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SCHOOL OF BIO AND CHEMICAL ENGINEERING

DEPARTMENT OF BIOTECHNOLOGY

UNIT – I – Biosafety – SBT1401

I. Introduction

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. 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. The international Cartagena Protocol on Biosafety deals primarily with the agricultural definition but many advocacy groups seek to expand it to include post-genetic threats: new molecules, artificial life forms, and even robots which may compete directly in the natural food chain.

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. 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. (note that in the US, several groups are involved, and efforts are being made to improve processes for government run labs, but there is no unifying regulatory authority for all labs.

Biosafety is related to several fields:

1. In ecology (referring to imported life forms from beyond ecoregion borders),

2. In agriculture (reducing the risk of alien viral or transgenic genes, genetic engineering or prions such as BSE/"MadCow", reducing the risk of food bacterial contamination)

3. In medicine (referring to organs or tissues from biological origin, or genetic therapy products, virus; levels of lab containment protocols measured as 1, 2, 3, 4 in rising order of danger),

4. In chemistry (i.e., nitrates in water, PCB levels affecting fertility)

5. In exobiology (i.e., NASA's policy for containing alien microbes that may exist on space samples)

6. In synthetic biology (referring to the risks associated with this type of lab practice). When biological warfare or new, currently hypothetical, threats (i.e., robots, new artificial bacteria) are considered, biosafety precautions are generally not sufficient. (link to incident report, i.e., such as problems with CDC research labs in 2014). The new field of biosecurity addresses these complex threats.

Hazards:

1. Chemical hazards typically found in laboratory settings include carcinogens, toxins, irritants, corrosives, and sensitizers.

2. Biological hazards include viruses, bacteria, fungi, prions, and biologically-derived toxins, which may be present in body fluids and tissue, cell culture specimens, and laboratory animals. Routes of exposure for chemical and biological hazards include inhalation, ingestion, skin contact, and eye contact.

3. Physical hazards include ergonomic hazards, ionizing and non-ionizing radiation, and noise hazards. Additional safety hazards include burns and cuts from autoclaves, injuries from centrifuges, compressed gas leaks, cold burns from cryogens, electrical hazards, fires, injuries from machinery, and falls.

In synthetic biology:

A complete understanding of experimental risks associated with synthetic biology is helping to enforce the knowledge and effectiveness of biosafety. With the potential future creation of man-made unicellular organisms, some are beginning to consider the effect that these organisms will have on biomass already present. Scientists estimate that within the next few decades, organism design will be sophisticated enough to accomplish tasks such as creating biofuels and lowering the levels of harmful substances in the atmosphere. Scientist that favor the development of synthetic biology claim that the use of biosafety mechanisms such as suicide genes and nutrient dependencies will ensure the organisms cannot survive outside of the lab setting in which they were originally created. Organizations like the ETC Group argue that regulations should control the creation of organisms that could potentially harm existing life. They also argue that the development of these organisms will simply shift the consumption of petroleum to the utilization of biomass in order to create energy. These organisms can harm existing life by affecting the prey/predator food chain, reproduction between species, as well as competition against other species (species at risk, or act as an invasive species). Synthetic vaccines are now being produced in the lab. These have caused a lot of excitement in the pharmaceutical industry as they will be cheaper to produce, allow quicker production, as well as enhance the knowledge of virology and immunology.

In medicine, healthcare settings and laboratories:

Biosafety, in medicine and health care settings, specifically refers to proper handling of organs or tissues from biological origin, or genetic therapy products, viruses with respect to the environment, to ensure the safety of health care workers, researchers, lab staff, patients, and the general public. Laboratories are assigned a biosafety level numbered 1 through 4 based on their potential biohazard risk level. The employing authority, through the laboratory director, is responsible for ensuring that there is adequate surveillance of the health of laboratory personnel. The objective of such surveillance is to monitor for occupationally acquired diseases. The World Health Organization attributes human error and poor technique as the primary cause of mishandling of biohazardous materials.

Biosafety is also becoming a global concern and requires multilevel resources and international collaboration to monitor, prevent and correct accidents from unintended and malicious release and also to prevent that bioterrorists get their hands-on biologics sample to create biologic weapons of mass destruction. Even people outside of the health sector needs to be involved as in the case of the Ebola outbreak the impact that it had on businesses and travel required that private sectors, international banks together pledged more than $2 billion to combat the epidemic. The bureau of international Security and nonproliferation (ISN) is responsible for managing a broad range of U.S. nonproliferation policies, programs, agreements, and initiatives, and biological weapon is one their concerns Biosafety has its risks and benefits. All stakeholders must try to find a balance between cost-effectiveness of safety measures and use evidence-based safety practices and recommendations, measure the outcomes and consistently reevaluate the potential benefits that biosafety represents for human health. Biosafety level designations are based on a composite of the design features, construction, containment facilities, equipment, practices and operational procedures required for working with agents from the various risk groups.

Classification of biohazardous materials is subjective and the risk assessment is determined by the individuals most familiar with the specific characteristics of the organism. There are several factors taken into account when assessing an organism and the classification process.

1. Risk Group 1: (no or low individual and community risk) A microorganism that is unlikely to cause human or animal disease.

2. Risk Group 2: (moderate individual risk, low community risk) A pathogen that can cause human or animal disease but is unlikely to be a serious hazard to laboratory workers, the community, livestock or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of spread of infection is limited.

3. Risk Group 3: (high individual risk, low community risk) A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another. Effective treatment and preventive measures are available.

4. Risk Group 4: (high individual and community risk) 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.

Investigations have shown that there are hundreds of unreported biosafety accidents, with laboratories self-policing the handling of biohazardous materials and lack of reporting. Poor record keeping, improper disposal, and mishandling biohazardous materials result in increased risks of biochemical contamination for both the public and environment. Along with the precautions taken during the handling process of biohazardous materials, the World Health Organization recommends: Staff training should always include information on safe methods for highly hazardous procedures that are commonly encountered by all laboratory personnel and which involve:

1. Inhalation risks (i.e. aerosol production) when using loops, streaking agar plates,
2. pipetting, making smears, opening cultures, taking blood/serum samples, centrifuging, etc.
3. Ingestion risks when handling specimens, smears and cultures
4. Risks of percutaneous exposures when using syringes and needles
5. Bites and scratches when handling animals
6. Handling of blood and other potentially hazardous pathological materials
7. Decontamination and disposal of infectious material.

II. Biosafety Issues in Biotechnology

The current topics of debate on the ethical issues:

1. Development of genetically modified organisms (GMO) such as plants, animals and microbes that are used as biological control agents to the environment could cause ecological imbalance that could be disastrous for the whole ecosystem.

2. Introduction of genetically modified microbes (GMM) for industrial purposes can lead to the generation of new infectious organisms.

3. Development of herbicide resistance and enhanced photosynthesis could lead to originate more tolerant weeds as a result of cross pollination with related species.

4. In vitro fertilization (IVF) and other reproductive technologies may be harmful for the individual autonomy, equality, protection of vulnerable, accountability, respect for human life and dignity, non- commercialization of reproduction, appropriate use of resources and balancing individual and collective interests.

5. Stem cell technology i.e., use of embryonic stem cell and adult stem cell is also supposed to fight against nature and killing a yet to be born child. This technology is still considered as an illegal practice in some of the countries.

Issues in medical and health care:

1. Red biotechnology is the branch of biotechnology which deals with improvements in medical and health care by using living organisms in designing novel therapeutics.

2. A few well-known examples of red biotechnology include antibiotic production, vaccine development and genetic engineering.

3. The main concern with red biotechnology seems to be production of transgenic animals and subsequent unethical application of the gained knowledge (on such animals) on humans.

Issues /Risks associated with red biotechnology:

1. Potential harmful impact on the environment.

2. Health of animals.

3. Food safety and drug resistance associated with the foods derived from GM animals.

4. Unknown risks associated with the permits to research on animals without doing the thorough risk analysis.

5. Transfer of viruses and/or other infective agents from animals to humans; which generally do not infect human and are only confined to the specific animal.

Issues due to antibiotic resistance genes:

1. Antibiotic resistance genes are used as selectable markers for plant transformation. The use of these marker genes has led to the suspicion that these genes might be transferred to the environment and result in creation of antibiotic resistant human pathogens.

2. The mechanisms of transfer of the genes from GM crop to bacteria are itself questionable and it has not been experimentally shown.

3. Antibiotics commonly used in development of transgenic crops are not the ones which are usually used in treatment of human diseases.

4. In spite of the doubtful status of any harm conferred by these marker genes, plant biotechnologists are now using techniques to generate “marker-free plants”. It is also referred to as the “clean gene technology”.

III. Biological Safety Cabinets

A biosafety cabinet (BSC)—also called a biological safety cabinet or microbiological safety cabinet—is an enclosed, ventilated laboratory workspace for safely working with materials contaminated with (or potentially contaminated with) pathogens requiring a defined biosafety level. Several different types of BSC exist, differentiated by the degree of biocontainment required. BSCs first became commercially available in 1950.

The primary purpose of a BSC is to serve as a means to protect the laboratory worker and the surrounding environment from pathogens. All exhaust air is HEPA-filtered as it exits the biosafety cabinet, removing harmful bacteria and viruses. This is in contrast to a laminar flow clean bench, which blows unfiltered exhaust air towards the user and is not safe for work with pathogenic agents. Neither are most BSCs safe for use as fume hoods. Likewise, a fume hood fails to provide the environmental protection that HEPA filtration in a BSC would provide. However, most classes of BSCs have a secondary purpose to maintain the sterility of materials inside (the "product").

Classes:

1. Class 1: Class I cabinets provide personnel and environmental protection but no product protection. In fact, the inward flow of air can contribute to contamination of samples. Inward airflow is maintained at a minimum velocity of 75 ft/min (0.38 m/s). These BSCs are commonly used to enclose specific equipment (e.g. centrifuges) or procedures (e.g. aerating cultures) that potentially generate aerosols. BSCs of this class are either ducted (connected to the building exhaust system) or unducted (recirculating filtered exhaust back into the laboratory).

2. Class 2: Class II cabinets provide both kinds of protection (of the samples and of the environment) since makeup air is also HEPA-filtered. There are five types: Type A1 (formerly A), Type A2 (formerly A/B3), Type B1, Type B2 and Type C1. Each type's requirements are defined by NSF International Standard 49, which in 2002 reclassified A/B3 cabinets (classified under the latter type if connected to an exhaust duct) as Type A2, and added the Type C1 in the 2016 standard. About 90% of all biosafety cabinets installed are Type A2

cabinets. Principles of operation use motor driven blowers (fans) mounted in the cabinet to draw directional mass airflow around a user and into the air grille - protecting the operator. The air is then drawn underneath the work surface and back up to the top of the cabinet where it passes through the HEPA filters. A column of HEPA filtered, sterile air is also blown downward, over products and processes to prevent contamination. Air is also exhausted through a HEPA filter, and depending on the Type of Class II BSC, the air is either recirculated back into the laboratory or pulled by an exhaust fan, through ductwork where it is expelled from the building. The Type A1 cabinet, formerly known as Type A, has a minimum inflow velocity of 75 ft/min. The downflow air, considered contaminated, splits just above the work surface (the BSCs smoke split) and mixes with the inflow. This air is drawn, through ductwork, up the back of the cabinet where it is then blown into a positive pressure, contaminated plenum. Here, the air is either recirculated, through a HEPA filter, back down over the work zone, or exhausted out of the cabinet (also through a HEPA filter). Sizing of HEPA filters and an internal damper are used to balance these air volumes. This type is not safe for work with hazardous chemicals even when exhausted with a "thimble" or canopy to avoid disturbing internal air flow. The Type A2 cabinet, formerly designated A/B3, has a minimum inflow velocity of 100 ft/min. A negative air pressure plenum surrounds all contaminated positive pressure plenums. In other respects, the specifications are identical to those of a Type A1 cabinet. Type B1 and B2 cabinets have a minimum inflow velocity of 100 ft/min, and these cabinets must be hard-ducted to an exhaust system rather than exhausted through a thimble connection. Their exhaust systems must also be dedicated (one BSC per duct run, per blower). In contrast to the type A1 and A2 cabinets, Type B BSCs use single pass airflow (air that does not mix and recirculate) in order to also control hazardous chemical vapors. Type B1 cabinets split the airflow so that the air behind the smoke-split is directed to the exhaust system, while air between the operator and the smoke-split mixes with inflow air and is recirculated as downflow. Since exhaust air is drawn from the rear grille, the CDC advises that work with hazardous chemistry be conducted in the rear of the cabinet. This is complicated, since the smoke split (demarking the "rear of the cabinet") is an invisible line that extends the width of the cabinet (approximately 10-14 inches from the front grille) and drifts as the internal HEPA filters load with particulate. The Type B2 cabinet (also known as a Total Exhaust BSC) is expensive to operate because no air is recirculated within. Therefore, this type is mainly found in such applications as toxicology laboratories, where the ability to safely use hazardous chemistry is important. Additionally, there is the risk that contaminated air would flow into the laboratory if the exhaust system for a Type B1 or B2 cabinet were to

fail. To mitigate this risk, cabinets of these types generally monitor the exhaust flow, shutting off the supply blower and sounding an alarm if the exhaust flow is insufficient. The Type C1 BSC was borne out of necessity to control infectious material, chemical hazards, reduce operating costs and add flexibility in modern laboratories. The Type C1 moves air by mixing inflow air with the air in the columns of downflow air marked for recirculation. Air above a clearly delineated section of the work surface is drawn by a second internal fan where it is exhausted through a HEPA filter. The C1 differs from a Type A in that it can use this single pass airflow, and when installed in a ducted operating mode, can protect from hazardous chemistry, like the Type Bs. The C1 also differs from the Type B BSCs in several ways; (1) it does not require a hard connected, dedicated exhaust system and blower to operate, (2) pending a risk assessment, the BSC can run for an extended duration to increase operator protection during a remote exhaust system failure, and (3) Type C1 BSCs can run without being connected to an exhaust system at all.

3. Class 3: The Class III cabinet, generally only installed in maximum containment laboratories, is specifically designed for work with BSL-4 pathogenic agents, providing maximum protection. The enclosure is gas-tight, and all materials enter and leave through a dunk tank or double-door autoclave. Gloves attached to the front prevent direct contact with hazardous materials (Class III cabinets are sometimes called glove boxes). These custom-built cabinets often attach into a line, and the lab equipment installed inside is usually custom-built as well.

4. Biosafety Levels

A biosafety level (BSL), or pathogen/protection 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). In the United States, the Centers for Disease Control and Prevention (CDC) have specified these levels. In the European Union, the same biosafety levels are defined in a directive. In Canada the four levels are known as Containment Levels. Facilities with these designations are also sometimes given as P1 through P4 (for pathogen or protection level), as in the term P3 laboratory.

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.

History:

The first prototype Class III (maximum containment) biosafety cabinet was fashioned in 1943 by Hubert Kaempf Jr., then a U.S. Army soldier, under the direction of Arnold G. Wedum, Director (1944–69) of Industrial Health and Safety at the United States Army Biological Warfare Laboratories, Camp Detrick, Maryland. Kaempf was tired of his MP duties at Detrick and was able to transfer to the sheet metal department working with the contractor, the H.K. Ferguson Co.

On 18 April 1955, 14 representatives met at Camp Detrick in Frederick, Maryland. The meeting was to share knowledge and experiences regarding biosafety, chemical, radiological, and industrial safety issues that were common to the operations at the three principal biological warfare (BW) laboratories of the U.S. Army. Because of the potential implication of the work conducted at biological warfare laboratories, the conferences were restricted to top level security clearances. Beginning in 1957, these conferences were planned to include non-classified sessions as well as classified sessions to enable broader sharing of biological safety information. It was not until 1964,

however, that conferences were held in a government installation not associated with a biological warfare program.

Over the next 10 years, the biological safety conferences grew to include representatives from all federal agencies that sponsored or conducted research with pathogenic microorganisms. By 1966, it began to include representatives from universities, private laboratories, hospitals, and industrial complexes. Throughout the 1970s, participation in the conferences continued to expand and by 1983 discussions began regarding the creation of a formal organization. The American Biological Safety Association (ABSA) was officially established in 1984 and a constitution and bylaws were drafted the same year. As of 2008, ABSA includes some 1,600 members in its professional association.

In 1977 Jim Peacock of the Australian Academy of Science asked Bill Snowdon, then Chief CSIRO AAHL if he could have the newly released USA NIH and the British equivalent requirements for the development of infrastructure for bio-containment reviewed by AAHL personnel with a view to recommending the adoption of one of them by Australian authorities. The review was carried out by CSIRO AAHL Project Manager Bill Curnow and CSIRO Engineer Arthur Jenkins. They drafted outcomes for each of the levels of security. AAHL was notionally classified as "substantially beyond P4". These were adopted by the Australian Academy of Science and became the basis for Australian Legislation. It opened in 1985 costing $185 million, built on Corio Oval.[9] The Australian Animal Health Laboratory is a Class 4/ P4 Laboratory.

Levels:

1. Biosafety Level 1: Biosafety level 1 (BSL-1) is suitable for work with well-characterized agents which do not cause disease in healthy humans. In general, these agents should pose minimal potential hazard to laboratory personnel and the environment. At this level, precautions are limited relative to other levels. Laboratory personnel must wash their hands upon entering and exiting the lab. Research with these agents may be performed on standard open laboratory benches without the use of special containment equipment. 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. This level of biosafety is appropriate for work with several kinds of microorganisms including non-pathogenic strains of *Escherichia coli* and *Staphylococcus*, *Bacillus subtilis*, *Saccharomyces cerevisiae* and other organisms not suspected to contribute to human disease. Due to the relative ease and safety of maintaining a BSL-1 laboratory, these are the types of laboratories generally used as teaching spaces for high schools and colleges.

2. Biosafety Level 2: At this level, all precautions used at Biosafety Level 1 are followed, and some additional precautions are taken. BSL-2 differs from BSL-1 in that:

    1. Laboratory personnel have specific training in handling pathogenic agents and are directed by scientists with advanced training.

    2. Access to the laboratory is limited when work is being conducted.

    3. Extreme precautions are taken with contaminated sharp items.

    4. Certain procedures in which infectious aerosols or splashes may be created are conducted in biological safety cabinets or other physical containment equipment.

    5. Biosafety level 2 is suitable for work involving agents of moderate potential hazard to personnel and the environment. This includes various microbes that cause mild disease to humans, or are difficult to contract via aerosol in a lab setting. Examples include Hepatitis A, B, and C viruses, human immunodeficiency virus (HIV), pathogenic strains of *Escherichia coli* and *Staphylococcus, Salmonella, Plasmodium falciparum*, and *Toxoplasma gondii*.

3. Biosafety Level 3: Biosafety level 3 is appropriate for work involving microbes which can cause serious and potentially lethal disease via the inhalation route. This type of work can be done in clinical, diagnostic, teaching, research, or production facilities. Here, the precautions undertaken in BSL-1 and BSL-2 labs are followed, as well as additional measures including:

    1. All laboratory personnel are provided medical surveillance and offered relevant immunizations (where available) to reduce the risk of an accidental or unnoticed infection.

    2. All procedures involving infectious material must be done within a biological safety cabinet.

    3. Laboratory personnel must wear solid-front protective clothing (i.e. gowns that tie in the back). This cannot be worn outside of the laboratory and must be discarded or decontaminated after each use.

    4. A laboratory-specific biosafety manual must be drafted which details how the laboratory will operate in compliance with all safety requirements.

    5. 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.

    6. Biosafety level 3 is commonly used for research and diagnostic work involving various microbes which can be transmitted by aerosols and/or cause severe disease. These include *Francisella tularensis*, *Mycobacterium tuberculosis*, *Chlamydia*

psittaci, Venezuelan equine encephalitis virus, Eastern equine encephalitis virus, SARS-CoV-1, SARS-CoV-2, MERS-CoV, Coxiella burnetii, Rift Valley fever virus, *Rickettsia rickettsii*, several species of Brucella, chikungunya, yellow fever virus, West Nile virus, *Yersinia pestis*.

4. Biosafety Level 4: Biosafety level 4 (BSL-4) is the highest level of biosafety precautions, and is appropriate for work with agents that could easily be aerosol-transmitted within the laboratory and cause severe to fatal disease in humans for which there are no available vaccines or treatments. BSL-4 laboratories are generally set up to be either cabinet laboratories or protective-suit laboratories. In cabinet laboratories, all work must be done within a class III biosafety cabinet. Materials leaving the cabinet must be decontaminated by passing through an autoclave or a tank of disinfectant. The cabinets themselves are required to have seamless edges to allow for easy cleaning. Additionally the cabinet and all materials within must be free of sharp edges in order to reduce the risk of damage to the gloves. In a protective-suit laboratory, all work must be done in a class II biosafety cabinet by personnel wearing a positive pressure suit. In order to exit the BSL-4 laboratory, personnel must pass through a chemical shower for decontamination, then a room for removing the positive-pressure suit, followed by a personal shower. Entry into the BSL-4 laboratory is restricted to trained and authorized individuals, and all persons entering and exiting the laboratory must be recorded. As with BSL-3 laboratories, BSL-4 laboratories must be separated from areas that receive unrestricted traffic. Additionally airflow is tightly controlled to ensure that air always flows from "clean" areas of the lab to areas where work with infectious agents is being performed. The entrance to the BSL-4 lab must also employ airlocks to minimize the possibility that aerosols from the lab could be removed from the lab. All laboratory waste, including filtered air, water, and trash must also be decontaminated before it can leave the facility. 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, and 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 is only performed at the Centers for Disease Control and

Prevention in Atlanta, United States, and the State Research Center of Virology and Biotechnology in Koltsovo, Russia.

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DEPARTMENT OF BIOTECHNOLOGY

UNIT – II – Biosafety Guidelines – SBT1401

I. Biosafety Guidelines & Regulations

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: biorisk 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.

Biosafety guidelines must be made clear, practical and suitable for each facility and must be available for easy reference by all staff, must be reviewed, and updated regularly. While it provides guidance in the application of biosafety practices, this technical guide cannot solely ensure a safe working environment without the commitment of each person to adhere adequately to the biosafety guidelines at all times. Continuous research on biosafety can improve the development of future guidelines.

II. GMOs & LMOs

Genetically engineered crops refer to alterations in the genetic makeup of the crop by introgression new traits such as herbicide tolerance, virus resistance, drought, flood and frost resistance, delay in maturation time of the crop and increased crop yield. They can be made resistant to pests and diseases which can significantly reduce the consumption of insecticide. Biodiversity is the feedstock for biotechnology industries. Although the benefits of transgenic technology are clear, the potential risks have created public concerns about the wisdom of releasing and consuming genetically modified (GM) crops. Biotechnological tool such as recombinant DNA technology has come a long way in solving the problem of food security. Genetic modification can help humankind to face new challenges as a result of high population growth, biodiversity loss and climate change. Therefore, it is imperative to have robust biosafety protocols/ procedures for India. While designing GM crops, the native species and gene in question needs to be taken into account. GM crops might become agricultural weeds or invade natural habitats if proper risk assessment (RA) is not performed prior to their release. The possible impacts of GM crops are as follows:

1. Weediness and invasiveness: One of the potential concerns about genetically modified organisms (GMOs) is that they will become agricultural weeds or invade natural habitats, as the traits introduced by GMOs might increase the reproductive success or fitness of the crop, thereby increasing its competitive ability. One conjectural risk is that GMOs will either cause the host species to become invasive or will escape from the original host species or cause other species to become invasive. Ellstrand et al. suggested that new combinations can create genotypes with different and surprising ecological behaviors. Researches have shown that the gene flow from transgenic crop is easy to escape to the weedy relative Brassica campestris. Canola is also capable of cross pollinating with several other weed species including wild radish (Raphanus raphanistrum) and buchan weed (Alternanthera philoxeroides).

2. The transgene escape to weedy relatives through pollen is one of the potential risks of GM crops. Gene flow indicates the movement of genes or genetic materials from one population into another. There are three avenues for gene flow to occur: pollen-mediated, seed-mediated and vegetative-propagule-mediated gene flow. To minimize the possibility of transgene flow, a number of strategies have been developed or proposed, applying physical and biological

approaches include confined field trial, transgenic mitigation, maternal inheritance, male sterility, cleistogamy, apomixis, incompatible genomes, temporal control via inducible primers and seed sterility. These are called “genetic use restriction technologies” or GURTs. Some of the mitigation techniques are as follows:

1. Confined field trial strategy: One of the ways to understand the gene flow is to conduct confined field trial (CFT). CFT is a small-scale experiment, done in the open field, with the intention of confining plant genes and plant material to trial site. CFTs are needed for breeding trials to incorporate traits into locally adapted varieties or to create populations for genetic study, to collect safety data to inform regulatory decisions on GM crops commercial release, to scale up experimental crops so that sufficient seed or other plant material is available for animal-feeding studies, or to study possible environmental impacts such as plant characteristics, potential for weediness, changes in pollen production, or gene flow.

2. Transgenic mitigation strategy: A transgenic mitigation (TM) strategy is also available for reducing the potential risks of escaped transgene(s) to the weedy or wild populations by co-introducing “mitigator” genes that are tandemly linked to the target transgene(s) to deliberately reduce the fitness of any hybrid and its progene i.e. the individuals carrying those traits would be eliminated in natural populations through competition with other more highly fit native individuals. Some of the deleterious traits that have been proposed are abolition of secondary dormancy, dwarfing and inhibition of shattering of seeds. A mitigator dwarfing Δgai (gibberelic acid-insensitive) gene, when transformed into tobacco, reduced fitness by 17% and was predicted to slow escape from a few generations to many thousands, depending on rates of gene flow and levels of recombination. Thus, TM would limit transgene escape through pollen and seed flow.

3. Chloroplast transformation: To prevent gene flow via pollen, transgenes can be targeted to chloroplast genomes, which are generally transmitted only through ovules of the female parent. Numerous transgenes have been successfully integrated into chloroplasts in wide variety of plant species, and this approach has been shown to block pollen flow of the transgene in tobacco and tomato. Although targeting

transgenes to the chloroplast will not completely limit all the gene flow, as it does not restrict transgene movement via seed dispersal.

4. Male sterility: Inserting transgenes into male sterile lines is another means of preventing transgene escape via pollen flow. Either naturally derived male sterile lines can be used or male-sterility mutants can be engineered. One approach is to use tapetum-specific promoters to derive expression of a recombinant RNase gene. Plant Genetics Systems (Ghent, Belgium) has engineered male-sterile and male-restorer lines of GM rapeseed utilizing two genes from Bacillus amyloliquefaciens-barnase, which cleaves RNA and barstar, a protein that binds to barnase and prevents its function. The central pitfall of using male-sterile lines, is it can only be used for vegetative crops.

III. Roles of IBSC

Institutional Biosafety Committees (IBSCs) were established as per the "Rules for the manufacture, use/import/export and storage of hazardous microorganisms/ genetically engineered organisms or cells, 1989" (commonly referred as Rules, 1989) notified by the Ministry of Environment Forests and Climate Change (MoEF&CC), Government of India under the Environment (Protection) Act (1986) to provide review at institutional level and oversight of nearly all forms of research utilizing recombinant or synthetic nucleic acid molecules. Additional responsibility regarding biological materials (e.g., infectious agents) and other potentially hazardous agents (e.g., carcinogens) is also assigned to them.

Responsibilities of IBSCs:

1. Containment levels or its modification warranted; including physical containment, biological containment, physical containment for large-scale uses of organisms containing recombinant or synthetic nucleic acid molecules, physical and biological containment for recombinant or synthetic nucleic acid molecule research involving plants, physical and biological containment for recombinant or synthetic nucleic acid molecule research involving animals.

2. Facilities at the institute;

3. Institutional procedures and practices;

4. Training and expertise of personnel involved

5. Research projects are in compliance with the institution's health surveillance requirements and data and adverse event reporting requirements.

6. Implement contingency plans for handling accidental spills and personnel infection resulting from research involving recombinant or synthetic nucleic acid molecules; and

7. Report to RCGM of any substantial problems or violations of the guidelines; and significant research related accidents or illnesses.

RCGM:

The RCGM is constituted by the DBT to monitor the safety aspects of ongoing research projects and activities involving genetically engineered organisms. The committee is also mandated to bring out Manuals of Guidelines specifying procedures for regulatory process with respect to activities involving genetically, engineered organisms in research, use and application including industry with a view to ensure environmental safety.

All ongoing projects involving high risk category and controlled field experiments shall be reviewed by the RCGM to ensure that adequate precautions and containment conditions are followed. The RCGM can lay down procedures restricting or prohibiting production, sale, importation and use of GMOs.

1. RCGM can approve applications for generating research information on transgenic plants. RCGM can also direct the generation of toxicity, allergenicity and any other relevant data on transgenic materials in appropriate systems.

2. The RCGM can issue clearances for import/export of etiologic agents and vectors, transgenic germplasms including transformed calli, seed and plant parts for research use only.

3. The RCGM can put such conditions as would be required to generate long term environmental safety data from the applicants seeking release of transgenic plants into the open environment.

GEAC:

This Committee functions as a body in the Ministry of Environment & Forests and is responsible for approval of activities involving large scale use of GMOs in research, industrial production and applications. The clearance of GEAC is only from environmental angle under the EPA.

All other relevant laws would apply even though EPA clearance is available for using GMOs and products thereof; for example, drugs made through GMOs would require separate approval for manufacture and use under the Indian Drugs Acts; production of GMOs is also authorised under Indian Industries (Development, and Regulation) Act, and therefore these, clearances are also mandatory. Now, this committee is known as Genetic Engineering Appraisal Committee.

RDAC:

This Committee constituted by the Department of Biotechnology (DBT) of the Union Ministry of Science & Technology is to monitor the developments in biotechnology at national and international levels. The RDAC submits recommendations from time to time that are suitable for implementation for upholding the safety regulations in research and application of GMOs and products thereof.

IBSC:

This Committee is constituted by the organizations involved in research with GMOs. The committee requires the approval of the DBT. IBSC also has a nominee from the DBT who oversees the activities to ensure that safety aspects in accordance with the safety guidelines are fully adhered to by the organisation.

Every R&D project using GMOs has to have an identified investigator who is required to inform the IBSC about the status and results of the experiments being conducted.

SBCC:

This Committee, headed by the Chief Secretary of the respective State is constituted in each Indian state where research application of GMOs are contemplated. The Committee has the powers to inspect, investigate and take punitive actions in case of violations of the statutory provisions.

DLC:

This Committee is constituted at the district level to monitor the safety regulations in installations engaged in the use of GMOs in research and applications. The District Collector heads the Committee, who can induct representatives from State agencies to enable the smooth functioning and inspection of the installations with a view to ensure the implementation of safety guidelines while handling GMOs under the Indian EPA.

IV. RCGM

This committee shall function in the Department of Biotechnology. Its Functions are:

1. To review the reports in all approved /ongoing projects involving high risk category and controlled field experiments research in four areas namely human and animal healthcare, agriculture, industry and environmental management.

2. To visit site of experimental facilities periodically where projects with biohazard potential are being pursued and also at a time prior to the commencement of the activity to ensure that adequate safety measures are taken as per the guidelines.

3. To issue clearance for import/export of etiologic agents and vectors, germ plasms, organelle, etc. needed for experimental work/training and research.

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DEPARTMENT OF BIOTECHNOLOGY

UNIT – III – INTELLECTUAL PROPERTY RIGHTS – SBT1401

I. Types of IPR

Patent:

1. A patent is used to prevent an invention from being created, sold, or used by another party without permission. Patents are the most common type of intellectual property rights that come to people's minds when they think of intellectual property rights protection. A Patent Owner has every right to commercialize his/her/its patent, including buying and selling the patent or granting a license to the invention to any third party under mutually agreed terms.

2. There are three different categories that patents can fall under:
   a. Utility: A utility patent protects the creation of a new or improved product, process, composition of matter, or machine that is useful. An example of utility patent: Method for a driver assistance system of a vehicle US9772626B2
   b. Design: A design patent protects the ornamental design on a useful item. An example of design patent: Electric bicycle USD845178S1
   c. Plant: A plant patent protects new kinds of plants produced by cuttings or other nonsexual means. An example of plant patent: Crapemyrtle plant named 'JM1' USPP31585P2

Trademark:

Trademarks are another familiar type of intellectual property rights protection. A trademark is a distinctive sign which allows consumers to easily identify the particular goods or services that a company provides. Some examples include McDonald's golden arch, the Facebook logo, and so on. A trademark can come in the form of text, a phrase, symbol, sound, smell, and/or color scheme. Unlike patents, a trademark can protect a set or class of products or services, instead of just one product or process.

Copyright:

Copyright does not protect ideas. Rather, it only covers “tangible” forms of creations and original work–for example, art, music, architectural drawings, or even software codes. The copyright owner has the exclusive right to sell, publish, and/or reproduce any literary, musical, dramatic, artistic, or architectural work created by the author.

Trade Secret:

Trade secrets are the secrets of a business. They are proprietary systems, formulas, strategies, or other information that is confidential and is not meant for unauthorized commercial use by others. This is a critical form of protection that can help businesses to gain a competitive advantage.

Although intellectual property rights protection may seem to provide a minimum amount of protection, when they are utilized wisely, they can maximize the benefit and value of a creation and enable world-changing technology to be developed, protected, and monetized.

II. Industrial Design

An industrial design right is an intellectual property right that protects the visual design of objects that are not purely utilitarian. An industrial design consists of the creation of a shape, configuration or composition of pattern or color, or combination of pattern and color in three-dimensional form containing aesthetic value. An industrial design can be a two- or three-dimensional pattern used to produce a product, industrial commodity or handicraft.

Under the Hague Agreement Concerning the International Deposit of Industrial Designs, a WIPO-administered treaty, a procedure for an international registration exists. To qualify for registration, the national laws of most member states of WIPO require the design to be novel. An applicant can file for a single international deposit with WIPO or with the national office in a country party to the treaty. The design will then be protected in as many member countries of the treaty as desired. Design rights started in the United Kingdom in 1787 with the Designing and Printing of Linen Act and have expanded from there. Registering for an industrial design right is related to granting a patent.

Legislation:

1. Kenya: According to industrial property Act 2001, an industrial design is defined as "any composition of lines or colours or any three-dimensional form whether or not associated with lines or colours, provided that such composition or form gives a special appearance to a product of industry or handicraft and can serve as pattern for a product of industry or handicraft". An industrial design is registrable if it is new. An industrial design is deemed to be new if it has not been disclosed to the public, anywhere in the world, by publication in tangible form or, in Kenya by use or in any other way, prior to the filing date or, where applicable, the priority date of the application for registration. However a disclosure of the industrial design is not taken into consideration if it occurred not earlier than twelve months before the filing date or, where applicable, the priority date of the application and if it was by reason or in consequence of acts committed by the applicant or his predecessor in title; or an evident abuse committed by a third party in relation to the applicant or his predecessor in title.

2. India: India's Design Act, 2000 was enacted to consolidate and amend the law relating to protection of design and to comply with the articles 25 and 26 of Trade-Related Aspects of Intellectual Property Rights TRIPS agreement. The new act, (earlier Patent and Design Act, 1911 was repealed by this act) now defines "design" to mean only the features of shape, configuration, pattern, ornament, or composition of lines or colours applied to any article, whether in two- or three-dimensional, or in both forms, by any industrial process or means, whether manual or mechanical or chemical, separate or combined, which in the finished article appeal to and are judged solely by the eye; but does not include any mode or principle of construction.

3. Indonesia: In Indonesia the protection of the Right to Industrial Design shall be granted for 10 (ten) years commencing from the filing date and there is not any renewal or annuity after the given period. Industrial Designs that are Granted Protection

    a. The Right to Industrial Design shall be granted for an Industrial Design that is novel/new

    b. An Industrial Design shall be deemed new if on the filing date, such Industrial Design is not the same as any previous disclosure.

    c. The previous disclosure as referred to in point 2 shall be one which before:
        i. The filing date or
        ii. The Priority Date, if the applicant is filed with priority right.
        iii. Has been announced or used in Indonesia or outside Indonesia.

    d. An industrial design shall not be deemed to have been announced if within the period of 6 (six) months at the latest before the filing date, such industrial design:

        i. Has been displayed in a national or international exhibition in Indonesia or overseas that is official or deemed to be official; or,
        ii. Has been used in Indonesia by the designer in an experiment for the purposes of education, research or development.

III. Traditional Knowledge

Recognition of intellectual property rights (IPRs) over traditional knowledge (TK) held by indigenous peoples and local communities (ILCs), particularly TK associated with biodiversity and genetic resources (GRs), is an important step in actualising sustainable development. This paper argues that TK can act as an enabler of sustainable development for ILCs through recognition of IPRs over TK relating to natural capital and effective sharing of fair and equitable benefits as envisioned under international treaties and conventions. First, a brief background will be provided to illustrate the increasing trend in international law towards recognition and establishment of protections relating to TK, and to define sustainable development and TK for the purposes of this discussion. Second, contemporary points of divergence will be summarised to highlight perceived tensions relating to the use of IPRs to govern TK. Third, arguments favouring recognition of IPRs over TK held by ILCs are put forward to illustrate current legal trends and mechanisms supporting recognition. Fourth, critical considerations are provided to reconcile perceived tensions, illustrating the compatibility and importance of recognising IPRs in TK and of vesting ownership with ILCs in operationalising the 2030 development agenda. Finally, concluding thoughts are offered which summarise key findings and identify remaining challenges. For sustainable development to become a reality, legal recognition and protection of IPRs relating to TK through the empowerment of ILCs is a prerequisite enabling catalyst.

Background:

Beginning around the mid-twentieth century, the international community began a progressive migration towards recognition of the need for sustainable development, and appreciation for the importance of TK held by ILCs in achieving such a profound policy objective. Early policy consideration, which began among the United Nations Economic and Social Council, United Nations Educational, Scientific and Cultural Organization, and International Union for the Protection of Nature, expanded global recognition through the first UN Conference on the Human Environment held in Stockholm in 1972,1 and gained wider appeal in policy nomenclature through the 1987 report of the World Commission on Environment and Development (WCED), 'Our Common Future.'2 Where the Brundtland Report —named for the WCED Chair— established sustainable development as a policy objective, the 1992 United Nations Conference on Environment and Development in Rio

de Janeiro (Rio Earth Summit) conceptually endorsed and empowered the model concurrent to the opening for signature of the Rio Treaties: 1992 United Nations Convention on Biological Diversity (CBD), the 1992 United Nations Framework Convention on Climate Change (UNFCCC), and the 1994 United Nations Convention to Combat Desertification (UNCCD), which collectively establish rules and regimes committed to sustainable development.3 Evolving in parallel, the World Trade Organization (WTO) in 1994 established as part of the covered agreements the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS),4 which aimed to standardise IPRs across Member States to facilitate international trade.

The CBD, along with the 2010 Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol), establish the preeminent international regime for the recognition and protection of TK. Under Article 8(j) of the CBD, Parties are required to respect and maintain knowledge held by ILCs, and to encourage wider application of TK based on fair and equitable benefit-sharing.5 TK is further recognised in Article 16 as a vital 'technology' for effective practices of conservation and sustainable use of biodiversity,6 with procedural requirements established in Article 15(4–5) for access to genetic resources including based on prior informed consent (PIC) and mutually agreed terms (MAT). The Nagoya Protocol,7 which entered into force in 2014, expands upon the CBD provisions establishing a substantive regime governing access and benefit-sharing (ABS).8 Specifically requirements are established relating to: access to genetic resources and TK based on PIC and MAT,9 mandatory benefit-sharing obligations,10 recognition of community protocols and customary use of GRs and TK among ILCs,11 and compliance and monitoring measures.12 Other relevant evolutions relating to TK which developed concurrently to progress in the CBD leading up to the Protocol include the establishment of: (1) the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) passed by the Food and Agriculture Organization Conference in 2001, and entering in force on 29 June 2004,13 which provides for protections relating to 'farmers rights' including TK and traditional breading practices,14 (2) the Intergovernmental Committee (IGC) on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore established under the World Intellectual Property Organization (WIPO) in 2000,15 which provides a forum for negotiations on issues underlying development of a binding international instrument on TK,16 and (3) the 2007 United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP) which vests rights relating to 'control, protection and development' of TK, as well as IPRs relating to TK, with ILCs.

IV. Importance of IPR

Intellectual property rights are accepted all over the world due to some important reasons. They were essentially recognized for the acceptations of these rights are:-

1. Provides incentive to the individual for new creations.
2. Providing due recognition to the creators and inventors.
3. Ensuring the material reward for intellectual property.
4. Ensuring the availability of the original products.
5. For economic growth and advancement in technology sector protection of Intellectual property protection is important.
6. They are benefited for the growth of the business in the field of technology.

INTELLECTUAL PROPERTY LAW INTRODUCTION

INTELLECTUAL PROPERTY LAW Comprises of the following Laws:-

1. The Laws relating to Trade Marks / Brands (Trade Marks Act, 1999), Property Marks
2. The Laws relating to Copyright (Copyright Act, 1957) Artistic Work, Literary Work, Audio Video Records and Software
3. The Laws relating to Industrial Designs (Designs Act, 2000)
4. The Laws relating to Patents (The Patent Act, 1970)
5. The Laws relating to Geographical Indications. The geographical Indications of (Registration and Protection) Act, 1999
6. The Laws relating to Internet (Information Technology Act, 2000)

INTELLECTUAL PROPERTY RIGHT INFRINGEMENT-An intellectual property infringement is the infringement or violation of an intellectual property right.

Copyright infringement-

Copyright-It is a type of protection which is given to the authors of original works including literary, dramatic, and musical and certain other intellectual works, which may be published and unpublished.

Copyright infringement (or copyright violation) is the use of material unauthorised that is covered by copyright law, that violates one of the copyright owner's exclusive rights, such as the right to perform the copyrighted work. It is also known as copyright violation.

Patent infringement-

Patent-It is issued by United States Patent and Trademark Office. A patent is the right to the inventor for an invention.

Patent infringement prohibition act with respect to a patented invention without permission from the patent holder. By means of the licence permission may be granted. It is also known as patent violation.

Trademark – A trademark gives separate identity to the goods and services to make them distinguish from the others. It protects words, names, symbols, sounds. Trademarks can be renewed for forever or as long as they are going to be used. There is no need for registration of a trademark in the U.S.

Trademark infringement is a violation of the exclusive rights attaching to a trademark without the authorization of the trademark owner or any licensees. Infringement may occur when one party, the "infringer", uses a trademark which is identical to a trademark owned by another party, in relation to products or services which are identical or similar to the products or services which the registration covers. An owner of a trademark may commence legal proceedings against a party which infringes its registration. It is also known as trademark violation.

Objectives-

1. To know the reasons infringement of the intellectual property rights.

2. To know why to care about IPR?
3. What the protection measures and provisional measures?
4. Case related to Intellectual Property Right Infringement.

Review of literature-

Economic Effect of Intellectual Property Right Infringement

There is a great effect of Intellectual Property Right Infringement .U.S companies suffer losses in recent years because their Intellectual Property Rights (trademarks, copyrights and patents) are not properly protected abroad. International Trade Commission data is collected from 244 US firms and the data is used to study economic effect of foreign infringement of US intellectual property rights in five sectors of industry. The profit and losses of US suppliers is much as compared to total profits, this implies that the losses are greater than the profits earned by suppliers who are infringing on rights, but that the losses may be least than the benefits to infringers and consumers.

From Research it is pointed out that research results suggest that Lessing profits lost to infringers by one percent would require significant increases in identification and enforcement costs.

RESEARCH METHODOLGY-

TYPES OF DATA USED-Secondary data

SOURCES OF SECONDARY DATA- Data is collected from the journals, Newspapers, Internet

CAUSES OF INFRINGEMENT OF INTELLECTUAL PROPERTY RIGHTS INFRINGEMENT

1. Too much cost of Research and development.
2. Globalisation
3. Litigation delays in implementing ip rights and award of damages
4. Software piracy

WHY CARE ABOUT IPR-

1. Patents are benefit to the owner of the IP and it add importance to industrial as well as business concerns , discoveries and provide incentives for private sector investment into their development. They all should have separate Research and development center.
2. Globalization and advancement of technology has played an important role in intellectual property protection for small and medium sized enterprises. The intangible nature of intellectual property creates challenges for those businesses, to protect their inventions, brands, and business in foreign markets.
3. Intellectual property protection is necessary to the success of biotechnology companies. For these companies, the patent system serves to encourage them for the development of new medicines and diagnostics for treatment and monitoring diseases, and agricultural products.

HOW TO OBTAIN INFORMATION ABOUT INFRINGEMENT OF TRADE MARK / COPYRIGHT

The best way to get information about the piracy of trade mark / copyright is companies marketing strategies.

The best alternative is engagement of detective agencies on contractual basis, which have their own other network.

By surveys in major metropolitan cities of India, the information can be obtained about the infringement / piracy of goods and these surveys will lead to and result in the identification of manufacturing, go downs, distribution network.

JUDICIAL SYSTEM IN INDIA

The Indian judicial system is independent from executive / government and it is creation of Constitution of India. It is mandatory to obey the orders of the Courts in India by

Central & State Governments and any non-compliance of the order of the courts are taken as very serious and that may result in the fine and / or imprisonment. In India High Court and Supreme Court judgments has the force of the law. Even in the world the Indian Judicial System is one of the best legal systems which have codified laws and established procedures.

REMEDIES AVAILABLE UNDER INDIAN LAWS:

CIVIL REMEDIES

1. Injunction/ stay against the use of trade

2. Damages can be claimed

3. Accounts and handing over of profits

4. For custody there is appointment of local commissioner/infringing material sealing.

5. Under order 39 rule 1 & 2 of the CPC the application is filed.

CRIMINAL REMEDIES

1. Before the chief judicial magistrate the complaint is filed.

2. Evidence of the infringement of the IPR.

3. Under sec. 93/94 the application is filed.

4. Search of infringing material is done by Police as per orders and directions given by the court.

5. Lodging of fir and search under section. 156 of the criminal procedure code, 1973.

JURISDICTION FOR FILING CIVIL / CRIMINAL LITIGATION

Civil Cases- The jurisdiction for filing in a civil suit will include given facts and fulfillment of given conditions:-

1. From where the cause of action has occrued?

2. Where the violations of IPRs are taking place?

3. Where the defendants work for gain?

4. Trade Marks Act, 1999, it provides an exception, to registered trade mark and the registered Trade Mark owner can file a case with in court, from where the holder is carrying its business.

5. The jurisdiction for filing a case depends on the activities of the defendants.

6. There is no need to file a suit in different courts separately.

PROTECTION AGAINST INTELLECTUAL PROPERTY RIGHTS INFRINGEMENT

The infringement of intellectual property rights (IPRs) are by administrative procedures and legal proceedings. In civil liabilities, the infringer may ordered to stop the violated activities, eradicate the damage done, make public apologies and compensate for all the damages. In administrative measures, they include warnings in order to stop the violating activities, fines, and compensation for damages made.

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UNIT – IV – Aggreements and Treaties – SBT1401

I. History of GATT and TRIPS aggreement

TRIPS was negotiated during the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) in 1986–1994. Its inclusion was the culmination of a program of intense lobbying by the United States, supported by the European Union, Japan and other developed nations. Campaigns of unilateral economic encouragement under the Generalized System of Preferences and coercion under Section 301 of the Trade Act played an important role in defeating competing policy positions that were favored by developing countries like Brazil, but also including Thailand, India and Caribbean Basin states. In turn, the US strategy of linking trade policy to intellectual property standards can be traced back to the entrepreneurship of senior management at Pfizer in the early 1980s, who mobilized corporations in the United States and made maximizing intellectual property privileges the number one priority of trade policy in the United States (Braithwaite and Drahos, 2000, Chapter 7).

After the Uruguay round, the GATT became the basis for the establishment of the World Trade Organization. Because ratification of TRIPS is a compulsory requirement of World Trade Organization membership, any country seeking to obtain hard access to the numerous international markets opened by the World Trade Organization must enact the strict intellectual property laws mandated by TRIPS. For this reason, TRIPS is the most important multilateral instrument for the globalization of intellectual property laws. States like Russia and China,[5] that were very unlikely to join the Berne Convention have found the prospect of WTO membership a powerful enticement.

Unlike other agreements on intellectual property, TRIPS has a powerful enforcement mechanism. States can be disciplined through the WTO's dispute settlement mechanism.

II. Madrid Aggreement

The Madrid system (officially the Madrid system for the international registration of marks) is the primary international system for facilitating the registration of trademarks in multiple jurisdictions around the world. Its legal basis is the multilateral treaty Madrid Agreement Concerning the International Registration of Marks of 1891, as well as the Protocol Relating to the Madrid Agreement (1989).

The Madrid system provides a centrally administered system of obtaining a bundle of trademark registrations in separate jurisdictions. Registration through the Madrid system does not create a unified registration, as in the case of the European Union trade mark[1] system; rather, it creates a bundle of national rights through an international registration able to be administered centrally. Madrid provides a mechanism for obtaining trademark protection in many countries around the world which is more effective than seeking protection separately in each individual country or jurisdiction of interest.

The Madrid Protocol system provides for the international registration of trade marks by way of one application that can cover more than one country. The opportunity of having a single registration to cover a wide range of countries gives advantages, both in terms of portfolio management and cost savings, as opposed to a portfolio of independent national registrations.

Madrid now permits the filing, registration and maintenance of trade mark rights in more than one jurisdiction, provided that the target jurisdiction is a party to the system. The Madrid system is administered by the International Bureau of the World Intellectual Property Organization (WIPO) in Geneva, Switzerland. There are 90 countries part of the Madrid System.

History:

The Madrid system comprises two treaties; the Madrid Agreement Concerning the International Registration of Marks, which was concluded in 1891, and entered into force in 1892, and the Protocol

Relating to the Madrid Agreement, which came into operation on 1 April 1996. The Madrid Agreement and Madrid Protocol were adopted at diplomatic conferences held in Madrid, Spain.

The Madrid Agreement was originally intended to provide for an international registration system, but did not achieve this for two significant reasons:

1. The lack of international acceptance. Many non-member countries, including the United Kingdom, the United States, and Central American, South American and Asian countries, such as Japan, were not adherents, which undermined recognition of the system as a truly "international" regime. Significantly, many of these countries represent the largest numbers of trademark filings and registrations in the world; and
2. The mere forwarding by the International Bureau of a uniform application to member countries, rather than the registration of the applicable trademark in the national trademark registers, precludes an actual "registration" system.

Some of the large trading nations like the United States, Japan, and Canada, which have a large number of filings at the national level, did not join the Madrid Agreement due to another perceived flaw in the system: if the home registration upon which an international registration was based came under 'central attack', the international registration would be cancelled or limited to the same extent that the home registration was cancelled or limited.

During 1966 and 1967, attempts were made to address this issue by establishing a new treaty that would reflect the need of the times rather than the world of the 1890s when the agreement was adopted. This led to the drafting of the Trademark Registration Treaty (TRT) which was adopted in Vienna in 1973, and entered into effect in 1980, with five contracting states, namely, Burkina Faso, Congo, Gabon, Soviet Union and Togo. In the absence of more accessions to the TRT and the low number of registrations since its inception, it was clear that the TRT was unlikely to supplant the Madrid Agreement.

As the realization of the introduction of a multi-jurisdictional (or at least pan-European) European Community Trade Mark (CTM) approached, the relevancy of the Madrid system came under scrutiny. Pressure increased on WIPO to maintain its relevance and strengthen the agreement by increasing membership, possibly through amendments. This culminated in the introduction of the Madrid Protocol, pursuant to which a CTM registration could be a 'foundation' or 'home' registration upon which an international registration could then be established. This mechanism is referred to as a "linking provision." The Protocol, after considerable lobbying efforts by WIPO, was signed by many countries, including most of the present members of the Madrid Agreement, and some countries that are members of the European Union, but were not members of the Madrid Agreement. The Protocol entered into force on December 1, 1995 and became operative on April 1, 1996.

Many countries have needed to modify or consider modifying their trademark laws in order to adhere to the Protocol, in addition to the modifications required by GATT-TRIPS/WTO.

In Europe, resistance to the Protocol was brought by trademark attorneys who were afraid of losing business because a Community Trade Mark application could be filed directly through the Madrid Protocol process.

In the United States, the proposal bogged down due to a trademark dispute between two businesses who were heavy campaign contributors to certain Congressmen, followed by a repeated reshuffling of the Senate due to elections and a subsequent defection of a Republican senator. The treaty was eventually ratified during the Presidency of George W. Bush.

Japan revised its trademark law with the official acceptance of the Nice Classification (an international trademark classification system for products and services), as well as applications covering service using service marks. The members of the European Community have amended their laws to conform to the European Community Harmonization Directive. In recent years trademark laws in several other countries such as Malaysia, New Zealand and South Africa have also been amended to accommodate the changes.

Members:

Adherence to the convention or the protocol includes membership of the "Madrid Union." As of June 2019, there are 104 members made out of 120 countries. The original treaty has 55 members, all of which are also party to the protocol (when Algeria joined the Madrid Protocol on October 31, 2015, all of the members of the Madrid Agreement were also members of the Madrid Protocol and many of the aspects of the Madrid Agreement ceased to have any practical effect). The term 'Madrid Union' can be used to describe those jurisdictions party to either the agreement or the protocol (or both).

The protocol has been in operation since 1996 and has 100 members making it more popular than the agreement, which has been in operation for more than 110 years and has 55 members. The primary reason the protocol is more popular than the agreement is that the protocol introduced a number of changes to the Madrid system which significantly enhanced its usefulness to trademark owners.

For example, under the protocol it is possible to obtain an international registration based on a pending trademark application, so that a trademark owner can effectively apply for international registration concurrently, or immediately after, filing an application in a member jurisdiction. By comparison, the agreement requires that the trademark owner already holds an existing registration in a member jurisdiction, which may often take many months and sometimes years to obtain in the first place. In addition, the agreement does not provide the option to 'convert' international registrations which have been 'centrally attacked.'

Table of Madrid Union members with year of accession to the agreement and protocol, as applicable

Contracting party	Agreement	Protocol
Afghanistan		2018
African Intellectual Property Organization (OAPI)		2015
Albania	1995	2003
Algeria	1972	2015
Antigua and Barbuda		2000
Armenia	1991	2000
Australia		2001
Austria	1909	1999
Azerbaijan	1995	2007
Bahrain		2005
Belarus	1991	2002
Belgium[a]	1892	1998
Bhutan	2000	2000

Bosnia and Herzegovina	1992	2009
Botswana		2006
Brazil		2019
Brunei Darussalam		2017
Bulgaria	1985	2001
Cambodia		2015
Canada		2019
China[b]	1989	1995
Colombia		2012
Croatia	1991	2004
Cuba	1989	1995
Cyprus	2003	2003
Czech Republic	1993	1996
North Korea	1980	1996
Denmark[c]		1996

Egypt	1952	2009
Estonia		1998
Eswatini	1998	1998
European Union[d]		2004
Finland		1996
France	1892	1997
The Gambia		2015
Georgia		1998
Germany	1922	1996
Ghana		2008
Greece		2000
Hungary	1909	1997
Iceland		1997
India		2013
Indonesia		2018

Iran	2003	2003
Ireland		2001
Israel		2010
Italy	1894	2000
Japan		2000
Kazakhstan	1991	2010
Kenya	1998	1998
Kyrgyzstan	1991	2004
Lao People's Democratic Republic		2016
Latvia	1995	2000
Lesotho	1999	1999
Liberia	1995	2009
Liechtenstein	1933	1998
Lithuania		1997
Luxembourg[a]	1924	1998

Madagascar		2008
Malawi		2018
Malaysia		2019
Mexico		2013
Monaco	1956	1996
Mongolia	1985	2001
Montenegro	2006	2006
Morocco	1917	1999
Mozambique	1998	1998
Namibia	2004	2004
Netherlands[a][e]	1893	1998
New Zealand[f]		2012
North Macedonia	1991	2002
Norway		1996
Oman		2007

Philippines		2012
Poland	1991	1997
Portugal	1893	1997
South Korea		2003
Republic of Moldova	1991	1997
Romania	1920	1998
Russian Federation	1976	1997
Rwanda		2013
Samoa		2019
San Marino	1960	2007
Sao Tome and Principe		2008
Serbia	1992	1998
Sierra Leone	1997	1999
Singapore		2000
Slovakia	1993	1997

Slovenia	1991	1998
Spain	1892	1995
Sudan	1984	2010
Sweden		1995
Switzerland	1892	1997
Syrian Arab Republic		2004
Tajikistan	1991	2011
Thailand		2017
Trinidad and Tobago		2020
Tunisia		2013
Turkey		1999
Turkmenistan		1999
Ukraine	1991	2000
United Kingdom[g]		1995
United States of America		2003

Uzbekistan		2006
Vietnam	1949	2006
Zambia		2001
Zimbabwe		2015

III. WIPO Treaty

The World Intellectual Property Organization (WIPO; French: Organisation mondiale de la propriété intellectuelle (OMPI)) is one of the 15 specialized agencies of the United Nations (UN Pursuant to the 1967 Convention Establishing the World Intellectual Property Organization, WIPO was created to promote and protect intellectual property (IP) across the world by cooperating with countries as well as international organizations. It began operations on 26 April 1970 when the convention entered into force.

WIPO's activities include hosting forums to discuss and shape international IP rules and policies, providing global services that register and protect IP in different countries, resolving transboundary IP disputes, helping connect IP systems through uniform standards and infrastructure, and serving as a general reference database on all IP matters; this includes providing reports and statistics on the state of IP protection or innovation both globally and in specific countries. WIPO also works with governments, nongovernmental organizations (NGOs), and individuals to utilize IP for socioeconomic development.

WIPO administers 26 international treaties that concern a wide variety of IP issues, ranging from the protection of broadcasts to establishing international patent classification.[8] It is governed by the General Assembly and the Coordination Committee, which together set policy and serve as the main decision making bodies. The General Assembly also elects WIPO's chief administrator, the Director-General, currently Francis Gurry of Australia, who took office on 1 October 2008 and was reappointed in May 2014 for a second six-year term. WIPO is administered by a secretariat that helps carry out its day-to-day activities.

Headquartered in Geneva, Switzerland, WIPO has "external offices" around the world, including in Algiers, Algeria; Rio de Janeiro, Brazil; Beijing, China, Tokyo, Japan; Moscow, Russia; and Singapore. Unlike most UN organizations, WIPO does not rely heavily on assessed or voluntary contributions from member states; 95 percent of its budget comes from fees related to its global services.

WIPO currently has 193 member states,including 190 UN member states and the Cook Islands, Holy See and Niue; Palestine has permanent observer status.The only nonmembers are the Federated States of Micronesia, Palau and South Sudan.

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SCHOOL OF BIO AND CHEMICAL ENGINEERING

DEPARTMENT OF BIOTECHNOLOGY

UNIT – V – Engineering Ethics & Bioethics – SBT1401

I. Engineering Ethics

Engineering ethics is the field of system of moral principles that apply to the practice of engineering. The field examines and sets the obligations by engineers to society, to their clients, and to the profession. As a scholarly discipline, it is closely related to subjects such as the philosophy of science, the philosophy of engineering, and the ethics of technology.

Background & Origin:

1. The 18th century & growing concern: As engineering rose as a distinct profession during the 19th century, engineers saw themselves as either independent professional practitioners or technical employees of large enterprises. There was considerable tension between the two sides as large industrial employers fought to maintain control of their employees. In the United States growing professionalism gave rise to the development of four founding engineering societies: The American Society of Civil Engineers (ASCE) (1851), the American Institute of Electrical Engineers (AIEE) (1884), the American Society of Mechanical Engineers (ASME) (1880), and the American Institute of Mining Engineers (AIME) (1871). ASCE and AIEE were more closely identified with the engineer as learned professional, where ASME, to an extent, and AIME almost entirely, identified with the view that the engineer is a technical employee. Even so, at that time ethics was viewed as a personal rather than a broad professional concern.

2. Turning of the 20th century and turning point: When the 19th century drew to a close and the 20th century began, there had been series of significant structural failures, including some spectacular bridge failures, notably the Ashtabula River Railroad Disaster (1876), Tay Bridge Disaster (1879), and the Quebec Bridge collapse (1907). These had a profound effect on engineers and forced the profession to confront shortcomings in technical and construction practice, as well as ethical standards. One response was the development of formal codes of ethics by three of the four founding engineering societies. AIEE adopted theirs in 1912. ASCE and ASME did so in 1914. AIME did not adopt a code of ethics in its history. Concerns for professional practice and protecting the public highlighted by these bridge failures, as well as the Boston molasses disaster (1919), provided impetus for another movement that had been underway for some time: to require formal credentials (Professional Engineering licensure in

the US) as a requirement to practice. This involves meeting some combination of educational, experience, and testing requirements. In 1950, the Association of German Engineers developed an oath for all its members titled 'The Confession of the Engineers', directly hinting at the role of engineers in the atrocities committed during World War II. Over the following decades most American states and Canadian provinces either required engineers to be licensed, or passed special legislation reserving title rights to organization of professional engineers. The Canadian model is to require all persons working in fields of engineering that posed a risk to life, health, property, the public welfare and the environment to be licensed, and all provinces required licensing by the 1950s. The US model has generally been only to require the practicing engineers offering engineering services that impact the public welfare, safety, safeguarding of life, health, or property to be licensed, while engineers working in private industry without a direct offering of engineering services to the public or other businesses, education, and government need not be licensed. This has perpetuated the split between professional engineers and those in private industry. Professional societies have adopted generally uniform codes of ethics.

3. Recent developments: Efforts to promote ethical practice continue. In addition to the professional societies and chartering organizations efforts with their members, the Canadian Iron Ring and American Order of the Engineer trace their roots to the 1907 Quebec Bridge collapse. Both require members to swear an oath to uphold ethical practice and wear a symbolic ring as a reminder. In the United States, the National Society of Professional Engineers released in 1946 its Canons of Ethics for Engineers and Rules of Professional Conduct, which evolved to the current Code of Ethics, adopted in 1964. These requests ultimately led to the creation of the Board of Ethical Review in 1954. Ethics cases rarely have easy answers, but the BER's nearly 500 advisory opinions have helped bring clarity to the ethical issues engineers face daily. Currently, bribery and political corruption is being addressed very directly by several professional societies and business groups around the world. However, new issues have arisen, such as offshoring, sustainable development, and environmental protection, that the profession is having to consider and address.

II. Research Ethics

Research that involves human subjects or participants raises unique and complex ethical, legal, social and political issues. Research ethics is specifically interested in the analysis of ethical issues that are raised when people are involved as participants in research. There are three objectives in research ethics. Thefirst and broadest objective is to protect human participants. The second objective is to ensure that research is conducted in a way that serves interests of individuals, groups and/or society as a whole. Finally, the third objective is to examine specific research activities and projects for their ethical soundness, looking at issues such as the management of risk, protection of confidentiality and the process of informed consent.

For the most part, research ethics has traditionally focused on issues in biomedical research. The application of research ethics to examine and evaluate biomedical research has been well developed over the last century and has influenced much of the existing statutes and guidelines for the ethical conduct of research. However in humanities and social science research, different kinds of ethical issues arise. New and emerging methods of conducting research, such as auto-ethnography and participatory action research raise important but markedly different ethical issues and obligations for researchers.

Research involving vulnerable persons, which may include children, persons with developmental or cognitive disabilities, persons who are institutionalized, the homeless or those without legal status, also raises unique issues in any research context.

Research ethicists everywhere today are challenged by issues that reflect global concerns in other domains, such as the conduct of research in developing countries, the limits of research involving genetic material and the protection of privacy in light of advances in technology and Internet capabilities.

In Canada, current debates and challenges in research ethics include the changing notions of what constitutes research and therefore requires formal ethics review, the oversight and monitoring of the work of Research Ethics Boards (known as Institutional Review Boards, in the U.S.) at federal and provincial levels, the jurisdiction of Research Ethics Boards in academic, clinical and corporate settings, the increasing multidisciplinarity of research collaborations and pursuits and challenges created by rigorous federal and provincial privacy legislation. This is by no means an exhaustive list of the kinds of live issues there are in research ethics today. Aside from the epistemological and philosophical issues in this dynamic field, research ethicists also face anecdotal issues at the level of individual research ethics reviews, systemic issues related to the institutions in which research ethics reviews are carried out and social, legal and political issues related to governance and oversight of research ethics activities.

Research ethics is concerned with the moral issues that arise during or as a result of research activities, as well as the ethical conduct of researchers. Historically, the revelation of scandals such as Nazi human experimentation and the Tuskegee syphilis experiment led to the realisation that clear measures are needed for the ethical governance of research to ensure that people, animals and environments are not unduly harmed in research. The management of research ethics is inconsistent across countries and there is no universally accepted approach to how it should be addressed. Informed consent is a key concept in research ethics.

When making ethical decisions, we may be guided by different things and philosophers commonly distinguish between approaches like deontology, consequentialism, virtue ethics and value (ethics). Regardless of approach, the application of ethical theory to specific controversial topics is known as applied ethics and research ethics can be viewed as a form of applied ethics because ethical theory is applied in real-world research scenarios.

Ethical issues may arise in the design and implementation of research involving human experimentation or animal experimentation. There may also be consequences for the environment, for society or for future generations that need to be considered. Research ethics is most developed as a concept in medical research, the most notable Code being the 1964 Declaration of Helsinki.

Research in other fields such as social sciences, information technology, biotechnology, or engineering may generate different types of ethical concerns to those in medical research.

In countries such as Canada, mandatory research ethics training is required for students, professors and others who work in research.

Nowadays, research ethics is commonly distinguished from matters of research integrity that includes issues such as scientific misconduct (e.g. fraud, fabrication of data or plagiarism).