recognized in Principle 10 of the Rio Declaration and in the recently adopted Aarhus Convention on access to information, public participation in decision making, and access to justice in environmental matters.

Impacts of climate Change

Potential Impacts of Climate Change Climate change causes a cascade of negative effects on human health, agriculture, environment, natural resources and economic development. Rising global temperature can cause warming of the sea and melting of polar ice caps and glaciers leading to rise in sea levels (IPCC, 2001). Sea levels rose during the 20th century by 0.17 meters. By 2100, sea level is expected to rise between 0.18 and 0.59 meters. Further rise in temperature depends on the increase

in atmospheric carbon dioxide concentrations, which in turn depends on growth in emissions. Frequency and intensity of cyclones (including hurricanes and typhoons), floods, droughts and heavy precipitation events, are expected to rise in future due to the effect of global warming. Changes in rainfall pattern lead to severe water shortages and flooding. The consequences include melting of glaciers and rise in temperature can cause flooding and soil erosion and shifts in crop growing seasons which affect food security and changes in the distribution of disease vectors respectively. Temperature increases will severely increase rates of extinction for many habitats and species (upto 30 percent with a 2 °C rise in temperature).

Risk assessment and management - environment

Gene flow is a natural part of the biology of plant species and is important in the maintenance of genetic variation in populations, as well as in the spread of new traits among populations and across species boundaries. It typically involves movement of pollen and is dependent upon wind or animal vectors (pollinators). Gene flow occurs with all species, and thus with all crop species, but the amount of gene flow is a function of crop biology. The amount of gene flow will depend on how far pollen disperses from the GM plants and whether suitable plant relatives are present within range of pollen movement (also known as pollen flow). Plant species that have pollen that is readily dispersed considerable distances by wind (such as maize) or by insect pollinators (such as canola) will have the greatest amount of gene flow. Likewise, gene flow will be greatest where GM crop plants are grown together with abundant wild or feral relatives, particularly in centers of origin.

3.11. GENE ESCAPES

Genetic escapes' are plants or animals that are either not native to an area or have been selectively bred or genetically modified and have escaped from mariculture enclosures. Escapes pose a threat to ecological and socioeconomic stability if they compete with or prey upon native species. Even if native species are cultivated, they are often bred to emphasize traits that could reduce the fitness of wild populations if escapees interbreed with wild specimens. Escape of non-native species could also introduce foreign parasites into the local ecosystem. Improving standards for containment methods, limiting the cultivation of exotic species, and restricting mariculture to sterile populations may effectively minimize the risk of genetic escapes.

Measurement of gene escape

Measurement of the potential for harmful genetic escape was based on whether the species being cultured is native or introduced. Data came from the Mariculture Sustainability Index (MSI), which reported data for 359 country-species combinations (53 countries

represented). In the MSI analysis each species grown received a score from 1 to 10. Low scores indicate lower potential for ecological harm. Native species received the highest score (10), while foreign and introduced species received the lowest (1), based upon the premise of potential impacts to local biodiversity if these species were to escape.

Native but non-local species received intermediate scores, based on the assumption that they could negatively affect local genetic biodiversity but to a lesser extent than foreign or introduced species. In regions where multiple species are grown, each species was scored and the yield-weighted average of all scores was used. Scores for all regions were then rescaled from 0 to 1, using the maximum raw score of 10 and minimum of 1. All pressures are ranked for their differing effects on different goals. For each goal, the effect of each pressure is weighted low (1), medium (2) or high (3). The actual data-derived value of the pressure is then multiplied by the weight assigned to it for that goal. That process is repeated for each pressure-goal combination. The sum of those values divided by 3 (the maximum pressure-goal value) expresses the total affect of pressures on the goal. Genetic escape affects three goals, Food Provision (Fisheries), Livelihoods & Economies and Biodiversity.

3.12. TARGET ORGANISMS

The target species consists of a representative of the lineage that expresses the trait of interest and for which a high-quality genome is available. The contrast species, on the other hand, consists of a representative species of a lineage that lacks the trait, but is also as close as possible phylogenetically to the target species. Furthermore, since the gene predictions of the contrast species are used to identify orthologous genes in the target species, the contrast species should also have a high-quality genome, preferably with a well-annotated set of gene predictions. A close phylogenetic distance between the target and contrast species minimizes the chance that possible differences in genomic features are due to the evolutionary distance between species rather than the presence/absence of a given trait of interest. However, the need for high-quality genomes can also substantially limit options. We initially analyzed the genomes of zebra finch versus chicken, since these represented the highest-quality and best-annotated avian genome assemblies available.

Ideally, species from more closely related avian groups to songbirds, such as a sister taxon among the suboscines (also vocal nonlearners; e.g., Golden-collared manakin), would represent a much more stringent contrast to zebra finches than chicken. However, in this case, all available suboscine genomes are currently substantially more incomplete, which would create several other obstacles to the comparative analyses discussed subsequently. Nonetheless, after conducting our initial screening of zebra finch versus chicken, the inclusion of multiple genomes from other relevant avian species, even in cases where their genomes and

gene predictions were incomplete, greatly facilitated the tasks of confirming or disproving the initial candidates.

3.13. TOLERANCE

Organisms are able to survive only within certain maximum and minimum limits with respect to each environmental factor such as water, light and temperature. These are called the tolerance limits and the range in between these limits is the tolerance ranges. Different organisms have different tolerance ranges. Beyond the maximum and minimum limits of this range no member of a particular species can survive. For example, fish generally tolerate a narrow range of water temperature. If the water cools below the range of tolerance they die or move to warmer waters.

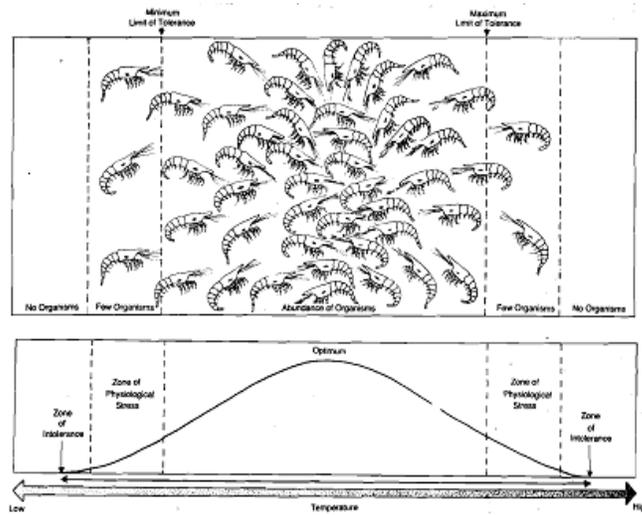


Fig.4: Range of tolerance for a population of organisms of the same species, to an environmental factor in this case temperature. The organisms shown here are scarlet prawns

3.14. SUPER-WEEDS

Herbicide-resistant weeds-often referred to as “superweeds”-are nuisance plants that have developed resistance to one or more herbicides. They have been a serious problem for decades, but increasingly, GMO critics have focused criticism on weeds that have developed immunity to the popular herbicide glyphosate (patented as Roundup), which is often paired with genetically engineered herbicide tolerant crops, mostly corn, soybeans, cotton and alfalfa in the United States. These GMO crops are called herbicide tolerant (Ht).

Herbicide-GMO seed pairings offer many advantages for farmers, including lower overall costs, increased yields and a reduction in total

chemical use. But weed resistance is compromising those advantages, worrying farmers who are forced to deal with a growing and expensive weed problem and consumers who fear trace chemicals in the food supply. It's also fueling criticism from advocacy groups who blame conventional "industrial farming", and GMO crops in particular, for the rise of hardier weeds, and say proposed solutions, such as stacking herbicide resistant traits, could compound the problem.

Scientists say the challenge of herbicide tolerant weeds pre-dated the introduction of GMO varieties in 1996 and note that some of the most severe weed problems affect non-GMO crops, such as conventionally-bred herbicide tolerant sunflower plants. Scientists say weeds are inevitable in modern farming unless farmers rotate and mix their chemicals and include some non-herbicide defenses.

3.14.1. Virus and Evolution/Super Virus

Just as natural selection has shaped the evolution of humans, plants, and all living things on the planet, natural selection shapes viruses, too. Though viruses aren't technically living, they need a host organism in order to reproduce; they are subject to evolutionary pressures. The human immune system uses a number of tactics to fight pathogens. The pathogen's job is to evade the immune system, create more copies of itself, and spread to other hosts. Characteristics that help a virus do its job tend to be kept from one generation to another. Characteristics that make it difficult for the virus to spread to another host tend to be lost.

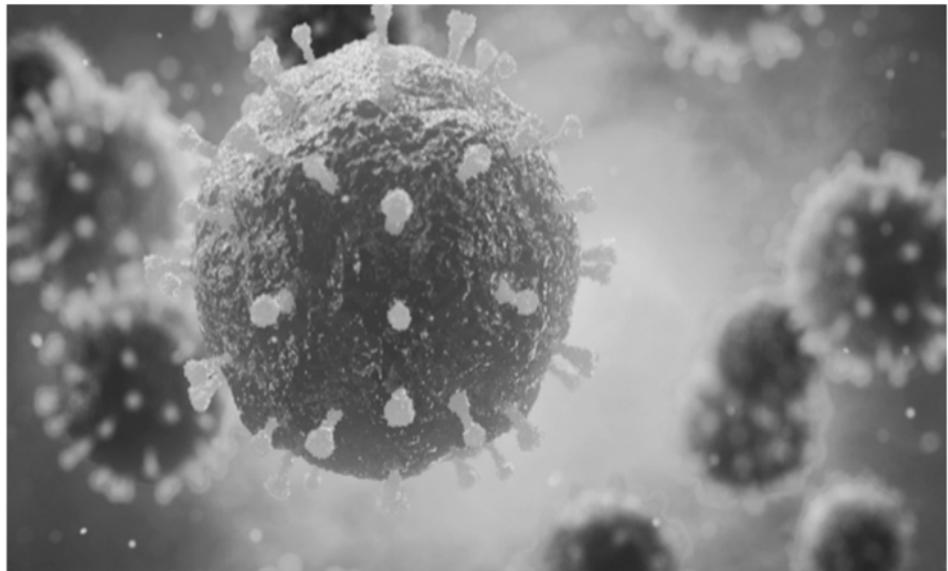
If a virus that has a mutation that makes it particularly deadly to its human host and kills the host within a few hours of infection. The virus needs a new, healthy host for its descendents to survive. If it kills its host before the host infects others, that mutation will disappear. One way hosts protect themselves from a virus is to develop antibodies to it. Antibodies lock onto the outer surface proteins of a virus and prevent it from entering host cells. A virus that appears different from other viruses that have infected the host has an advantage: the host has no pre-existing immunity, in the form of antibodies, to that virus. Many viral adaptations involve changes to the virus's outer surface.

Below we look at two special cases in viral evolution: how evolution occurs in influenza viruses and in the human immunodeficiency virus (HIV, the virus that causes AIDS). Both of these viruses are RNA viruses, meaning that their genetic material is encoded in RNA, not DNA. DNA is a more stable molecule than RNA, and DNA viruses have a proofreading check as part of their reproductive process. They manage to use the host cell to verify viral DNA replication. If the virus makes a mistake in copying the DNA, the host cell can often correct the mistake. DNA viruses, therefore, do not change, or mutate, much. RNA, however, is an unstable molecule, and RNA viruses don't have a built-in proofreading step in their replication. Mistakes in copying RNA happen frequently, and the host cell does not correct these mistakes. RNA virus mutations are frequent and can have important consequences for their hosts.

Viral evolution is a subfield of evolutionary biology and virology that is specifically concerned with the evolution of viruses. Viruses have short generation times and many, in particular RNA viruses, have relatively high mutation rates (on the order of one point mutation or more per genome per round of replication). This elevated mutation rate, when combined with natural selection, allows viruses to quickly adapt to changes in their host environment. In addition, most viruses provide many offspring, so any mutated genes can be passed on to many offspring quickly. Although the chance of mutations and evolution can change depending on the type of virus (double stranded DNA, double stranded RNA, single strand DNA, etc.), viruses overall have high chances for mutations.

Viral evolution is an important aspect of the epidemiology of viral diseases such as influenza (influenza virus), AIDS (HIV), and hepatitis (e.g. HCV). The rapidity of viral mutation also causes problems in the development of successful vaccines and antiviral drugs, as resistant mutations often appear within weeks or months after the beginning of a treatment. One of the main theoretical models applied to viral evolution is the quasi-species model, which defines a viral quasi-species as a group of closely related viral strains competing within an environment.

3.14.2 Killing Dangerous Super Viruses with Cold Plasma



There are a lot of ways to kill viruses, but it's not that easy to kill them in the air. For the most part, if you want to prevent viruses from infecting someone, or from entering a room, for example, you use a face mask or air filters. In some cases, such as in laboratory spaces, ultraviolet light is used to kill off pathogens. Of course, in some cases of specific disease-causing viruses, vaccines can be used in people, which safely trains your immune system to recognize and kill the viruses.

Now, researchers at the University of Michigan have shown that dangerous airborne viruses can be killed “on-the-fly” when exposed to so-called “cold plasma,” or energetic, charged air molecule fragments. They published their work in the *Journal of Physics D: Applied Physics*.

“The most difficult disease transmission route to guard against is airborne because we have relatively little to protect us when we breathe

The researchers evaluated the virus-killing speed and effectiveness of nonthermal plasma, that ionized particles created around electrical discharges, such as sparks. They found the reactor inactivated or removed 99.9% of a test virus, mostly because of inactivation. The reactor had borosilicate glass beads packed into a cylinder. They initiated sparks between the void spaces and passed a model virus via flowing air into the reactor. Outbreaks of airborne infectious diseases such as measles or severe acute respiratory syndrome (SARS) can cause significant public alarm. Where ventilation systems facilitate disease transmission to humans or animals, there exists a need for control measures that provide effective protection while imposing minimal pressure differential.”

The researchers also evaluated the amount of viral genome in the air samples. They determined that more than 99% of the air sterilizing effect of the reactor was caused by inactivating the virus, while the rest was the result of filtering the virus. The results tell us that nonthermal plasma treatment is very effective at inactivating airborne viruses.

3.15. SUMMARY

The release of genetically modified plants is governed by regulations that aim to provide an assessment of potential impact on the environment. One of the most important components of this risk assessment is an evaluation of the probability of gene flow. In this review, we provide an overview of the current literature on gene flow from transgenic plants, providing a framework of issues for those considering the release of a transgenic plant into the environment. For some plants gene flow from transgenic crops is well documented, and this information is discussed in detail in this review. Mechanisms of gene flow vary from plant species to plant species and range from the possibility of asexual propagation, short- or long-distance pollen dispersal mediated by insects or wind and seed dispersal. Volunteer populations of transgenic plants may occur where seed is inadvertently spread during harvest or commercial distribution.

The various methods that have been proposed to prevent gene flow from genetically modified plants are also described. The current “transgenic traits” in the major crops confer resistance to herbicides and certain insects. Such traits could confer a selective advantage (an increase in fitness) in wild plant populations in some circumstances, were gene flow to occur. However, there is ample evidence that gene flow from crops to related wild species occurred before the development of transgenic crops and this should be taken into account in the risk assessment process.

3.16. TERMINAL QUESTIONS

Q.1. Explain germplasm and their types of conservation.

Answer: -----

Q.2. What do you mean by cryopreservation?

Answer: -----

Q.3. Write a short note on nucleic acid and draw their structures.

Answer: -----

Q.4. Explain gene and its flow.

Answer: -----

Q.5. Explain genetically modified organisms and its risk management issues.

Answer: -----

Q.6. Write a brief note on super-weeds.

Answer: -----

3.17. FURTHER READINGS

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UNIT-4 GMO AND HUMAN HEALTH

Structure

- 4.1. Introduction
 - Objectives
- 4.2. Genetically modified organisms (GMOs)
 - 4.2.1. Consequences of GMOs for biodiversity
- 4.3. Ecological aspects of GMOs
 - 4.3.1. Positive impacts of GMOs
 - 4.3.2. Negative impacts of GMOs
- 4.4. Benefits of GMOs
- 4.5. Transgenic
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- 4.7. Development of transgenic crops
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- 4.9. Detection of transgenic animals
- 4.10. Identification of transgenic animals:
 - 4.10.1. Dots blot technique:
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 - 4.10.3. Analysis of transgenic integration:
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- 4.11. Advantages and disadvantages
 - 4.11.1. Advantages of transgenic animals:
 - 4.11.2. Disadvantages of transgenic animals
- 4.12. Radiation safety
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- 4.13. Isotopic and non- isotopic labeling systems

4.13.1. Isotopic labeling systems

4.13.2. Non-isotopic probes (cold probes)

4.14. Benefits from transgenic

4.14.1. Transgenic plants: issues and future prospects

4.15. Summary

4.16. Terminal questions

4.17. Further reading

4.1. INTRODUCTION

The term GMO is quite common and is gaining significance in a variety of food products. GMO which stands for Genetically Modified Organisms has been a subject of debate ever since it's discovery among various scientific communities as to whether they are actually advantageous or not. The most common applications GM products are in the food and pharmaceutical industries. However, GMOs can also be used in the environment for its protection and monitoring. Before getting into the impacts of GMOs in various fields it is quite essential to be clear with the concept of GMOs

Objectives:

- To discuss about genetically modified organisms (GMOs)
- To discuss about consequences of GMOs for biodiversity
- To cover the ethical controversy
- To discuss about detection, advantages and disadvantages of transgenic species

4.2. GENETICALLY MODIFIED ORGANISMS (GMOS)

A genetically modified organism (GMO) is any organism whose genetic material has been altered using genetic engineering techniques. The exact definition of a genetically modified organism and what constitutes genetic engineering varies, with the most common being an organism altered in a way that "does not occur naturally by mating and/or natural recombination". A wide variety of organisms have been genetically modified (GM), from animals to plants and microorganisms. Genes have been transferred within the same species, across species (creating transgenic organisms) and even across kingdoms. New genes can be introduced, or endogenous genes can be enhanced, altered or knocked out.

GMOs are basically organisms that are genetically engineered to include a particular trait of another organism or remove certain traits. So basically it is the manipulation of living organisms at the molecular level which is done by using recombinant DNA technology. A gene from one organism is transferred to another one through the use of suitable vectors. The GMO products that find their uses every day include soy, corn, tomatoes, milk, etc. A wide range of applications is in the field of pharmaceuticals, food technology, agriculture as well as environmental management.

Creating a genetically modified organism is a multi-step process. Genetic engineers must isolate the gene they wish to insert into the host organism and combine it with other genetic elements, including a promoter and terminator region and often a selectable marker. A number of techniques are available for inserting the isolated gene into the host genome. Recent advancements using genome editing techniques, notably CRISPR, have made the production of GMO's much simpler.

Herbert Boyer and Stanley Cohen made the first genetically modified organism in 1973, bacteria resistant to the antibiotic kanamycin. The first genetically modified animal, a mouse, was created in 1974 by Rudolf Jaenisch, and the first plant was produced in 1983. In 1994 the Flavr Savr tomato was released, the first commercialized genetically modified food. The first genetically modified animal to be commercialized was the GloFish (2003).

Bacteria are the easiest organisms to engineer and have been used for research, food production, industrial protein purification (including drugs), agriculture, and art. There is potential to use them for environmental, purposes or as medicine. Fungi have been engineered with much the same goals. Viruses play an important role as vectors for inserting genetic information into other organisms. This use is especially relevant to human gene therapy. There are proposals to remove the virulent genes from viruses to create vaccines. Plants have been engineered for scientific research, to create new colors in plants, deliver vaccines and to create enhanced crops. Genetically modified crops are publicly the most controversial GMOs. The majority are engineered for herbicide tolerance or insect resistance. Golden rice has been engineered with three genes that increase its nutritional value. Other prospects for GM crops are as bioreactors for the production of biopharmaceuticals, biofuels or medicines.

Animals are generally much harder to transform and the vast majority are still at the research stage. Mammals are the best model organisms for humans, making ones genetically engineered to resemble serious human diseases important to the discovery and development of treatments. Human proteins expressed in mammals are more likely to be similar to their natural counterparts than those expressed in plants or microorganisms. Livestock are modified with the intention of improving economically important traits such as growth-rate, quality of meat, milk composition, disease resistance and survival. Genetically modified fish are

used for scientific research, as pets and as a food source. Genetic engineering has been proposed as a way to control mosquitos, a vector for many deadly diseases. Although human gene therapy is still relatively new, it has been used to treat genetic disorders such as severe combined immunodeficiency, and Leber's congenital amaurosis.

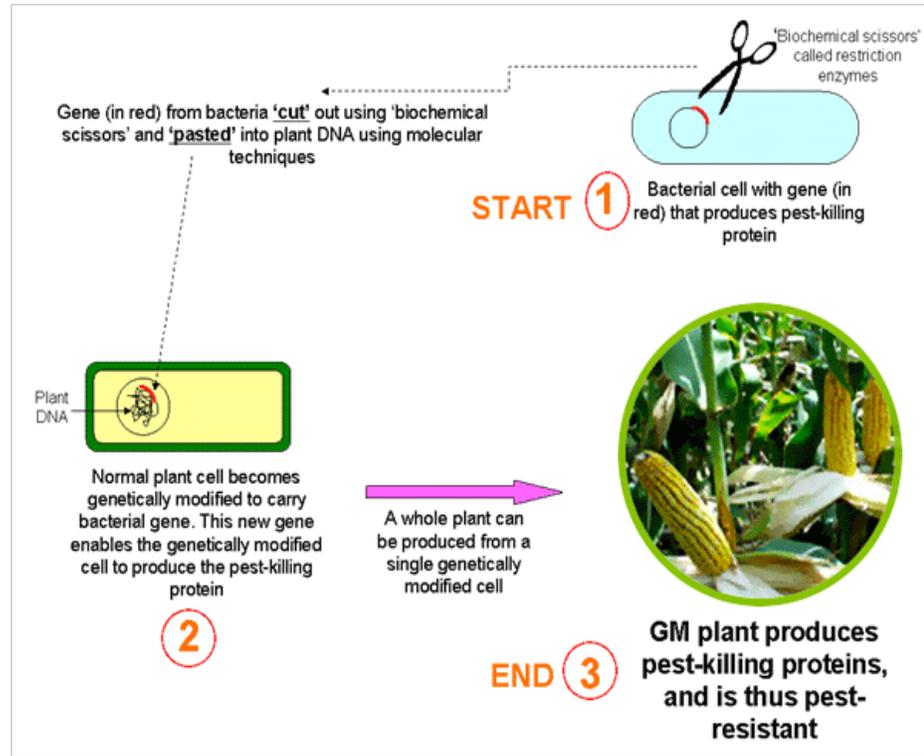


Fig. 4.1: Creation of a genetically modified drought resistant plant (GMAC 2007)

Many objections have been raised over the development of GMO's, particularly their commercialization. Many of these involve GM crops and whether food produced from them is safe and what impact growing them will have on the environment. Other concerns are the objectivity and rigor of regulatory authorities, contamination of non-genetically modified food, control of the food supply, patenting of life and the use of intellectual property rights. Although there is a scientific consensus that currently available food derived from GM crops poses no greater risk to human health than conventional food, GM food safety is a leading issue with critics. Gene flow, impact on non-target organisms and escape are the major environmental concerns. Countries have adopted regulatory measures to deal with these concerns. There are differences in the regulation for the release of GMOs between countries, with some of the most marked differences occurring between the US and Europe. One of the key issues concerning regulators is whether GM food should be labeled and the status of gene edited organisms.

4.2.1. Consequences of GMOS for Biodiversity

Genetic modification produces genetically modified animals, plants and organisms. If they are introduced into the environment they can affect biodiversity. For example, existing species can be overrun by more dominant new species. These and other potential effects are considered during the licensing procedure. (Such effects can of course also occur following the introduction of non-genetically modified animals plants and organisms.)

Assessing the impact on biodiversity requires knowledge. This knowledge must be constantly updated so the State can assess the effects of future GMOs on biodiversity. A major ecological research programme, ERGO, aimed to amass ecological knowledge, for example, on the impact of new GMOs on their environment. The United Nations has proclaimed May 22 the International Day for Biological Diversity (IDB) to increase understanding and awareness of biodiversity issues. This theme is "Our Biodiversity, Our Food, and Our Health."

4.3. ECOLOGICAL ASPECTS OF GMOS

It is evident from many recent analyses that the world's population will increase significantly in the near future. As a result, the demand for healthy, affordable food will also grow. Given that the area of available arable land required to produce food will not expand, new and environmentally sound technologies allowing farmers to produce more on the same amount of land must be developed. The development of genetically modified crops through biotechnology is one of several technologies now available to help address the world's increasing future demand for food. The first products from genetic engineering have been introduced recently into the market. Genetically modified plants tolerant to herbicides with superior environmental properties, along with crops that are protected from insect predation while posing negligible risks to beneficial insects, are now commercial realities. Unlike their traditionally bred counterparts, genetically modified crops have been studied in great detail to assure their food, feed and environmental safety. For the genetically modified crops currently on the market, the risk has been assessed in relationship to the benefits.

4.3.1. Positive Impacts Of Gmos

The protection and maintenance of the environment are one of the most significant topics that are gaining significance among people. However, by manipulating certain living organisms like bacteria, plants, etc. the wastes generated in the environment can be treated effectively. In order to degrade non-degradable wastes, either restructuring an already existing metabolic pathway or assembling a whole new pathway is done by using suitable techniques of genetic engineering.

GMOs also play a vital role in monitoring the contents of the environment. A known quantity of pollutants present in the environment can help one to put effective methods to control the level of that particular pollutant. A pollutant can be sensed by using biosensors that can detect the concentration of pollutants. The biosensor consists of a biological element which can be a nucleic acid, antibody or a microorganism which can help to detect the concentration of a particular pollutant. The biological elements can be genetically modified to produce more effective signals, detect new pollutants, etc.

GM crops are the plants whose genetic makeup has been manipulated in order to inculcate certain desirable traits. For e.g. a genetically modified corn plant which is made resistant to certain pests would result in increased yield as corn would not be susceptible to pest-related diseases as well as invasions. GMOs are quite essential for the production of various pharmaceutical compounds that are generally obtained through living organisms such as plants, animals as well as microbes. Plants and animals could be injected with genetically modified hormones whereas microbes are manipulated at the genetic level in order to improve the quality as well as yield of the required pharma products.

4.3.2. Negative Impacts of GMOS

Since GMOs are a new variety of species their reaction with the elements of the environment is unknown. Some predict that they can interact with other species to produce a mutant strain which may prove to be dominating over the other species thus resulting in a lack of biodiversity in the future period. The by-products mutant strains could also produce toxic effects on the environment as well as its components.

Recombinant bovine growth hormone is a synthetic hormone which is injected into the cows in order to increase the yield of milk. However, according to the American Public Health Association, this milk has more of the hormone IGF-1 which can prove to be carcinogenic. The use of GMOs should be avoided as it can affect fertility, immune system and many more functions in human bodies. The consumption of genetically modified crop plants by the predators could also prove to be harmful to them.

The unknown distribution of GM crops could result in the production of the genetically modified compound. For e.g. it was proved that most of the honey found in the areas surrounded by GM crops showed different characteristics than the naturally existing honey.

This is due to the fact that honeybee's secret nectar from genetically modified crop plants that result in honey is genetically modified. This could prove to be a bane for the people who are allergic to GMOs as they are unaware about its genetically modified nature.

4.4. BENEFITS OF GMOS

Crops	Animals
<ul style="list-style-type: none"> ✓ Enhanced taste and quality ✓ Reduced maturation time ✓ Increased nutrients, yields, and stress tolerance ✓ Improved resistance to disease, pests, and herbicides ✓ New products and growing techniques 	<ul style="list-style-type: none"> ✓ Increased resistance, productivity, hardiness, and feed efficiency ✓ Better yields of meat, eggs, and milk ✓ Improved animal health and diagnostic methods
Environment	Society
<ul style="list-style-type: none"> ✓ "Friendly" bioherbicides and bioinsecticides ✓ Conservation of soil, water, and energy ✓ Bioprocessing for forestry products ✓ Better natural waste management ✓ More efficient processing 	<ul style="list-style-type: none"> ✓ Increased food security for growing populations

Fig.4.2: Benefits of genetically modified products in reference to crops, animals, the environment, and society (HGP 2008).

4.5. TRANSGENIC

Agricultural and horticultural crops offer substantial inputs to crop productivity, nutritional quality and human health. In recent times, with advances in scientific and technological knowledge, there has been a high degree of success in crop improvement through marker assisted selection (MAS) and genetic modification. The conventional breeding by MAS increases the efficiency of breeding but, it is limited by the available gene pool. With the advances in recombinant DNA technology, the genes of interest coding for useful traits have been successfully incorporated into the genomes of important crop plants. However, conflicting assessments of the benefits, risks and limitations of transgenic crops have raised several controversies. A major roadblock to the rapid adoption of transgenic crops is the prolonged process of regulatory approval. There is

an urgent need for appropriate science-based, cost- effective and time-effective regulatory system that will be responsible and rigorous but also simple and encouraging to the developing countries. Agricultural and horticultural crops offer substantial inputs to crop productivity, nutritional quality and human health. In recent times, with advances in scientific and technological knowledge, there has been a high degree of success in crop improvement through marker assisted selection (MAS) and genetic modification. The conventional breeding by MAS increases the efficiency of breeding but, it is limited by the available gene pool. With the advances in recombinant DNA technology, the genes of interest coding for useful traits have been successfully incorporated into the genomes of important crop plants. However, conflicting assessments of the benefits, risks and limitations of transgenic crops have raised several controversies. A major roadblock to the rapid adoption of transgenic crops is the prolonged process of regulatory approval. There is an urgent need for appropriate science-based, cost- effective and time-effective regulatory system that will be responsible and rigorous but also simple and encouraging to the developing countries.

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Transgenic organisms have also been developed for commercial purposes. Perhaps the most famous examples are food crops like soy and corn that have been genetically modified for pest and herbicide resistance. These crops are widely known as “GMOs” (genetically modified organisms). Here are few other examples of transgenic organisms with commercial value:

- Golden rice: modified rice that produces beta-carotene, the precursor to vitamin A. Vitamin A deficiency is a public health problem for millions of people around the world, particularly in Africa and Southeast Asia. Golden rice is still waiting regulatory approval.
- Goats that produce important proteins in their milk: goats modified to produce FDA-approved human antithrombin (**ATryn**), which is used to treat a rare blood clotting disorder in humans. Goats have also been genetically modified to produce spider silk, one of the strongest materials known to man, in their milk. Proposed uses for this recombinant spider silk range from artificial tendons to bulletproof vests.
- Vaccine producing bananas: genetically engineered bananas that contain a vaccine. Bananas provide an easy means for delivering a vaccine (especially to children) without the need for a medical

professional that is trained in giving shots. Edible vaccines are still in development.

- Chymosin producing microorganisms: yeast, fungi, or bacteria modified to produce the enzyme chymosin, which splits milk to make cheese. Traditionally, rennet (found in cow stomachs) is used to clot cheese. But, when the demand for firm cheeses surpassed the amount of rennet available, recombinant chymosin was developed and is used widely today.

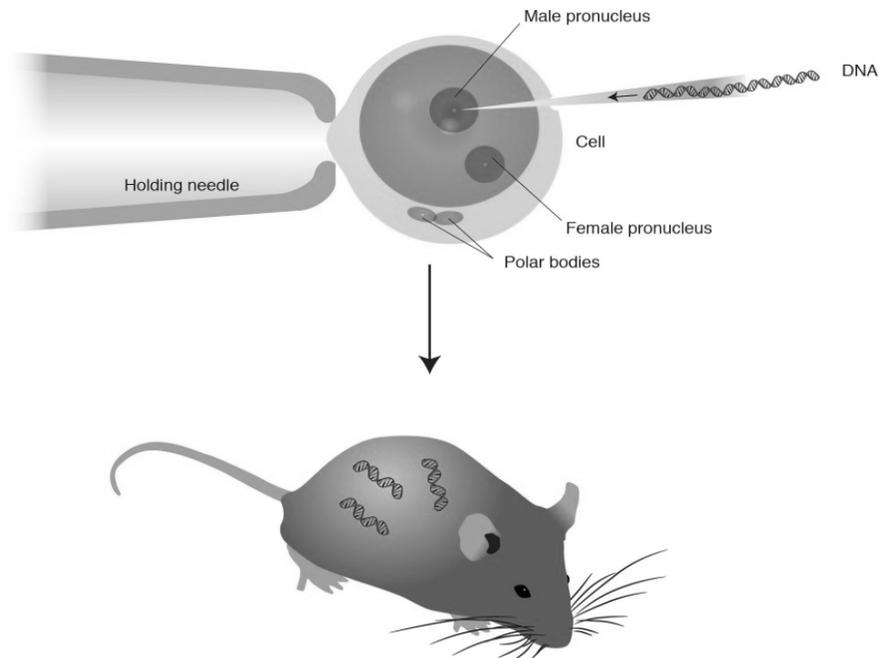


Fig. 43: Image courtesy of the National Human Genome Research Institute

4.6. RECOMBINANT DNA TECHNOLOGY (RDT)

All organisms on Earth evolved from a common ancestor, so all organisms use DNA as their molecule of heredity. At the chemical level, DNA is the same whether it is taken from a microscopic bacterium or a blue whale. As a result, DNA from different organisms can be “cut and pasted” together, resulting in “recombinant DNA”. The first recombinant DNA molecule was produced in 1972 by Stanford researcher Paul Berg. Berg joined together DNA fragments from two different viruses with the help of particular enzymes: restriction enzymes and ligase.

Restriction enzymes (such as EcoR1 in the figure below) are like “molecular scissors” that cut DNA at specific sequences. If the DNA from the different sources is cut with the same restriction enzyme, the cut ends can be joined together and then sealed into a continuous DNA strand by the enzyme ligase. In 1973, the first organism to contain recombinant

DNA was engineered by Herb Boyer (UCSF) and Stanley Cohen (Stanford University). Together they introduced an antibiotic resistance gene into *E.coli* bacteria. Notably, they also produced bacteria that contained genes from the toad *Xenopus laevis*, which showed DNA from very different species could be spliced together. Paul Berg was awarded the 1980 Nobel Prize in Chemistry “for his fundamental studies of the biochemistry of nucleic acids, with particular regard to recombinant-DNA”.

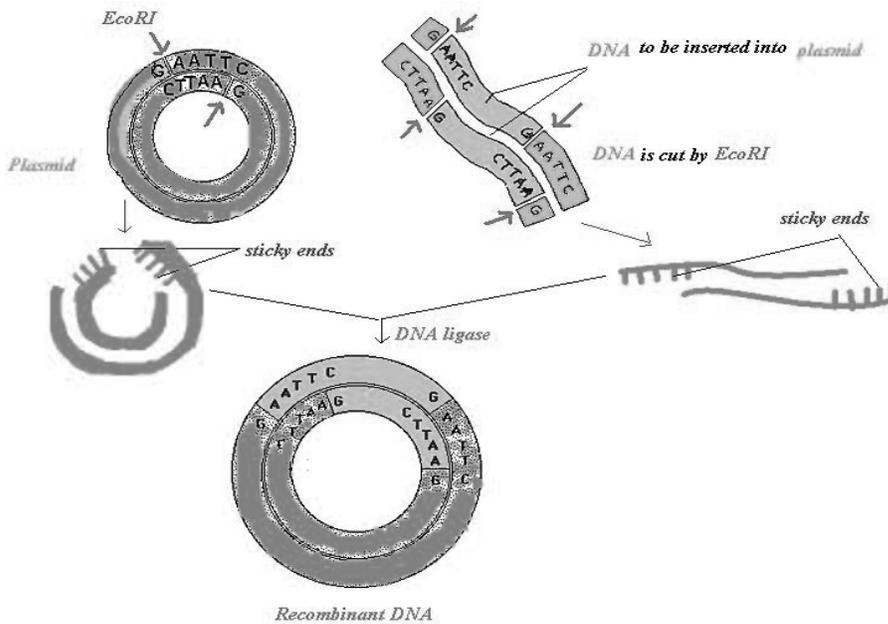


Fig. 4.4: The production of recombinant DNA involves cutting two different pieces of DNA with the same restriction enzyme and then ligating (“glueing”) the pieces together.

The ability to cut, paste, and copy molecules of DNA was not only a watershed moment for scientific research but spawned an entire industry built on genetic engineering. Genentech, the first biotechnology company, was founded by Herb Boyer in 1976. By 1982, the FDA approved Genentech’s first successful product, a synthetic form of human insulin produced by bacteria that were engineered to contain the insulin gene. Today recombinant DNA technology is used extensively in research laboratories worldwide to explore myriad questions about gene structure, function, expression pattern, regulation, and much more. One widely used application involves genetically engineering “knock-out” animals (typically mice) to contain a non-functional form of a particular gene of interest.

The goal of such experiments is to determine gene function by analyzing the consequences of the missing gene. While knockout mice are generated to answer questions in many different fields, they are particularly useful in developmental biology and have led to an

understanding of some of the essential genes involved in the development of an organism from a single fertilized egg.

Recombinant DNA techniques are also a cornerstone of the biotechnology industry. One example is the generation of genetically engineered plants to produce an insect toxin called Bt toxin. The Bt gene is derived from a bacterium called *Bacillus thuringiensis* and produces a toxin that disrupts gut function in the larvae (caterpillars) of certain insects that are crop pests. The gene that produces Bt toxin is introduced into such plants by recombinant DNA technology, and results in the selective killing of crop-feeding insects. This development has had a major economic impact and reduced the expenses of pesticides used per year and has increased the longevity and success of several crops.

4.7. DEVELOPMENT OF TRANSGENIC CROPS

Genetically engineered plants are generated in a laboratory by altering the genetic-make-up, usually by adding one or more genes of a plant's genome. The nucleus of the plant-cell is the target for the new transgenic DNA. Most genetically modified plants are generated by the biolistic method (Particle gun method) or by *Agrobacterium tumefaciens* mediated transformation method. The “Gene Gun” method, also known as the “Micro-Projectile Bombardment” or “Biolistic” method is most commonly used in the species like corn and rice. In this method, DNA is bound to the tiny particles of Gold or Tungsten, which is subsequently shot into plant tissue or single plant cells, under high pressure using gun.

The accelerated particles are penetrating both into the cell wall and membranes. The DNA separates from the coated metal and it integrates into the plant genome inside the nucleus. This method has been applied successfully for many crops, especially monocots, like wheat or maize, for which transformation using *Agrobacterium tumefaciens* has been less successful. This technique is clean and safe. The only disadvantage of this process is that serious damage can be happened to the cellular tissue.

The next method, used for the development of genetically engineered plants, is the “Agrobacterium” method. It involves the use of soil-dwelling bacteria, known as *Agrobacterium tumefaciens*. It has the ability to infect plant cells with a piece of its DNA. The piece of DNA, that infects a plant, is integrated into a plant chromosome, through a tumor inducing plasmid (Ti plasmid). The Ti plasmid can control the plant's cellular machinery and use it to make many copies of its own bacterial DNA. The Ti plasmid is a large circular DNA particle that replicates independently of the bacterial chromosome.

The importance of this plasmid is that, it contains regions of transfer DNA (t-DNA), where a researcher can insert a gene, which can be transferred to a plant cell through a process known as the floral dip. A Floral Dip involves, dipping flowering plants, into a solution of Agro

bacterium carrying the gene of interest, followed by the transgenic seeds, being collected directly from the plant. This process is useful, in that, it is a natural method of transfer and therefore thought of as a more acceptable technique. In addition, *Agrobacterium* is capable of transferring large fragments of DNA very efficiently. One of the biggest limitations of *Agrobacterium* is that, not all important food crops can be infected by these bacteria. This method works especially well for the dicotyledonous plants like potatoes, tomatoes and tobacco plants.

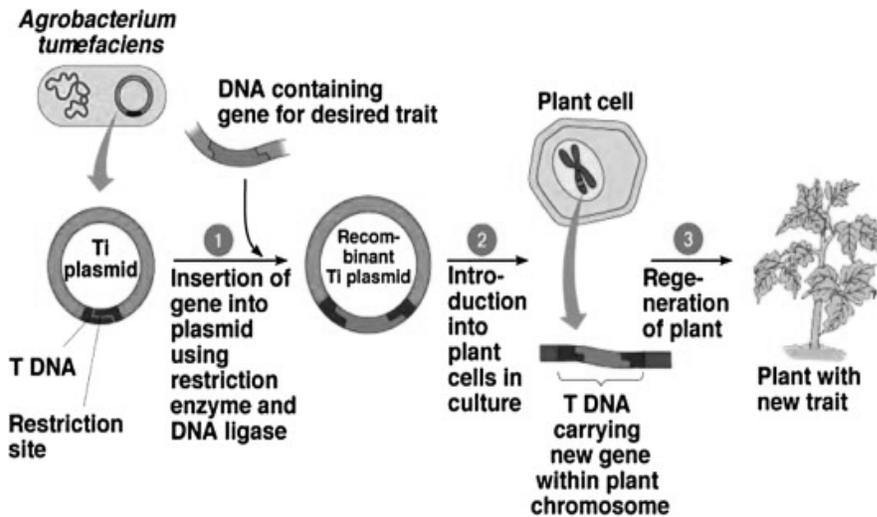


Fig. 4.5. Agrobacterium mediated transformation.

4.8. ETHICAL CONTROVERSY

Transgene use in humans is currently fraught with issues. Transformation of genes into human cells has not been perfected yet. The most famous example of this involved certain patients developing T-cell leukemia after being treated for X-linked severe combined immunodeficiency (X-SCID). This was attributed to the close proximity of the inserted gene to the LMO2 promoter, which controls the transcription of the LMO2 proto-oncogene. In common with most forms of genetic engineering, the use of transgenic for purposes other than to correct life-threatening genetic abnormalities is a major bioethical issue.

4.9. DETECTION OF TRANSGENIC ANIMALS

In recombinant DNA technology after the gene of interest has been isolated and transferred efficiently, the next major step is to ensure its proper and maximum expression in order to obtain proposed results. Thus in a group of transgenic animals it is important that the animal with proper transgenic integration is identified.

4.10. IDENTIFICATION OF TRANSGENIC ANIMALS

The identification of transgenic animals is done using different mechanism. In animals, where the transgenic produces a distinctive phenotypic effect, the transgenic successful animals can be noted easily. But the results of all the gene transfer does not result in such distinct effects therefore other techniques have to be employed. The dot blot technique and PCR technique are to name a few.

4.10.1. Dots Blot Technique

This technique helps in detecting several samples in one experiment. The sample of DNA collected is fixed onto a support like nitro cellulose filter. This then undergoes denaturation so that the double helix separates. Such membrane containing denatured sample when treated with radioactively labelled probe of corresponding transgene, the sample DNA incorporated with transgene binds with the probe. Upon removal of free probes by washing and analysed by autoradiography, it reveals presence of transgene which can be detected by fluorescence produced by radioactive probes. The strength of radioactivity exhibited shows the strength of transgene integration.

4.10.2. PCR Technique

This is the most important and wide speed used technology to identify the transgenic successful animals. The primers corresponding to the integrated transgene is used to amplify the test DNA sequences isolated from the transgenic animals. This results in the amplification of the transgene. The amplified DNA when blotted and hybridized, the presence of transgene is confirmed. But the techniques adopted for identification of transgenic animals does not reveal the actual level and site of integration. For achieving these further steps has to be adopted like:

4.10.3 Analysis of Transgenic Integration

In order to analyse the transgene integrated, the isolated gene samples which are detected with transgene integration, undergo restriction digestion with known restriction endonucleases. The fragments are separated by agarose gel electrophoresis and these fragments are analysed by southern blotting procedure. The fragments on the gel are transferred to a nitrocellulose filter membrane and denatured and probed with radioactive probe to reveal the actual site of transgenic integration. The integration of transgene can be confirmed by choosing the appropriate restriction enzyme. The presence of single or multiple integration of transgene is indicated by southern blotting.

4.10.4. Analysis of mRNA Production

The mRNA produced from a transgene can be detected as it is different from the native mRNA of the organisms. These can be purified and hybridized with a radioactive probe to detect mRNA production.

4.10.5. Analysis of Protein Expression

The final aim of transgenic integration is to produce proteins coded by the transgenic and its efficient expression. Therefore the detection of transgene integration is possible by protein expression of the transgene. The analysis of transgenic proteins can be done by two methods: by identifying specific antibodies produced by transgenic proteins and by studying the enzymatic properties of the concerned proteins. In the case of antibody identification, various immunologic assays can be used. ELISA test is a classic example of the same. In this case, the antibody specific to the antigenic protein is added and allowed to react. Following the first reaction, this is further reacted with an antibody specific to the former antibody results in formation of a complex. This when treated with the substrate of corresponding enzyme, it produces colour proportional to the strength of the antibody indicating the amount of corresponding transgenic protein expressed. The other assays included are immuno-blotting, radioimmuno-precipitation, immune-histochemical staining etc.

Enzyme activities can be detected by using transgenic genes which produces different enzymatic activities or different pathway which is not shown by host enzymes. Various procedures can be employed to detect this. The main procedure followed is by transfer of scorable marker genes. Scorable marker genes are those which produce a definite phenotype. Main examples for these are *chloramphenicol acetyltransferase (CAT)* genes used mainly in fish or mammal cells, betagalactocidase and luciferase gene used in fish. All this analysis has to be repeated in two or more different potentially transgenic animals so as to determine the level of transgenic integration as, in different organisms it tend to differ. This occurs because the site of integration may differ among animals. The animals has to be studied to confirm which site integration yield maximum expression and further research must be forwarded to achieve the same.

4.11. ADVANTAGES AND DISADVANTAGES

The main advantages and disadvantages of transgenic are as given

4.11.1 Advantages of Transgenic Animals

- Gene requires certain cellular mechanism to help for the production of protein. The animals used for transgenic purpose naturally carry the mechanism needed to produce complex protein. Theses mechanism is absent in cell culture.

- Expression through cell culture or bacterial culture requires constant monitoring and sampling.
- The isolation and purification of expressed protein in conventional method is more difficult than purifying proteins from an animal's milk or body fluid.
- It is more cost effective as the product is efficiently passed through milk with an average yield of 53% and with 99% purity.
- It has been estimated that transgenic animal can produce in its lifetime \$100 to \$200 million worth of pharmaceuticals.

4.11.2. Disadvantages of Transgenic Animals

- Transgenic animal project is extremely expensive.
- Generation of transgenic animals is also expensive, because of long gestation period, litter size and higher maintenance cost of the recipient animals.
- There may be high mortality rate and other deleterious effects on animals used by researchers to create transgenic breeds. It has been observed that transgenic pigs having enhanced growth rate and efficient feed conversion exhibit reduced reproductive performance and may suffer from arthritis and dermatitis etc.
- Similarly, transgenic sheep expressing growth hormone may show diabetic like conditions. Mayer argues that we do not understand the long term effects of genetic engineering on animals.
- Large number of recipients is required for embryo transfer because of low transgenesis rate.
- Transgenic foods have been produced and offer better productivity in terms of both yield and quantity. However, there are some apprehensions about the safety of transgenic foods.

4.12. RADIATION SAFETY

Radiation protection, also known as radiological protection, is defined by the International Atomic Energy Agency (IAEA) as the protection of people from harmful effects of exposure to ionizing radiation, and the means for achieving this. Exposure can be from a source of radiation external to the human body or due to internal irradiation caused by the ingestion of radioactive contamination. Ionizing radiation is widely used in industry and medicine, and can present a significant health hazard by causing microscopic damage to living tissue. There are two main categories of ionizing radiation health effects. At high exposures, it can cause tissue effects, also called deterministic effects due to the certainty of them happening, conventionally indicated by the unit gray and resulting in acute radiation syndrome. For low level

exposures there can be statistically elevated risks of radiation-induced cancer, called stochastic effects.

Fundamental to radiation protection is the avoidance or reduction of dose using the simple protective measures of time, distance and shielding. The duration of exposure should be limited to that necessary, the distance from the source of radiation should be maximized, and the source shielded wherever possible. To measure personal dose uptake in occupational or emergency exposure, for external radiation personal dosimeters are used, and for internal dose due to ingestion of radioactive contamination, bioassay techniques are applied. For radiation protection and dosimetry assessment the International Commission on Radiation Protection (ICRP) and International Commission on Radiation Units and Measurements (ICRU) publish recommendations and data which is used to calculate the biological effects on the human body of certain levels of radiation, and thereby advise acceptable dose uptake limits.

4.12.1. Precautions from Radiations

Some important precautions can be taken to avoid radiations as given below.

- Require adequate training to better understand the nature of radiation hazards.
- Reduce handling time of radioactive materials and equipment.
- Be mindful of your distance from sources of radiation. Increase distance as much as possible.
- Use proper shielding for the type of radiation.
- Isolate or contain harmful radioactive materials properly.
- Armor yourself with appropriate protective clothing and dosimeters.
- Conduct contamination surveys in the work area.
- Do not eat, drink, smoke, or apply cosmetics in an area where unsealed radioactive substances are handled.
- Observe proper radioactive waste disposal
- Conduct regular radiation safety self-inspections

4.13. ISOTOPIC AND NON-ISOTOPIC LABELING SYSTEMS

Labeling can be performing by two ways as given below.

4.13.1. Isotopic labeling systems

Traditionally, nucleic acids have been labeled with radioisotopes such as ^{32}P and ^{35}S which are detected by autoradiography. These *radiolabeled probes (hot probes)* are very sensitive but their handling is subject to strict safety precautions and the signal decays relatively quickly.

4.13.2. Non-Isotopic Probes (Cold Probes)

- Non-isotopic probes (cold probes) generate colorimetric or chemiluminescent signals. A widely used label is digoxigenin, a plant steroid isolated from digitalis.
- This can be conjugated to nucleotides and incorporated into DNA, RNA or oligonucleotide probes and then detected using an antibody.
- Another system uses *biotin*, a vitamin, and the bacterial protein streptavidin which binds to biotin. Biotin conjugated nucleotides are incorporated as a label and detected using streptavidin.
- The presence of a target nucleotide sequence in a DNA sample can be determined with a DNA probe. This procedure is called DNA hybridization and depends on the formation of stable base pairs between the probe and the target sequence.
- For a DNA hybridization assay, the target DNA is denatured and the single strands are irreversibly bound to a matrix (e.g. nitrocellulose or nylon), this process is often carried out at a high temperature.
- Then, the DNA probe which is labeled with either a radioisotope (hot probe) or another tagging system (cold probe) is incubated with the bound DNA sample.
- If the sequence of nucleotides in the DNA probe is complementary to a nucleotide sequence in the sample, then base pairing (i.e. hybridization) occurs.
- The hybridization can be detected by autoradiography (hot probe) or other visualization procedures (cold probe), depending on the nature of the probe label.
- If the nucleotide sequence of the probe does not base pair (bind) with a DNA sequence in the sample, then no hybridization occurs and the assay gives a negative results.

4.14. BENEFITS FROM TRANSGENIC

The following points highlight the eight main advantages of transgenic plant. The advantages are as under:

- Improvement in yield

- Improvement in insect and disease resistance
- Improvement in quality
- Herbicide resistance
- Resistance to abiotic stresses
- Industrial products
- Rapid and accurate technique
- No barrier for gene transfer

4.14.1. Transgenic Plants: Issues and Future Prospects

The development of transgenic plant illustrates two main categories of discussion: the scientific and ethical issues. Science is concerned with understanding the world in which we live and in particular the causal relationships that shape that world: for example, the association between genes as a molecular sequence and the characteristics, such as resistance disease that the genes express. Understanding such causal patterns is necessary; if we are to alter or change the characteristics of plants. Ethics in contrast are concerned with what we ought or ought not to do for example indicating that it would be wrong to carry out a certain genetic modification because to do so would threaten human health or harm the environment.

Although it may be scientifically possible to undertake a certain experiment or introduce a new type of crop for commercial planting, it does not follow that it would be ethically right to do so. Working out what it is right or permissible to do involves therefore, bringing together our scientific understanding with our ethical principles to decide what we should do given the capacities for genetic modification that have been developed. Practical reasoning involves weighing up or balancing the benefits of a technology like genetic modification with its potential harms or disadvantages. It is precluded that the transgenic technology will raise agricultural productivity, assist the development of safer, more nutritious foods with a longer shelf-life and contribute to the goal of increased food security for the poor in developing countries.

Most people lack the opportunity to gain an understanding about the science involved in the creation of transgenic crops and the differences between transgenic and non transgenic crops. They also lack a way of explaining their fears and concerns to those responsible for the development, Transgenic Plants: Issues and Future Prospects production and sale of such crops. We also acknowledge that the credibility of the government information on food safety is impaired in recent years. Thus, it could be more expedient for non- governmental entities, supermarkets and food manufacturers to take on some of the task of informing the public. The public's distrust of information from those with vested interest suggests that companies marketing GM crops carry little weight with

them. In fact, company's efforts to persuade people of the benefits of GM crops are probably counter-productive. This may also be true of attempts by food manufacturers that go far beyond the provision of simple and balanced information.

4.15. SUMMARY

A genetically modified organism, or GMO, is an organism that has had its DNA altered or modified in some way through genetic engineering. In most cases, GMOs have been altered with DNA from another organism, be it a bacterium, plant, virus or animal; these organisms are sometimes referred to as "transgenic" organisms. Genetics from a spider that helps the arachnid produce silk, for example, could be inserted into the DNA of an ordinary goat. It sounds far-fetched, but that is the exact process used to breed goats that produce silk proteins in their goat milk. Their milk is then harvested, and the silk protein is then isolated to make a lightweight, ultra strong silk material with a wide range of industrial and medical uses.

The co-existence of crops for human consumption alongside related varieties grown for industrial products, that would be harmful if consumed by people, is not a new phenomenon, nor one that is confined to GM plants. For example, farmers in Canada grow two varieties of (non-GM) rapeseed – high and low erucic acid producers. The erucic acid extracted from the high producing variety is used as an industrial lubricant and is toxic to humans if consumed, whilst the low producing rapeseed variety, called canola, is used to make cooking oil. Canadian farmers have developed systems to routinely keep the two apart during growth and processing.

There is an adverse effects on the environment through the large-scale growth of GM plants may indirectly affect human health. The following concerns have been expressed with regard to GM plants and the environment: That GM plants will sexually hybridize with non-GM plants through the transfer of pollen, GM plants may themselves become invasive weeds and the conditions required to grow GM plants will affect local wildlife populations.

4.16. TERMINAL QUESTIONS

Q.1. Write a short note on GMOs. What are the consequences for biodiversity?

Answer:-----

Q.2. Describe positive and negative aspects of GMOs.

Answer:-----

Q.3. Write a short note on recombinant DNA technology (RDT).

Answer:-----

Q.4. Explain identifications of transgenic animals.

Answer:-----

Q.5. Write a short note on radiation safety and its precautions.

Answer:-----

Q.6. Describe particle gun method.

Answer:-----

4.17. FURTHER READINGS

1. IPR, Biosafety and Bioethics: Deepa Goel, Shomini Parashar; Pearson, 2013
2. General Biochemistry: J.H.Weil., Wiley Eastern, Limited, 1990
3. An Introduction to Ethical, Safety and Intellectual Property Rights Issues in biotechnology: Padma Nambisan, Academic press 20107.
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5. Plant Biotechnology: Principles and Applications, Malik Zainul Abdin, Usha Kiran, Kamaluddin, Athar Ali, Springer, 2017.



॥ सरस्वती नः सुभगा मयस्करन् ॥

**Uttar Pradesh Rajarshi Tandon
Open University**

PGBCH-116

Biosafety and IPR

BLOCK

3

PATENT AND AGREEMENTS

UNIT-5

Patent and Amendments

UNIT-6

International Agreements

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BLOCK INTRODUCTION

This is the third block of biosafety and IPR, which cover Patents and amendments. The block third consists of following two units:

Unit-5 : This unit covers the Patents and amendments. The Protection of plant variety and farmers right act is discuss in this unit. The rules of Indian patent act, amendments, patent filing is briefly covered. Apart from that the implications of intellectual property rights on the commercialization of biotechnology products is also discussed

Unit-6 : Under this unit the International agreements of bio-safety and convention is covered. The international agreements associated with WTO are briefly discussed. The Intellectual properties, copyrights, trademarks, trade secret, patents, geographical indications, etc. is also discussed in briefly.

UNIT-5 PATENT AND AMENDMENTS

Structure

5.1. Introduction

Objectives

5.2. PPVFRA

5.2.1. History of PPVFRA

5.2.2. Objectives of the PPV

5.2.3. Rights under the Act

5.2.4. Implementation of the Act

5.3. Indian patent act and amendments

5.3.1. History

5.3.2. Current Position

5.4. Patent Filing Procedure in Indian

5.4.1. Patent life-cycle flow chart

5.4.2. Patent registration in India

5.5. Intellectual property rights (IPR) Biotechnology

5.5.1. Rights in plant varieties

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5.5.3. Patent Cooperation Treaty (PCT)

5.6. Regulated Trading in Wildlife Products

5.6.1. The evolution of CITES

5.6.2. The Implications of Intellectual Property Rights
for Agricultural Biotechnology in India

5.7. Legal Intellectual Property Rights Mechanisms in India:

5.7.1. The Role of the Patent in Agricultural
Biotechnology:

5.7.2. Patentable Subject Matter in Biotechnology in
India:

5.7.3. Patenting of Microorganisms and Cells

5.7.4. Patentability of Animals and Plants:

5.8. Summary

5.9. Terminal Question

5.10. Further readings

5.1. INTRODUCTION

In order to provide for the establishment of an effective system for the protection of plant varieties, the rights of farmers and plant breeders and to encourage the development of new varieties of plants it has been considered necessary to recognize and to protect the rights of the farmers in respect of their contributions made at any time in conserving, improving and making available plant genetic resources for the development of new plant varieties. The Govt. of India enacted “The Protection of Plant Varieties and Farmers' Rights (PPV&FR) Act, 2001” adopting sui generis system. Indian legislation is not only in conformity with International Union for the Protection of New Varieties of Plants (UPOV), 1978, but also have sufficient provisions to protect the interests of public sector breeding institutions and the farmers.

Objectives

- To discuss the role of patent and amendment in the biosafety
- To discuss about rights under the act and implementation of the act
- To discuss about Indian patent act and amendments
- To discuss the patent registration in India
- To discuss Intellectual property rights (IPR) in biotechnology.

5.2. PROTECTION OF PLANT VARIETY AND FARMERS RIGHT ACT (PPVFRA)

In order to provide for the establishment of an effective system for the protection of plant varieties, the rights of farmers and plant breeders and to encourage the development of new varieties of plants it has been considered necessary to recognize and to protect the rights of the farmers in respect of their contributions made at any time in conserving, improving and making available plant genetic resources for the development of new plant varieties. The Govt. of India enacted “The Protection of Plant Varieties and Farmers' Rights (PPV&FR) Act, 2001” adopting sui generis system. Indian legislation is not only in conformity with International Union for the Protection of New Varieties of Plants (UPOV), 1978, but

also have sufficient provisions to protect the interests of public sector breeding institutions and the farmers.

5.2.1. History of PPVFRA

The Protection of Plant Varieties and Farmers' Rights Act (PPVFRA), which introduced intellectual property protection in Indian agriculture, faced its biggest test when PepsiCo India initiated legal proceedings against potato farmers of Gujarat for “illegally” growing its potato variety registered under the PPVFRA.

The PPVFRA was enacted in 2001 after engaging debates were held in the country on how intellectual property rights should be introduced in Indian agriculture after the country joined the World Trade Organization in 1995 and agreed to implement the Agreement on **Trade-Related Aspects of Intellectual Property Rights (TRIPS)**.

The choice before India was to either enact a law that protected the interests of farming communities or to accept the framework of plant breeders' rights given by the International Union for Protection of New Plant Varieties (**UPOV Convention**). **The latter option was rejected** primarily because the current version of UPOV, which was adopted in 1991, **denies the farmers the freedom to reuse farm-saved seeds and to exchange them with their neighbours.**

Therefore, in the PPVFRA, India introduced a chapter on Farmers' Rights, which has three legs:

- 1. Farmers are recognised as plant breeders and they can register their varieties;**
- 2. Farmers engaged in the conservation of genetic resources of landraces and wild relatives of economic plants and their improvement through selection and preservation are recognized and rewarded;** and,
- 3. Protecting the traditional practices of the farmers of saving seeds** from one harvest and **using the saved seeds either for sowing for their next harvest or sharing** them with their farm neighbors.

5.2.2. Objectives of The PPV & FR Act, 2001

1. To establish an effective system for the protection of plant varieties, the rights of farmers and plant breeders and to encourage the development of new varieties of plants.
2. To recognize and protect the rights of farmers in respect of their contributions made at any time in conserving, improving and making available plant genetic resources for the development of new plant varieties.

3. To accelerate agricultural development in the country, protect plant breeders' rights; stimulate investment for research and development both in public & private sector for the development new of plant varieties.
4. Facilitate the growth of seed industry in the country which will ensure the availability of high quality seeds and planting material to the farmers.

5.2.3. Rights under the Act

1. **Breeders' Rights:** Breeders will have exclusive rights to produce, sell, market, distribute, import or export the protected variety. Breeder can appoint agent/ licensee and may exercise for civil remedy in case of infringement of rights.
2. **Researchers' Rights:** Researcher can use any of the registered variety under the Act for conducting experiment or research. This includes the use of a variety as an initial source of variety for the purpose of developing another variety but repeated use needs prior permission of the registered breeder.
3. **Farmers' Rights**
 - A farmer who has evolved or developed a new variety is entitled for registration and protection in like manner as a breeder of a variety;
 - Farmers variety can also be registered as an extant variety;
 - A farmer can save, use, sow, re-sow, exchange, share or sell his farm produce including seed of a variety protected under the PPV&FR Act, 2001 in the same manner as he was entitled before the coming into force of this Act provided farmer shall not be entitled to sell branded seed of a variety protected under the PPV&FR Act, 2001;
 - Farmers are eligible for recognition and rewards for the conservation of Plant Genetic Resources of land races and wild relatives of economic plants;
 - There is also a provision for compensation to the farmers for non-performance of variety under Section 39 (2) of the Act, 2001 and
 - Farmer shall not be liable to pay any fee in any proceeding before the Authority or Registrar or the Tribunal or the High Court under the Act.

5.2.4. Implementation of the Act

To implement the provisions of the Act the Department of Agriculture, Cooperation and Farmers Welfare, Ministry of Agriculture

and Farmers Welfare established the Protection of Plant Varieties and Farmers' Rights Authority on 11th November, 2005. The Chairperson is the Chief Executive of the Authority. Besides the Chairperson, the Authority has 15 members, as notified by the Government of India (GOI). Eight of them are ex-officio members representing various Departments/ Ministries, three from SAUs and the State Governments, one representative each for farmers, tribal organization, seed industry and women organization associated with agricultural activities are nominated by the Central Government. The Registrar General is the ex-officio Member Secretary of the Authority.

General Functions of the Authority

1. Registration of new plant varieties, essentially derived varieties (EDV), extant varieties;
2. Developing DUS (Distinctiveness, Uniformity and Stability) test guidelines for new plant species;
3. Developing characterization and documentation of varieties registered;
4. Compulsory cataloging facilities for all variety of plants;
5. Documentation, indexing and cataloguing of farmers' varieties;
6. Recognizing and rewarding farmers, community of farmers, particularly tribal and rural community engaged in conservation and improvement;
7. Preservation of plant genetic resources of economic plants and their wild relatives

5.3. INDIAN PATENT ACT AND AMENDMENTS

The word Patent originated from the Latin Word "**Patene**" which means '**to open**'. A **patent** is a set of exclusive rights granted by a state (national government) to an inventor or their assignee for a limited period of time in exchange for a public disclosure of an invention.

The Patents Act 1970, along with the Patents Rules 1972, came into force on 20th April 1972, replacing the Indian Patents and Designs Act 1911. The Patents Act was largely based on the recommendations of the Ayyangar Committee Report headed by Justice N. Rajagopala Ayyangar. One of the recommendations was the allowance of only process patents with regard to inventions relating to drugs, medicines, food and chemicals.

Later, India became signatory to many international arrangements with an objective of strengthening its patent law and coming in league with the modern world. One of the significant steps towards achieving this objective was becoming the member of the Trade Related Intellectual Property Rights (TRIPS) system.

Significantly, India also became signatory of the Paris Convention and the Patent Cooperation Treaty on 7th December 1998 and thereafter signed the Budapest Treaty on 17th December 2001.

5.3.1. History

Being a signatory to TRIPS, India was under a contractual obligation to amend its Patents Act to comply with its provisions. India had to meet the first set of requirements on 1st January 1995 to give a pipeline protection till the country starts granting product patent.

History of Indian Patent System	
1856	The act vi of 1856 on protection of inventions based on the British patent law of 1852. Certain exclusive privileges granted to inventors of new manufacturers for a period of 14 years.
1859	The act modified as act xv; patent monopolies called exclusive privileges (making. Selling and using inventions in India and authorizing others to do so for 14 years from date of filing specification).
1872	The patents & designs protection act.
1883	The protection of inventions act.
1888	Consolidated as the inventions & designs act.
1911	The Indian patents & designs act.
1972	The patents act (act 39 of 1970) came into force on 20 th April, 1972.
1999	On march 26, 1999 patents (amendment) act, (1999) came into force from 01-01-1995.

2002	The patents (amendment) act 2002 came into force from 20 th may 2003
2005	The patents (amendment) act 2005 effective from 1 st January 2005

On 26th March, 1999, Patents (Amendment) Act, 1999 came into force retrospective effect from 1st January, 1995. The main amendments are as follows:

- I. **Section 5(2)** was introduced which provides for filing of applications for patent in the field of drugs, medicines and agro-chemicals. These applications were kept pending in the **mailbox or black box**. This mailbox was to be opened on 1st January 2005.
- II. Provision of **Exclusive Marketing Rights (EMR)** was brought in by way of Chapter IV A. Thus, pipeline protection was provided for pharmaceutical and agro-chemical manufacturers whose applications for product were lying in black box.
- III. **Section 39** was omitted from the Act, thereby enabling the Indian residents to file the applications for in an outside India simultaneously.
- IV. **Chapter II (A)** was inserted in the Indian Patent Rules dealing with International Applications under PCT.

The second phase of amendment was brought in by the Patents (Amendment) Act, 2002 which came into force on 20th May 2003. The main features of the amendments included:

- i. **Term of patent** was extended from 14 to 20 years, wherein the date of patent was the date of filing of complete specification. Also the difference in term of a drug/food patent and other patent was removed.
- ii. The definition of "invention" was made in conformity with the provisions of TRIPS Agreement by introducing the **concept of inventive step**, thereby enlarging the scope of invention.
- iii. **Deferred examination system** was introduced.
- iv. Introduction of the provision of publication of application after 18 months from the date of filing thereby bringing India at par with the rest of the world.
- v. **Microorganisms** became patentable, whereas inventions relating to traditional knowledge were included in the list of "*what are not inventions*".

- vi. The concept of unity of invention in accordance with EPC and PCT.
- vii. **Section 39 was reintroduced** thereby prohibiting the Indian residents to apply abroad without prior permission or first filing in India.
- viii. Provisions of Appellate Board were brought in by inserting section 116. All appeals to the decision of the Controller would be appealable before the Appellate Board. The Head Quarter of the Appellate Board is to be in Chennai.
- ix. Section 117 provided for Bolar provision for the benefit of agrochemical and pharmaceutical industry.

The third and final amendment to the Patents Act, 1970 came by way of Patents (Amendment) Ordinance, 2004, which was later replaced by The Patent (Amendment) Act, 2005, and Patents (Amendment) Rules, 2006 with retrospective effect from 1st January, 2005. With the third amendment India met with the international obligations under the TRIPS. Significant achievements of this amendment were:

- i. Deletion of section 5, opening of mailbox and grant of product patents. Thus this amendment led to the dawn of the "product patent regime" in India.
- ii. Abolition of Exclusive Marketing Rights (EMR).

5.3.2. Current Position

The present Indian position in respect of patent law is governed by the provisions of the Patents Act, 1970 as amended by the Patents (Amendment) Act, 2005 (hereinafter referred to as the Act) and Patents Acts Rules, 2006 (hereinafter referred to as the Rules)

The Head Patent Office is located at Kolkata and its branch offices are located at Delhi, Mumbai and Chennai. Patent system in India is administered by the Controller General of Patents, Designs, Trademarks and Geographical Indications. Each office has its own territorial jurisdiction for receiving patent applications and is empowered to deal with all sections of Patent Act.

The jurisdiction for filing the patent application depends upon

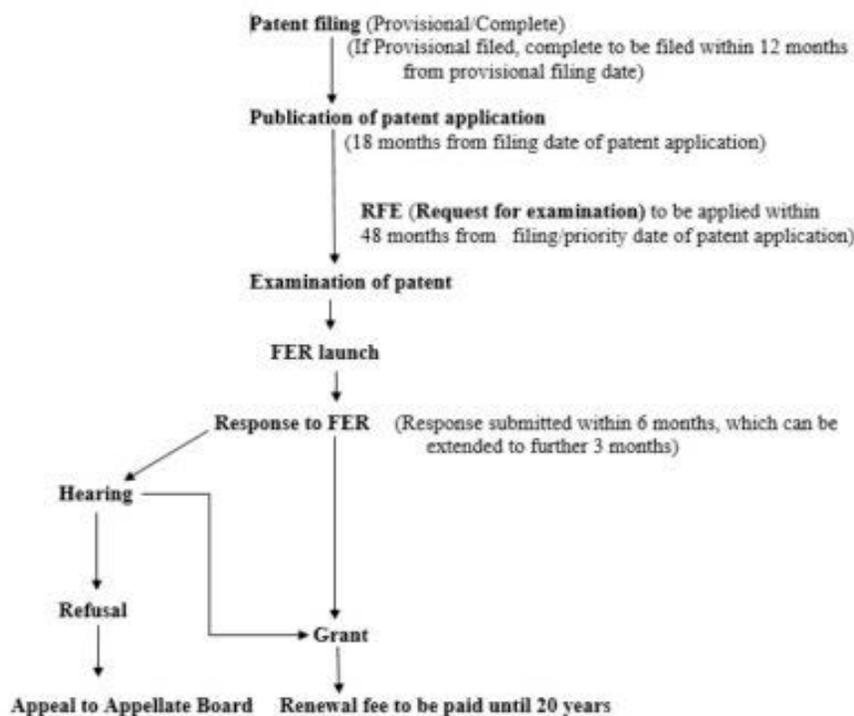
- i. Indian applicant(s): determined according to place of residence, place of business of the applicant or where the invention actually originated.
- ii. Foreign applicant(s): determined by the address for service in India.

5.4. PATENT FILING PROCEDURE IN INDIA

A patent is a right granted to an individual or enterprise by the government that excludes others from making, using, selling or importing the patented product or process without prior approval.

Patent is one of the pillars of Intellectual Property (IP). A patent gives its owner the right to exclude others from making, using, selling, and importing an invention for a limited period of time, usually twenty years. A Patent provides exclusive rights to the Patent Owner and restricts others from using the patented technology. These rights also exclude others from selling, making, using and importing patented technology for a time duration, which is twenty years in India. This concept of exclusivity provides a cutting edge advantage to the Patentee to launch the monopolistic products in the market and maximize their revenue. This can also be verified from the fact that almost every known company in today's scenario is going towards having Patent Protection.

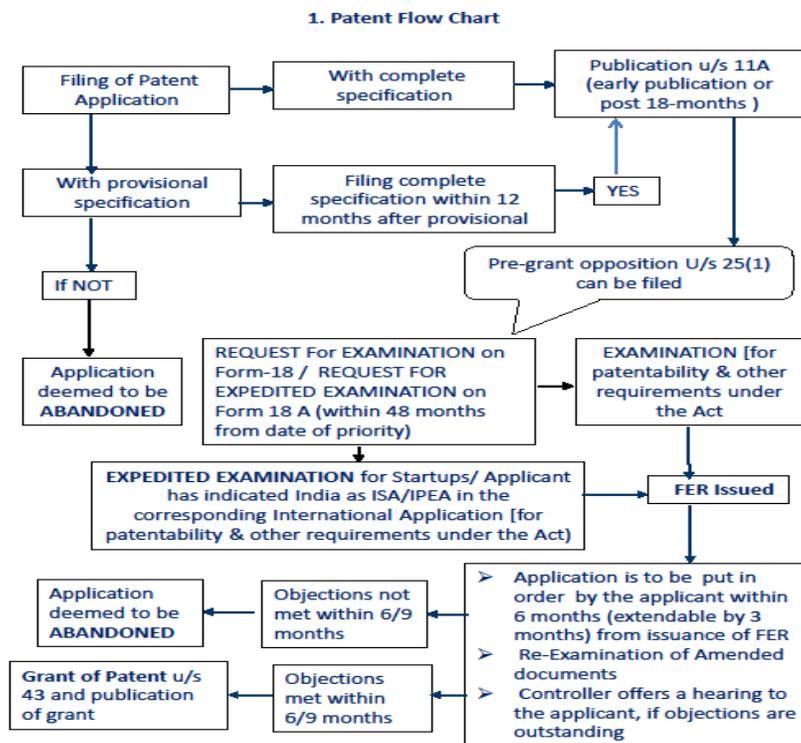
Now the question arise is “how to get these Patents in India”? Indian Patent System has following stages during the lifecycle of a Patent



5.4.1. Patent Life-Cycle Flow Chart

The first stage in life cycle is patent filing after drafting a provisional/complete specification, which is followed by publication of patent application. The Publication of Patent Application takes place in the Patent Journal issued by Indian patent office. The publication of a patent application takes around 18 months from the Priority date/ date of Filing (whichever is earlier). The publication is followed by next stage i.e.

“Examination of patent application” by Indian Patent Office: A Request for Examination (RFE) has to be submitted to Patent Office after Publication of Patent and within 48 months of Priority Date / Date of Filing (whichever is earlier). The publication stage is next followed by examination stage of patent application. The examination reports i.e. First examination reports (FER’s) are being issued by Indian patent office. The Patent Office provides an Examination Report after checking the patent application on grounds of the Patentability Criteria and provides the First Examination Report (FER). Response for the objections are raised in FER has to be submitted within 6 month of date of Issuance of FER, which can be further extended to three months. After submission of response to FER by the applicant, the Controller of Patent considers all the objections and check whether all the objections have been compiled or not. The controller then either issue a hearing notice and appoint a hearing or may grant patent application and publish the patent application in official journal accordingly. Once the patent is granted, Annual Fees are required to be paid on and after third year of grant of the Patent. Annuities are required to be paid each year throughout the life of the patent i.e. 20 years from the Priority Date / Date of Filing (whichever is earlier).



5.4.2. Patent Registration in India

Procedure of Patent Registration in India starts with performing patent searches before patent application filing. After determining the novelty of the invention, the patent application can be filed with the Indian

Patent Office in any of the branches i.e Delhi, Mumbai, Chennai or Kolkata. The patent application can be filed as the provisional application or as the non-provisional application with the Indian Patent Office. It would be easier to explain the procedure of **patent registration in India** in steps.

Step by Step Procedure for Patent registration in India

STEP 1: Patent Searches

Step by Step Procedure for Patent registration in India **Procedure Patent Registration in India** searches is conducted and worldwide to know the novelty of an invention. Generally, it is considered safe to do patent searches before patent application filing. If an invention is found in prior arts or closes to prior arts then the novelty of that invention can be challenged by the Indian Patent Office. Therefore, it is important to perform prior art searches in order to save the money and time of an applicant.

STEP 2: Patent Drafting

Step by Step Procedure for Patent registration in India After conducting thorough searches worldwide, the invention is written in a techno-legal language known as the specification which can be with or without claims. Without claims is the provisional specification and with claims is the complete specification. The specification specifies the field of invention, detailed description of the invention with working examples and the best method to perform an invention so that a person skilled in the art can perform the invention. The legal part comes with the claims of the invention which define the legal protection sought by an inventor.

STEP 3: Patent Application Filing

Step by Step Procedure for Patent registration in India .A patent application filing is the first step towards obtaining a patent.

Procedure Patent Registration in India application filed as a provisional application is generally filed to claim priority date over other applications. A patent application consists of series of forms prepared according to the Indian Patent Act, 1970. The drafted provisional or complete specification is filed in Form-2 of the Indian Patent Act, 1970. If a provisional patent application is filed then within 12 months of its filing complete specification has to be filed. There are 6 different kinds of filing filed in the Indian Patent Office. These are:

1. Ordinary application
2. PCT National phase application
3. PCT International application
4. Convention application
5. Divisional application

6. Patent of addition application

STEP 4: Publication of Patent Application

Once the **Procedure Patent Registration in India** has been filed, then after the expiry of 18 months from the date of filing or date of priority whichever is earlier, the application is published in an official journal and is open to the public. This is a chance given to the public to raise an objection if any.

STEP 5: Examination of Patent Application/Patent Prosecution

The patent application is examined only when a request for examination has been filed. The request for examination has to be filed within 48 months of the application filing date or date of the priority. The patent examiner examines a patent application and issues an examination report. The examination report contains a series of objections raised by an examiner. The response to an examination report has to be filed within 12 months of the issuance of the examination report. If needed examiner call applicant or his agent for hearing. This phase is called as patent prosecution.

STEP 6: Grant of a Patent

After all objections to the examination report have been compiled and the examiner is satisfied with the reply of an applicant, the application is put in order for grant. On the other hand, if the examiner is not satisfied with the reply and arguments of an applicant, then he/she can reject the application.

Implications of intellectual Property Rights on the Commercialization of Biotechnology Products:

5.5. INTELLECTUAL PROPERTY RIGHTS FOR BIOTECHNOLOGY

Intellectual Property is the term used to describe the branch of law which protects the application of thoughts, ideas and information which are of commercial value. It thus covers the law relating to patents, copyrights, trademarks, trade secrets and other similar rights (Cornish, 1989).

The development of the genetic resources of biodiversity is known as Biotechnology. Biotechnology includes any technique that uses living organisms or parts of organisms to make or modify products, to improve plants or animals, or to develop microorganisms for specific uses (Congress of the United States, Office of Technology Assessment, 1990). Mankind has used forms of Biotechnology since the dawn of civilization. However, it has been the recent development of new biological techniques (e.g., recombinant DNA, cell fusion, and monoclonal antibody

technology) which has raised fundamental social and moral questions and created problems in intellectual property rights.

Intellectual property protection for Biotechnology is currently in a state of flux. Whilst it used to be the case that living organisms were largely excluded from protection, attitudes are now changing and increasingly Biotechnology is receiving some form of protection. These changes have largely taken place in the USA and other industrialized countries, but as other countries wish to compete in the new biotechnological markets, they are likely to change their national laws in order to protect and encourage investment in biotechnology.

There is at the moment no clear international consensus on how Biotechnology should be treated. Although bodies such as the World Intellectual Property Organization (WIPO, the United Nations permanent body primarily responsible for international cooperation in intellectual property), and the Organization for Economic Cooperation and Development (OECD) have conducted separate studies and produced various reports, these have only sought to make governments more aware of the potential problems and to offer some suggested solutions. In view of the highly controversial nature of providing intellectual property protection for Biotechnology, it is likely that in the short term developments will be at a national and regional level.

Intellectual property protection currently available

There are currently two main systems of protection for Biotechnology: **rights in plant varieties**, and **patents**. Both systems provide exclusive, time-limited rights of exploitation and are described in more detail below.

5.5.1. Rights in Plant Varieties

Prior to the mid-1960s only a few countries (e.g., Germany, USA) gave any intellectual property protection to plant varieties. Because of pressure from their plant breeding industries, 10 western European countries entered into a diplomatic process in the early-1960s which eventually culminated in the formation of an International Union for the Protection of New Varieties of plants (UPOV) and the signing of a Convention (the UPOV Convention 1961). Since that time a number of other countries have become parties to the UPOV Convention (the full list of 19 parties appears in Table 31.3). Amendments were made to the UPOV Convention in 1978, principally to facilitate the entry of the USA.

The UPOV Convention requires that each member country must adopt national legislation to give at least 24 genera or species protection, in accordance with the provisions of the convention, within eight years of signing. A plant variety is protectable ("a protectable variety") under the UPOV system if it is distinct, uniform, stable (DUS) and satisfies a novelty requirement. Novelty and distinctiveness equate broadly to novelty under patent law, but are more leniently applied in comparison to

the patent rule. Satisfaction of the DUS criteria is conducted by the national authority responsible, usually by growing the variety over at least two seasons. There is also an important requirement that the variety be maintained throughout the duration of protection. A country may apply the system to all genera or species, but there is no obligation to do so and thus the system has been extended only gradually. In addition, the UPOV Convention allows national legislation to discriminate against foreigners (including nationals of a UPOV Convention country) under the principle of reciprocity. Thus amongst the UPOV members there is still some disparity in protection.

Duration of protection depends on national legislation and on the plant species to which the variety belongs, but is generally for 20-30 years. Grant of plant variety rights confers certain exclusive rights on the holder, including the exclusive right to sell the reproductive material (e.g. seed, cuttings, whole plants) of the protected variety. However the rights do not extend to consumption material (e.g. fruit, wheat seed grown for milling flour). Essentially the exclusive rights define what others may or may not do in relation to the protected varieties.

Plant breeders were for some time dissatisfied with the protection provided by the UPOV system. This eventually resulted in a major diplomatic conference in March 1991, at which the UPOV Convention was substantially revised. The new 1991 text will provide far greater protection than is afforded at present, most notably by requiring that all member countries apply the convention to all genera and species, by extending the exclusive rights to include harvested material (e.g., fruit, wheat grown for milling into flour) and, most controversially, by allowing enforcement against farm-saved seed (where a farmer produces further seed of the protected variety from the previous year's crop). However, until the national governments ratify the new convention the system will continue to be based on the 1978 text. There will be considerable national opposition to the strengthening of plant variety rights and thus these changes may take years before they are implemented and may even be superseded by greater availability of patent protection in the meantime.

5.5.2. Patents for Biotechnology

A patent is a grant of exclusive rights for a limited time in respect of a new and useful invention. The exact requirements for grant of a patent, the scope of protection it provides and its duration differs depending on national legislation. However, generally the invention must be of patentable subject matter, novel (new), non-obvious (inventive), of industrial application and sufficiently disclosed. A patent will provide a wide range of legal rights, including the right to possess, use, transfer by sale or gift, and to exclude others from similar rights. Duration will be for around 20 years (although for only 17 years in the USA). These rights are generally restricted to the territorial jurisdiction of the country granting the patent and thus an inventor wishing to protect his/her invention in a

number of countries will need to seek separate patents in each of those countries. Whilst the majority of countries provide some form of patent protection, only a few provide patent protection for biotechnology (these include: Australia, Bulgaria, Canada, Czechoslovakia, Hungary, Romania, Japan, the Soviet Union and the parties to the European Patent Convention).

It has largely been the USA which has broken new ground in providing the possibility of patent protection for "anything under the sun that is made by man". Patents have been granted for plants since 1930 in the USA, under The Plant Patent Act. However, prior to 1980, the US Patent Office would not grant utility patents (separate from The Plant Patent Act) living matter because it deemed products of nature not to be within the terms of the utility patent statute. That was until the landmark decision of the US Supreme Court in *Diamond v Chakrabarty* (from which the above quote is taken), which held that a particular genetically engineered bacterium was statutory subject matter for a utility patent. This decision has been the basis upon which patents have been granted for higher life forms. Subsequently it has been held that a utility patent may be granted for plants and a patent has been granted for an animal. Polyploid oysters, not naturally occurring, were held to be patentable subject matter and US Patent No.3,736,866, was issued in respect of a "transgenic nonhuman mammal all of whose germ cells and somatic cells contain a recombinant activated oncogene sequence introduced into the said mammal, or an ancestor of said animal, at an embryonic stage" - popularly known as the 'onco-mouse'.

Elsewhere, the treatment of applications for patents for living matter is far from certain. Whilst patents are granted in many countries for plants and microorganisms, it has been the issue of patents for animals which has been most controversial. Whilst it is not possible to summarize succinctly the position in the rest of the world, it is possible to describe the present approach of those countries which are party to the European Patent Convention (the EPC, see Table 31.3).

There are three international intellectual property treaties which are of particular importance for the protection of Biotechnology

- 1. Paris Convention for the Protection of Industrial Property (the Paris Convention) ;**

The Paris Convention was originally signed in 1883 by just 11 countries, but now the majority of countries who have any form of intellectual property law are parties to it. The keystone to the convention is the principle of national treatment: an applicant from one convention country shall have the same rights in a second convention country as a national of that second country.

The most important practical result of the convention is that it is possible to claim priority from an application made in a convention country for all subsequent convention countries within 12 months of the original filing.

2. Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (the Deposit Treaty)

Deposit Treaty, as the full title suggests, is concerned with the deposit of examples of microorganisms for the purposes of patent applications. Applications for patents for biotechnology often face considerable difficulties in describing the nature of the invention sufficiently. The Deposit Treaty is a vehicle for solving these problems, primarily through the setting up of a series of International Depository Authorities (IDA) and through the recognition by all member countries of a deposit in a single IDA.

3. Patent Cooperation Treaty (PCT)

The PCT simplifies the process of filing patent applications simultaneously in a number of countries. Under the PCT a single application may be filed in one of the official receiving offices, designating any number of PCT member countries, which can eventually result in a national patent being granted in each of the designated states (and/or a Europatent). A prior-art search is performed by the receiving office and a report sent to the applicant. The application and report are published and the application will then move on either to an international preliminary examination followed by national examination, or alternatively straight to the national examination stage. Unfortunately, the eventual outcome is not a 'world patent' and there is no harmonization patent law under the PCT apart from the procedural aspects.

5.6. REGULATED TRADING IN WILDLIFE PRODUCTS

Regulated trading in wildlife products has the capacity of returning benefits to the users of natural habitats. It could do this if the trade were regulated in such a way as to support prices, much as is done at present with respect to agricultural commodities, where price supports provide incentives for maintaining land in its current state, as opposed to converting it to other purposes.

At present, there is no regulated trading mechanism of exactly this nature. There are, however, a number of existing international agreements which do seek to regulate trade in wildlife products. Early examples are the Western Hemisphere Convention and the 1950 Paris International Convention for Protection of Birds. These simply outlined in broad terms an obligation to control trade in wildlife products but created little structure within which these controls could be implemented. Both conventions consequently became 'sleeping treaties'. Undoubtedly the most important and effective convention which places some control on the economic exploitation of wildlife products and thereby protects biological

diversity is the **Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)**.

5.6.1. The Evolution of Cites

CITES is the most widely accepted of international treaties on the conservation of natural resources. The number of Parties has been steadily increasing from the initial signing of the convention in 1973 to a total of 113 in 1992.

The convention attempts to prevent commercial trade in species of wildlife which are in danger of extinction and to control the trade in species which might become so if their trade was allowed to continue unchecked. It does this by means of two lists of species: Appendix I contain those species banned from international commercial trade and Appendix II, those for which trade may take place provided that export permits have been issued. Importing countries are obliged to ensure that all imports of Appendix II specimens are accompanied by correct export permits.

The convention covers not only live animals and plants but also products and derivatives of the species listed. These range from whole skins and manufactured leather products, through ivory carvings, tortoiseshell jewelry, meat, seeds, and feathers to medicinal products extracted from plants such as ginseng. This causes problems for the implementation of the Convention because it is necessary for enforcement of officers to determine not only what species the product is derived from but also whether the species is included in the Appendices. In order to minimize the problems of identification, where numerous species are very

5.6.2. The Implications of Intellectual Property Rights for Agricultural Biotechnology in India

IPRs are a set of laws that confers exclusive rights on inventors or products of inventors for a given period of time (Blakeney, 2011). The role of IPRs became prominent in the protection of plant varieties in the second half of the 20th century (Wright et al., 2007). The practice of IPRs to plant protection first took place in the USA when the vegetative propagated plant was patented in 1930. Prior to this event, traditional farming was based on free exchange, saving, collecting and replanting of seeds among farmers. However, the initiation of IPRs, particularly for agricultural research tools and databases through various patenting systems, has led to the expression of concerns among different communities such as farmers, academia, scientists, industries and Governmental agencies especially in developing countries (Adenle et al., 2012).

Forms of Intellectual Property Rights Used in Agriculture and Biotechnology

With the significant scientific upgrading of agricultural biotechnology, enhancement of food production is expected to improve the food security position of India (Science and Technology Policy, 2001). This scientific upgradation also enhances the productivity of land by reducing the pressure to extend the hectarage under cultivation, however anxiety has been increased by the risks involved (Sharma, 2001; Shiva, 2001). The formulation of a clear policy on the protection of biotechnological innovation has been hampered by the disparity of various interests. The formulation of a clear policy on the protection of biotechnological innovation has been hampered by the disparity of various interests. By accomplishing the ‘new norms of intellectual property rights’ the Government of India has sanctioned the following policy objectives:

- To assure the basic needs and food security of the people on a sustainable basis;
- To encourage a forward and enhancing livelihood by the elimination of hunger and malnutrition; and
- To create an IPR regime promptly having a strong, supportive and exhaustive policy environment, which boosts the incentives for the generation and protection of intellectual property by all category of inventors (Science and Technology Policy, 2003).

Legal mechanisms consist of patents, trademarks, trade secrecy rights, plant variety protection and plant breeders’ rights, among others, while biological mechanisms are composed of genetic use restriction technologies (GURTs) and hybridization. These legal and biological mechanisms are summarized in Table given below-

Table 1. Forms of IPRs used in agriculture (Fuglie et al., 1996; Fernandez-Cornejo, 2004).

Form of IPR	Example	Focus crops/products	Year	Country
Technology (hybrids) ^a	Hybrids	Sexually propagated plants	1920	USA
Plant patents	US Plant Patent Act	Asexually propagated plants	1930	USA
Plant variety protection	Plant Variety Protection Act	Sexually propagated plants ^b	1970	USA
Utility	US Patent Act	Microorganisms	1980	USA

patents		Plants	1985	USA
		Animals	1987	USA
Trade secret law	US Uniform Trade Secrets Act	Parental lines of hybrids	1994	USA
Technology	Genetic Use Restriction Technology (GURT)	Genetic modification technology/crops	1998	USA

- a) Hybrids of maize, sorghum, and wheat were developed in 1920, 1952 and 1968, respectively.
- b) Hybrids became allowable for protection in the USA in 1985.

5.7. LEGAL INTELLECTUAL PROPERTY RIGHTS MECHANISMS IN INDIA

The Indian Patent Act, 1970 was revised to grant patents for product, drugs, agro-chemicals and microorganisms over an ephemeral period. A product patent regime has been recognized in India since 1 January 2005. The new patent law increased the protection period for inventions from 14 to 20 years. Sui-generis legislation in the form of the Protection of Plant Varieties and Farmers Rights (PPVFR) Act in 2001 has been passed by the Parliament to confer protection of IPRs in respect of new plant varieties. These developments have created permissible authorized situations for international partnerships in biotechnology R&D. By determining the foreign direct investment (FDI) reserves in biotechnology, the Government of India has sent suitable signals to international investors. Further, these modifications have been in conformity with the WTO-TRIPs, which sealed superior creditability to these changes. Meanwhile, the government has also brought in regulations for agricultural biotechnology. Apart from the bio-safety policies and their regulations that shape part of the Environment (Protection) Act 1986, the Indian Parliament endorsed the National Biodiversity Act in 2002 to bestow regulatory controls over admittance to biological resources in India.

5.7.1. The Role of the Patent in Agricultural Biotechnology

The earlier accessible IPRs applicable to agricultural biotechnology were complex (Safrin, 2002). The utilization of IPRs is the

key feature influencing the success of any technological invention evolved in the market or to be made, thereby propping up the competitiveness of the industry of the country (Usha and Annadurai, 2010). The coming phase of technologies specifically in the biotechnology sector related to IPR is emerging with their own complications (Archana, 2013). The competent management of IPRs is thus vital in giving the right inducements for long-lasting technological innovations. IPRs are thus valuable for new business opportunities and for value in the knowledge-based industry. It is high time that India swiftly adapts to the continuously developing technological environment of the world (Commission on Intellectual Property Rights, 2002). Biotechnology has played a significant role by showing massive commercial significance to turn out a whole new industry and patent protection. Patents are elite rights granted to inventions that satisfy the decisive factors of patentability in the form of novelty, non-obviousness and potential for industrial utility. However, patent law and practice have met serious difficulties in keeping up with the rapid scientific progress in this field and issues such as innovative steps, sufficiency of disclosure and permissible breadth of claims have proved troublesome. There has been much litigation where courts have found it difficult to determine what the general knowledge of a skilled person was at the time invention was made. A process to explore and clone a specific gene of a suitable target organism/ plant was a breakthrough at the time when it was first achieved, and not many years later it is now merely a routine procedure. Many special interest groups also create the problem of disagreement against anything involved with genetic engineering and, in particular, against the continuation of patents in this arena (Arnold and Eve, 2002). Article 27.3(b) of TRIPs covers the patenting of living processes and life-forms. This article is designed to allow the broadest categories of patents, including genetic engineering and other new biotechnologies. The following grounds of this scientific briefing give details why such patents should be banned and revoked.

1. All engross biological processes which are not under direct control of the scientist. They cannot be considered as inventions, but expropriations from life.
2. The hit or miss technologies do not meet the criteria as 'inventions', and are intrinsically hazardous to health and biodiversity.
3. There is no scientific foundation to sustain the patenting of genes, genomes, cells and microorganisms.
4. Many patents are unethical; they contravene basic human rights, destroy livelihoods, create unnecessary suffering in animals or are otherwise contrary to public morality and order.
5. Many patented 'inventions' have been utilized by local communities for millennia and therefore involve acts of plagiarism of indigenous knowledge and bio-piracy of plants/animals bred (Cooper, 1985).

6. Only the procedure itself is patentable not any substance that is made or produced by a chemical process which involves several biotechnological, biochemical and microbiological methods/ techniques

5.7.2. Patentable Subject Matter in Biotechnology in India

Patent protection is accessible for nearly all biotechnological innovations and thus acts as an incentive for further growth and technical innovations. By tolerating the conventional approach, the new principle of patent law states that natural life is the creation of God and could not be patented, but human intellect creating non-natural life by involving the application of human intelligence to natural things could be patentable. The underlying principle behind patent protection for biotechnology inventions is applicable to the fact that:

- Patents give the leeway to the inventor to recover the development expenses of a new biotech product; and
- Patents have need of the revelation of the new technology for the profit of society. Putting the latest technology into the public domain motivates further innovation and expansion by competing companies, much like scientific publications spawn new-fangled discovery efforts and new lines of query. Thus patents are a very affluent source of technical information. As with patents, biotechnology patents also include:
 - An explanation of the invention itself with precise particulars and the advantages that this invention fetches in contrast with the identified state of the art, and examples
 - A set of claims, which defines the issue for which protection is required. In biotechnology, claims are mainly concerned with:
 - Product claims;
 - Utility claims; and
 - Method of production claims.

5.7.3. Patenting of Microorganisms and Cells

Patenting of biotechnological practices is not new in the USA; a classical example of this is the patent awarded to Louis Pasteur for a procedure of fermenting beer. Acetic acid fermentation was patented in the early 1800s and consequently in 1895 therapeutic patents in biotechnology were given. The progress of recombinant DNA technology (rDNA), i.e. the proscribed joining of DNA from distinct organisms, has intensely increased the understanding of the genetic and molecular beginnings of life. The lawsuit judgment of the US Supreme Court in 1980 in *Diamond v. Chakrabarty*¹ unlocked the gates for discoveries in the field of biotechnology, predominantly in microorganisms. Ananda Chakrabarty evolved a naturally occurring bacterium into a modified microorganism that has the capability of catabolizing crude oil. The Patent Commissioner

in the USA maintained that the topic of the invention was a living organism and was for this reason not patentable, but the US Supreme Court judge affirmed that anything beneath the sun is patentable and determined in favour of the patentee. This landmark verdict paved the way for the grant of numerous biotechnology-related patents. Chakrabarty asserted that the bacteria were rejected on two grounds:

1. Microorganisms are ‘products of nature’; and
2. As living things, microorganisms are not patentable.

The Chakrabarty pronouncement provided a great economic motivation to the patenting of cells and microorganisms, which in turn gave stimulus to the development of industrial biotechnology in the 1980s (Tripathi, 2002).

5.7.4. Patentability of Animals and Plants

The majority of the international agreements concentrate on various aspects of agricultural IPRs that are managed by distinct sets of guidelines, rules and policies (Adenle et al., 2012). For example, the International Union for the Protection of New varieties of Plants (UPOV) put their attention on protecting the right of seed producers (e.g. commercial plant breeders). The Convention on Biological Diversity (CBD) concentrates on protecting the rights of growers using landraces. The Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) of the World Trade Organization (WTO) works exclusively on intensification of the rights of inventors (Moschini, 2012).

The Indian Patents (Amendment) Act, 2002, has a section that furnishes that animals and plants and any part of a plant or animal, not including microorganisms but including seeds, are not patentable. Similarly, species, varieties and essentially biological processes used for propagation or production of plants and animals are unpatentable. Last, although the act does not permit patents for a procedure of horticulture, as noted above, the act does clearly specify that any method linking to the treatment of plants is patentable. Thus, the act permits an invention to be patented that is purely a procedure of making plants free of disease, as is a method for enhancing the plant’s value or increasing the value of the plant’s products. In India a system called the sui generis system was evolved for the protection of plant varieties, incorporating the rights of farmers, breeders and village communities. Sui generis is a system of rights designed to act as an exclusive alternative to standard patent protection. In India, the PPVFR Act was enacted in 2001 for IPR protection of new plant varieties, and formed auspicious legal conditions for international partnerships in biotechnology R&D (Dewan, 2011). Some people sense that patenting living things modifies the relationship between humanity and the rest of nature. Animals and plants owned by the farmers who produce them and use them as agricultural commodities, whether of patented or unpatented organisms, are bound to respect animal

welfare legislation (Archana, 2013). A suitable internationally accepted legal system with respect to utilizing livestock biodiversity and patenting of novel genes may lead to economic benefit sharing. Synchronization of IP regimes paves the way for the assessment of technologies needed for biotechnological R&D through uncomplicated licensing and/or patent exemptions, particularly for public benefit-oriented research, and also for creating private investments, subsequently encouraging private–public participation (Ramesha, 2011).

Genetically modified organisms together with agriculturally important animals and plants are subject to the Cartagena Protocol on Biosafety, which was taken on in 2000 by parties to the Convention on Biodiversity, and to other domestic regulations in developed as well as in developing countries. In developing countries the authoritarian structure is characteristically less established, and the regulations in force might themselves be viewed, in particular cases, as institutional experiments developing towards feasible implementation (Wright and Pardey, 2006). The exploitation of IPRs in crop research is swiftly evolving, with an arising number of intergovernmental organizations and countries becoming members of and thereby passing the framework furnished by UPOV (Jefferson et al., 2014). The objective of integrating the protection of ancestral farming methods with a desire to encourage agricultural innovation could be more willingly achieved if the provisions of UPOV were joined with other international treaty frameworks, such as that provided by the CBD (Ganguli, 2000). The Indian Patent Law Sections 3i and 3j states that all animals and surgical processes are not patentable; hence, animal models are not patentable in India. It would unlock novel vistas in the research field if the appropriate amendments were made, then animal models could also be patentable in India (Bagle et al., 2012).

5.8. SUMMARY

The Patents Act 1970, along with the Patents Rules 1972, came into force on 20th April 1972, replacing the Indian Patents and Designs Act 1911. The Patents Act was largely based on the recommendations of the Ayyangar Committee Report headed by Justice N. Rajagopala Ayyangar. One of the recommendations was the allowance of only process patents with regard to inventions relating to drugs, medicines, food and chemicals. Later, India became signatory to many international arrangements with an objective of strengthening its patent law and coming in league with the modern world. One of the significant steps towards achieving this objective was becoming the member of the Trade Related Intellectual Property Rights (TRIPS) system. Significantly, India also became signatory of the Paris Convention and the Patent Cooperation Treaty on 7th December 1998 and thereafter signed the Budapest Treaty on 17th December 2001. Being a signatory to TRIPS, India was under a contractual obligation to amend its Patents Act to comply with its provisions. India had to meet the first set of requirements on 1st January 1995 to give a pipeline protection till the country starts granting product patent. On 26th March, 1999, Patents (Amendment) Act, 1999 came into

force retrospective effect from 1st January, 1995. The present Indian position in respect of patent law is governed by the provisions of the Patents Act, 1970 as amended by the Patents (Amendment) Act, 2005 and Patents Acts Rules, 2006. The Head Patent Office is located at Kolkata and its branch offices are located at Delhi, Mumbai and Chennai. Patent system in India is administered by the Controller General of Patents, Designs, Trademarks and Geographical Indications. Each office has its own territorial jurisdiction for receiving patent applications and is empowered to deal with all sections of Patent Act.

5.9. TERMINAL QUESTION

Q.7. Explain History of Protection of plant variety and farmers right.

Answer:-----

Q.8. What are rights under the act and implementation of the act?

Answer:-----

Q.9. Write short note on the following: (i) patent registration in India (ii) Intellectual property right (iii) patent cooperation treaty (iv) Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Answer:-----

Q. 4 What are the rights in plant varieties?

Answer:-----

Q. 5. Describe the paris Convention for the Protection of Industrial Property.

Answer:-----

Q.6 Describe the Role of the Patent in Agricultural Biotechnology.

Answer:-----

5.10. FURTHER READINGS

1. Principles of Biochemistry: Lehninger, Nelson and Cox. Student Edition, CBS 1439 Publishers and Distributors, Delhi.
2. IPR, Biosafety and Bioethics: Deepa Goel, Shomini Parashar; Pearson, 2013
3. Bioethics and Biosafety: M.K. Sateesh, I. K. International Pvt Ltd, 2013
4. Plant Biotechnology: Principles and Applications, Malik Zainul Abdin, Usha Kiran, Kamaluddin, Athar Ali, Springer, 2017
5. An Introduction to Applied Cognitive Psychology: A Esgate and David Groom, TMH.

UNIT-6 INTERNATIONAL AGREEMENTS

Structure

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ABS

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6.3.4. Bonn Convention on the Conservation of
Migratory Species of Wild Animals (CMS)

6.3.5. Convention on International Trade in Endangered
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6.3.6. Bern Convention

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6.5.2. Determining Scope

6.5.3. Comparing right and obligations among members of the WTO, one of which is not a party to the biosafety protocol.

6.5.4. Conflict between members of the WTO both of which are parties to the biosafety protocol.

6.6. Summary

6.7. Terminal questions

6.8. Further readings

6.1. INTRODUCTION

International law is the set of rules, agreements and treaties that are binding between countries. A treaty can be called a Convention, a Protocol, a Pact, an Accord, etc.; it is the content of the agreement, not its name, which makes it a treaty. Thus, the Geneva Protocol and the Biological Weapons Convention are both treaties even though neither have the word treaty in its name. Under U.S. law, a treaty is specifically a legally binding agreement between countries that requires ratification and the advice and consent of the Senate. All other agreements (treaties in the international sense) are called Executive Agreements, but are nonetheless legally binding for the U.S. under international law.

A treaty is negotiated by a group of countries, either through an organization set up for that specific purpose, or through an existing body such as the United Nations (UN) Council for Disarmament. The negotiation process may take several years, depending on the topic of the treaty and the number of countries participating. After negotiations are finished, the treaty is signed by representatives of the governments involved. The terms may require that the treaty be ratified as well as signed before it becomes legally binding. A government ratifies a treaty by depositing an instrument of ratification at a location specified in the treaty; the instrument of ratification is a document containing a formal confirmation that the government consents to the terms of the treaty. The ratification process varies according to the laws and Constitutions of each country. In the U.S., the President can ratify a treaty only after getting the advice and consent of two thirds of the Senate.

Objectives

- To briefly discuss international law for biosafety and IPR.
- To discuss about protocol on the CBD.

- To discuss about international treaty on plant genetic resources for food and agriculture (ITPGRFA) Intergovernmental platform on biodiversity and ecosystem services (IPBES).
- To discuss about bio-safety protocol on WTO and its agreements.

6.2. WORLD TRADE ORGANIZATION (WTO)

World Trade Organization (WTO), international organization established to supervise and liberalize world trade. The WTO is the successor to the General Agreement on Tariffs and Trade (GATT), which was created in 1947 in the expectation that it would soon be replaced by a specialized agency of the United Nations (UN) to be called the International Trade Organization (ITO). Although the ITO never materialized, the GATT proved remarkably successful in liberalizing world trade over the next five decades. By the late 1980s there were calls for a stronger multilateral organization to monitor trade and resolve trade disputes. Following the completion of the Uruguay Round (1986–94) of multilateral trade negotiations, the WTO began operations on January 1, 1995.

Origins

The ITO was initially envisaged, along with the International Monetary Fund (IMF) and the World Bank, as one of the key pillars of post-World War II reconstruction and economic development. In Havana in 1948, the UN Conference on Trade and Employment concluded a draft charter for the ITO, known as the Havana Charter, which would have created extensive rules governing trade, investment, services, and business and employment practices. However, the United States failed to ratify the agreement. Meanwhile, an agreement to phase out the use of import quotas and to reduce tariffs on merchandise trade, negotiated by 23 countries in Geneva in 1947, came into force as the GATT on January 1, 1948.

Although the GATT was expected to be provisional, it was the only major agreement governing international trade until the creation of the WTO. The GATT system evolved over 47 years to become a de facto global trade organization that eventually involved approximately 130 countries. Through various negotiating rounds, the GATT was extended or modified by numerous supplementary codes and arrangements, interpretations, waivers, reports by dispute-settlement panels, and decisions of its council.

During negotiations ending in 1994, the original GATT and all changes to it introduced prior to the Uruguay Round were renamed GATT 1947. This set of agreements was distinguished from GATT 1994, which comprises the modifications and clarifications negotiated during the Uruguay Round (referred to as Understandings) plus a dozen other multilateral agreements on merchandise trade. GATT 1994 became an integral part of the agreement that established the WTO. Other core

components include the General Agreement on Trade in Services (GATS), which attempted to supervise and liberalize trade; the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which sought to improve protection of intellectual property across borders; the Understanding on Rules and Procedures Governing the Settlement of Disputes, which established rules for resolving conflicts between members; the Trade Policy Review Mechanism, which documented national trade policies and assessed their conformity with WTO rules; and four plurilateral agreements, signed by only a subset of the WTO membership, on civil aircraft, government procurement, dairy products, and bovine meat (though the latter two were terminated at the end of 1997 with the creation of related WTO committees). These agreements were signed in Marrakech, Morocco, in April 1994, and, following their ratification, the contracting parties to the GATT treaty became charter members of the WTO. By the 2010s the WTO had more than 160 members.

Objectives and Operation

The WTO has six key objectives: (1) to set and enforce rules for international trade, (2) to provide a forum for negotiating and monitoring further trade liberalization, (3) to resolve trade disputes, (4) to increase the transparency of decision-making processes, (5) to cooperate with other major international economic institutions involved in global economic management, and (6) to help developing countries benefit fully from the global trading system. Although shared by the GATT, in practice these goals have been pursued more comprehensively by the WTO. For example, whereas the GATT focused almost exclusively on goods—though much of agriculture and textiles were excluded—the WTO encompasses all goods, services, and intellectual property, as well as some investment policies. In addition, the permanent WTO Secretariat, which replaced the interim GATT Secretariat, has strengthened and formalized mechanisms for reviewing trade policies and settling disputes. Because many more products are covered under the WTO than under the GATT and because the number of member countries and the extent of their participation has grown steadily—the combined share of international trade of WTO members now exceeds 90 percent of the global total—open access to markets has increased substantially.

Resolution of Trade Disputes

The GATT provided an avenue for resolving trade disputes, a role that was strengthened substantially under the WTO. Members are committed not to take unilateral action against other members. Instead, they are expected to seek recourse through the WTO's dispute-settlement system and to abide by its rules and findings. The procedures for dispute resolution under the GATT have been automated and greatly streamlined, and the timetable has been tightened.

Dispute resolution begins with bilateral consultations through the mediation, or “good offices,” of the director-general. If this fails, an independent panel is created to hear the dispute. The panel submits a private draft report to the parties for comment, after which it may revise the report before releasing it to the full WTO membership. Unlike the IMF and the World Bank, both of which use weighted voting, each WTO member has only one vote. As in the earlier GATT system, however, most decisions are made by consensus. Unless one or both of the parties files a notice of appeal or the WTO members reject the report, it is automatically adopted and legally binding after 60 days. The process is supposed to be completed within nine months, and, if an appeal is lodged, the WTO Appellate Body hears and rules on any claim of legal error within 60 days. Appellate rulings are automatically adopted unless a consensus exists among members against doing so.

Trade-Policy Reviews

The WTO also seeks to increase awareness of the extent and effects of trade-distorting policies, a goal that it accomplishes through annual notification requirements and through a policy-review mechanism. Notices of all changes in members’ trade and trade-related policies must be published and made accessible to their trading partners. For many developing countries and countries whose economies were formerly centrally planned, this requirement was a major step toward more transparent governance. The WTO reviews the trade policies of the world’s four largest traders (the European Union, the United States, Japan, and China) once every two years, the policies of the 16 next largest traders once every four years, and the policies of all other traders once every six or more years. After extensive consultations with the member country under review, the WTO Secretariat publishes its review together with a companion report by the country’s government. The process thus monitors the extent to which members are meeting their commitments and provides information on newly opened markets. It also provides a firmer basis for subsequent trade negotiations and the resolution of trade disputes.

The pace of international economic integration via the GATT and WTO rounds of multilateral trade negotiations has been slower and less comprehensive than some members would prefer. Some have suggested that there should be additional integration among subgroups of (often neighboring) member economies—e.g., those party to the European Union, the North American Free Trade Agreement, and the Asia-Pacific Economic Cooperation—for political, military, or other reasons. Notwithstanding the most-favoured-nation clauses in the agreements establishing the WTO, the organization does allow such preferential integration under certain conditions. Even though many such integration agreements arguably do not involve “substantially all trade”- the WTO’s main condition—there has been little conflict over the formation of free-trade areas and customs unions. The most common omissions from such agreements are politically sensitive sectors such as agriculture.

Beginning in the late 1990s, the WTO was the target of fierce criticism. Opponents of globalization, and in particular those opposed to the growing power of multinational corporations, argued that the WTO infringes upon national sovereignty and promotes the interests of large corporations at the expense of smaller local firms struggling to cope with import competition. Environmental and labour groups (especially those from wealthier countries) have claimed that trade liberalization leads to environmental damage and harms the interests of low-skilled unionized workers.

6.3. INTERNATIONAL AGREEMENTS

The Convention on Biological Diversity (CBD) was established on the occasion of the United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro in 1992. The Cartagena Protocol on Biosafety, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, and the global Strategic Plan for Biodiversity 2011-2020 are important supplementary agreements which have been adopted under the umbrella of the CBD.

Other conventions also exist which cover certain species or particular natural environments, such as the Bonn Convention on the Conservation of Migratory Species of Wild Animals (CMS), the Ramsar Convention on Wetlands, the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), and the Berne Convention on the Conservation of European Wildlife and Natural Habitats, etc. Switzerland is also a member of the International Union for Conservation of Nature (IUCN) and the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services (IPBES), which was established in 2012, as well as the Global Biodiversity Information Facility (GBIF).

All of these agreements contribute to the implementation of the global Strategic Plan for Biodiversity 2011-2020 and the efforts being made to attain the Biodiversity Targets for 2020 (20 Aichi Targets). The latter were adopted in October 2010 in Nagoya (prefecture of Aichi) for the concrete implementation of the CBD.

1. Convention on Biological Diversity (CBD)
2. Cartagena Protocol on Biosafety
3. Nagoya Protocol on Access and Benefit-Sharing ABS
4. Ramsar Convention on Wetlands
5. Bonn Convention on the Conservation of Migratory Species of Wild Animals (CMS)

6. Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES)
7. Bern Convention
8. International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)
9. Intergovernmental Platform on Biodiversity and Ecosystem Services (IPBES)

6.3.1. Convention on Biological Diversity (CBD)

The Convention on Biological Diversity (Biodiversity Convention, CBD) was adopted at the United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro in 1992. The Convention now has a total of 193 Parties. It was ratified by Switzerland in 1994.

The signatory states of the CBD undertake to conserve biodiversity in their own territories, support appropriate measures for the conservation and sustainable use of biodiversity in developing countries, and regulate equitably the access to genetic resources and their utilisation.

In April 2002, the Parties to the CBD undertook to reduce the rate of biodiversity loss significantly by 2010. Unfortunately, the agreed target of significantly reducing the current rate of biodiversity loss by 2010 was not attained. The global Strategic Plan for Biodiversity 2011-2020 and new biodiversity goals, the 20 Aichi Biodiversity Targets, for the decade to 2020, known as the Aichi Biodiversity Targets, were defined at the Conference of the Parties in Nagoya in October 2010. The measures to be attained under the strategic plan and goals include the elimination of counterproductive incentives, the improved interconnection of protected areas and the sustainable use of areas with an economic function.

To ensure the long-term conservation of biodiversity, on behalf of the Federal Council, the Department of Environment, Transport, Energy and Communications (DETEC) developed a national biodiversity strategy. It was passed by the Federal Council on 25 April 2012. The associated action plan should be completed by the end of 2017. It will define concrete measures for the ten strategic goals so that the conservation of biodiversity in Switzerland can be guaranteed in the long term.

6.3.2. Cartagena Protocol on Biosafety

Under the umbrella of the Biodiversity Convention, the same states also adopted the Cartagena Protocol on Biodiversity in the year 2000. The Cartagena Protocol was ratified by Switzerland in 2002. The Cartagena Protocol is an international law instrument concerned with the environmental and health issues that arise in relation to the use of genetically modified, living organisms. It is designed to ensure the safe transport and use of living organisms that have been modified using

biotechnology, which could pose risks to the conservation and sustainable use of biodiversity.

The Nagoya-Kuala Lumpur Supplementary Protocol was passed in Nagoya in 2010 as a supplement to the Cartagena Protocol on Biosafety. The supplementary protocol specifies international rules and processes in relation to liability and redress in the event of damage caused to biodiversity by genetically modified organisms (GMOs). Switzerland ratified the supplementary protocol on 27 October 2014. The supplementary protocol is still in effect, but its provisions are harmonised with the applicable Swiss Gene Technology Act (GTA SR 814.91).

The Biosafety Clearing-House is the website set up for the exchange of information related to the Cartagena Protocol.

3. Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Access and Benefit-Sharing, ABS)

The Nagoya Protocol, which was negotiated within the framework of the Biodiversity Convention (CBD), regulates the access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation (Access and Benefit-Sharing, ABS). Hence the Nagoya Protocol serves the implementation of the third objective of the Convention on Biological Diversity and contributes to the conservation of biodiversity and the sustainable use of its components. There is often an interrelationship between the traditional knowledge of indigenous and local communities and genetic resources. That is why the Nagoya Protocol also has provisions concerning access and benefit-sharing when such knowledge is used.

6.3.3. Ramsar Convention on Wetlands

The Convention on Wetlands of International Importance especially Waterfowl Habitat was concluded in Ramsar, Iran, in 1971. Therefore, it is one of the oldest international agreements on the protection of nature. The Ramsar Convention came into force in 1976 in Switzerland. The secretariat for the Ramsar Convention is located in Gland (canton of Vaud).

6.3.4. Bonn Convention on the Conservation of Migratory Species of Wild Animals (CMS)

The Convention on the Conservation of Migratory Species of Wild Animals (Convention on Migratory Species, CMS) was concluded in Bonn, Germany, in 1979 and entered into force in Switzerland on 1 July 1995. The CMS secretariat is located in Bonn.

6.3.5. Convention on International Trade in Endangered Species Of Wild Fauna And Flora (CITES)

Also known as the Washington Endangered Species Convention, the Convention on International Trade in Endangered Species of Wild

Fauna and Flora (CITES) was passed in Washington in 1973. It entered into force in Switzerland on 1 July 1975. The CITES secretariat is in Geneva. The authority responsible for the CITES in Switzerland is the **Federal Food Safety and Veterinary Office (FSVO)**

6.3.6. Bern Convention

The Convention on the Conservation of European Wildlife and Natural Habitats was signed by the Council of Europe in Bern in 1979. It is the first agreement to regulate the protection of biodiversity at European level.

The aim of the Bern Convention is to conserve wild flora and fauna and their habitats, and to promote **cooperation between European countries** in the conservation of biodiversity. Particular attention shall be paid here to threatened and particularly sensitive species. The Bern Convention implements many of the global goals defined in the Convention on Biological Diversity (1992) at regional level.

6.3.7. International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)

The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) was passed in Rome in 2001 and came into force in Switzerland on 20 February 2005. The authority in Switzerland responsible for the ITPGRFA is the Federal Office for Agriculture FOAG.

6.3.8. Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services (IPBES)

The vast number of scientific insights available into biodiversity and the functioning of ecosystems are currently too fragmented to provide a general overview and enable the extrapolation of policy measures. The purpose of the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services (IPBES), which was established in April 2012, is to provide assistance in this regard and assume a mediation role between science and politics. The IPBES is meant to inform policymakers and international forums about the state of and changes in biodiversity and about the necessary reactions. The Technical Support Unit (TSU) for the regional assessment of biodiversity and ecosystem services in Europe and Central Asia has been located at the University of Bern since 2015 and receives financial support from Switzerland.

6.4. INTELLECTUAL PROPERTY

Intellectual property refers to creations of the mind: inventions; literary and artistic works; and symbols, names and images used in commerce.

Need of promotion and protection of intellectual property

There are several compelling reasons. First, the progress and well-being of humanity rest on its capacity to create and invent new works in

the areas of technology and culture. Second, the legal protection of new creations encourages the commitment of additional resources for further innovation. Third, the promotion and protection of intellectual property spurs economic growth, creates new jobs and industries, and enhances the quality and enjoyment of life. An efficient and equitable intellectual property system can help all countries to realize intellectual property's potential as a catalyst for economic development and social and cultural well-being.

The intellectual property system helps strike a balance between the interests of innovators and the public interest, providing an environment in which creativity and invention can flourish, for the benefit of all.

Intellectual property rights are like any other property right. They allow creators, or owners, of patents, trademarks or copyrighted works to benefit from their own work or investment in a creation. These rights are outlined in Article 27 of the Universal Declaration of Human Rights, which provides for the right to benefit from the protection of moral and material interests resulting from authorship of scientific, literary or artistic productions. The importance of intellectual property was first recognized in the Paris Convention for the Protection of Industrial Property (1883) and the Berne Convention for the Protection of Literary and Artistic Works (1886). Both treaties are administered by the **World Intellectual Property Organization (WIPO)**.

A creative mind does not need to imitate the work of others. A creative mind is always capable of creating something new, something of value. And the problem of piracy arises when one runs short of own imagination and creativity and in order to get quick money and fame resort to the practice of stealing. In other words piracy of creativity or Intellectual Property Rights is nothing but a form of stealing.

Prominent examples of IPR

People identify different products with the help of various logos, but does not understand the intrinsic value or importance of the same. IPR in itself can be called to be the identity of an organization or an individual. IPR can be of different types ranging from trademark to shapes and designs. Say for example – The Uber logo is unique and therefore is an identity of the business. The same is true with Ola , Indian Railways , Delhi Metro Railway Corporation , Kolkata Metro , iPleaders , ClikLawyer , MobiKwik , Quickheal , UrbanClap , BMW, TATA Group etc.

The logos are an identity in itself and the popularity of the same can be manifested by how people connect to these logos. The uniqueness and innovativeness of the design for every company is the USP of the particular company. These logos are primarily involves the trademark aspect. The peculiar shape of a bottle of an alcoholic beverage or a lighter or a packaging (otherwise known as trade-dress) can be considered as

prominent examples of intellectual property rights. IPR helps in distinguishing products of same nature produced by different brands.

6.4.1. Types of Intellectual Property

Intellectual property in India can be of different types and can be broadly classified into two types, namely – industrial property and copyright.

Industrial Property includes patents for inventions, trademarks, industrial designs and geographical indications.

Copyright covers literary works (such as novels, poems and plays), films, music, artistic works (e.g., drawings, paintings, photographs and sculptures) and architectural design. Rights related to copyright include those of performing artists in their performances, producers of phonograms in their recordings, and broadcasters in their radio and television programs.

6.4.1.1. INDUSTRIAL PROPERTY

6.4.1.1.1. Patent

A patent is an exclusive right granted for an invention –a product or process that provides a new way of doing something, or that offers a new technical solution to a problem. A patent provides patent owners with protection for their inventions. Protection is granted for a limited period, generally 20 years.

The novelty, utility, inventive step and the necessity of industrial application is a must for an invention be made patentable. The patent application also needs to be made in such a way so that it has clarity and completeness of all the technical details in a lucid style so that any layman can understand the same without any difficulty. The main purpose as to why patent information needs to be made public is to reduce the chances of duplication of effort and finances in inventions.

Often for the purpose of protecting an invention, some people takes the route of trade-secret by which they do not disclose important information and can therefore protect the secret of an invention for an infinite period of time without the danger of disclosing at the end of certain time period.

6.4.1.1.2. Trademark

A trademark is a distinctive sign that identifies certain goods or services produced or provided by an individual or a company. Its origin dates back to ancient times when craftsmen reproduced their signatures, or “marks”, on their artistic works or products of a functional or practical nature. Over the years, these marks have evolved into today’s system of

trademark registration and protection. The system helps consumers to identify and purchase a product or service based on whether its specific characteristics and quality – as indicated by its unique trademark– meet their needs.

A trademark can also be defined as a shape, mark ,device, name, signature, brand, heading, label, word, letter, numeral, shape of goods, colors, slogans individually or a combination of several of them which gives it an unique and aesthetic look capable of distinguishing the goods of one person or company from the other. The chief utility of trademark is that it protects the public from confusion and deception and on the other hand protects the trademark owner's trademark and goodwill and the business in the long run. Trademark can also be a certification trademark or collective mark or a composite mark or a trademark for goods and services.

Registration of Trademark

First, an application for registration of a trademark must be filed with the appropriate national or regional trademark office. The application must contain a clear reproduction of the sign filed for registration, including any colors, forms or three-dimensional features. It must also contain a list of the goods or services to which the sign would apply. The sign must fulfill certain conditions in order to be protected as a trademark or other type of mark. It must be distinctive, so that consumers can distinguish it from trademarks identifying other products, as well as identify a particular product with it. It must neither mislead nor deceive customers nor violate public order or morality.

Finally, the rights applied for cannot be the same as, or similar to, rights already granted to another trademark owner. This may be determined through search and examination by national offices, or by the opposition of third parties who claim to have similar or identical rights.

Collective Mark – There are certain companies which want to get multiple trademarks of their subsidiary companies at one go. And the trademark they apply for have certain similarities. For example almost all TATA Sons companies have the iconic TATA mark. In this case TATA is the collective mark.

Composite Mark – Marks which cannot be registered solely by combination of words and for inducing the uniqueness and distinguishing factor of products or services are needed to be registered in a design format preferably with a tagline or a combination of words can be called as composite marks. For example – The mark of McDonald's or ClikLawyer's mark are some of the examples of composite marks.

Trademark for goods and services – Every goods and services are classified into certain number of classes, thirty four classes of goods and eleven classes of services in total forty-five classes of goods and services based on which different products are classified.

Domain names are nothing but the internet address of a website which is essentially a combination of the name of a person or a company, unique in its nomenclature which will help a person in finding someone or something affiliated to a person in the World Wide Web. There is no law for the protection of domain names; however the law of passing off can be used to seek protection. Just like trademark which helps the customers in distinguishing the products and the owners of business in protecting the goodwill of the business, the domain name helps the customers or people in distinguishing people and products and the goodwill involved with them. For example Bandhan Bank and United Bank of India are both financial and banking service companies. People know the two banks by their names and goodwill they have.

Designs or Industrial Designs –

An industrial design refers to the ornamental or aesthetic aspects of an article. A design may consist of three-dimensional features, such as the shape or surface of an article, or two-dimensional features, such as patterns, lines or color. Industrial designs are applied to a wide variety of industrial products and handicrafts: from technical and medical instruments to watches, jewelry and other luxury items; from house wares electrical appliances to vehicles and architectural structures; from textile designs to leisure goods.

Designs in India are protected by the Designs Act, 2000 and the protection can be extended to shapes (in case of three-dimensional objects) and configuration, pattern, ornament or composition of lines or colors used in any article (in case of two-dimensional objects) or a combination of one or two more features of them. The only parameter for judging the design is that the features of the object and the appeal should be judged solely by eyes and no other parameter can be used.

6.4.1.1.3. Protection of Industrial Design

Designs in India are protected by the Designs Act, 2000 and the protection can be extended to shapes (in case of three-dimensional objects) and configuration, pattern, ornament or composition of lines or colors used in any article (in case of two-dimensional objects) or a combination of one or two more features of them.

In most countries, an industrial design must be registered in order to be protected under industrial design law. As a rule, to be registrable, the design must be “new” or “original”. Countries have varying definitions of such terms, as well as variations in the registration process itself. Generally, “new” means that no identical or very similar design is known to have previously existed. Once a design is registered, a registration certificate is issued. Following that, the term of protection granted is generally five years, with the possibility of further renewal, in most cases for a period of up to 15 years. Generally, industrial design protection is limited to the country in which protection is granted.

The Hague Agreement Concerning the International Registration of Industrial Designs, a WIPO administered treaty, offers a procedure for international registration of designs. Applicants can file a single international application either with WIPO or the national or regional office of a country party to the treaty. The design will then be protected in as many member countries of the treaty as the applicant designates. Protecting industrial designs helps to promote economic development by encouraging creativity in the industrial and manufacturing sectors, as well as in traditional arts and crafts. Designs contribute to the expansion of commercial activity and the export of national products.

6.4.1.1.4. Geographical Indications

A geographical indication is a sign used on goods that have a specific geographical origin and possess qualities or a reputation due to that place of origin. Most commonly, a geographical indication consists of the name of the place of origin of the goods.

Geographical indication is essentially a very important aspect of a business which indicates the country or region of origin of particular goods. GI as it otherwise referred to as is a sort of an identity of a good the mere reference of which determines a class among the similar class of goods, while it guarantees a quality too. For example Darjeeling Tea or Champagne or Roquefort Cheese or Porto or Swiss Watches. As the names suggests the commodities signifies the area of origin of the product. Protection in India on the same can be done by the Geographical Indications of Goods (Registration & Protection Act, 1999). Unlike the exclusive nature of copyright or patents, the exclusivity is not centered on only individual or organization but can be extended to all the products belonging to multiple parties originating from the same place. Like Benarasi Sarees. All the producers of Benaras producing the same saree and maintaining the same quality can claim protection under GI legislation in India or abroad.

Geographical indications may be used for a wide variety of agricultural products, such as, for example, “Tuscany” for olive oil produced in a specific area of Italy, or “Roquefort” for cheese produced in that region of France.

Appellation of Origin

An appellation of origin is a special kind of geographical indication used on products that have a specific quality exclusively or essentially due to the geographical environment in which the products are produced.

The term geographical indication encompasses appellations of origin. Examples of appellations of origin that are protected in states party to the Lisbon Agreement for the Protection of Appellations of Origin and their International Registration are “Bordeaux” for wine produced in the Bordeaux region of France, “Prosciutto di Parma” – or Parma ham – for ham produced in the Parma province of Italy or “Habana” for tobacco

grown in the Havana region of Cuba.

Protection of Geographical Indications

Geographical indications are protected in accordance with national laws and under a wide range of concepts, such as laws against unfair competition, consumer protection laws, laws for the protection of certification

Marks or special laws for the protection of geographical indications or appellations of origin. In essence, unauthorized parties may not use geographical indications if such use is likely to mislead the public as to the true origin of the product. Applicable sanctions range from court injunctions preventing unauthorized use to the payment of damages and fines or, in serious cases, imprisonment of damages and fines or, in serious cases, imprisonment.

Role of WIPO in the Protection of Geographical Indications

WIPO administers a number of international agreements that deal partly or entirely with the protection of geographical indications (in particular, the Paris Convention and the Lisbon Agreement). WIPO meetings offer Member States and other interested parties the opportunity to explore new ways of enhancing the international protection of geographical indications.

6.4.1.1.5. Trade Secrets

Trade secret is essentially confidential information which is very important to one's business or enterprise and may prove to be very costly for one's business in case the information is compromised with individuals outside the business and enterprise and may totally affect or jeopardize the business of the person who is the original owner of the same. The owner of the trade-secret should take utmost care to protect the secret and should never share with any other individual who is an employee of the business and they may prove injurious in future when the same person comes in the same business. Once the trade-secret goes public, it will be totally disastrous.

Therefore it is always advisable to keep trade-secret to one self, specifically in franchisee businesses. The following are some examples of the trade-secrets – designs, drawings, architectural plans, algorithms and processes implemented in computer programs and software, teaching instructions and methods, techniques and know how, manufacturing process, marketing plans, information related to R&D procedure. Google's Page Rank and Coca Cola's preservation of its secret ingredient are the best examples of how trade-secret should be kept secure from prying eyes.

6.4.2. COPYRIGHT

Copyright laws grant authors, artists and other creators protection for their literary and artistic creations, generally referred to as "works". A closely associated field is "related rights" or rights related to copyright

that encompass rights similar or identical to those of copyright, although sometimes more limited and of shorter duration.

Copyright is the right given by law to an individual or an organization to reproduce his/ her work any number of times with a profit or non-profit motive. Copyright is essentially a bundle of rights and can be used as a bundle or separately as per the terms and conditions of the author or the publisher whoever owns it.

The beneficiaries of related rights are:

Performers (such as actors and musicians) in their performances; producers of phonograms (for example, compact discs) in their sound recordings; and broadcasting organizations in their radio and television programs. Works covered by copyright include, but are not limited to: novels, poems, plays, reference works, newspapers, advertisements, computer programs, databases, films, musical compositions, choreography, paintings, drawings, photographs, sculpture, architecture, maps and technical drawings.

Protection of Copyrights

The Indian copyright law, Copyright Act, 1957 provides protection primarily to three kinds of areas – **original literary, dramatic, musical and artistic works, cinematograph films and sound recording.**

6.5. THE BIOSAFETY PROTOCOL AND THE WTO

Just a few votes shy of entering into force, the Cartagena Protocol on Biosafety is poised to become the next multilateral environmental agreement that has the potential to pit trade interests against environmental concerns. Nevertheless, concerns over impending conflict with the WTO trade regime may be misplaced. A detailed analysis of the rights and obligations of the parties to the Protocol and the applicable WTO disciplines reveals few instances of probable conflict. The United States, one of the largest exporters of LMOs, has not signed or ratified the Protocol. Thus, the determination that no conflict exists is of particular importance if the Protocol is to be effective in the likely scenario where the exporting country is not a party to the Protocol but both it and the importing country are members of the WTO.

The Cartagena Protocol on Biosafety (Biosafety Protocol or Protocol), adopted in January 2000 as a supplementary agreement to the 1992 United Nations Convention on Biological Diversity (CBD), could soon become one of the first binding multilateral international agreements dealing specifically and exclusively with some of the challenges created by “modern biotechnology.” To date, the Biosafety Protocol has been signed by 102 Countries and ratified by forty-six countries. The Protocol requires fifty ratifications before it can enter into force.

6.5.1. WTO Agreements: The Negative Obligations

The WTO is the institutional framework of the international multilateral trading system.¹⁴⁸ Every member of the WTO has entered into commitments related to its trade policy regime and measures with relation to its trade in goods among other things. The rights and obligations of the WTO members can be enforced through a dispute settlement system.

WTO obligations constitute limits, or what has been termed “negative obligations,” upon its members to refrain from enacting certain governmental regulations. The following agreements, and their negative obligations, have been selected for review because of their potential to conflict with the positive obligations that the Biosafety Protocol places upon its parties.

A. *The GATT*

The GATT covers all international trade in goods.¹⁵¹ Within the WTO, three GATT 1947 “principles” or “disciplines” continue to be the framework upon which the ideal of “free trade” is built. These are as follows: Article I, prohibiting discrimination between the products imported by member states, also referred to as the most favored nation principle; Article III, prohibiting discrimination between imported and domestic goods, also referred to as national treatment; and Article XI, prohibiting quantitative restrictions on trade.

Articles I and III embody the principle of non-discrimination among “like products.” Under Article I, like products from different countries should receive the same treatment by the importing country. Under Article III, like products from foreign member countries must be treated no differently than the like domestic products. Thus, determining if products are alike is central to any claim that there has been a violation of these Articles.

The most recent expression of the Appellate Body with regard to like products can be found in *European Communities—Measures Affecting Asbestos and Asbestos-Containing Products (Asbestos Case)*. It stated that a finding that two products are alike must be made on a case-by-case basis by examining four general characteristics that the products might share: (1) “the physical properties of the products”; (2) “the extent to which the products are capable of serving the same or similar end-uses”; (3) “the extent to which consumers perceive and treat the product as alternative means of performing particular functions in order to satisfy a particular want or demand”; and (4) “the international classification of the products for tariff purposes.”

B. *The TBT Agreement*

There are measures that can also fall into the categories covered by another WTO agreement, the TBT. The TBT’s purpose is ensuring that WTO members do not use technical regulations and standards in a way

that creates unnecessary obstacles to international trade. To date, no case has been decided under the TBT.

The TBT covers all technical regulations, standards, and conformity assessment procedures that may bear upon all imported products including “industrial and agricultural products.”^{170A} technical regulations is defined by the TBT as:

[A] Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

C. The SPS Agreement

The SPS’s stated purpose is to limit the use of SPS measures as disguised barriers to trade. Three cases have already been resolved by the Appellate Body under the SPS: *EC Measures Concerning Meat and Meat Products (Beef Hormones Case)*; *Australia—Measures Affecting Importation of Salmon (Australian Salmon Case)*; and *183 Japan—Measures Affecting Agricultural Products (Japan Agricultural Products Case)* Significantly, in each of the cases, the measure has been deemed inconsistent with the members’ SPS obligations. Interestingly, these cases all involved disputes between highly developed countries with intricate regulatory frameworks and were decided prior to the WTO Ministerial Conference in Seattle.

All measures enacted by members of the WTO that come under the scope of the SPS must be in accordance with the provisions of the Agreement. A sanitary or phytosanitary measure is defined in Annex A, paragraph 1 of the SPS as any measure applied:

- a. to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
- b. to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
- c. to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
- d. to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

6.5.2. Determining scope

An important part of any analysis that aims to identify or resolve conflict among international agreements is determining whether the subject matter—or more specifically, the scope of the treaties—coincide before further determining if the rights and obligations created by the treaties are in any way incompatible. In the context of determining the existence of a conflict between any MEA and the WTO, this analysis is important because it could reveal that there is no shared scope and therefore, no potential for conflict. In the case of the Biosafety Protocol and the WTO trade regime, this analysis is particularly significant because the rights and obligations of the parties and the rigors of the disciplines will vary depending on which WTO subsidiary agreement is used to analyze a measure.

The first and most obvious distinction between the WTO and the Biosafety Protocol is that the former is a trade agreement and the latter is an environmental agreement. The Protocol requires affirmative regulatory action from the parties' governments to ensure that trade in LMOs is adequately regulated in order to protect biodiversity. The WTO requires members to practice restraint from imposing measures that will have an impact on the movement of goods from one member state to another.

Another interesting distinction between trade regimes and environmental regimes is pointed out by authors Brown and Jackson:

The environmental culture contrasts sharply with that prevalent in the trade field. The environmental community is generally an open one that relies on public access to information and is accustomed to demanding public participation (especially by NGOs) in decision-making. Because the public views the environment as “their” issue, governments in the democratic tradition necessarily operate to varying degrees in a transparent fish bowl.

By contrast, the trade culture is more closed. Trade matters have been viewed by many governments as being within the exclusive competence of governments The culture surrounding much of trade law, especially negotiations, neither promotes public access to information nor invites public participation by NGOs and individuals in its processes.

6.5.3. Comparing right and obligations among members of the WTO, one of which is not a party to the biosafety protocol

The only obligation that affects trade in LMOs between parties to the Protocol and non-parties is that transboundary movement among the two be conducted in accordance with the objective of the Protocol, as stated in Article 24.244 Complying with the Article 1 objectives²⁴⁵ would mean establishing a set of measures that would ensure an adequate level of protection to the conservation and sustainable use of biodiversity from

adverse effects resulting from the introduction of LMOs into the environment of the importing country, in accordance with the precautionary approach contained in Principle 15 of the Rio Declaration.

The Protocol provides ample room for negotiating an agreement between a party and a non-party that would satisfy both sides and thus, avoid any confrontation under the WTO.²⁴⁶ But, notwithstanding this situation, it would also be possible for an importing country to determine that the simplest way to ensure compliance with the objectives of the Protocol is to conform all transboundary movement of LMOs to the Biosafety Protocol's specific provisions.²⁴⁷ As an importing country, this could mean that the party to the Protocol may require both parties and non-parties: (1) to conform to the provisions on notification and approval prior to a transboundary movement; (2) to prohibit the entrance of a certain LMO under Article 10; and (3) to establish measures to comply with Article 18 on identification of imported LMOs. These examples adequately represent the range of measures that could require analysis under the WTO disciplines.

A. *Requiring an AIA*

The AIA procedure is a requirement that previous authorization be obtained from the importing party prior to the export of certain LMOs. As detailed in Part II of this article, the AIA procedure provides certain time constraints in order to reduce the effects such a measure could have on trade. The procedure, as set out in the Protocol, is also restricted to the first introduction of any particular LMO into the importing country, which further limits its effect on trade. The AIA procedure is also similar to the prior informed consent procedure found in other environmental treaties. It is significant that this procedure has not found its way into the ongoing debate of MEA measures and their compatibility with trade disciplines.

Nevertheless, at least one commentator has suggested that the AIA procedure itself might be subject to WTO discipline, particularly the SPS. Still, most commentators simply do not consider the AIA procedure to be worrisome with regards to WTO trade disciplines.²⁴⁸ One of them suggests that this type of measure would not be subject to the same rigors as other more trade-restrictive measures.²⁴⁹

It is interesting to note that the SPS itself asserts in the last paragraph of Annex C(1):

Where an importing Member operates a system for the approval of the use of food additives or for the establishment of tolerances for contaminants in food, beverages or feed stuffs which prohibits or restricts access to its domestic market for products based on the absence of an approval, the importing Member shall consider the

use of a relevant international standard as the basis for access until a final determination is made.²⁵⁰

B. *Imposing a Ban on an LMO*

The second measure to be analyzed is a determination, by a party to the Protocol, to prohibit or ban a certain LMO from being imported. It is important to remember the following aspects of a ban pursuant to the Biosafety Protocol: first, that a ban, although permitted by the Protocol, is not specifically required; second, that any determination regarding the import of an LMO, including a ban, must be preceded by a risk assessment carried out in a scientifically sound manner;²⁵¹ third, that a determination to ban a product must set out the reasons on which this decision is based;²⁵² fourth, that although a ban could be a result of the application of the precautionary principle, as established in Article 10(8), this Article requires a prior determination of a potential adverse effect; finally, that the measure banning a LMO must also be consistent with Article 16(2) of the Protocol which states that such measures should be applied to the extent necessary to prevent adverse effects on biodiversity.

1. A Ban and SPS Disciplines

The simplest and most desirable way of ensuring compliance with the SPS disciplines is to compel a member to base its measure on international standards. Thus, if the banning of a certain LMO was based on an international standard, guideline, or recommendation, no incompatibility should exist between the ban and the SPS obligations. However, in the case of the SPS, only three international organizations have been recognized as providers of standards: the Codex, the IOE, and the IPPC.²⁵³ The Codex establishes standards with relation to the quality and safety of food.²⁵⁴ The IOE establishes veterinary regulations designed to prevent the spread of transmissible diseases to animals and to human beings.²⁵⁵ The IPPC aims to provide standards for measures to protect plant resources from harmful pests.²⁵⁶ Commentator Cors, citing documentation prepared by the BSWG, has pointed out that none of these organizations have specific coverage of biosafety concerns and their dealings with LMOs is, at best, incidental to their objectives.²⁵⁷ If WTO members are intent on dealing with Biosafety measures under the SPS, it might be wise for the SPS Committee to recognize the Biosafety Protocol as the standard-setting body in this area. Still, given that the SPS Committee's determinations require consensus,²⁵⁸ and given the controversies surrounding trade in LMOs, it is difficult to envision the United States allowing for such consensus to form.

Moreover, at least one of these organizations, the IPPC, has been actively coordinating its work with the Convention of Biodiversity and, in particular, with the Biosafety Protocol.²⁵⁹ Thus, another possibility is that, to the degree in which these organizations could overlap with the Protocol, their standards will reflect those considered appropriate by the Protocol. Such organization could, in some circumstances, justify measures taken pursuant to the Protocol based on the recognized international standards.

2. A Ban and TBT Disciplines

The TBT also pursues the goal of harmonization through the use of relevant international standards, but unlike the SPS, it does not provide for any particular international organization as the recognised standard-setting body in any field. Thus, a ban established pursuant to the procedures set out in the Protocol possibly could benefit from the presumption in Article 2.5 of the TBT that it is not an unnecessary obstacle to international trade. Different from the case under the SPS, the only apparent requisite for an international organization or agreement to be considered a standard-setting body is that its membership be open to the relevant bodies of all WTO members.²⁶⁹ Therefore, there appears to be no impediment, under the TBT, for the Biosafety Protocol to become the standard-setting body with regards to technical regulations referring to LMOs that may have an impact on biodiversity.

Aside from this possibility, a ban pursuant to the Protocol simply would not appear to conflict with any of the obligations of the TBT. First, the ban's objective would probably best be catalogued as that of protection of the environment, an objective expressly recognized in TBT's Article 2.2. Nevertheless, the conservation and sustainable use of biodiversity, an objective not only of the Protocol but also present in the CBD—which actually has more parties than the WTO—could also be considered a separate legitimate objective in the open ended listing of the TBT. Second, the risk assessment procedure provided in the Protocol would, in all probability, be considered adequate under the TBT. The TBT has very few indications as to what needs to be considered in an adequate risk assessment; but, for example, two of its mentioned considerations, *scientific information* and a *products' end uses*, are integral parts of the Protocol's risk assessment.²⁷⁰

3. A Ban and GATT Disciplines

None of the obligations of the Biosafety Protocol require a party to establish measures that discriminate among local and

foreign LMOs or LMOs exported by different countries. Thus, again, there is no conflict between the Article I and Article III obligations of an importing party and the obligations under the Protocol of such parties.

But even if the ban were considered a violation of Article XI, which prohibits quantitative restrictions to trade, it could likely find refuge under Article XX(g). In this hypothetical situation, a ban has been placed on a specific LMO after a risk assessment had identified the likelihood of it having an adverse effect on the conservation or sustainable use of biodiversity. Therefore, the ban is a measure “related to the conservation of exhaustible natural resources.”²⁷³ Admittedly, fitting a ban, pursuant to the Protocol, under the exception of Article XX (g), would require interpreting biodiversity as an exhaustible resource.

The WTO has already determined that dolphins, salmon and clean air are examples of natural resources.²⁷⁴ These determinations, coupled with the fact that there exists an international recognition by the CBD that biodiversity is an exhaustible resource (hence the need to conserve it), make it difficult to imagine the WTO reaching any other conclusion. Still, after fitting under the exception of Article XX(g), a party to the Protocol (who is a member of the WTO) is still under the obligation of the “Chapeau” to ensure that its measure is not an arbitrary or unjustifiable discrimination between countries where the same conditions prevail, nor that it constitutes a disguised restriction on trade.²⁷⁵ Commentators Gaston and Abate have provided a persuasive analysis of why a determination to implement a ban, or any other measure, pursuant to the Protocol would satisfy these obligations. Based on this analysis, it is again difficult to find that a conflict exists between the rights and obligations of the GATT and those of the Biosafety Protocol.

C. *Handling, Transport, Packaging, and Identification Requirements*

Per the analysis conducted in Part IV of this article, it is hard to envision the measures required under Article 18 of the Protocol as coming within the scope of the SPS. Still these requirements do seem to fall comfortably within the scope of the TBT. As discussed previously, there would seem to be no obstacles for the requirements of Article 18, and any subsequent standards agreed to by the “COP serving as the meeting of the Parties to the Protocol,” to become the applicable international standard with regard to the handling, transport, packaging, and identification requirements of transboundary movements of LMOs. The possibility of conflict with TBT obligations would therefore be substantially reduced.

Nevertheless, an analysis of the requirements of Article 18—as they were discussed in Part II—reflect that they are directly related to the objectives of the Protocol, which, as stated before, should be considered a legitimate objective under the TBT.

6.5.4. Conflict between members of the WTO both of which are parties to the biosafety protocol

The Vienna Convention on the Law of Treaties²⁸¹ (VCLT) states, (in Article 30 paragraph 3) with regard to successive treaties relating to the same subject matter, that “[w]hen all the parties to the earlier treaty are parties also to the later treaty but the earlier treaty is not terminated or suspended in operation under Article 59, the earlier treaty applies only to the extent that its provisions are compatible with those of the latter treaty.”

Regarding the interpretation of this Article Professor David Wirth has stated:

In other words, the obligations in international agreements ought to be harmonized where possible to give effect to all commitments simultaneously, an approach that counsels reconciling agreements with each other whenever possible. The obligations stemming from multiple agreements among the same Parties ought to be interpreted against the background of a presumption that gives life to them all, except to the extent that, in the words of the Vienna Convention, those obligations are not “compatible” with each other.

The previous sections have exposed a true lack of incompatibility among the rights and obligations of the Biosafety Protocol and the WTO regime. Thus, there would seem to be no need to resort to the specific instructions of Article 30 of the VCLT with regard to conflict. It could also be considered unnecessary to refer to the preambular phrases of the Biosafety Protocol to resolve a conflict that does not exist.

Most preambles are a restatement of the intentions of the parties who have agreed to a particular operative text, and constitute the context in which an agreement should be interpreted. It is in this sense that the three controversial phrases should be analyzed. However, one commentator has argued for a weightier reading of the preamble indicating that the preamble is in effect calling off the effects of Article 30 of the VCLT and referring to Article 31.3. He states:

These two statements appear to cancel one another out to some degree. The matter may be resolved with reference to the Vienna Convention on the Law of Treaties. Article 30 on the application of successive treaties relating to the same subject matter, would not seem to apply in the light of the Preamble which clearly intends both agreements to be regarded on the same level; neither is intended to be superior to the other. Thus, the applicable rule of interpretation would be Article 31.3 of the Vienna Convention, which provides that “[t]here shall be taken into account, together with the context, any subsequent agreement between the

parties regarding the interpretation of the treaty or the application of its provisions.”²⁸³

Conclusion

The Protocol’s negotiators were primarily concerned with filling in regulatory gaps in international law that could allow for biodiversity-related biosafety preoccupations to remain unattended. The BSWG’s documentation reflects the fact that the interaction and overlapping of the Protocol’s scope with other existing international obligations was constantly being avoided.²⁸⁷ It is also of importance to note that the driving forces behind much of the negotiations were developing countries. This fact is relevant because traditionally, developing countries have been suspicious of environmental measures, viewing them as a way of limiting their developmental possibilities and their products’ market access. Thus, it seems consistent that an environmental treaty pushed forward by concerns from developing countries would not substantially alter aspects of the existing trade regime which could benefit them.

The 1996 CTE report approved by the Singapore Ministerial Conference, as summarized by Charnovitz, included the following recommendations with regards to the relationship between MEAs and the WTO:

1. The CTE endorses and supports multilateral solutions based on international co-operation and consensus as the best and most effective way for governments to tackle environmental problems of a transboundary or global nature.
2. Due respect must be afforded to both WTO Agreements and MEAs.
3. Adequate international co-operation provisions, including among them financial and technological transfers and capacity building, as part of a policy package in MEAs are important to facilitate the ability of governments, particularly of developing countries, to become parties to an MEA.
4. Trade measures based on specifically agreed-upon provisions can also be needed in certain cases to achieve the environmental objectives of an MEA, *particularly where trade is related directly to the source of an environmental problem*. They have played an important role in some MEAs in the past, and they may be needed to play a similarly important role in certain cases in the future.

6.6. SUMMARY

In order to make the global system less chaotic and unpredictable, states often make agreements with one another to modify their behavior. International Agreements are treaties signed by a number of states that establish global rules of conduct. Some agreements focus on

single issues, whereas others cover many areas. Theoretically, international agreements benefit the states that sign them. States that break these rules, sometimes called Rogue States-are usually treated with wariness by the rest of the world. International Law is the collection of rules and regulations that have evolved over the past few centuries. These rules define the rights and obligations of states. Sometimes treaties codify and formalize international law, but just as often, international law arises from custom and habit. The International Court of Justice, in the Netherlands, is the judicial body of the United Nations and is responsible for resolving disputes among states. International treaties serve as an important part of international law. States sign treaties to end wars, protect their interests, and make international law. The treaties listed in the chart below have significantly contributed to the structure of the international systems.

6.7. TERMINAL QUESTIONS

Q.1. What is international agreement? Explain its objective and principles.

Answer : -----

Q.2. Describe world trade organization (WTO). Explain its origin, objectives and operation.

Answer : -----

Q.3. Write a short note on convention on biological diversity (CBD).

Answer:-----

Q.4. What is the Berne Convention and why is it important to copyright?

Answer: -----

Q.5. Write a short note on intellectual property right (IPR) and its types?

Answer : -----

Q.6. Write a short note on GATT.

Answer:-----

6.8. FURTHER READINGS

1. IPR, Biosafety and Bioethics: Deepa Goel, Shomini Parashar; Pearson, 2013
2. Bioethics and Biosafety: M.K. Sateesh, I. K. International Pvt Ltd, 2013
3. Plant Biotechnology: Principles and Applications, Malik Zainul Abdin, Usha Kiran, Kamaluddin, Athar Ali, Springer, 2017
4. General Biochemistry: J.H.Weil., Wiley Eastern, Limited, 1990
5. An Introduction to Ethical, Safety and Intellectual Property Rights Issues in biotechnology: Padma Nambisan, Academic press 20107.

Notes