SRINIVASAN COLLEGE OF ARTS & SCIENCE

(Affiliated to Bharathidasan University, Trichy)

PERAMBALUR – 621 212.

DEPARTMENT OF MICROBIOLOGY

Course : M.Sc Year: **I** Semester: **II**

Course Material on:

QUALITY CONTROL & IPR

Sub. Code : P16MBE2B

Prepared by :

Mr. C.RAVICHANDRAN, M.Sc., M.Phil., B.Ed.,

ASSISTANT PROFESSOR / MB

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SRINIVASAN COLLEGE OF ARTS & SCIENCE

PERAMBALUR.

ELECTIVE COURSE

QUALITY CONTROL AND IPR

SUBJECT CODE – P16MBE2B

Mr. C.RAVICHANDRAN

ASSISTANT PROFESSOR

DEPARTMENT OF MICROBIOLOGY

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OBJECTIVES

To gain knowledge about intellectual property rights, copyrights, trademarks and geographical limitation. Explain various concepts of biotechnological inventions and their commercialization. Ethics of biological Goods manufacturing practice, usage of animals, plants and their biosafety assessment.

Unit – I Bioethics

Legality, Morality and Ethics, the principles of bioethics, autonomy, human rights, beneficience, privacy, justice and equality.

Unit – II Biosafety

Concept and issues, rational vs subjective, perceptions of risk and benefits of Biosafety. Biosafety concern levels – Individual, institution, society, region, country and world- Lab associated Infections.

Unit – III Biosafety Assessment (BSA)

BSA of biotechnology and pharmaceutical products such as drugs, vaccines and biomolecules.

Unit – IV Quality Control

Quality control in food process technology- WHO Standards- Quality Control in Dairy product technology- Quality control in portable water.

Unit – V IPR

GATT and IPR, IPR in India, WTO Act, Convention on Biodiversity (CBD), patent cooperation treaty (PCT), forms of patents and patentability, process of patenting, Indian and international agencies involved in IPR and patenting, Global scenario of patents and India's position, patenting of biological material, GLP and GMP.

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UNIT I: BIOETHICS

Legality, Morality and Ethics, the principles of bioethics, autonomy, human rights, beneficience, privacy, justice and equality.

LEGALITY: Definition:

Legality can be defined as an act, agreement, or contract that is consistent with the law or state of being lawful or unlawful in a given jurisdiction.

PRINCIPLE OF LEGALITY:

- ✓ Legality is the legal ideal that requires all **law** to be clear, ascertainable and non-retrospective.
- ✓ It requires **decision makers to resolve disputes by applying legal rules** that have been declared beforehand, and not to alter the legal situation retrospectively by discretionary departures from established law.
- ✓ In **criminal law** it can be seen in the general prohibition on the imposition of criminal sanctions for acts or omissions that were not criminal at the time of their commission or omission.
- ✓ The principle is also thought **to be violated** when the sanctions for a **particular crime are increased with retrospective effect.**

In administrative law it can be seen in the desire for state officials to be bound by and apply the law rather than acting upon whim. As such advocates of the principle are normally against discretionary powers.

MORALITY:

- Morality speaks of a system of behavior in regards to standards of right or wrong behavior.
- The word carries the concepts of:

  (1) Moral standards, with regard to behavior;

  (2) Moral responsibility, referring to our conscience; and

  (3) A moral identity, or one who is capable of right or wrong action.
- Common synonyms include ethics, principles, virtue, and goodness. Morality has become a complicated issue in the multi-cultural world we live in today. Let's explore what morality is, how it affects our behavior, our conscience, our society, and our ultimate destiny.

Morality principles concerning the distinction between right and wrong or good and bad behaviour.

ETHICS:

- The field of ethics (or moral philosophy) involves systematizing, defending, and recommending concepts of right and wrong behavior.
- "The **rules of conduct** recognized in respect to a **particular class of human actions** or a particular group, culture"

Ethics and **morals** relate to "right" and "wrong" conduct. While they are sometimes used interchangeably, they are different: **ethics** refer to rules provided by an external source, e.g., codes of conduct in workplaces or principles in religions. **Morals** refer to an individual's own principles regarding right and wrong.

BIOETHICS:

Bioethics is the study of the **ethical issues** emerging from advances in **biology** and **medicine**. It is also moral discernment as it relates to medical policy and practice. Bioethicists are concerned with the ethical questions that arise in the relationships among **life sciences, biotechnology, medicine, politics, law**, and **philosophy. It includes the study of values ("the ethics of the ordinary") relating to primary care and other branches of medicine.**

- The term **"bioethics"** was introduced in the **70's** by **Van Rensselaer Potter** for a study aiming at ensuring the **preservation of the biosphere.**
- It was later used to refer a study of the ethical issues arising from health care, biological and medical sciences.

Some historical examples:

- Abortion
- Contraception
- Kidney dialysis machine (Who had the priority?)
- Organ transplant, artificial ventilator, and brain death
- *In vitro* fertilization (IVF)
- Cloning and stem cell research
- Genetic engineering

COMPARISON CHART:

Ethics versus Morals comparison chart

	Ethics	**Morals**
What are they?	The rules of conduct recognized in respect to a particular class of human actions or a particular group or culture.	Principles or habits with respect to right or wrong conduct. While morals also prescribe dos and don'ts, morality is ultimately a personal compass of right and wrong.
Where do they come from?	Social system - External	Individual - Internal
Why we do it?	Because society says it is the right thing to do.	Because we believe in something being right or wrong.
Flexibility	Ethics are dependent on others for definition. They tend to be consistent within a certain context, but can vary between contexts.	Usually consistent, although can change if an individual's beliefs change.
The "Gray"	A person strictly following Ethical Principles may not have any Morals at all. Likewise, one could violate Ethical Principles within a given system of rules in order to maintain Moral integrity.	A Moral Person although perhaps bound by a higher covenant, may choose to follow a code of ethics as it would apply to a system. "Make it fit"
Origin	Greek word "ethos" meaning "character"	Latin word "mos" meaning "custom"
Acceptability	Ethics are governed by professional and legal guidelines within a particular time and place	Morality transcends cultural norms

BASIC PRINCIPLES IN BIOETHICS:

In bioethics they are **four basic principles** and they were proposed by **Beaucham and Childress (1979):**

- Autonomy
- Beneficence
- No malfeasance
- Justice

Bioethics we find several grounded ethical theories. Two of these are **deontological ethics** and **utilitarian ethics.**

1. Deontological ethics:

- Proposed by Immanuel Kant
- It consists in that reason identifies actions like good or bad, independent of their consequences. (Importance / Effect of what has gone before)

2. Utilitarian ethics:

- ✓ Proposed by Jeremy Bentham and John Stuart-Mill
- ✓ It says that actions are good or bad depend on their consequences. (Importance / Effect of what has gone before)
- ✓ The balance between purposes that give benefits or damage is produced by utilitarian ethics.

These **principles can be grouped in two levels**:

- **Minimum levels:**

  Obligations that generate universal duties and these involve negative transitive duties (facts that you cannot do other people). Here, there are principles of no malfeasance and justice.

- **Maximum levels:**

  They are related with the choice of the vital project that every person chooses to depend on their scale of values. They generate imperfect obligations: facts that I can auto impose, but I cannot call for other people (neither other people to me). Here, there are principles of autonomy and beneficence.

- **The Principle of Respect for autonomy:**

  Autonomy is Latin for "self-rule" We have an obligation to respect the autonomy of other persons, which is to respect the decisions made by other people concerning their own lives. This is also called the principle of human dignity. It gives us a negative duty not to interfere with the decisions of competent adults, and a positive duty to empower others for whom we're responsible.

  Corollary principles: honesty in our dealings with others & obligation to keep promises.

- **The Principle of Beneficence:**

  We have an obligation to bring about good in all our actions.

  Corollary principle? We must take positive steps to prevent harm. However, adopting this corollary principle frequently places us in direct conflict with respecting the autonomy of other persons.

- **The Principle of non malfeasance:**

  (It is not "non-malfeasance," which is a technical legal term & it is not "no malevolence," which means that one did not intend to harm.)

  We have an obligation not to harm others: "First, do no harm."

  - **Corollary principle:**

    Where harm cannot be avoided, we are obligated to minimize the harm we do.

  - **Corollary principle:** Don't increase the risk of harm to others.
  - **Corollary principle:** It is wrong to waste resources that could be used for good.

  Combining beneficence and non malfeasance: Each action must produce more good than harm.

- **The Principle of justice:**

  We have an obligation to provide others with whatever they are owed or deserve. In public life, we have an obligation to treat all people equally, fairly, and impartially.

  Corollary principle: Impose no unfair burdens.

  Combining beneficence and justice: We are obligated to work for the benefit of those who are unfairly treated.

OTHER IMPORTANT PRINCIPLES

There are other important principles in bioethics.

- **Fidelity (Faith / Loyal / Strict / Accuracy):** protection of people, based on caution, proportionality, no discrimination and respect for people's dignity. It includes privacy's protection and confidentiality, keeping the promises and commitment.
- **Transparency:** gives law and access to information. All information has to communicate clearly, comprehensively, honest and real.
- **Caution:** based on analysis of risks. All investigations that could put at risk people's health and future generations have to avoid.
- **Principle of proportionality:** it is related to the principle of beneficence and looks at the relationship between the benefit obtained and the "costs" of means, human and monetary resources, risks and what the negative effects are.
- **Principle of non-discrimination:** all persons who must be treated equally.

- **Principle of respect for dignity:** no one has to be subjected to humiliation, must receive help in situations of need, have a minimum quality of life without suffering and freedom of action and decision, and not be used as the purpose of others.
- **Principle of respect for privacy and confidentiality:** not unnecessarily reveal and/or interested personal and sensitive data concerning the subject. It is not an absolute principle and in front of a crime is not fulfilled.
- **Principle of respect for the right to information:** all those involved in the process must know all the information (before, during and after the investigation).
- **Principle of free participation and donation:** participation and donation are free and altruistic since if we are not talking about sale or exchange.

AUTONOMY – Definition:

- Autonomy is derived from a Greek word **"Autos"** means **"Self"** and **"Nomos"** means **"Laws".**
- Autonomy can be defined as '"self-rule with no control, undue influence or interference from other"
- It is about respecting other people's wishes and supporting them in their decisions.
- The patient has the right to refuse or choose their treatment.
- Autonomy can be defined as the ability of the person to make his or her own decisions. This faith in autonomy is the central premise of the concept of informed consent and shared decision making.

ABOUT AUTONOMY:

- In practice, the principle requires respect for the decision-making capacity of competent adults.
- Respect for self-determination is deeply rooted in American history and imagination.
- We are "… a culture that celebrates the individual." The rise of autonomy in bioethics is quite recent. Until the 1960s, medical ethics, as the field was then called, was largely "internal to medicine— those values, norms, and rules intrinsic to the actual practice of health care."
- Physicians dealt with their codes of conduct and professional etiquette internally, as a family matter of sorts.
- During the last half of the 20th century, however, many traditional aspects of authority in our society were questioned, as manifested in the civil rights, feminist, and anti-war movements.
- The practice of medicine was affected as well. The discourse on medical morality that previously had been held within the profession gave way to a - New way of thinking in which the ethical values of society at large— including the rights of the individual— were applied to the practice of medicine.

PRINCIPLES OF AUTONOMY:

- The principle of autonomy recognizes the rights of individuals to self- determination.

- The increasing importance of autonomy can be seen as a social reaction to a "paternalistic" tradition within healthcare.
- Respect for autonomy is the basis for informed consent and advance directives.
- Autonomy is a general indicator of health.
- This makes autonomy an indicator for both personal well-being, and for the well-being of the profession.

NOTION (Concept / Idea) OF AUTONOMY:

✓ Personal autonomy is, at minimum, self-rule that is free from both controlling interference by others and from limitations, such as inadequate understanding, that prevent meaningful choice.

✓ The autonomous individual acts freely in accordance with a self-chosen plan, analogous to the way an independent government manages its territories and sets its policies.

✓ A person of diminished autonomy, by contrast, is in some respect controlled by others or incapable of deliberating or acting on the basis of his or her desires and plans.

Autonomy – Models MANDATORY (Compulsory):

- "It is practically unwise and morally objectionable for the patient to for swear making medical decisions personally".
- Although this model seems to eliminate any residue of medical paternalism is it not in danger of replacing it with an equally (or possibly even more) unacceptable paternalism by bioethicists?

OPTIONAL:

➢ Defines this as entitling but not requiring a patient to take an active role in decision making regarding treatment.

AUTONOMY – CLINICAL APPLICATION:

✓ Autonomy rights make sense and are easiest to defend and implement in the context of the well-informed adult of sound mind.

✓ But we are routinely confronted with patients whose competence (legal status) or capacity (current ability) may be in question because they are minors, are imprisoned, have a cognitive impairment, are mentally ill, or are intoxicated.

✓ We sometimes suspend or abridge autonomy for such patients; but rarely do we put it aside in favor of another ethical principle—beneficence, non malfeasance, or justice. Instead, we stretch and extend autonomy.

AUTONOMY – END OF LIFE:

- In end-of-life care, the extension of autonomy has been promoted vigorously, but with mixed results.
- To be sure, deference to the wishes of the patient and his or her family is a valuable starting point for all end-of-life care.
- However, it is reasonable to question the role of autonomy when continued aggressive care will not lead to recovery, but only prolong dying.
- Death teaches us that some things cannot be controlled. As the end of life approaches, the domains over which the patient or family can exercise control diminish to the vanishing point.
- It is reasonable to ask whether it is even possible for a human being to exercise autonomy in any meaningful way when nearing death.
- The approach of death signals that the other principles of medical ethics— beneficence, non malfeasance, and justice—may be needed, and that perhaps they should even trump autonomy.

AUTONOMY VS PHYSICIAN:

- Today, we have "a patient-centered medical ethics that emphasizes autonomy rights over professional obligations of beneficence when they conflict."
- The rise of autonomy has brought "unprecedented challenges to [medical professional] authority." A worst-case scenario illustrates the point.
- When patients insist on decision-making authority, it is tempting to defer to them. However, the "it's your decision" approach can be a form of abandoning the patient.
- The physician may feel that without full authority to make decisions, he or she should not assume responsibility for outcomes.
- The physician may dispense with some of the soul-searching about the right course of action thinking that the patient will decide what he wants, anyway.

RESPECT FOR AUTONOMY (Person):

- Includes respect for their privacy and confidentiality
- Need to provide sufficient information for them to make informed choices
- Truth telling protection of persons with diminished or impaired autonomy.
- **Recognize the capacity of mentally and legally competent patients :**
  - To think and make decisions independently
  - To act on the basis of their decisions
  - To communicate their wishes to health workers
  - Uphold patient confidentiality

PROMOTING AUTONOMOUS BEHAVIOUR:

- Presenting all treatment options to a patient.
- Explaining risks in terms that a patient understands.
- Ensuring that a patient understands the risks and agrees to all procedures before going into surgery.

AUTONOMY Vs. PATERNALISM:

Paternalism is defined as the overriding of individual choices or intentional actions in order to provide benefit to that individual.

Autonomy:

✓ Agents have a right to be self-determining; individuals have a right to conduct their lives as they see fit.

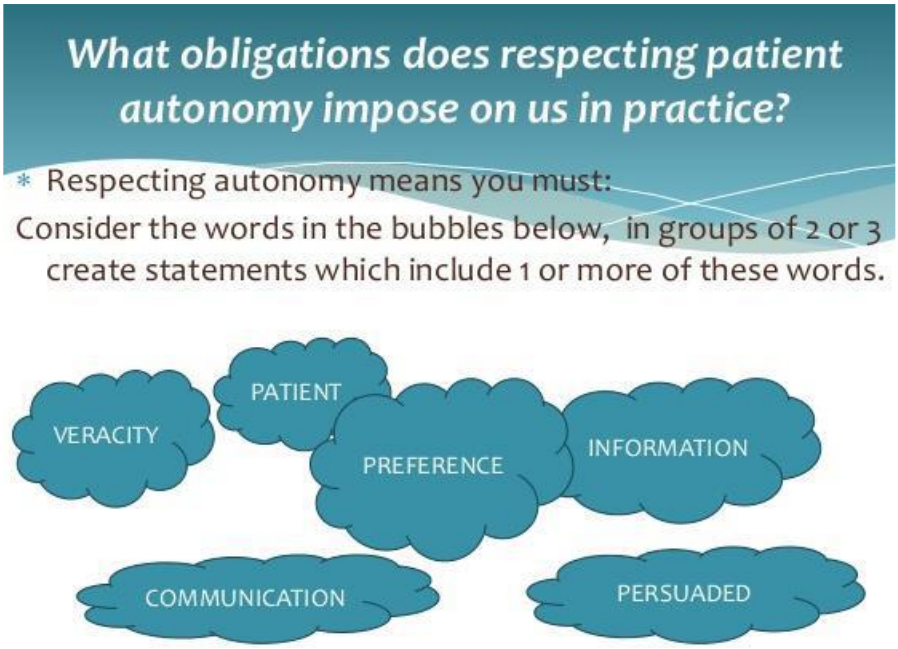
✓ Autonomy is typically taken to be a core component of a "good life."

Paternalism:

✓ It is sometimes legitimate to restrict agent autonomy, for their own good.

✓ Soft paternalism-agent is - incompetent in some relevant way.

✓ Hard paternalism-agent has less-than-ideal values



HUMAN RIGHTS: Definition:

Human rights are the **basic** freedoms and protections that belong to every single one of us. All **human** beings are born with equal and inalienable **rights** and fundamental freedoms. ... **Human rights** are based on dignity, equality and mutual respect – regardless of your nationality, your religion or your beliefs.

Human rights are:

• Universal legal guarantees

• protecting individuals and groups

• Against actions and omissions

• That interferes with fundamental freedoms, entitlements and human dignity.

• Human rights law obliges Governments and other duty-bearers to do certain things and prevents them from doing others.

❖ RIGHTS:

- moral power **to hold** (rights to life, nationality, own property, rest and leisure)
- **to do** (rights to marry, peaceful assembly, run for public office, education)
- **to omit** (freedom from torture and cruel, inhuman or degrading punishment, freedom from arbitrary arrest, detention or exile) **(or)**
- **to exact something** (equal protection of the law, equal access to public service, equal pay for equal work)

❖ **HUMAN RIGHTS** coined by **Eleanor Roosevelt** to replace ***Rights of Man***

❖ **NATURE** – Human rights are more than legal concepts: they are the essence of man. They are what make man human. That is why they are called human rights; deny them and you deny man's humanity

PRINCIPLES OF HUMAN RIGHTS:

- **Universal:** All individuals are equal as human beings and by virtue of the inherent dignity of each human person.
- **Inalienable:** All people everywhere in the world are entitled to human rights. A person cannot voluntarily give them up. Nor can others take them away from him or her.
- **Indivisible and interrelated:** Rights are completely interdependent and depend on each other for their effectiveness.

- **Non-discrimination:** Everyone is entitled to human rights without discrimination.
- **Empowerment/participation:** These rights endow people the power to claim them from their governments, as opposed to charity which is an act of generosity. Human rights are *owned* by everyone.
- **Accountability:** Governments have certain duties and obligations to *respect, protect* and *fulfil* human rights. (Individuals and non-state actors also have duties to others)

CHARACTERISTICS OF HUMAN RIGHTS:

- ✓ Universal
- ✓ Internationally guaranteed
- ✓ Legally protected
- ✓ Protects individuals and groups
- ✓ Cannot be taken away
- ✓ Equal and indivisible
- ✓ Obliges States and State actors

FIVE CATEGORIES OF HUMAN RIGHTS:

- **Civil –** the right to be treated as an equal to anyone else in society

- **Political –** the right to vote, to freedom of speech and to obtain information
- **Economic –** the right to participate in an economy that benefits all; and to desirable work
- **Social –** the right to education, health care, food, clothing, shelter and social security
- **Cultural –** the right to freedom of religion, and to speak the language, and to practice the culture of one's choice

SOME CIVIL RIGHTS:

- Life
- Belief in own religion
- Opinion
- Free speech
- Non-discrimination according to sex
- Marry
- Race
- Cultural background

SOME POLITICAL RIGHTS:

- ✓ Vote in elections
- ✓ Freely form or join political parties
- ✓ Live in an independent country
- ✓ Stand for public office
- ✓ Freely disagree with views and policies of political leaders

SOME ECONOMIC RIGHTS:

- Jobs
- Work without exploitation
- Fair wage
- Safe working conditions
- Form trade unions
- Have adequate food
- Protection against labor malpractices

SOME SOCIAL RIGHTS:

- Housing
- Education
- Health services

- Recreation facilities
- Clean environment
- Social security

SOME CULTURAL RIGHTS:

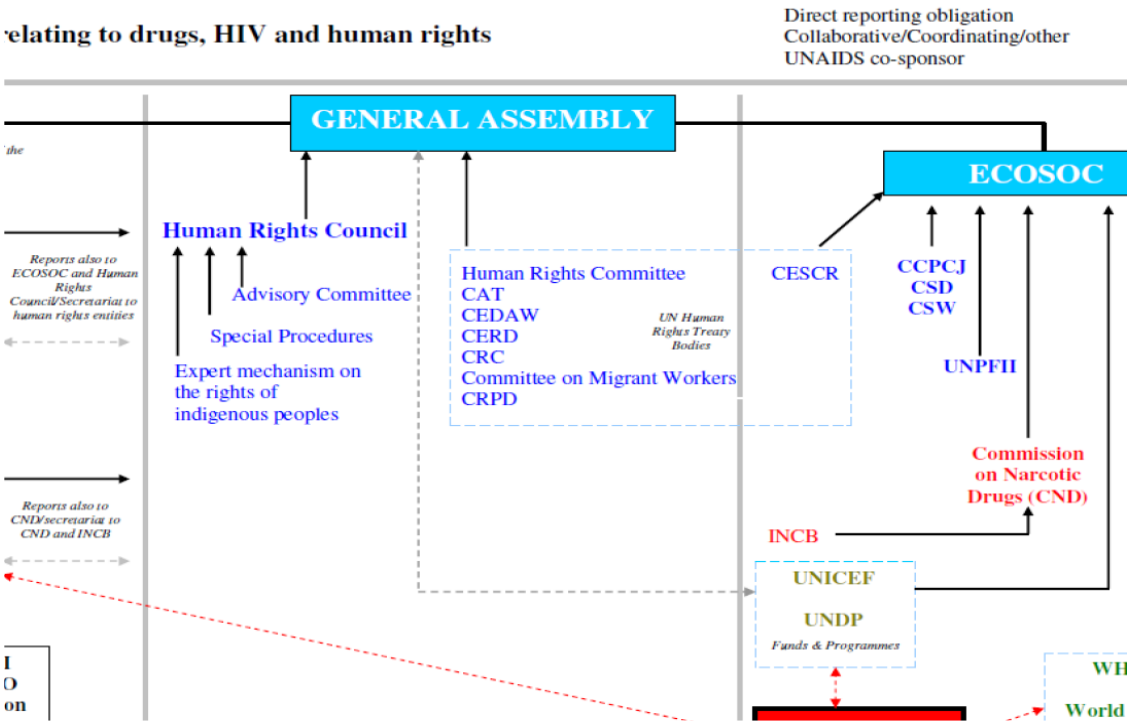
- Use own language
- Develop cultural activities
- Ancestral domains
- Develop own kind of schooling

WHEN CAN RIGHTS BE RESTRICTED?

It is not the norm for rights to be limited but the exception. They can only be limited if the following 5 criteria are met:

1. The restriction must be allowed for in law
2. The restriction must respond to a pressing public or social need
3. The restriction is strictly necessary in a democratic society to achieve the public/social need
4. There are no less intrusive and restrictive means available to reach the same objective; and
5. The restriction is based on scientific evidence and not drafted or imposed arbitrarily — that is, in an unreasonable or otherwise discriminatory manner.

Any restriction must be of a limited duration, respectful of human dignity, and subject to review



POLITICAL/INTER-GOVERNMENTAL:

- ✓ General Assembly (3rd Committee)
- ✓ ECOSOC
- ✓ Human Rights Council – Regular sessions 3 times a year for 3 weeks
  – Special sessions
  – Universal Periodic Review
  – Special Procedures
  – 1503 complaint procedure (gross and systematic violations)

PROGRAMMATIC/SECRETARIAT:

• Secretary General
  – Special Representatives (e.g. Violence Against children)

• Office of the High Commissioner for Human Rights
  – Department of UN Secretariat (alongside UNODC)
  – Headed by UN High Commissioner for Human rights
  – Secretariat for Human Rights Council and Treaty Bodies
  – Technical assistance and capacity building to states
  – Mandate to mainstream human rights in UN system

TREATY MONITORING:

• Each UN human rights treaty has a corresponding independent committee (a Treaty Body)
  – Consideration of state reports
  – Complaints mechanisms (All but CRC)
  – Inquiry procedures (CAT, CEDAW)
  – General Comments (Provide more detail on specific articles)
  – Days of General Discussion
  – NGOs central to all the work of Treaty Bodies

INDEPENDENT EXPERT:

• **Special Procedures**
  – Special Rapporteurs
  e.g. SR on Torture, SR on the right to health
  – Independent Experts
  E.g. IE on
  – Working Groups

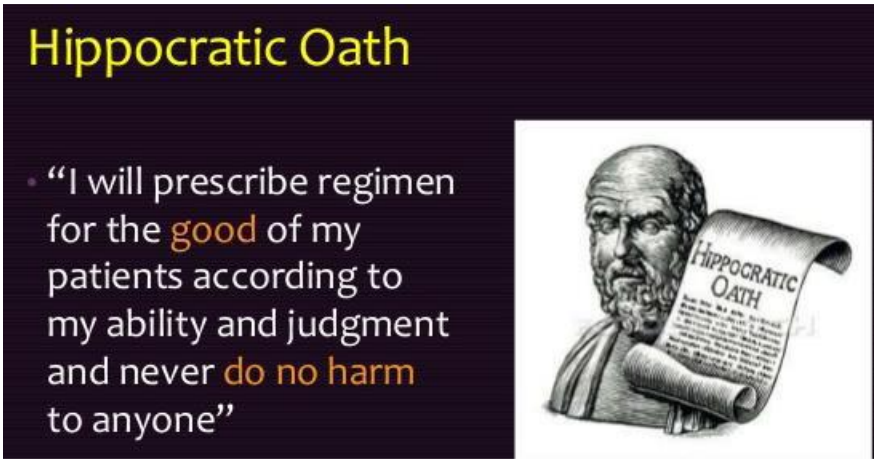
E.g. WG on Arbitrary Detention

• Country missions, complaints mechanisms, urgent appeals, annual reports to GA and Human Rights Council

• NGOs frequently initiate complaints; urgent appeals etc and are points of contact for country missions

BENEFICENCE:

***Definition*:** Beneficence is action that is **done for the benefit of others**. Beneficent actions can be **taken to help prevent or remove harms or to simply improve the situation of others**.



ELEMENTS:

These four concepts often arise in discussions about beneficence:

1. One should not practice evil or do harm
2. One should prevent evil or harm
3. One should remove evil or harm
4. One should practice well

CLINICAL APPLICATIONS:

- ✓ Physicians are expected to refrain from causing harm, but they also have an obligation to help their patients. Ethicists often distinguish between obligatory and ideal beneficence.
- ✓ Ideal beneficence comprises extreme acts of generosity or attempts to benefit others on all possible occasions.
- ✓ Physicians are not necessarily expected to live up to this broad definition of beneficence. However, the goal of medicine is to promote the welfare of patients, and physicians possess skills and knowledge that enable them to assist others.
- ✓ Due to the nature of the relationship between physicians and patients, doctors do have an obligation to

    1) Prevent and remove harms, and

2) Weigh and balance possible benefits against possible risks of an action. Beneficence can also include protecting and defending the rights of others, rescuing persons who are in danger, and helping individuals with disabilities.

EXAMPLES OF BENEFICENT ACTIONS:

Resuscitating a drowning victim, providing vaccinations for the general population, encouraging a patient to quit smoking and start an exercise program, talking to the community about STD prevention.

BALANCING AUTONOMY AND BENEFICENCE:

- Some of the most **common and difficult ethical issues** to navigate arise when the **patient's autonomous decision** conflicts with the physician's beneficent duty to look out for the **patient's best interests**.
- **For example**, a patient who has had **bypass surgery** may want to continue **to smoke or a patient with pneumonia may refuse antibiotics**.
- In these situations the **autonomous choice of the patient conflicts** with the **physician's duty of beneficence** and following each ethical principle would lead to different actions.
- As long as the patient meets the criteria for making an autonomous choice (the patient understands the decision at hand and is not basing the decision on delusional ideas), then the **physician** should **respect the patient's decisions** even while trying to convince the patient otherwise.

PRIVACY:

Information privacy, or **data privacy** (or **data protection**), is the relationship between the collection and dissemination of **data, technology**, the public **expectation of privacy**, and the **legal** and **political** issues surrounding them.

Privacy concerns exist wherever **personally identifiable information** or other **sensitive information** is collected, stored, used, and finally destroyed or deleted – in digital form or otherwise. Improper or non-existent disclosure control can be the root cause for privacy issues. Data privacy issues may arise in response to information from a wide range of sources, such as:

- **Healthcare** records
- **Criminal justice** investigations and proceedings
- **Financial** institutions and transactions
- **Biological** traits, such as **genetic material**
- **Residence** and geographic records
- **Privacy breach**

- **Location-based service** and **geolocation**
- **Web surfing behavior** or user preferences using persistent cookies
- **Academic research**

INFORMATION TYPES

Various types of personal information often come under privacy concerns.

❖ **INTERNET:**

- The ability to control the information one reveals about oneself over the Internet, and who can access that information, has become a growing concern.
- These concerns include whether **email** can be stored or read by third parties without consent, or whether third parties can continue to track the websites that someone has visited.
- Another concern is if the websites that are visited can collect, store, and possibly share **personally identifiable information** about users.

Email isn't the only Internet use with concern of privacy. **Everything is accessible over the Internet nowadays**. However, a major issue with privacy relates back to social networking.

❖ For example, there are millions of users on **Facebook** and its regulations have changed.

❖ People may be **tagged in photos** or have valuable information exposed about themselves either by choice or, most of the time, unexpectedly by others.

❖ It is important to be **cautious of what is being said over the Internet and what information is being displayed as well as photos** because this all can be searched across the web and used to access private databases, making it easy for anyone to quickly go online and profile a person.

CABLE TELEVISION:

❖ This describes the ability to control what information one reveals about oneself over cable television, and who can access that information. For example, third parties can track IP TV programs someone has watched at any given time. "The addition of any information in a broadcasting stream is not required for an audience rating survey, additional devices are not requested to be installed in the houses of viewers or listeners, and without the necessity of their cooperation, and audience ratings can be automatically performed in real-time."

❖ **MEDICAL:**

- People may not wish for their medical records to be revealed / showed to others.
- This may be because they have concern that it might affect their insurance coverages or employment.
- Or, it may be because they would not wish for others to know about any medical or psychological conditions or treatments that would bring embarrassment (make / encumber) upon themselves. Revealing medical data could also reveal other details about one's personal life.
- There are **three major categories of medical privacy**:
  – Informational (the degree of control over personal information)
  – Physical (the degree of physical inaccessibility to others), and
  – Psychological (the extent to which the doctor respects patients' cultural beliefs, inner thoughts, values, feelings, and religious practices and allows them to make personal decisions).

- Physicians and psychiatrists in many cultures and countries have standards for **doctor-patient relationships, which include maintaining confidentiality.**
- In some cases, the **physician-patient privilege** is legally protected.
- These practices are in place to protect the dignity of patients, and to ensure that patients will feel free to reveal complete and accurate information required for them to receive the correct treatment

❖ **FINANCIAL:**

✓ Information about a **person's financial transactions**, including the amount of assets, positions held in stocks or funds, outstanding debts, and purchases can be sensitive.

✓ If criminals gain access to information such as a person's accounts or credit card numbers, that person could become the victim of **fraud** or **identity theft**.

✓ Information about a person's purchases can reveal a great deal about that person's history, such as places he/she has visited, whom he/she has contacted with, products he/she has used, his/her activities and habits, or medications he/she has used.

✓ In some cases, corporations may use this information to target individuals with marketing customized towards those individual's personal preferences, which that person may or may not approve.

❖ **LOCATIONAL:**

- As location tracking capabilities of mobile devices are advancing (Location-based service), problems related to user privacy arise.
- Location data is among the most sensitive data currently being collected.

- A list of potentially sensitive professional and personal information that could be inferred about an individual knowing only his mobility trace was published recently by the Electronic Frontier Foundation.

❖ **POLITICAL:**

- **Political privacy** has been a concern since **voting systems** emerged in ancient times.
- The **secret ballot** is the simplest and most widespread measure to ensure that political views are not known to anyone other than the voters themselves—it is nearly universal in modern democracy, and considered to be a basic right **of citizenship**.
- In fact, even where other rights of privacy do not exist, this type of privacy very often does.

❖ **EDUCATIONAL:**

- Kelly Fiveash of ***The Register*** said that this could mean **"a child's school life including exam results, attendance, teacher assessments and even characteristics"** could be available, with third-party organizations being responsible for anonymizing any publications themselves, rather than the data being anonymized by the government before being handed over. An example of a data request that Gove indicated had been rejected in the past, but might be possible under an improved version of privacy regulations, was for **"analysis on sexual exploitation".**

JUSTICE: Definition

The maintenance or administration of what is just especially by the impartial adjustment of conflicting

- **Justice** is the legal or philosophical theory by which fairness is administered.
- The concept of justice differs in every culture.
- An early theory of justice was set out by the Ancient Greek philosopher Plato in his work *The Republic*.
- Advocates of divine command theory argue that justice issues from God.

ABOUT:

- In the 17th century, theorists like John Locke argued for the theory of natural law.
- Thinkers in the social contract tradition argued that justice is derived from the mutual agreement of everyone concerned.
- In the 19th century, utilitarian thinkers including John Stuart Mill argued that justice is what has the best consequences.

- Theories of distributive justice concern what is distributed, between whom they are to be distributed, and what is the *proper* distribution. Egalitarians argued that justice can only exist within the coordinates of equality.
- John Rawls used a social contract argument to show that justice, and especially distributive justice, is a form of fairness.
- Property rights theorists (like Robert Nozick) take a deontological view of distributive justice and argue that property rights-based justice maximizes the overall wealth of an economic system.

THEORIES OF DISTRIBUTIVE JUSTICE:

Theories of distributive justice need to answer three questions:

1. *What goods* are to be distributed? Is it to be wealth, power, respect, opportunities or some combination of these things?

2. *Between what entities* are they to be distributed? Humans (dead, living, future), sentient beings, the members of a single society, nations?

3. What is the *proper* distribution? Equal, meritocratic, according to social status, according to need, based on property rights and non-aggression?

Distributive justice theorists generally do not answer questions of *who has the right* to enforce a particular favored distribution. On the other hand, property rights theorists argue that there is no "favored distribution." Rather, distribution should be based simply on whatever distribution results from lawful interactions or transactions (that is, transactions which are not illicit).

Rawls's *two principles of justice*:

- Each person is to have an equal right to the most extensive total system of equal basic liberties compatible with a similar system of liberty for all.
- Social and economic inequalities are to be arranged so that they are both o to the greatest benefit of the least advantaged, consistent with the just savings principle, and
- Attached to offices and positions open to all under conditions of fair equality of opportunity.

This imagined choice justifies these principles as the principles of justice for us, because we would agree to them in a fair decision procedure.

Rawls's theory distinguishes **two kinds of goods –**

(1) The good of liberty rights and

(2) Social and economic goods, i.e. wealth, income and power – and applies different distributions to them

- Equality between citizens for (1)

- Equality unless inequality improves the position of the worst off for (2).

In one sense, theories of distributive justice may assert that everyone should get what they deserve. Theories disagree on the meaning of what is "deserved". The main distinction is between theories that argue the basis of just deserts ought to be held equally by everyone, and therefore derive egalitarian accounts of distributive justice – and theories that argue the basis of just deserts is unequally distributed on the basis of, for instance, hard work, and therefore derive accounts of distributive justice by which some should have more than others.

Property rights

In ***Anarchy, State, and Utopia,*** **Robert Nozick** argues that distributive justice is not a matter of the whole distribution matching an ideal *pattern*, but of each individual entitlement having the right kind of *history*. It is just that a person has some good (especially, some **property right**) if and only if they came to have it by a history made up entirely of events of two kinds:

- Just *acquisition*, especially by working on unwonted(not usual) things; and
- Just *transfer*, that is free gift, sale or other agreement, but not theft (i.e. by force or fraud).

Theories of retributive justice

Walter Seymour Allward's *Justitia* (Justice),

Theories of retributive justice are concerned with punishment for wrongdoing, and need to answer three questions:

1. Why punish?

2. Who should be punished?

3. What punishment should they receive?

This section considers the two major accounts of retributive justice, and their answers to these questions. *Utilitarian* theories look forward to the future consequences of punishment, while *retributive* theories look back to particular acts of wrongdoing, and attempt to balance them with deserved punishment.

Utilitarianism

According to the utilitarian, as already noted, justice requires the maximization of the total or average welfare across all relevant individuals. **Punishment fights crime in three ways**:

1. **Deterrence. The credible** threat of punishment might lead people to make different choices; well-designed threats might lead people to make choices that maximize welfare. This matches some strong intuitions about just punishment: that it should generally be proportional to the crime.
2. **Rehabilitation.** Punishment might make bad people into better ones. For the utilitarian, all that 'bad person' can mean is 'person who's likely to cause bad things (like suffering)'. So, utilitarianism could recommend punishment that changes someone such that they are less likely to cause bad things.
3. **Security/Incapacitation.** Perhaps there are people who are irredeemable causers of bad things. If so, imprisoning them might maximize welfare by limiting their opportunities to cause harm and therefore the benefit lies within protecting society.

So, the reason for punishment is the maximization of welfare, and punishment should be of whomever, and of whatever form and severity, are needed to meet that goal. This may sometimes justify punishing the innocent, or inflicting disproportionately severe punishments, when that will have the best consequences overall (perhaps executing a few suspected shoplifters live on television would be an effective deterrent to shoplifting, for instance). It also suggests that punishment might turn out *never* to be right, depending on the facts about what actual consequences it has.

1. Retributivism

- ✓ The retributivist will think consequentialism is mistaken.
- ✓ If someone does something wrong we must respond by punishing for the committed action itself, regardless of what outcomes punishment produces.
- ✓ Wrongdoing must be balanced or made good in some way, and so the criminal *deserves* to be punished.
- ✓ It says that all guilty people, and only guilty people, deserve appropriate punishment.
- ✓ This matches some strong intuitions about just punishment: that it should be *proportional* to the crime, and that it should be of *only* and *all of* the guilty. However, it is sometimes argued that retributivism is merely revenge in disguise. However, there are differences between retribution and revenge: the former is impartial and has a scale of appropriateness, whereas the latter is personal and potentially unlimited in scale.

2. Restorative justice

- Restorative justice (also sometimes called "reparative justice") is an approach to justice that focuses on the needs of victims and offenders, instead of satisfying abstract legal principles or punishing the offender.

- Victims take an active role in the process, while offenders are encouraged to take responsibility for their actions, **"to repair the harm they've done – by apologizing, returning stolen money, or community service"**.
- It is based on a theory of justice that considers crime and wrongdoing to be an offense against an individual or community rather than the state.
- Restorative justice that fosters dialogue between victim and offender shows the highest rates of victim satisfaction and offender accountability.

Mixed theories

- **Some modern philosophers** have argued that Utilitarian and Retributive theories are not mutually exclusive. For example, **Andrew von Hirsch,** in his 1976 book ***Doing Justice***, suggested that we have a moral obligation to punish greater crimes more than lesser ones. However, so long as we adhere to that constraint then utilitarian ideals would play a significant secondary role.

Theories

Rawls' theory of justice

It has been argued **that 'systematic' or 'programmatic'** political and moral philosophy in the West begins, in **Plato's Republic**, with the question, **'What is Justice?'** According to most contemporary theories of justice, justice is overwhelmingly important: **John Rawls** claims that **"Justice is the first virtue of social institutions, as truth is of systems of thought."**

In classical approaches, **evident from Plato** through to **Rawls,** the concept of **'justice'** is always construed in **logical** or **'etymological'** opposition to the concept of injustice.

1. Concept – I : Justice

2. **Concept – II: Injustice**

Such approaches cite various examples of injustice, as problems which a theory of justice must overcome. A number of post-World War II approaches do, however, challenge that seemingly obvious dualism between those two concepts.

- Justice can be thought of as distinct from **benevolence, charity, prudence, mercy, generosity, or compassion**, although these dimensions are regularly understood to also be interlinked.
- Justice is the concept of **cardinal virtues,** of which it is one. Metaphysical justice has often been associated with concepts **of fate, reincarnation** or **Divine Providence**, i.e., with a life in accordance with a cosmic plan.
- The association of **justice with fairness is thus historically and culturally inalienable**.

Equality before the law

- Law raises important and complex issues concerning equality, fairness, and justice.
- There is an old saying that '**All are equal before the law**'. The belief in equality before the law is called legal egalitarianism.
- In criticism of this belief, the author **Anatole France** said in 1894, "In its majestic equality, the law forbids **rich and poor alike** to sleep under bridges, beg in the streets, and steal loaves of bread."
- With this saying, France illustrated the fundamental shortcoming of a theory of legal equality that remains blind to social inequality; the same law applied to all may have disproportionately harmful effects on the least powerful.

Theories of sentencing

- In **criminal law, a** sentence forms the final explicit act of a judge-ruled process, and also the symbolic principal act connected to his function.
- The sentence can generally involve a decree of **imprisonment, a fine** and/or other **punishments** against a **defendant convicted** of a crime.
- Laws may specify the range of penalties that can be imposed for various offenses, and sentencing guidelines sometimes regulate what punishment within those ranges can be imposed given a certain set of offense and offender characteristics. The most common purposes of sentencing in legal theory are:

Theory	**Aim of theory**	**Suitable punishment**
Retribution	Punishment imposed for no reason other than an offense being committed, on the basis that if proportionate, punishment is morally acceptable as a response that satisfies the aggrieved party, their intimates and society.	• Tariff sentences • Sentence must be proportionate to the crime
Deterrence	• To the individual – the individual is deterred through fear of further punishment. • To the general public – Potential offenders warned as to likely punishment	• Prison Sentence • Heavy Fine • Long sentence as an example to others

Rehabilitation	To reform the offender's behavior	• Individualized sentences • Community service orders • moral education • vocational education
Incapacitation	Offender is made incapable of committing further crime to protect society at large from crime	• Long prison sentence • Electronic tagging • Banning orders
Reparation	Repayment to victim(s) or to community	• Compensation • Unpaid work • Reparation Schemes

In **civil cases** the decision is usually known as a **verdict, or judgment,** rather than a sentence. Civil cases are settled primarily by means of monetary compensation for harm done **("damages")** and orders intended to prevent future harm (for example **injunctions**). Under some legal systems an award of damages involves some scope for retribution, denunciation and deterrence, by means of additional categories of damages beyond simple compensation, covering a punitive effect, social disapprobation, and potentially, deterrence, and occasionally disgorgement (forfeit of any gain, even if no loss was caused to the other party).

TYPES OF JUSTICE:

- Distributive justice
- Injustice
- Occupational injustice
- Open justice
- Spatial justice
- Organizational justice
- Poetic justice
- Social justice

QUALITY

Law and society

- ✓ Social equality, in which all people within a group have the same status o Economic equality, a form of social justice

o Egalitarianism, a trend of thought that favors equality for all people

o Equal opportunity, a stipulation that all people should be treated similarly

o Equality before the law, the principle under which all people are subject to the same laws

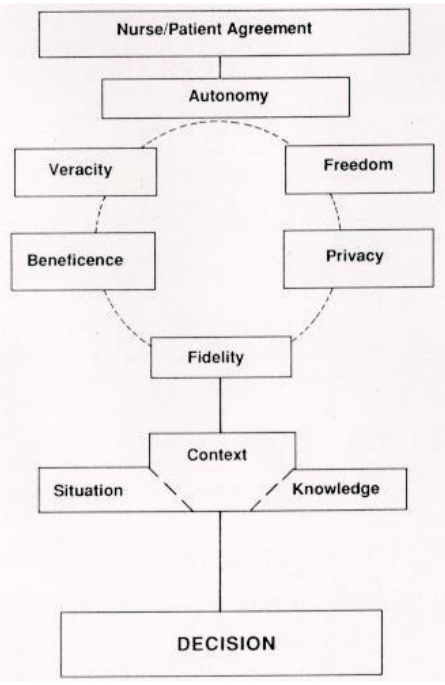
o Equality of outcome, in which the general economic conditions of people's lives are similar

  - o For specific groups:
    - Gender equality - Racial equality

- ✓ Consociationalism, in which an ethnically, religiously, or linguistically divided state functions by cooperation of each group's elites
- ✓ Equality Party (disambiguation), several political parties
- ✓ Equality Act (disambiguation), several pieces of legislation

Mathematics

- **Equality (mathematics),** the relationship between expressions that represent the same value or mathematical object
- **Extensional equality**, in logic, a principle that judges objects to be equal if they have the same external properties



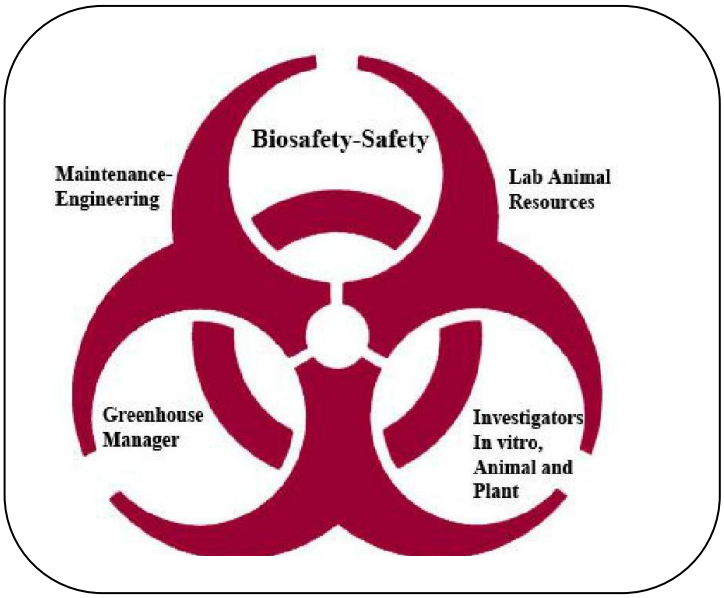
UNIT- II: BIOSAFETY

Concept and issues, rational vs subjective, perceptions of risk and benefits of Biosafety. Biosafety concern levels – Individual, institution, society, region, country and world- Lab associated Infections.

BIOSAFETY:

Biological safety or **biosafety** is the application of knowledge, techniques and equipment to prevent personal, laboratory and environmental exposure to potentially infectious agents or biohazards. Biosafety defines the containment conditions under which infectious agents can be safely manipulated.

BIOSAFETY SYMBOL:



BIOSAFETY IS RELATED TO SEVERAL FIELDS:

- ✓ In **ecology** (referring to imported life forms from beyond **ecoregion** borders),
- ✓ In **agriculture** (reducing the risk of alien viral or transgenic genes, or prions such as BSE/"MadCow", reducing the risk of food bacterial contamination)
- ✓ 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),
- ✓ In **chemistry** (i.e., nitrates in water, PCB levels affecting fertility) and
- ✓ In **exobiology** (i.e., NASA's policy for containing alien microbes that may exist on space samples - sometimes called **"bio safety level** 5").

BIOSAFETY ISSUES:

- Blood borne pathogens (BBP)
- Laboratory Safety
- Biosafety Issues Infectious substance
- Biological waste disposal

- Recombinant DNA (rDNA) and diagnostic specimen shipping
- Bioterrorism and Select agents
- Respiratory Protection
- Occupational safety and health in the use of research animals
- Biohazards used in animal models

BIOHAZARDOUS MATERIALS:

- Viruses
- Bacteria
- Chlamydiae/Rickettsiae
- Fungi
- Prions
- Recombinant DNA
- Transgenic Plants, Animals and Insects
- Human and Primate Cells, Tissues, and Body Fluids
- Brain Tissue from Demented Patients
- Viral Vectors
- Replication deficient viruses

PRINCIPLES OF BIOSAFETY:

✓ Practice and Procedures - Standard Practices
  - Special Practices & Considerations
  - Safety Equipment Facility

✓ Design and Construction

✓ Increasing levels of protection

✓ Biosafety Levels 1-4 (BSL)
  - Increasing levels of employee and environmental protection
  - Guidelines for working safely in research & medical laboratory facilities

✓ Animal Biosafety Levels 1- 4 (ABSL)
  - Laboratory animal facilities
  - Animal models that support research
  - Guidelines for working safely in animal research facilities

BIOSAFETY CONCEPTS:

(1) Standard Microbiological Practices

- Most important concept / Strict adherence
- Aware of potential hazard
- Trained & proficient in techniques
- Supervisors responsible for:
  - Appropriate Laboratory facilities
  - Personnel & Training
- Special practices & precaution
  - Occupational Health Programs

(2) Safety Equipment

- Primary Containment Barrier
- Minimize exposure to hazard
  - Prevent contact / Contain aerosols
- Engineering controls/ equipment
- Personal Protective Equipment (PPE)
  - Gloves, gowns, Respirator, Face shield, Booties
- Biological Safety Cabinets
- Covered or ventilated animal cage systems

(3) Facility Design and Construction

- Secondary Barrier/ Engineering controls
- Contributes to worker protection
- Protects outside the laboratory
  - Environment & Neighborhood
- Ex. Building & Lab design, Ventilation, Autoclaves, Cage wash facilities, etc.

Rational and Subjective biosafety:

A risk assessment is conducted prior to use of a pathogen and assists in determining the proper equipment and procedures required for safe research. The risk assessment for a given activity that includes work with infectious agents is a subjective process. Inherent in any risk evaluation of this nature is the

extent of knowledge concerning the potential for transmission of a given agent while performing a specific activity. This clearly points to the need to do risk assessment on a case-by-case basis. A risk assessment is the rational application of safety principles to available options for handling hazardous materials. The following characteristics are to be considered when evaluating use of a potential pathogen:

- Nature of agent (risk group)
- Source of agent
- Route of infection
- Dissemination of agent

Each time an individual at OHSU works with any animal or biological sample that may be a reservoir for a pathogen that affects humans, that individual has carried out a risk assessment concerning the potential for disease transmission under a given set of circumstances. This is true regardless of that individual's experience and educational background. The real issue is not whether or not a risk assessment has occurred, but rather how thoroughly the assessment has been conducted. Supervisors are responsible for the safety of any assigned employees and should be consulted for assistance regarding specific hazards of the task.

Risk perception:

Risk perception is the subjective judgement that people make about the characteristics and severity of a **risk**. The phrase is most commonly used in reference to natural hazards and threats to the environment or health, such as nuclear power.

Harm - is an adverse outcome or impact.

Hazard - is any potential source of harm (the possibility to cause harm).

Risk - is the probability of harm occurring under defined circumstances.

Safety - is the condition of not being exposed to or being protected from harm; not likely to be harmed.

The average person defining a risk is not an objective, quantitative calculation, our perceptions, experiences and emotions (personal frame of reference) also have a profound effect on our **perception** of and **response** to risk. Two different persons may therefore perceive and respond very differently to the same risk - the root cause of many of the heated disagreements about technical subjects such as GMOs.

The key determinants of your perception regarding a particular risk are

1. Any facts you may know of (technical know-how, statistics, etc.),
2. How familiar you are with a particular risk situation (driving a conventional car vs. sitting in a driverless car), and

3. If you consider it to be a dreaded risk (resulting in catastrophic, uncontrollable harms, e.g. nuclear war), and
4. How the possible risks are balanced out by the possible benefits.

In principle this means the less we know about a particular risk the higher we perceive it to be. Now add to this the fact that our perceptions are shaped more by our personal experiences and own frame of reference than externally communicated facts and you'll realise why people often view a specialised activity/technology/product as risky while the facts paint a completely different picture - the main reason why the public debate on GMOs has not evolved much over the last two decades.

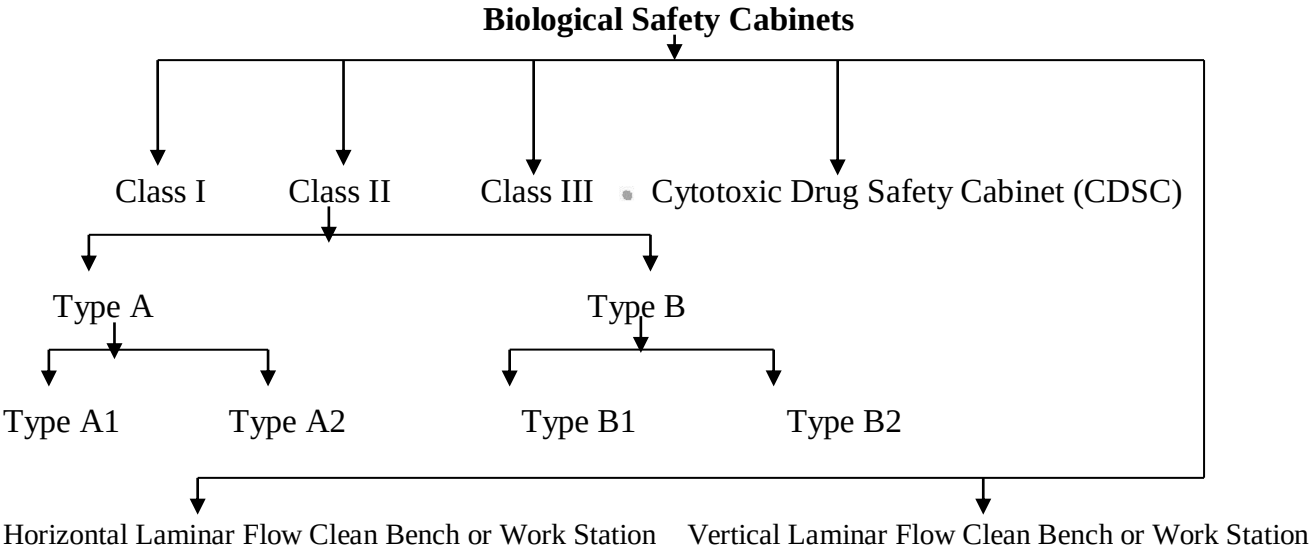
Biosafety Application

- ✓ Personnel change
- ✓ Addition of new biohazardous materials
- ✓ Change in procedures
- ✓ Location change

BIOSAFETY CABINETS

A **biosafety cabinet (BSC)** — also called **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.

CLASSIFICATION OF BIOSAFETY CABINET



Purposes

- The primary purpose of a BSC is to serve as the primary 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.
- Most classes of BSCs have a secondary purpose to maintain the sterility of materials inside (the "product").

1. Class I Biological Safety Cabinet

The Class I Biological Safety Cabinet provides **protection to the *operator and environment only*.** It provides ***no protection to the product*** (i.e. work inside the cabinet) from contamination. A Class I Biological Safety Cabinet is suitable for work with low to moderate risk biological agents (i.e. hazard groups 1, 2 & 3). It can be used for work with radionuclides and volatile toxic chemicals.

2. Class II Biological Safety Cabinet

The Class II Biological Safety Cabinet provides *protection to the operator, the environment and also the product*.

Type A1

The type A1 Biological Safety Cabinet is suitable for work with low to moderate risk biological agents (hazard group 1, 2 & 3) *in the absence of volatile toxic chemicals and volatile radionuclides*.

Type A2

The type A2 Biological Safety Cabinet is suitable for work with low to moderate risk (hazard group 1, 2 and 3) biological agents treated with minute quantities of toxic chemicals and trace quantities of radionuclides that will not interfere with the work if re-circulated in the down flow air.

Type B1

The type B1 Biological Safety Cabinet is suitable for work with low to moderate risk (hazard group 1, 2 and 3) biological agents. It may be used with biological agents treated with minute quantities of toxic chemicals and trace amounts of radionuclides if the chemicals or radionuclides will not interfere with the work when re-circulated in the down flow air.

Type B2

The type B2 Biological Safety Cabinet is suitable for work with low to moderate risk (hazard group 1, 2 and 3) biological agents. It may also be used with biological agents treated with toxic chemicals and radionuclides required in the microbiological studies.

3. Class III Biological Safety Cabinet

The Class III Biological Safety Cabinet provides the highest level of protection to the operator and the environment.

The Class III Biological Safety Cabinet is suitable for work with high-risk biological agents (hazard group 3 and 4). A class III Biological Safety Cabinet should not be used alone, but should incorporate the necessary equipment and be sited in specially designed laboratory facilities for handling high-risk samples (i.e. containment level 3 or 4). Several Class III cabinets can be joined together in a "line" which is custom-built to provide a larger work area. *A class III cabinet in basic laboratory should not be used to handle high risk samples.*

4. **Cytotoxic Drug Safety Cabinet (CDSC):**

The Cytotoxic Drug Safety Cabinet is also a ***partially enclosed*** ventilated cabinet that provides the same operator, product and environment protection as Class II Biological Safety Cabinet. In addition it ***provides protection to the maintenance staff servicing the fans and internal surfaces of the cabinet***.

5. **Horizontal Laminar Flow Clean Bench or Work Station**

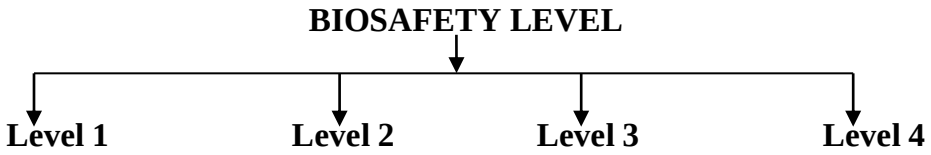
They are not Biological Safety Cabinets, provide only product protection and are not recommended for use in the University because in some instances can increase the risk of infection for the user.

6. **Vertical Laminar Flow Clean Bench or Work Station**

They are also not Biological Safety Cabinets, provide only product protection and are not recommended for use in the University because under some circumstances they can increase the risk of infection for the user.

BIOSAFETY LEVEL

A specific combination of work practices, safety equipment, and facilities which are designed to minimize the exposure of workers and the environment to infectious agents.



Biosafety Level-1 (BSL-1 or ABSL-1):

Level 1:

This level applies **to agents that do not ordinarily cause human disease.**

It includes several kinds of bacteria and viruses including canine hepatitis, non-pathogenic *Escherichia coli*, as well as some cell cultures and non-infectious bacteria. At this level precautions against the biohazardous materials in question are minimal, most likely involving gloves and some sort of facial protection.

The laboratory is not necessarily separated from the general traffic patterns in the building. Work is generally conducted on open bench tops using standard microbiological practices. Usually, contaminated materials are left in open (but separately indicated) waste receptacles. Decontamination procedures for this level are similar in most respects to modern precautions against everyday microorganisms **(i.e., washing one's hands with anti-bacterial soap, washing all exposed surfaces of the lab with disinfectants, etc.)**.

In a lab environment all materials used for cell and/or bacteria cultures are decontaminated via **autoclave.**

Biosafety Level-1 (BSL-1 or ABSL-1)

- Well characterized agents
- Agents not known to cause disease (in healthy human adults; now healthy immunocompetent adult)
- Prophylactic treatment available
- Open bench procedures
- Animals in open cage system or open environment(outdoors)
- Good laboratory practices

Risk Group 1 Agents:

- *E.coli* K-12
- Transgenic Plants
- Plasmids
- Fungi
- Mold
- Yeast

BSL-1 Practices:

- Bench-top work allowed
- Daily Decontamination
- Manual pipetting
- Required Hand washing
- Red bag waste

- Bio cabinet not required (unless creating aerosols)

Biosafety Level-2 (BSL-2 or ABSL-2):

Level 2 -- This level is appropriate for agents **that can cause human disease, but who's potential for transmission is limited.**

It includes various bacteria and viruses that cause only mild disease to humans, or are difficult to contract via aerosol in a lab setting, such as *C. difficile*, most Chlamydiae, hepatitis A, B, and C, influenza A, Lyme disease, *Salmonella*, mumps, measles, HIV, MRSA. 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; and
4. Certain procedures in which infectious aerosols or splashes may be created are conducted in biological safety cabinets or other physical containment equipment.

Risk Group 2 Agents:

- Human or Primate Cells
- Herpes Simplex Virus
- Replication Incompetent Attenuated Human Immunodeficiency Virus
- Patient specimens

BSL-2 – Biosafety Practices:

- Agents associated w/ human disease
- Treatment for disease available
- Agent poses moderate hazard to personnel and environment
- Direct contact or exposure
- Percutaneous exposure
    - Scratch, Puncture, Needle stick
- Mucus membrane exposure
    - Eyes, Mouth, open cut
- Limited access to lab when work in progress
- Daily decontamination
- Mechanical pipetting
- Lab. coat, safety glasses and gloves required

- Red bag & sharps containers required
- Biohazard Sign posted at entrance to lab
- Label all equipment (incubators, freezers, etc.)
- TC room – negative air flow
- Documented training
- Baseline serology or pre-vaccination may be required

Biosafety Level-3 (BSL-3 or ABSL-3):

Level 3 -- This level applies to agents that may be transmitted by the respiratory route which can cause serious infection.

It includes various bacteria, parasites and viruses that can cause severe to fatal disease in humans but for which treatments exist, such as *Leishmania donovani*, *Mycobacterium tuberculosis*, *Bacillus anthracis*, *Chlamydophila psittaci*, West Nile virus, Venezuelan equine encephalitis virus, Eastern equine encephalitis virus, Hendra virus, SARS coronavirus, *Salmonella typhi*, *Coxiella burnetii*, Rift Valley fever virus, *Rickettsia rickettsii*, and yellow fever virus.

All procedures involving the manipulation of infectious materials are conducted within biological safety cabinets, specially designed hoods, or other physical containment devices, or by personnel wearing appropriate personal protective clothing and equipment. The laboratory has special engineering and design features.

1. The filtered exhaust air from the laboratory room is discharged to the outdoors,
2. the ventilation to the laboratory is balanced to provide directional airflow into the room,
3. access to the laboratory is restricted when work is in progress, and
4. The recommended Standard Microbiological Practices, Special Practices, and Safety Equipment for Biosafety Level 3 is rigorously followed.

The decision to implement this modification of biosafety level 3 recommendations is made only by the laboratory director.

Risk Group 3 Agents:

- ✓ Human Immunodeficiency Virus
- ✓ *Mycobacterium tuberculosis*
- ✓ *Coxiella burnetii*

BSL-3 Practices:

- ✓ Public access NOT permitted
- ✓ Daily decontamination after spill and upon completion of experiment
- ✓ Autoclave required and waste is disposed at the end of day
- ✓ Required foot activated hand washing sink and controls
- ✓ No sharps unless absolutely necessary
- ✓ Aerosol minimization procedures required
- ✓ Wrap around disposable clothing is required. Specialized equipment may be required depending upon procedures Biohazard. Signs and labels posted
- ✓ Air flow from low hazard to high hazard "Pressure Mapping"
- ✓ Bench top work not permitted
- ✓ Documented training and personnel competency certification (for BSL-3 procedures)
- ✓ Baseline serology
- ✓ Spills – report immediately and treat accordingly
- ✓ Vaccinations/post exposure protocols and SOP's, Biosafety Manual, Biosafety Officer

Biosafety Level-4 (BSL-4 or ABSL-4):

Level 4 -- This level is used for the diagnosis of exotic agents that pose a high risk of life-threatening disease, which may be transmitted by the aerosol route and for which there is no vaccine or therapy.

This level is required for work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections, agents which cause severe to fatal disease in humans for which vaccines or other treatments are *not* available, such as Bolivian and Argentine hemorrhagic fevers, Marburg virus, Ebola virus, Lassa fever, Crimean-Congo hemorrhagic fever, smallpox, and various other hemorrhagic diseases.

When dealing with biological hazards at this level the use of a Hazmat suit and a self-contained oxygen supply is mandatory. The entrance and exit of a level four biolab will contain multiple showers, a vacuum room, an ultraviolet light room, and other safety precautions designed to destroy all traces of the biohazard.

Multiple airlocks are employed and are electronically secured to prevent both doors opening at the same time. All air and water service going to and coming from a biosafety level 4 (or P4) lab will undergo similar decontamination procedures to eliminate the possibility of an accidental release.

Agents with a close or identical antigenic relationship to biosafety level 4 agents are handled at this level until sufficient data is obtained either to confirm continued work at this level, or to work with them at a lower level.

Biosafety Level-4

- Maximum containment facilities
- Builds on BSL-3/ ABSL-3 practices
- Pressurized Containment Suite
- Chemical BSL-3 + Class III Biosafety Cabinet
- Liquid effluent collection / decontamination decontamination showers

Biosafety Level 4:

- Lassa fever Virus
- Ebola Hemorrhagic Fever Virus
- Marburg Virus
- Herpes B Virus

Risk Group	Biosafety Level	Laboratory type	Laboratory practices	Safety equipment
1	Basic - Biosafety Level 1	Basic teaching, research	GMT	None; open bench work
2	Containment - Biosafety Level 2	Primary health services, diagnostic, research	GMT plus protective clothing, biohazard sign	Open bench plus BSC for potential aerosols
3	High Containment - Biosafety Level 3	Special diagnostic, research	As Level 2 plus special clothing, controlled access, directional air flow	BSC and/or other primary devices for all activities
4	Maximum containment - Biosafety Level 4	Dangerous pathogen units	As Level 3 plus airlock entry, shower exit, special waste disposal	Class III BSC, or positive pressure suits in conjunction with Class II BSCs, double ended autoclave (through the wall), filtered air

GMT: Good Microbiological Techniques (Chapter 5)
BSC: Biological Safety Cabinet

RISK ASSESSMENT:

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.

- ✓ Risk Group 1
- ✓ Risk Group 2
- ✓ Risk Group 3
- ✓ Risk Group4

Risk Group 1:

- (No or low individual and community risk)
- A microorganism that is unlikely to cause human or animal disease.

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.

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.

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.

Risk Group Comparisons:

	Risk Group 1	**Risk Group 2**	**Risk Group 3**	**Risk Group 4**
Characteristics	Does not cause disease in healthy adults.	Can cause infection of varying severity. Rarely lethal. Can be controlled using standard laboratory	Agents associated with moderate to severe disease outcome. Can be lethal.	Capable of causing severe disease with lethal outcome.

		practices.		
Availability of Treatment	Not applicable.	Treatment may be available or host immune system is capable of controlling the infection.	Treatment may not be available.	Treatment is generally not available. Experimental Treatment regimens possible.
Routes of Transmission	Not applicable.	Ingestion, through the skin, and via facial mucous membranes.	Same as Risk Group 2 plus inhalation.	Same as Risk Group 3.
Disease Severity to Individual	None in healthy adults.	Low to moderate.	Moderate to high Higher mortality and morbidity.	High Highest mortality rates in this category.
Community Risk	Low	Low	Low to Moderate	High Perception risk also very high.
Infections Dose	Not applicable	Generally high (variable)	Lower doses capable of infection	Can be as low as 1 organism
Example Agents	Non-conjugative strains of E. coli, Sacchromyces cerevisiae.	Parasites (i.e. Plasmodium, Trypanosomes, Leishmania) GI pathogens (Salmonella, Shigella) Bloodborne Pathogens (HBV, HCV, Borrelia).	Mycobacterium tuberculosis, West Nile Virus, Yellow Fever Virus, Rickettsia rickettsi.	Ebola virus, Marburg virus, Sabia virus, Equine Morbillivirus.
Rule of Thumb	Don't drink it! Never eat, drink or smoke in the laboratory.	Don't touch it! Wear gloves, decontaminate work surfaces, avoid touching your face, make sure wounds are covered, work in a BSC, wear eye Protection, and work behind a shield.	Don't breathe it! Because of inhalation risk, perform all work inside of a biosafety cabinet. Wear respiratory protection if needed.	Don't do it! (Don't do it in your state unless you have a federally approved BSL4 laboratory!) Risk Group 4 Agents require significant containment.

Lab associated infection:

Risk of exposure to **infectious** agents that cause disease ranging from inapparent to life-threatening **infections**, but the precise risk to a given worker unknown.

Transmission and Preventing Laboratory Acquired Infections:

Workplace-acquired infections are rare but still a possibility. In order for infection and disease to occur, there must be

- an adequate number of organisms to cause disease (infectious dose), and
- a route of entry to the body.

Knowing how infectious organisms are transmitted and what their infectious dose is, can help to evaluate the risk and avoid infection. Information about the organism should be gathered prior to working with it.

Infectious agents are transmitted through one or more of the following routes of exposure:

- ✓ Sharps injuries (needlesticks, cuts with contaminated broken glass, etc., also known as parenteral exposure)
- ✓ Inhalation of aerosols (microscopic solid or liquid particles small enough to remain dispersed and suspended in air for long periods; about 5 micrometers or less in diameter)
- ✓ Ingestion
- ✓ Mucous membrane exposure (including the eyes, inside of the mouth and nose, and the genitals)

Using work practices that block routes of exposure can prevent workplace infection. Good microbiological techniques must always be used in the laboratory:

- ✓ Eating, drinking, smoking, applying cosmetics or storing food for human consumption in laboratories is strictly prohibited.
- ✓ Potentially contaminated hands should be kept away from the mouth, eyes, and non-intact skin.
- ✓ Hands should be washed frequently, even after wearing gloves, and scrubbed vigorously with soap and water for a full 30 seconds (as long as it takes to sing "Happy Birthday" or the "Cyclone Fight Song"). The physical removal of organisms from the skin is just as important as using a disinfectant.
- ✓ Work surfaces and equipment must be decontaminated immediately after using biohazardous materials.
- ✓ Wearing appropriate personal protective equipment (PPE) blocks potential routes of exposure.

Decontamination:

Biohazardous materials must be decontaminated and disposed of properly to keep personnel and the environment safe from unintended releases of material.

- Autoclaving is one way biological material can be decontaminated. For more information about autoclaving, consult the Autoclave page or complete the EH&S online Autoclave Safety Training.
- Items that cannot be autoclaved can generally be decontaminated using a chemical disinfectant.
- Choosing the appropriate chemical disinfectant depends on the surface or item needing decontamination, as well as the organism requiring inactivation.
- Section E of the *Biosafety Manual* provides detailed information about chemical disinfection.

Supplies:

Most supplies for decontaminating biohazardous waste, such as autoclave biohazard bags and sharps containers, may be purchased through Central Stores. An EH&S Biosafety Specialist can provide assistance with finding supplies for special disposal needs.

Biological security or biosecurity is the protection of microbial agents and research-related information from theft, loss, diversion or intentional misuse. While biosecurity includes the physical security of items, it also includes security for information stored on computers and other electronic devices.

In general, all laboratory personnel are responsible for

- controlling access to areas where hazardous materials are used and stored
- knowing who is in the laboratory and asking for identification if unsure
- knowing what materials are brought into and removed from the laboratory
- Reporting any undocumented visitors, missing biological, chemical or radioactive materials, unusual or threatening phone calls, etc. to the laboratory supervisor, EH&S and DPS.

UNIT – III: Biosafety Assessment

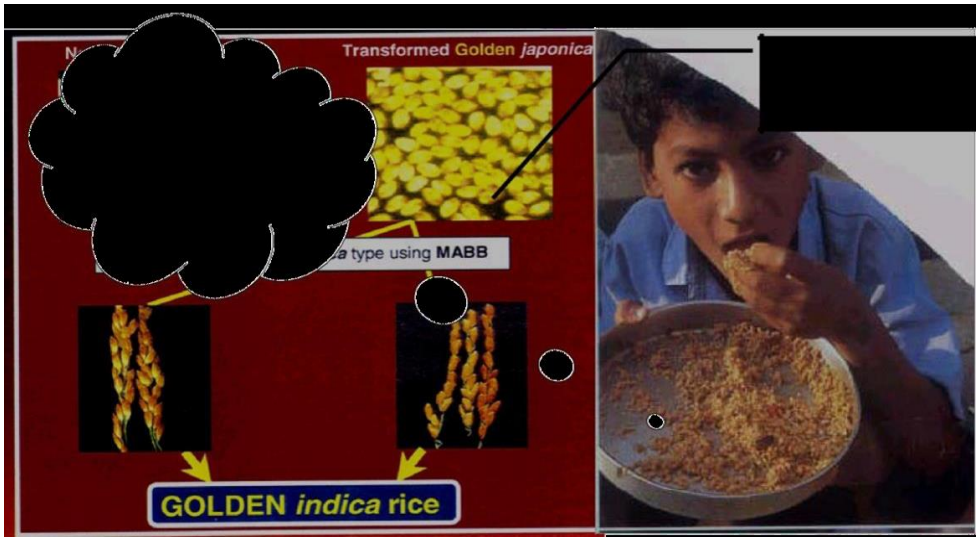
Biosafety

Biological safety or **biosafety** is the application of knowledge, techniques and equipment to prevent personal, laboratory and environmental exposure to potentially infectious agents or biohazards.

Biosafety Guidelines for Laboratories:

- ✓ Food storage, eating, drinking and smoking are prohibited in lab.
- ✓ Mouth pipetting is prohibited
- ✓ Laboratory coats are obligatory and should be removed when exiting the lab.
- ✓ Working surfaces must be decontaminated using soap and alcohol after each working day.
- ✓ Waste products must be decontaminated by incineration or by autoclaving.
- ✓ Frequent hand wash is obligatory (at (east one hand wash sink should be available).
- ✓ Avoid contact with GMO's and other exotic biological agents; disposable .gloves should be worn when handling such items.
- ✓ Laboratory door should be closed at all times.
- ✓ Working with fume-producing chemicals must be under the laboratory hood.
- ✓ Biohazard warning signs should be always posted in labs.

We need Biotech crops:



Various Insect & Herbicide tolerant crops etc

Biotechnology contributing in Agriculture:

- ✓ Pest management
- ✓ Trait improvement
- ✓ Increased productivity

- ✓ Fortification (Increases the nutritive values)
  - Golden rice (vitamin A rich rice)
  - Iron and Zinc rich rice
  - Quality Protein maize
  - *AmA1* gene in Potato

Advantages of Genetically Modified Crops:

1. Better for the Environment
2. Resistance to Disease
3. Sustainability
4. Increased Flavor and Nutrition
5. Longer Shelf Life
6. Keeps It Affordable

Disadvantages of Genetically Modified Crops:

1. Cross Contamination
2. Allergies on the Rise
3. Less Effective Antibiotics
4. Not Enough Testing

Biohazard:

Biological agents and materials which are potentially hazardous to humans, animals and or plants.

Genetically Modified Organisms (GMOs) used in agriculture:

- ✓ A **genetically modified organism (GMO)** or **genetically engineered organism (GEO)** is an organism whose genetic material has been altered using genetic engineering techniques

⇩

- ✓ These techniques, generally known as recombinant DNA technology, use DNA molecules from different sources, which are combined into one molecule to create a new set of genes

⇩

- ✓ This DNA is then transferred into an organism, giving it modified or novel genes

⇩

- ✓ Transgenic organisms, a subset of GMOs, are organisms which have inserted DNA that originated in a different species

⇩

- ✓ GMOs are the constituents of genetically modified foods**.**

Applications:

- GMOs are used in biological and medical research, production of pharmaceutical drugs, experimental medicine (e.g. gene therapy), and agriculture (e.g. golden rice). The term "genetically modified organism" does not always imply, but can include, targeted insertions of genes from one species into another.
- For example, a gene from a jellyfish, encoding a fluorescent protein called GFP, can be physically linked and thus co-expressed with mammalian genes to identify the location of the protein encoded by the GFP-tagged gene in the mammalian cell.

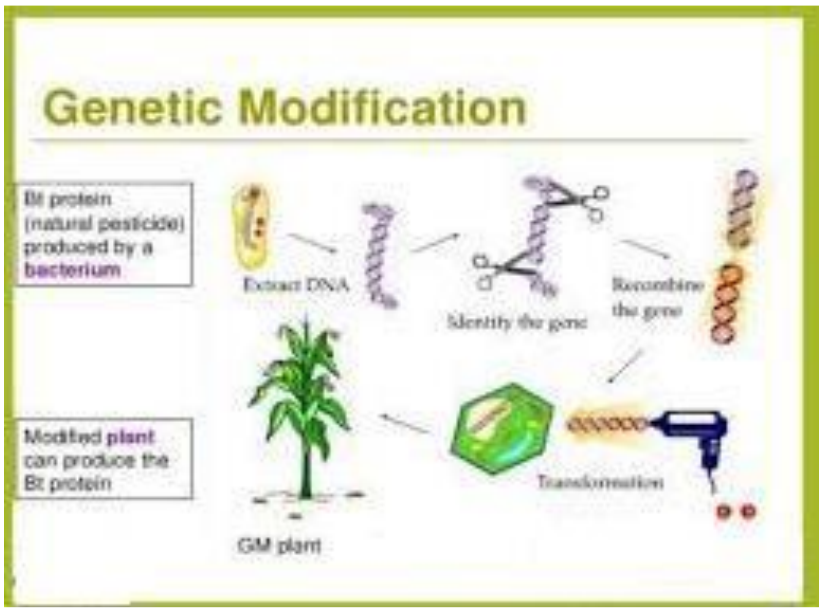
Transgenic Research in Agriculture:

Target Crops/ Vegetables

Cotton, Corn, Mustard, Rice, Soybean, Potato, Tobacco, Coffee, Tomato, Brinjal, Cauliflower, Pea, Cabbage, Banana, Muskmelon, Pigeonpea, Chickpea, Bell-pepper, Blackgram, Chilli, Watermelon etc.

Transgenes Employed

Bt. toxin genes, Herbicide tolerant genes (CP4 EPSPS, Bar gene), Xa21, ctx-B and tcp of *V.cholera*, Chitinase, Glucanase, ACC synthase, RIP, Protease Inhibitor, Lectin, Ama-1, OXDC gene, Rabies glycoprotein gene, Bar, Barnase, Barstar, GNA gene, *Vip*-3 gene, Bacterial Blight Resistance gene, Osmotin etc.



S.No.	Crop	Company Name	Trial	Trait	Gene/Event
1	Cauliflower	Sungro Seeds Research Ltd.	BRL-I	Insect Resistance	*cry1Ac*
		Nunhems India Pvt. Ltd	Event selection	Insect Resistance	*cry1b and cry 1C*
2	Cotton	Dow AgroSciences India Pvt. Ltd.	BRL-I	Insect Resistance	*cry1Ac& cry1F* (WideStrike = Event 3006-210-23 and Event 281-24-236)
		JK Agrigenetics Ltd.	BRL-I	Insect Resistance	*cry1Ac* (Event-1) and *cry1EC* (Event-24)
		MAHYCO	BRL-I	Insect resistance and Herbicide tolerance	*cry1Ac & cry2Ab* (MON 15985) and *CP4EPSPS* (MON 88913)
		Metahelix Life Sciences	LST	Insect Resistance	*cry1C* (MLS9124 event)
		Central Institute for	LST	Insect Resistance	*cry 1Ac*

		Cotton Research			
3	Rice	Bayer Bioscience Pvt. Ltd.	Event selection	Insect resistance	*cry 1 Ab, cry 1C & bar*
		Avesthagen Ltd.	Event Selection	Oxdative stress	*Orya sativa taipae 309*
4	Tomato	Avesthagen Ltd.	Event selection	Increased lycopene content	unedited *NAD9*
5	Groundnut	ICRISAT	Event selection	Tobacco streak virus against peanut stem necrosis disease.	Coat protein gene
6	Cabbage	Nunhems India Pvt. Ltd	Event selection	Insect Resistance`	*cry1b and cry 1C*
7	Potato	Central Potato Research Institute.	Event selection	Late blight resistance	*RB gene*
8	Corn	Monsanto India Ltd.	BRL-I	Insect resistance and herbicide tolerant	*Cry 1A.105 (chimeric gene) and cry2Ab2*

Why Regulations are Necessary for Using GMOs and Products Thereof?

- GMOs) and their products are to play important role including human and animal health care system, agriculture, industrial products, environment management
- Concurrently, there could be unintended hazards and risks from the use of GMOs and products thereof, if the new technology was not properly assessed before use
- A GMO can be safe but this can be unsafe too depending upon the trans-genes, the host organism and the environment where the GMO is being tested
- GMOs can be microorganisms, plants, and animals
- A case-by-case analysis of the safety of each GMOs and products thereof need to be conducted to assess their safety
- Whenever GMOs are released in environment they require safety evaluation for humans and animals; due to this

- Indian Government enacted the Environment (Protection) Act in 1986 and thereafter, notified Rules & Procedures (Rules) for handling GMOs and hazardous organisms through a Gazette Notification from the Union Ministry of Environment & Forests
- The Rules cover all kinds of GMOs and products thereof

IMPLEMENTING AGENCIES

- The implementation of Rules 1989 is being administered by the **Department of Biotechnology** (DBT) and **Ministry of Environment and Forests** (MoEF). These rules define the competent authorities and composition of such authorities for handling of various aspects of the rules. Presently there are six Competent Authorities i.e. The **Recombinant DNA Advisory Committee** (RDAC), **Institutional Biosafety Committee** (IBSC), **Review Committee on Genetic Manipulation** (RCGM), **Genetic Engineering Approval Committee** (GEAC), **State Biotechnology Coordination Committee** (SBCC), **District Level Committee** (DLC). While RDAC has an advisory role, IBSC, RCGM and GEAC are involved in regulations and SBCCs and DLCs are involved in monitoring.

S. No	**Statutory Bodies**	Role
1	The Recombinant DNA Advisory Committee (**RDAC)**	Advisory
2	Institutional Biosafety Committee (**IBSC)**	Approval
3	Review Committee on Genetic Manipulation (**RCGM**)	
4	Genetic Engineering Approval Committee (**GEAC**)	
5	State Biotechnology Coordination Committee (**SBCC**)	Monitoring
6	District Level Committee (DLC)	

Steps to be followed for developing Transgenic Crops with new gene in new gene cassette:

Proposal

⇩

Institutional Biosafety Committee with DBT Nominee

⇩

RCGM's approval for Lab & Green House Experiments & Generation of relevant data

⇩

RCGM's approval for Contained open field trials & Generation of biosafety data

⇩

RCGM's approval for Multi-location trials under RCGM for generation of biosafety and agronomic data

⇩

Large scale field trials under GEAC & ICAR

Trials for generation of biosafety and agronomic data

⇩

Commercialization of seeds as per the relevant Acts & Rules

For New Transgenic Event:

Institutional Biosafety Committee (IBSC)

⇩

Review Committee on Genetic Manipulation (RCGM)

⇩

Monitoring-cum-Evaluation Committee (MEC)

⇩

Genetic Engineering Approval Committee (GEAC)

Approval for large scale Field Trials and Evaluation Protocol**

Concurrent

⇩ ⇩

Field trials by Company/ Institutions **ICAR trials for VCU Involving SAUs and other State Agencies**

GEAC

⇩

Ministry of Agriculture (DAC/ICAR)

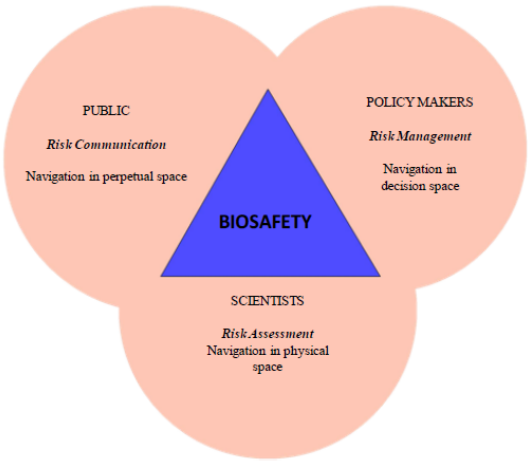
⇩

Approval for commercial release/notification/registration of variety (ies)/hybrid(s)

DAC/ICAR

Ministry of Agriculture & State Governments, Post-release monitoring

Environmental release of GMOs:



Microbiological risk analysis

One of the most helpful tools available for performing a microbiological risk assessment is the listing of risk groups for microbiological agents. However, simple reference to the risk grouping for a particular agent is insufficient in the conduct of a risk assessment. Other factors that should be considered, as appropriate, include:

1. Pathogenicity of the agent and infectious dose
2. Potential outcome of exposure
3. Natural route of infection
4. Other routes of infection, resulting from laboratory manipulations (parenteral, airborne, ingestion)
5. Stability of the agent in the environment
6. Concentration of the agent and volume of concentrated material to be manipulated
7. Presence of a suitable host (human or animal)
8. Information available from animal studies and reports of laboratory-acquired infections or clinical reports
9. Laboratory activity planned (sonication, aerosolization, centrifugation, etc.)
10. Any genetic manipulation of the organism that may extend the host range of the agent or alter the agent's sensitivity to known, effective treatment regimens
11. Local availability of effective prophylaxis or therapeutic interventions. On the basis of the information ascertained during the risk assessment, a biosafety level can be assigned to the planned work, appropriate personal protective equipment selected, and standard operating procedures (SOPs) incorporating other safety interventions developed to ensure the safest possible conduct of the work.

Risk Assessment:

Risk to the health of workers and others in the immediate vicinity of the work-place is one of the main concern in assessing the hazards associated with the contained use of GMOs. These risks are considered proportional to the scale of the operation and all regulatory systems distinguish small-scale use for research and development. As for large-scale use, the risk to health and possible risks to environment in the event of escape of organism from the production area must be evaluated and an appropriate level of containment applied. Containment may be physical, e.g. barriers limiting the escape of the organisms, or biological, e.g. physiological limitations to the survival and replication of the organism outside the process environment.

NAS posed the following three questions, used in making judgments of risk (1989):

- ✓ Are we familiar with the properties of the organism and the environment into which it may be introduced?
- ✓ Can we confine or control the organism effectively?
- ✓ What are the probable effects on the environment, should the introduced organism or a genetic trait persist longer than intended or spread to non target environment?

The development of new technology opens up a series of questions on risk for which there are few or no data to help in its evaluations

A definition that was suggested is: - **Risk = Probability of hazard X Magnitude of hazard**

As it was mentioned earlier biotechnology aims to produce crops with new properties presumably for the benefit of mankind. This means that if there is any increased in risk it has to be balanced against the benefits which would accrue from using that transgenic and we should consider redefining risk as "acceptable risk".

Acceptable risk = Probability of hazard X Magnitude of hazard

Benefits from product

In order to understand the circumstances under which a genetically engineered crop plant might become a persistent agricultural weed or become invasive of natural habitats, it is essential to know the value of the parameters in the following model:

The rate of increase of the transgenic plant = Plant development rate in a given habitat.

+ Its seed production (timing and duration)

+ Survival of vegetative parts (discounted by their mortality rate)
- The effects of competition with other plants of the same kind
- The effects of competition with other plant species.
- The effects of herbivores (insect and vertebrate)
- The effect of fungi and other plant diseases.
+ Immigration of transgenic seed from other sites.

+ Establishment of transgenic plants from dormant seed in the soil (seed bank).

The conditions under which research with a genetically modified organism can be conducted safely should be assessed relative to the conditions that are normally accepted for conducting research with the parental organism. Therefore, the safety evaluation determining the level of safety concern is essential.

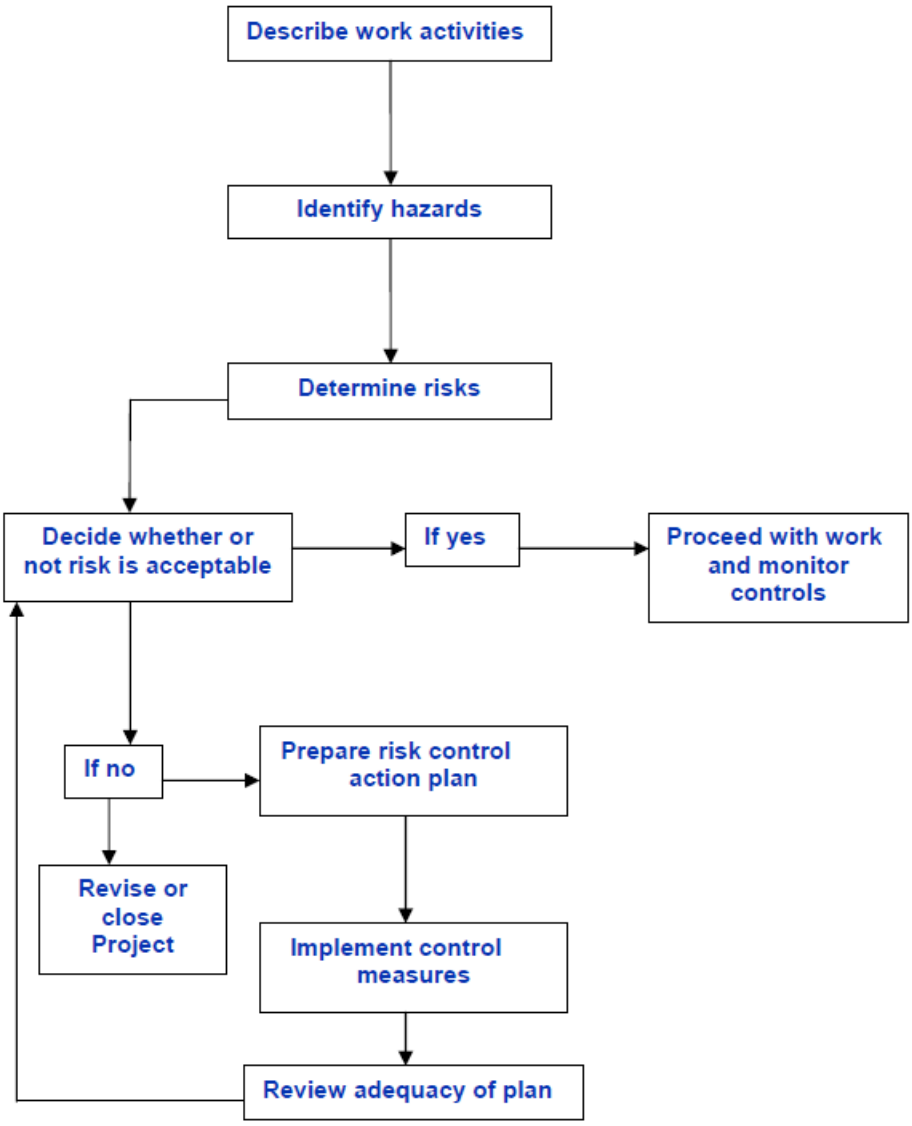
Biosafety management and communication:

1. It is the responsibility of the laboratory director (the person who has immediate responsibility for the laboratory) to ensure the development and adoption of a biosafety management plan and a safety or operations manual.
2. The laboratory supervisor (reporting to the laboratory director) should ensure that regular training in laboratory safety is provided.
3. Personnel should be advised of special hazards, and required to read the safety or operations manual and follow standard practices and procedures. The laboratory supervisor should make sure that all personnel understand these. A copy of the safety or operations manual should be available in the laboratory.
4. There should be an arthropod and rodent control programme.
5. Appropriate medical evaluation, surveillance and treatment should be provided for all personnel in case of need, and adequate medical records should be maintained.

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, pipetting, making smears, opening cultures, taking blood/serum samples, centrifuging, etc.
2. Ingestion risks when handling specimens, smears and cultures
3. Risks of percutaneous exposures when using syringes and needles
4. Bites and scratches when handling animals
5. Handling of blood and other potentially hazardous pathological materials

6. Decontamination and disposal of infectious material.



Risk assessment strategy

Advances made possible by recombinant DNA technology are:

1. Isolating proteins in large quantities: many recombinant products are now available, including follicle stimulating hormone (FSH), Follistim AQ vial, growth hormone, insulin and some other proteins.
2. Making possible mutation identification: due to this technology, people can be easily tested for mutated protein presence that can lead to breast cancer, neurofibromatosis, and retinoblastoma.
3. Hereditary diseases carrier diagnosis: tests now available to determine if a person is carrying the gene for cystic fibrosis, the Tay-Sachs diseases, Huntington's disease or Duchenne muscular dystrophy.

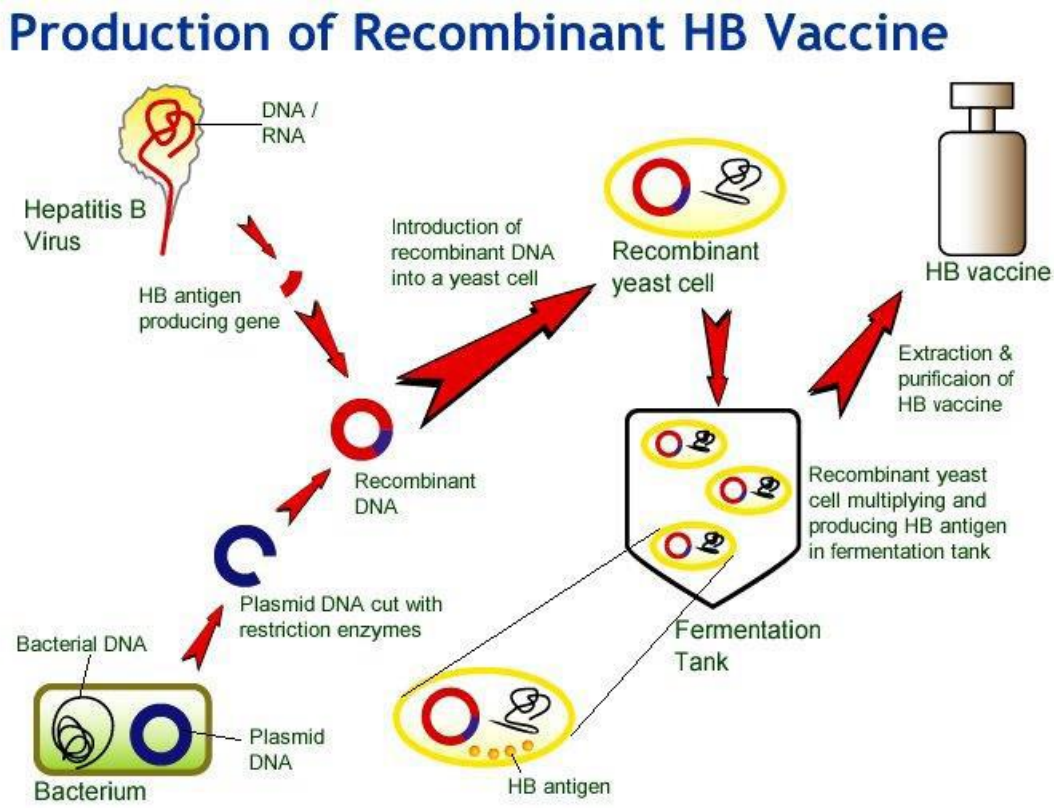
4. Gene transfer from one organism to other: the advanced gene therapy can benefit people with cystic fibrosis, vascular disease, rheumatoid arthritis and specific types of cancers.

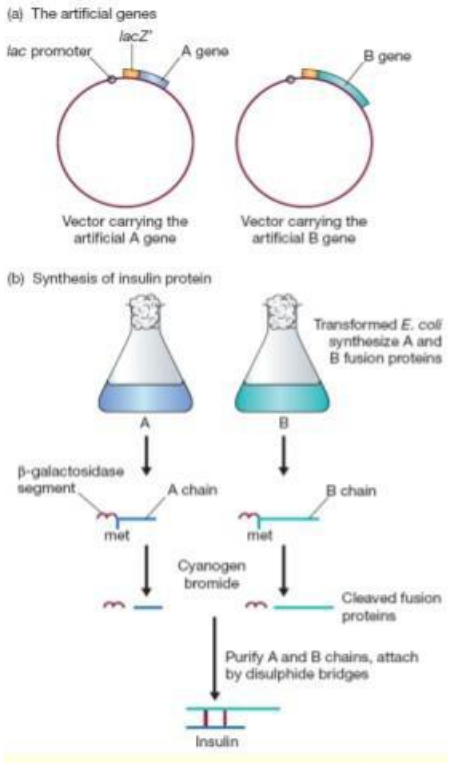
Pharmaceutical products – Vaccines:

Awareness is still lacking in the fields of pharmaceuticals and medical treatments such as gene therapy and xenotransplantation.

- ✓ The use of GMOs in the production of pharmaceutical products such as insulin and hepatitis vaccines raises issues related to production process, containment and possible human health effects.
- ✓ The development and imminent commercialization of live GE vaccines is taking place with very little public knowledge and even less regulatory scrutiny
- ✓ These require specific biosafety assessment and cannot be treated in the same manner as conventional vaccines
- ✓ They are GMOs and each vaccination is actually a "release" with all its environmental and health implications
- ✓ A human and animal health risk that has been meanwhile, live GE vaccines are already being tested in livestock. These vaccines raise the same issues and concerns.

Rapid developments in biotechnology, genetics and genomics already pose a variety of environmental, ethical, political and social questions. There are now increased biological warfare risks posed by the use of new and emerging technologies used to create new types of biological and bio-chemical weapons. These include material degrading microorganisms. There is a need for more understanding of the scientific research being done; the actual development of these biological weapons as well as the type of government actions required to address associated risks in biosafety frameworks, identified by some scientists is the creation of new viruses.





GE/ GM vaccines: - Live and Killed (Non-live)

1. Live:

- Define deletion mutant vaccine

- Non-defined attenuated strain vaccines

- **Vectored Vaccine:** Transgenic Salmonella, Vaccinia virus etc.

- **The transgenic plants:** edible vaccines viz., transgenic banana and tomato cure diseases like Cholera, Rabies and Hepatitis-B.

- For FMD transgenic sugar beet.

2. Killed (Non-live)

- Synthetic and recombinant antigen based vaccines

- Nano-particle based vaccines

- Nucleic acid based vaccines: Plasmid, DNA/ RNA/ PNA (Pneumococcal vaccine)/ siRNA (small-interfering RNA) based vaccines

More problems of GE Vaccines:

- Presence of extraneous agents in live vaccines while poor antigenicity of killed vaccines (require adjuvant).
- Poor predictability in its behavior
- Problems likely to arise are, identification of neutralisation antigen, need for proper co and post translational modifications of viral/ parasitic polypeptide, need for proper assembly of antigenic protein to avoid poor immunogenicity, and separation of recombinant protein from cell constituents
- In bacterial expression systems antigens from viruses of eukaryotes are not properly expressed due problems of co translational and post translational changes

Major Problems:

- Social acceptance
- Environmental safety concerns
- Since the genes for the desired antigens must be located, cloned, and expressed efficiently in the new vector, the cost of production is high
- Biological safety aspects: When engineered vaccinia virus/ Salmonella are used to vaccinate, care must be taken to spare immunodeficient individuals
- Potential integration of DNA into host genome leading to insertional mutagenesis
- Induction of autoimmune responses: anti-DNA antibodies may be produced against introduced DNA
- Induction of immunologic tolerance: The expression of the antigen in the host may lead to specific non-responsiveness to that antigen or eating of too much edible vaccine.

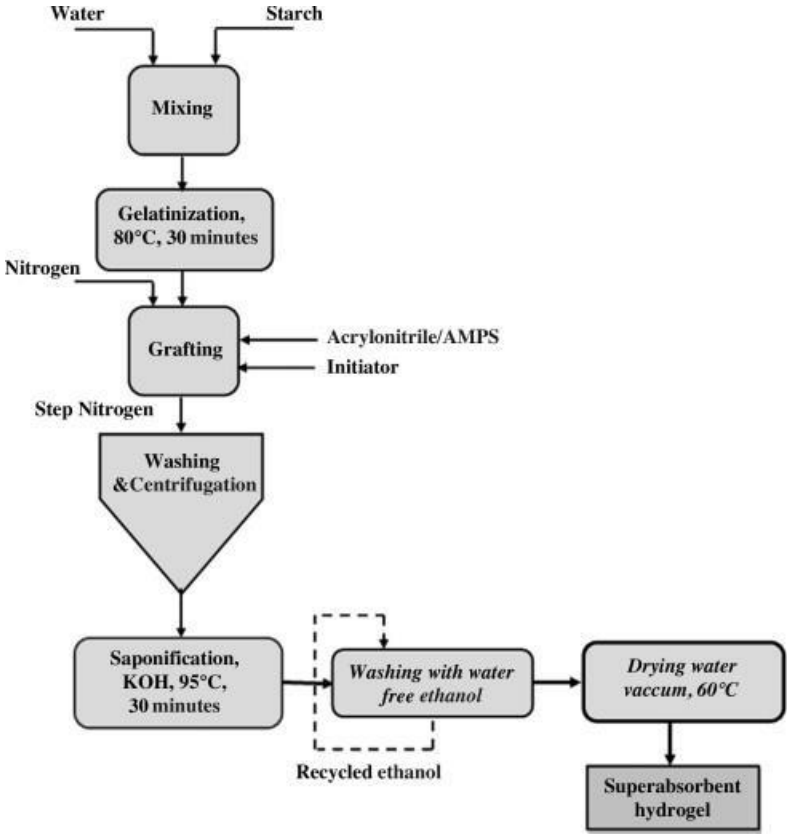
Advantages of GE Vaccines:

- ❖ GE Vaccines are either noninfectious or have defined virulence
- ❖ Production can easily be scaled to produce cheap vaccines
- ❖ Most vectors are safe, easy to grow and store
- ❖ Antigens which do not elicit protective immunity or which elicit damaging responses can be eliminated from the vaccine, e.g. Cholera toxin A from cholera vaccine
- ❖ Genes for protective antigens of even non-cultivable viruses/ bacteria/ parasites can used to produce a vaccine
- ❖ Chimerical vaccines can be made: Vectored vaccines for multiple pathogens

GE Drugs:

Any substance that, when absorbed into the body of a living organism, alters (changes) normal body function Examples: aspirin, Antibiotics, Nicotine, alcohol, Marijuana….

Preparation process of superabsorbent hydrogel:



NOTE: Explain the figure your knowledge

USES:

- ✓ Glimepiride is used with a proper diet and exercise program to control high blood sugar in people with type 2 diabetes
- ✓ It may also be used with other diabetes medications
- ✓ Controlling high blood sugar helps prevent kidney damage, blindness, nerve problems, loss of limbs, and sexual function problems
- ✓ Proper control of diabetes may also lessen your risk of a heart attack or stroke
- ✓ Glimepiride belongs to the class of drugs known as sulfonylureas
- ✓ It lowers blood sugar by causing the release of your body's natural insulin.

Biomolecules:

An organic compound normally present as an essential component of living organism.

Characteristics of Biomolecules:

1) Most of them are organic compounds.
2) They have specific shapes and dimensions.
3) Functional group determines their chemical properties.
4) Many of them arc asymmetric.
5) Macromolecules are large molecules and are constructed from small building block molecules.
6) Building block molecules have simple structure.
7) Biomolecules first gorse by chemical evolution.

Important Biomolecules of life:

1) **Water:** Being the universal solvent and major constituents (60%) of any living body without which life is impossible. It acts as a media for the physiological and biochemical reactions in the body itself. Maintain the body in the required turgid condition.

2) Carbohydrates: It is very important for source of energy for any physical body function.

3) Proteins: These are very important from body maintenance point of view, helps in tissue, cell formation.

4) Lipids: These are very important from energy source as well as human nutrition point of view.

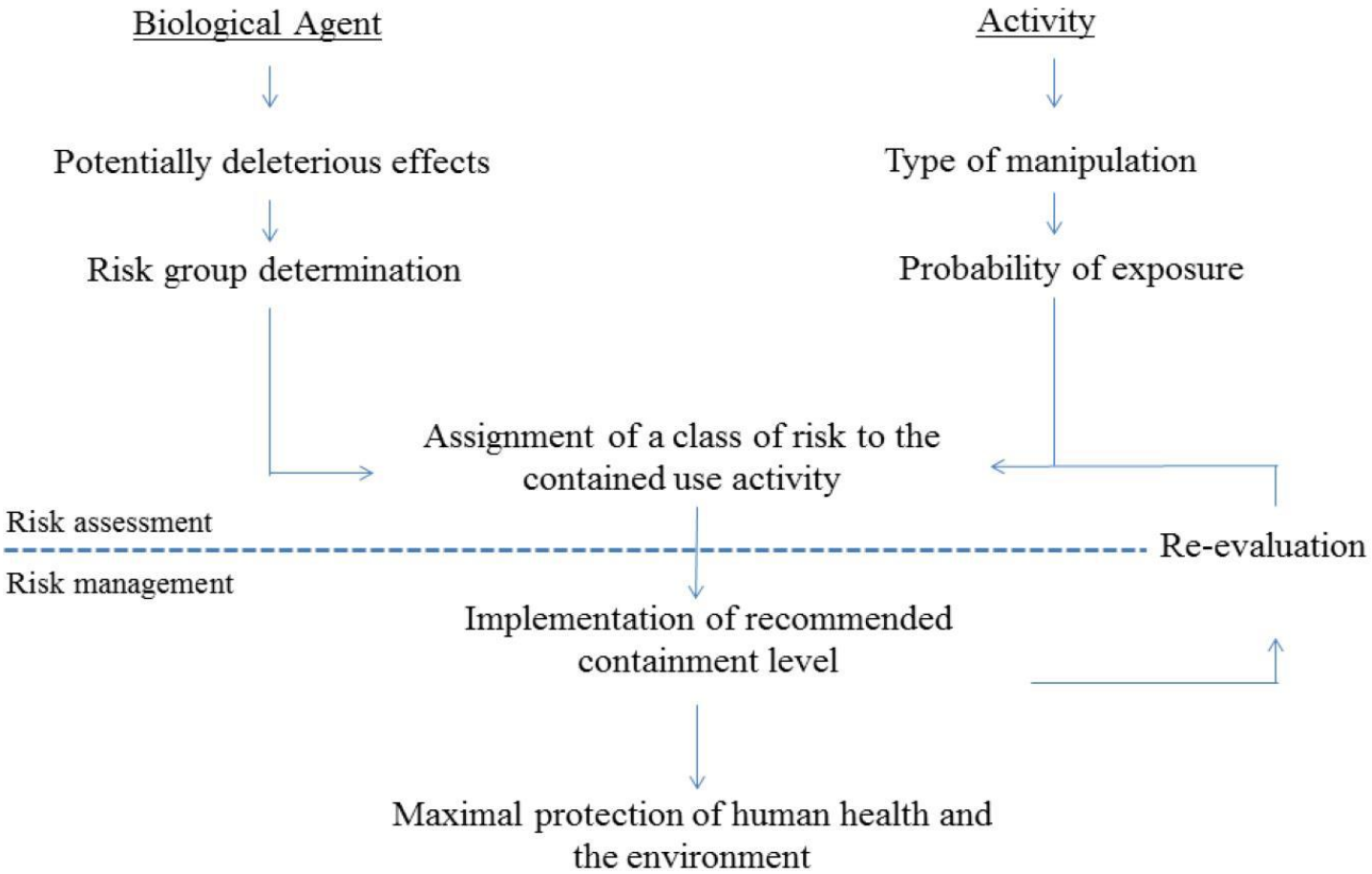
5) Nucleic Acids: Nucleic acids are very important as DNA carries the hereditary information and RNA helps in protein formation for the body.

6) Enzymes: Enzymes are simple or combined proteins acting as specific catalysts and activates the various biochemical and metabolic processes within the body.

Table: Fundamental Biological Molecules (Biomolecules):

Sr. No.	Small Molecule	Atomic Constituents	Derived Macro - Molecule
1	Amino Acid	C, H, O, N (S)	Proteins
2	Sugars	C, H, O	Starch, Glycogen
3	Fatty Acids	C, H, O	Fats, Oils
4	Purines and Pyrimidine	C, H, O, N	Nucleic Acids
5	Nucleotide	C, H, O, N, P	Nucleic Acids (DNA and RNA)

Biosafety Assessment of Biomolecules:



NOTE: Explain the figure your knowledge

UNIT IV: Quality control:

Quality control in food process technology- WHO Standards- Quality Control in Dairy product technology- Quality control in portable water.

An aggregate of activities (such as design analysis and inspection for defects) designed to ensure adequate quality especially in manufactured products.

Quality

- ✓ Food quality is a sensory property that includes appearance, taste, nutritional value (nutrient content), health benefit (functional ingredient) or safety (chemical, physical, biological).
- ✓ It includes those attributes which affect consumer's choice for a product.

Need for quality food:

- ✓ Major challenge for food industry is to **maintain the food quality**; the reason being well aware consumers
  - Quality
  - safety
  - diversity
  - practicality
  - value for "money
- ✓ For this reason food industry has to adopt certain techniques in order to meet the growing need of maintaining food quality; this is known as food quality control
- ✓ The main issue which is considered while quality control process is to deteriorate the level of microbes and other contaminants in food.

Food processing:

"Food Processing is the conversion of agricultural products to substances which have particular textural, sensory and nutritional properties using a set of methods and techniques called food processes"

Processed Foods WFP (*World Food Programme*) Buys*:*

Products: flours, fortified blended foods, biscuits and energetic bars, ready-to-use therapeutic foods, oils, noodles, canned foods, salt, sugar.

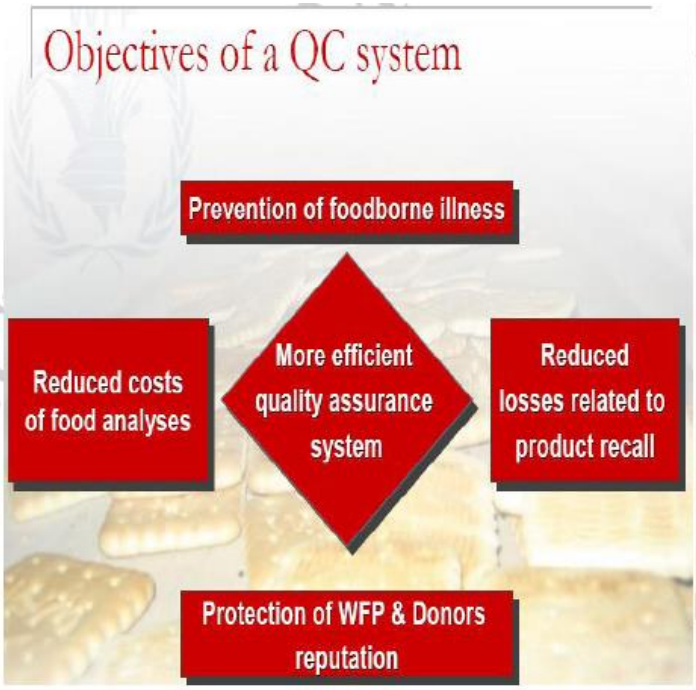
- ❖ **Product transformation:** to convert to edible products, to preserve, to extend shelf-life, to enhance the nutritive value, to delay or prevent biochemical, chemical and physio-chemical undesirable changes, to modify techno functional properties, to improve Quality.

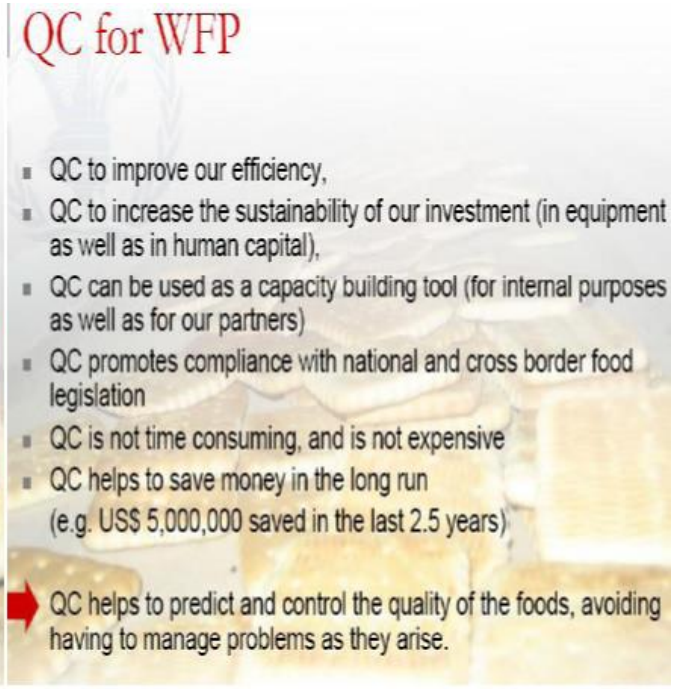
- **Nutritional and health value of WFP products**: energy, macro & micro-nutrient content, nutrient bio-availability, digestibility, nutrient availability at beneficiary level, allergicity, health allegations (pre- biotics), non-toxicity.
- **Other characteristics:** safe, well packaged, easy to transport and to store and to trace, cost-effective, versatile, easy to prepare, enabling fuel saving, culturally acceptable, and enabling easy targeting.

Food processing: WFP's areas of intervention:

1. Local production
2. Feasibility study
3. Factory inspection
4. Food fortification process
5. Quality assurance
5. Specification improvement

Increased shelf-life, less leaking, less losses, better nutritional quality, better digestibility, better suitability for specific population (HIV/AIDS patients, children under 2) …





Food industry's view of food control

The food industry takes a broad view of the term food control, which includes a large number of factors such as:

- ***Safety*** - setting standards for toxicological and microbiological hazards, and instituting procedures and practices to ensure that the standards are achieved;
- ***Nutrition*** - maintaining nutrient levels in food ingredients and formulating foods with nutritional profiles that contribute to consumer interest in healthful diets;
- ***Quality*** - providing sensory characteristics such as taste, aroma, palatability and appearance;
- ***Value*** - providing characteristics of consumer utility and economic advantage, involving attributes such as convenience, packaging and shelf-life. Some of these factors, such as value, are exclusively in the domain of industry and consumers; while others, such as safety, are shared interests of government, industry and consumers.

Setting and implementing food standards

At the heart of all food control activities is the establishment of safety, quality and labelling standards. These should be established on the broadest possible scale, in the recognition that food production and marketing is truly a global industry. Governments and intergovernmental organizations such as the Codex Alimentarius Commission have the principal role in establishing certain food control standards. It is the role of national governments to establish uniform safety standards so that

- ❖ All consumers receive equal levels of protection;
- ❖ All food producers, whether domestic or foreign, are equitably treated through application of the same levels of safety;
- ❖ Consumers are informed about the standards of protection that are being applied.

Industry's efforts to ensure quality:

Quality assurance programmes are designed today with particular emphasis on the use of **hazard analysis and critical control point (HACCP)** techniques, an approach that the food industry developed and has voluntarily adopted on a broad scale for the past 20 years. This approach consists of several elements:

-Conducting a hazard analysis to identify hazards and the needed controls;
- Identifying the critical control points;
- Establishing critical limits for each control point;
- Establishing monitoring procedures;
- Establishing corrective action procedures;
- Establishing verification procedures to ensure that corrective steps have been taken;

- Establishing appropriate documentation procedures to ensure that the control system is defined and that record will be maintained to permit auditing and verification that the system is properly applied.

The Importance of Quality Assurance for Food and Beverage Packaging:

Basic standards upheld by contract packaging companies to ensure the quality and safety of packaged food and drinks.

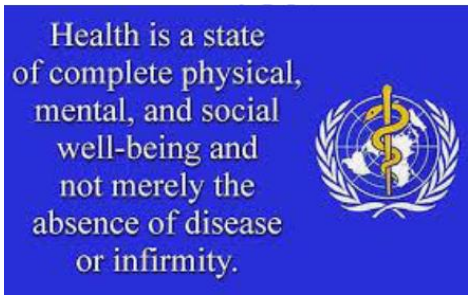
1. **Material Ingredient and Analysis** to confirm purity and durability.
2. **Pest control and good manufacturing programs (GMP)** to prevent the presence of pests in and near processing areas.
3. **Sanitation and good manufacturing programs (GMP)** to ensure all sanitary conditions are met in the manufacturing facility as well as prevention of direct product contamination or adulteration.
4. **Product safety equipment that include magnets, metal detectors and screens** to detect and prevent foreign matter contamination.
5. **Process control systems that include fill control and attribute audits** to monitor density and meet all packaging requirements.
6. **Ingredient identification and traceability** for product identification to track safe ingredients and aid in the removal of unsafe ingredients.
7. **Allergen management** for the labeling and management of allergenic ingredients.

In addition to the techniques listed above, several other measures to obtain the highest quality product possible:

1. **Validation of cleaning processes** through lab testing of product samples. Results are analyzed and used to determine the standardization of temperature and other production variables.
2. **Traceability** by way of bar codes. Every item is documented and tracked electronically, thus eliminating the risk of manual error.
3. **Heightened Security** through surveillance cameras and card access security systems. These measures allow controlled restrictions of manufacturing areas as well as around the clock inspection of all products and processes.
4. **Monthly Self Auditing** through unannounced inspections to proactively identify opportunities for improvement.

World Health Organization (WHO)

The **World Health Organization** (WHO) is a specialized agency of the United Nations that is concerned with international public **health**. It was established on 07 April 1948 headquartered in Geneva, Switzerland.



The World Health Organization, or the **WHO**, is a part of the United Nations that focuses on global health issues. This organization has been working for over 60 years on such issues as smallpox eradication, family planning, childhood immunizations, maternal morbidity rates, polio eradication, and AIDS.

The WHO outlines several **leadership priorities**, which are a part of the initiatives for better world health. These leadership priorities include:

- Assisting countries that seek progress toward universal health coverage
- Helping countries establish their capacity to adhere to International Health Regulations
- Increasing access to essential and high-quality medical products
- Addressing the role of social, economic, and environmental factors in public health
- Preventing non-communicable diseases
- And putting emphasis on other 'millennium development goals' such as combating poverty, hunger, disease, illiteracy, environmental degradation, and discrimination against women

Functions of WHO:

These functions are:

1. Providing leadership on matters critical to health and engaging in partnerships where joint action is needed;
2. Shaping the research agenda and stimulating the generation, translation and dissemination of valuable knowledge;
3. Setting norms and standards and promoting and monitoring their implementation;
4. Articulating ethical and evidence-based policy options;
5. Providing technical support, catalysing change, and building sustainable institutional capacity;

6. Monitoring the health situation and addressing health trends

Millennium Development Goals:

Before examining WHO's role in maternal health it is important to understand how the Millennium Development Goals (MDGs) have come to play such a prominent role in shaping WHO's work. The MDGs came out of the United Nations Millennium Declaration which was endorsed by 189 countries in September 2000 and resolves to work towards combating poverty, ill health, discrimination and inequality, lack of education and environmental degradation.

The MDGs are eight specific goals that the 191 United Nations (UN) states have committed themselves to achieving by 2015. The MDGs are:

1. To eradicate extreme poverty and hunger;
2. To achieve universal primary education;
3. To promote gender equality and empower women;
4. To reduce child mortality;
5. To improve maternal health;
6. To combat HIV/AIDS, malaria and other diseases;
7. To ensure environmental sustainability; and
8. To develop a global partnership for development

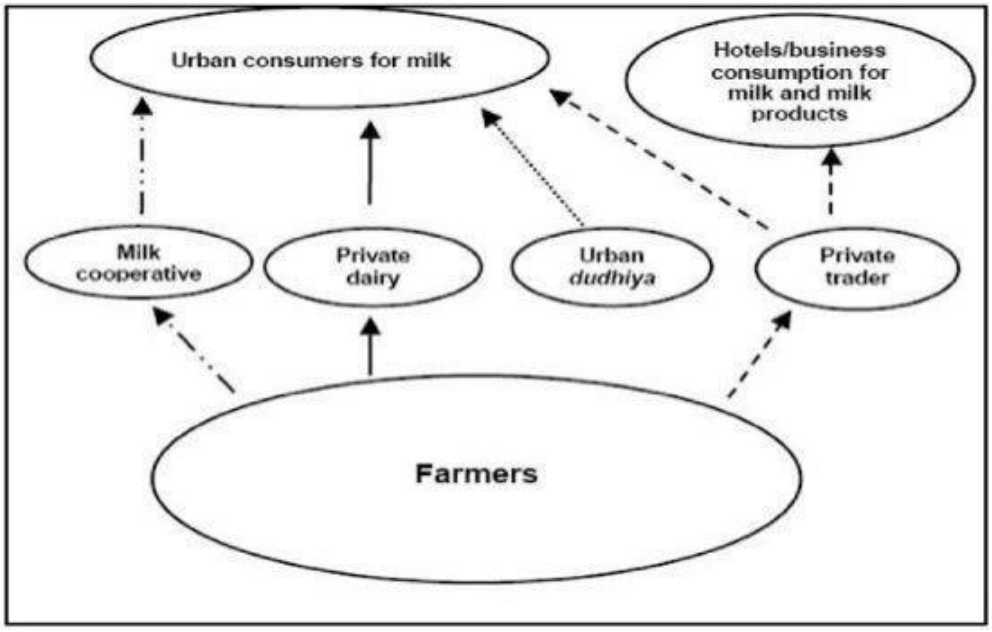
Quality Control in Dairy product technology:

Introduction:

The ultimate task of quality control is to provide the plant management and persons responsible for quality with information of fulfilment of previously defined quality criteria and standards at every stage of process as early as possible. Early warning about failures and inability to meet quality standards at any stage of processing helps correct the situation in time and decreases losses caused by irrelevant quality of the end product. The planning and establishment of quality control for a milk plant includes the following:

- Organisation and staffing of the quality control activity within the dairy plant Training the quality control personnel
- Definition of quality standards taking into account also the legal requirements for raw materials, ingredients, packaging materials, processing line and equipment, end products, storage, handling during distribution etc.

- Laboratory and methods for testing and analysing for the quality parameters including organoleptic, physical, chemical and microbiological methods - Sampling methods and schedules.
- Alarm limits (maximum/minimum) for quality parameters - Recording and reporting systems.



Quality control laboratory

The task of a quality control laboratory is to organize and carry out all the practical work included in the quality control activities of a milk processing plant. The laboratory has to be equipped with all necessary apparatus, testing and analyzing methods and staff in order to facilitate the above-mentioned function.

The laboratory should be able to control the following:

- Raw milk quality during collection and at reception
- Various quality aspects related to processing
- Quality of finished milk products
- Quality of milk products during storage/distribution
- Cleanliness and hygiene at the milk processing plant

Clear and regular recording of test results as well as regular and timely reporting to the personnel responsible for processing and the plant management.

Example:

- DAIRY PRODUCT:
  - Quality control of milk products and packing are carried out by equipped laboratories in the factory.
  - Procedural steps:
    - Receive Milk
    - Take a sample
    - Conduct Physical, chemical, sensory tests of raw milk
- Milk received in the lab is to identify whether it meets the necessary standards or not.
- Example of an Ice-cream: it needs to be smooth not grainy so therefore testing should be done so that the quality of the product can be maintained.
- Example of a table: it should be smooth not rough from the top so therefore testing should be done to maintain the quality of the product.

Milk sampling:

It is very important that the sampling of milk is always made in correct and hygienic way so that the milk sample will represent the whole lot of milk (e.g. the whole contents of milk can) and that neither the milk nor the milk sample will be contaminated during sampling.

- Sampling of liquid milks always involves thorough agitation before the sample is taken in order to make the contents of a milk container as homogenous as possible for obtaining a representative sample.
- Too vigorous agitation should, however, be avoided because air bubbles if dispersed in milk will change its physical properties and disturb analysing.
- Very clean and for microbiological purposes even sterile device and sample bottles made of materials (stainless steel, glass, plastic of appropriate quality) which will not affect the milk nor tests are used.

The milk samples need to be taken special care of. If the samples have to wait for analysing or this need to be transported to a laboratory the samples should be cooled down and kept under refrigerated conditions during subsequent storage and transport. Using potassium dichromate tablets or solution (10% water solution, 1 ml to 100-ml milk) can also preserve samples for physic-chemical analyses. It is clear that before analysing each sample needs to be carefully agitated once again.
Sample bottles and test tubes should be clearly marked or labelled so that each sample can be easily identified and related to the original milk container.

Sampling from milk can:

A. Agitate the milk with at least ten full lengths of plunger or dipper and immediately after this take the sample of required size into a sample bottle and close it. In order to make sure that a sample will well represent the whole contents of milk can take the half of the required sample from the lower portion and another half from upper part of the milk can.

B. If no plunger is available, agitate the milk as well as possible with a dipper having a handle long enough for doing this. Take half of the sample from the lover portion and half from the upper portion of milk can.

C. Sampling from a smaller milk container can be done after turning the container upside down not less than ten times before sampling. This can be done providing that container in question can be closed well. This method of agitation of milk applies also to milk samples in a laboratory before testing.

QUALITY CONTROL PRACTICES:

These methods vary from rapid platform tests to **more sophisticated** and **time consuming analysing** methods including, e.g. microbiological quality tests.

The quality control needs standards and methodology used should be under continuous evaluation and development according to increases in and diversification of production and improvement of processing methods.

Platform tests:

Platform tests or milk reception tests are the commonly used names for the tests carried out by the persons responsible for raw milk collection and/or reception.

1. Organoleptic Quality Tests for Milk

This involves all the preliminary quality tests conducted at the farm level, at the processing plant's reception platform or at the collection center.

It is a simple, quick and cost effective method of checking quality of milk and allows for segregation of good quality and poor quality milk.

The grader must have good **senses of sight**, **smell,** and **touch** because the result of this test is obtained instantly.

Start testing by shaking the milk can a little bit then opening the lid and check for any **aroma/flavor** that emanates from the can by *smelling it.*

Check for visual appearance on the milk such as **colour**, any other *foreign objects* on the surface of the milk and the sanitary condition of the milk can. The sanitation of the *can* indicates how the milk has been handled.

Feel the milk can to check the **milk temperature**. The temperature of the milk can give more information about when the milking was done.

Application to raw/liquid milk

- The organoleptic test should be carried out immediately after opening the lid of the milk can/container.
- Observe the colour, appearance, and cleanliness of milk - Smell from milk can be sensed just above the milk surface immediately after removal the lid. - Taste of milk is more permanent and easy to define than smell. Taste raw milk only after making sure that it is from healthy animals.
- After emptying the can/container inspect the insides of the lid and the can/container for visible dirt and impurities.

The appearance, colour, smell and taste of milk should be normal and typical to, e.g. those of fresh goat's milk.

The following abnormal colours, appearances, smells and flavours can be, however, detected:

A. Abnormal colour/consistency

- ✓ **Pink colour:** Polluted with blood;
- ✓ **Yellowish creamy colour:** Colostrum or late milk;
- ✓ **Blue thin colour:** Adulterated by adding water;
- ✓ **Large clots or flakes:** Sour milk or mastitis milk;
- ✓ **Small white clots or grains:** Mastitis milk or adulterated with flour and skim milk powder;

Visible dirt and impurities: Produced under unhygienic conditions.

B. Abnormal smell and/or taste

- ✓ **Souring: Lactose** fermenting, acid producing bacteria
- ✓ **Malt:** Streptococcus lactis var. maltigenes Bitter: Peptonising of milk by Streptococcus liquefraciens
- ✓ **Blue souring:** Unpleasant sweet and sour smell, thin and waterish appearance caused by bacterial activity and storage in a closed container without ventilation
- ✓ **Fruit aroma:** Pseudomonas fragi producing esters
- ✓ **Slimy milk:** Capsule forming bacteria, e.g. Aerobacter aerogenes and Alcaligenes viscosus

Bubbles, coagulation and whey separation: Fermentation by yeast

C. Chemical changes

- ✓ **Salt:** Increase in chlorine content and decrease in lactose content. Mastitis milk, colostrums
- ✓ **Boiled:** Release of volatile sulphides
- ✓ **Rancidity:** Lipolysis of fat

- ✓ **Tallow:** Oxidation of fat

D. Off-flavours from feeds

Garlic, onion, beets, bad silage, certain plants and pastures can cause off-flavours to milk

E. Absorption of off-flavours from air, milk containers etc

- ✓ It is well known that milk and cream can absorb smelling compounds from the air. This is caused by the ability of butter fat to absorb, especially after milking when the milk is warm, strong smells like paint, phenol, cresol, lysol, petroleum, etc. Strongly smelling paints, disinfectants and other chemicals should be not handled and stored in places where the dairy animals are kept and milked.
- ✓ Storage of milk together with fruits and fish also causes off-flavours to milk

2. Lactometer test (Lactodensimeter test, Specific gravity)

This test is used to determine whether the milk is likely adulterated:

A. Contains added water

B. Sub-standards in total solids content

C. Fat removed from original milk

D. Contains added skim milk or skim milk powder, dissolved in water or as powder

Procedure:

- ✓ **Agitate the milk carefully** with a plunger before sampling. Take care not to introduce air bubbles into the milk. **Air bubbles would interfere the test reading the result**.
- ✓ Place the milk sample in a **cylinder the size** of which is determined by the **dimensions of lactometer.**
- ✓ Place the cylinder on a table or other level surface. **Place and lower down the lactometer** slowly into the milk till it is **floating freely**.
- ✓ Read the result at **eye level at the point of the scale** where the surface of milk cuts across the stem of lactometer. The reading result is recorded together with the milk temperature.
- ✓ The **lactometer can give correct results only when the milk temperature corresponds** with the calibration temperature indicated on the lactometer stem. For other temperatures **temperature correction** is to be applied for correct results.

3. Clot on Boiling Quality Tests for Milk

- ✓ This is a **cheap, quick and easy to perform quality test** that is mainly used to give information on the acidity of the milk. A **small amount of milk is boiled in a test tube** and **checked** for any signs of **coagulation**.

- ✓ **If the milk coagulates**, it is an indication that the **milk will not be able to withstand processing conditions due to high acidity**.
- ✓ This test is however not quantitative and does not detect any acidity level below 0.2% of lactic acid concentration. Any milk that fails this test is considered too sour for processing.
- ✓ Like the alcohol test also this test is used during milk collection for detection of instability of milk proteins for heating because either lactic acid or rennin enzymes produced by bacteria.

4. Alcohol Quality Tests for Milk

This is a simple and quick method used to test the acidity of milk. Mix equal amounts of alcohol (72% ethanol concentration) and milk sample and check for signs of coagulation.

Procedure:

- A **small amount of milk is boiled over a flame** or immersed in constantly boiling water in a test tube.
- The result will **show up instantly**.
- The content of a **test tube is examined** by running the milk along and around the inner walls of the test tube.
- **No coagulation** indicates that **milk is fit for heating operations** at the time of testing.
- **If coagulation**, **thickening, lumping, flaking, graining** or precipitation is observed milk is likely **not fit for pasteurisation**.

5. Dye Reduction Quality Tests for Milk

These quality tests show comparative activity of the micro-organism in milk hence used as a rough indication of the microbial load in milk. It is based on the observation of the blue colour imparted in the milk, which will disappear with time.

The length of time depends on the number of microorganisms present in the milk holding all other factors (such as nutrient content, moisture content, and temperature) constant.

The **colour change** is assumed to be **due to two reasons**:

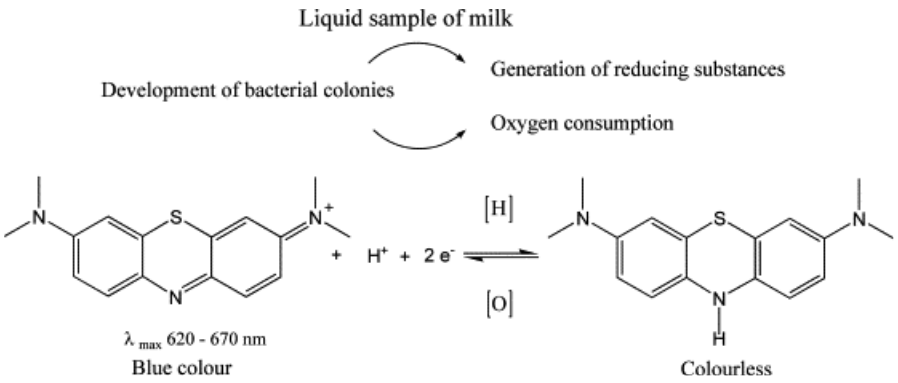
1. Consumption of oxygen in milk by the microorganism
2. Enzyme reductase produced by the microorganisms

- The **time reduction indicates the possible number of microorganism**. This test has low correlation with other tests especially those that show presence of bacteria.
- To perform this test, take a definite amount of methylene blue and mix with 10 ml of milk. Mix uniformly and incubate at 37°C in a water bath and wait for colour change.
- The longer **it will take for the colour to change, the lower the microbial load**. All the glassware used must be sterile. The interpretation of the results is as follows:

Table: Dye reduction test result intepretation of pasteurized milk

Length of time (hours)	Quality of milk	Grade of milk
5 or more	Excellent	1
3 – 5	Good	2
2 – 3	Fair	3
Less than 2 hours	Poor	4

Mechanism of Colour change:

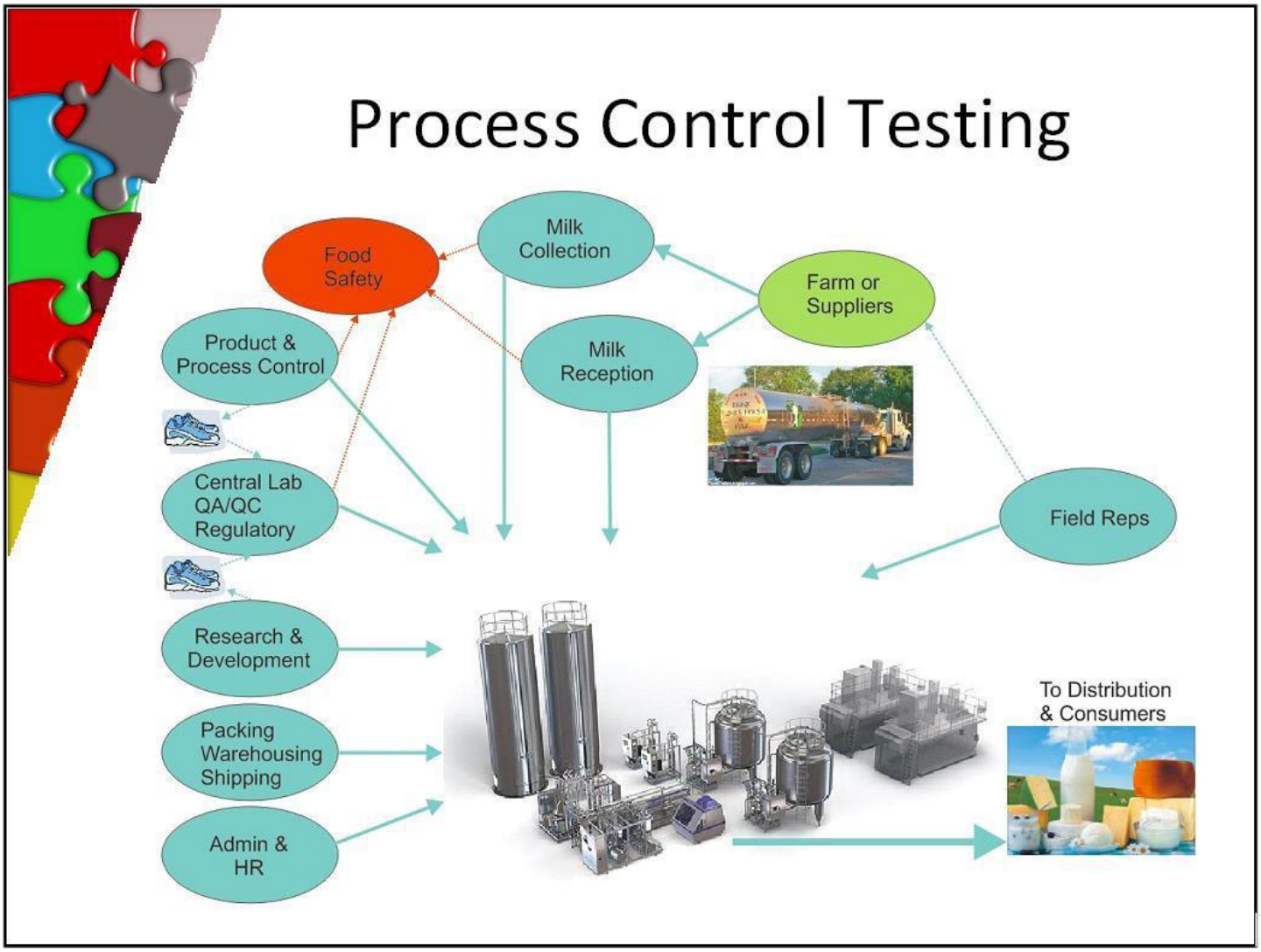


Quality control during milk processing:

One of the most important tasks amongst the quality control is to control and follow up regularly the fulfilment of quality standards at every stage of process flow in order to guarantee the best possible quality of end products. In this order the quality control activities include the following:

- Quality of all raw materials, ingredients, additives, packaging materials, etc. used in processing;
- Control on standardisation of, e.g. fat content of raw milk for production of various products;
- Quality and activity of dairy cultures (lactic acid starters), rennet etc.
- Hygienic quality of packaging materials;
- Quality and strength of cleaning and sanitation solutions;
- Hygienic status of processing line, milk tanks, pipes line, packaging machines, etc.;
- Overall cleanliness and hygiene during reception, processing, storage and distribution;
- Organoleptic, hygienic, chemical and physical qualities of the end products including packages;
- Keeping quality properties (shelf life) of end products;

- Well organised recording of test results and findings as well as regular and timely reporting.



MAINTENANCE OF LABORATORY EQUIPMENT

The laboratory equipment should all times kept clean and free from traces of milk residues and chemicals, which might interfere the testing. At the end of each working day the glassware and equipment are rinsed first with cold water and then washed in a detergent, rinsed with distilled water and dried.

The glass ware and equipment used for microbiological samples, dairy cultures, agitating, sampling and other equipment in contact with milk should be not only kept constantly clean but must also be sterilised before use.

Routine sanitising of all equipment

- ✓ Rinse with cold water;
- ✓ Wash and brush in hot water containing detergent in 1% solution, e.g. washing soda;

- ✓ Rinse in hot distilled water and examine for cleanliness;
- ✓ Allow to get dry upside-down in dust-free surrounding;
- ✓ Pipettes should after use be placed vertically in a cylinder containing a mild solution of hypochlorite in concentration of 200ppm. This eases cleaning and minimizes the risk of contamination.

Simple sterilization methods of equipment

- ✓ Immersion in boiling water for not less than five minutes Ensure that the water is kept on the boil all the time;
- ✓ Heating in a hot air oven 160 C for two hours;
- ✓ Steam under pressure in an autoclave 120 C for 20 minutes;
- ✓ Immersion in 70% ethanol and flaming just before use.

SCOPE OF QUALITY CONTROL

The quality control activity in the dairy industry must cover all the quality aspects of milk and milk products and all the way from the dairy cow to the consumer. The list of subjects of quality control activity below gives an idea about the scope of the tasks of the quality control in the dairy industry.

Dairy farm:

- dairy animal
- personnel
- cow shed and milking parlour
- milk handling and storage rooms
- cold and hot water
- milking including milking machines, utensils and materials
- milk handling including utensils and materials
- quality of cleaning and washing
- milk cooling and storage
- delivery for collection
- possible direct sales of milk on farm

Transport of milk from farm to Milk Collecting Point/Centre or to Milk Plant:

- cleanliness and condition of transport vehicle
- temperature during transport
- duration of transport
- unloading and reception methods

Milk Collection Point/Centre, Milk Processing Plant:

- overall cleanliness and condition
- personnel
- cold and hot water
- milk reception timetable
- milk cooling and storage
- storage time
- heat treatments
- milk handling and processing
- packaging and labelling (production and best before dates)
- storage
- loading and transport for distribution

Transport of milk products:

- cleanliness and condition of transport vehicle
- loading and transport system
- temperature during transport
- duration of transport
- unloading system and place

Distribution and resale:

- general cleanliness and condition
- personnel
- cold and hot water
- quality of cleaning
- storage time of milk products
- storage temperature
- methods of handling, distribution and sale

Microbiological Testing Procedures in Dairy Quality Assurance

Microbiological testing is a crucial part of the quality assurance process because it anchors the safety of the food product. Every product that passes through the plant must be attested to have high standards that the consumers expect. It is important to conduct a series of microbiological testing procedures on dairy

products to ensure that the final product meets the required standards by passing all the stringent measures required for a satisfactory product.

Here is the list of microbiological testing procedures applicable to dairy products

1. Standard Plate Count:

The purpose of this work instruction is to ensure that the number of colony forming units (CFU) per millimetre or per gram of the original sample is determined correctly. A defined test portion or series of decimal dilutions of the sample are mixed with culture media in Petri dishes and incubated. The number of colony forming units (CFU) per millilitre or per gram of the original sample is calculated from the number of colonies counted on selected dishes.

Microbiological Testing Instructions:

Preparation of standard plate count media

- Suspend 24gms of Tryptone Glucose Extract Agar in 1 litre of distilled water. Bring to boil to dissolve completely.
- Dispense into bottles and sterilize by autoclaving at 1210C for 15 minutes.

Preparation of quarter strength ringer's solution:

- Dissolve 1 tablet in 500ml distilled water. Sterilize by autoclaving at 1210C for 15minutes and let cool.

Microbiological Testing Method:

- Preparation of media
- Sterilization (Autoclaving)
- Poured into sterile plates
- Inoculation and incubation

Calculations of results:

Calculate the number of colonies per ml in each dilution having between 10 and 300 colonies per plate.

Read the results and express the answer as number of colony forming units per ml (or g)

2. Determination of Yeasts and Moulds

The purpose of this work instruction details the enumeration of yeasts and moulds in milk and milk products. Here, we show the methods for the detection and enumeration of yeast and moulds.

Requirements for this microbiological testing procedure:

- Quarter strength sterile ringers solution
- Malt Extract Agar; Oxoid

- 10% lactic acid to adjust pH to 3.5
- Incubator at 22-250c

Preparation of Malt Extract Agar:

- As per the manufacturer's instructions on the tub
- Add 1 ml of lactic acid 10% to each 100ml of sterilized medium at 50-550 The medium must not be heated after the addition of acid, as the gelling properties of the medium will be lost
- Mix well before pouring.

Microbiological Testing Procedure:

- ✓ Prepare serial tenfold dilutions of the sample in 9ml. sterile quarter strength ringers solution
- ✓ Pipette 1ml from each dilution onto a sterile Petri dish, add 15ml of Malt Extract Agar and mix by swirling the plate
- ✓ Allow to solidify
- ✓ Invert and incubate the plates at room temperature or 300C incubator for 5 days
- ✓ Count plates containing 10-150 colonies.
- ✓ If many yeast are present, plates with 150 colonies are usually readily countable
- ✓ Report in colonies/ml
- ✓ Prepare slides of the colonies, identify and record what organism is present.

If more than one dilution plate has been counted, calculate the number of CFU/ml for each plate counted. Mean the result and express as colony forming units/ml (CFU/ml)

3. Detecting Coliforms Through Microbiological Testing

This method instructs on how to conduct an experiment to check for the presence or absence of both faecal and non-faecal coliforms in milk and milk products.

Presence of Coliforms in dairy products is suggestive of unsanitary conditions or practices during production, processing or storage.

Preparation of violet red bile agar:

- Suspend 38.5 g of violet red bile agar in one litre of distilled water.
- Bring to the boil to dissolve completely.
- N/B no further sterilization is necessary. Cool to 450c in a water bath.

Microbiological Testing Method:

- ✓ The specimen/sample to be plated should be diluted to avoid medium overgrowth. If the colonies lie too closely together in the medium they will become uncharacteristic and difficult to count or identify. The most suitable number of colonies is 15-150 per Petri dish.
- ✓ Prepare a tenfold dilution series in quarter strength sterile ringers solution for milk and milk products and in peptone water for ingredients and swabs transfer 1ml of the original solution of 1ml from the chosen dilution with a sterile pipette into a sterile Petri dish
- ✓ Pour 15ml of violet red bile agar (VRBA) at 450C into each petri dish and swirl to mix.
- ✓ After the media has solidified, invert the Petri dishes and place in an incubator at 370C for 24 hrs.
- ✓ Count the colonies of coliform bacteria, if necessary by a counter or manually marking the underside of the plate with a marker pen. Only petri dishes containing 10-150 colonies per plate should be counted.

Calculation of the results:

- ✓ Count the number of coliform organisms per plate noting the dilution of the sample on the plate.
- ✓ Calculate the number of CFU/ml for each plate. If more than one plate was counted, get the mean of the results.

4. Sampling of Milk and Milk Products for Microbiological Testing And Analysis

This is the outline for the procedure for sampling milk from the silos, in process products, and finished products from the stores for microbial analysis.

Sterilization of sampling equipment

- ✓ Sterilize the sampling equipment for bacteriological testing by autoclaving at 1210c for 15-20 minutes
- ✓ The sampling bottles/bags shoud have caps/closed adequately
- ✓ Containers and closures should be sterilized and dry
- ✓ Containers shall be of a material, which adequately protects the sample during handling, storage and in transit

Sampling technique for bacteriological testing purposes

Depends on the purpose for which sampling is done and the type of the products being sampled.

- Random sampling from the stores
- For sampling of milk from tanks with nozzles, wipe the nozzle with 70% ethanol or surgical spirit before sampling; let the milk run for some few seconds before taking a sample

- Take some sample into the sterilized bottle swirl and drain. Repeat this. Take a sample for analysis and tightly cap the bottle.

Preservation of samples for bacteriological testing

- ✓ Bacteriological samples should not have preservatives
- ✓ Hold the samples at low temperatures 0-50 The cool box used to store these samples should ensure the temperatures range is maintained.
- ✓ Transfer products to refrigerator as soon as possible
- ✓ Microbiological analysis should start not later than 24hrs after sampling

5. Isolation and Enumeration of Thermodurics in Raw Milk

This work instruction covers isolation and enumeration of thermoduric bacteria in raw milk. The purpose of this work instruction is to ensure the enumeration and detection of bacteria which survive exposure to pasteurization temperatures. Thermodurics microorganisms are generally gram positive rods, often spore forming and gram positive cocci.

Microbiological Testing Procedure:

- ✓ Aseptically take 10mls of well agitated milk aseptically and heat for 35minutes in a water bath at 650C
- ✓ Cool the sample and prepare 10 fold dilutions in a quarter strength ringers solution
- ✓ Add 1ml of the diluted sample to 15ml of cooled standard plate count agar. Pour into a sterile Petri dish and incubate at 370C for 48hrs
- ✓ Count the plates having between 10-300 colonies per plate, note the dilution

Calculations:

Thermoduric count (organisms) per ml of milk = colony count x dilution factor. If more than one plate was counted, calculate the number of CFU/ml and then the results.

6. Wash Up And Sterilization Of The Oven For Microbiological Testing Purposes

This work instruction covers glass wares used in micro biology analysis. The purpose of this work instruction is to ensure proper cleaning and sterilization of the glassware used in bacteriological analysis.

Glassware sterilization:

Wash with warm soapy water and rinse thoroughly with cold tap water so as to remove any soap residue. Put in wire baskets and dry in a hot air oven.

Sterilization (hot air oven):

- Before sterilization all glassware must be clean and dry. Wrap glassware in grease paper, aluminium foil or put in sterilization tins and cover well with cotton wool.
- Apply sterilization tape to indicate complete sterilization and place in a hot air oven
- Set the oven temperatures at 1700C and maintain temperature of 1700C for 2 hours. Check the sterilization tape indicator. If ok, turn off the oven and allow the glassware to cool gradually.

7. Decontamination of Benches, Equipment, and Rooms After Microbiological Testing

This work instruction covers bacteriological facilities likely to bring out cross contamination. Decontamination usually means making equipment and waste free from infectious agents

Instructions:

- Wipe down the benches with 70% alcohol or surgical spirit at the beginning of work, during work and at the end of the day.
- Disinfect all accessible parts of the equipment with 70% alcohol.
- Take swabs inside of the incubators with 70% alcohol after removing and incubating the plates.

Cleaning the Floors:

- ✓ Dilute powder disinfectant detergent in a bucket of clean water.
- ✓ Thoroughly scrub the floor and rinse well.
- ✓ Ensure that you clean the floor at least twice a day and immediately incase of spillages.

8. Disposing Laboratory Waste After Microbiological Testing:

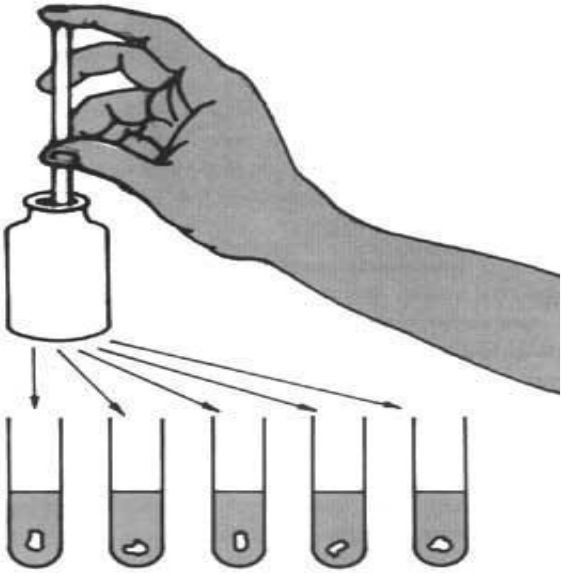
The purpose of this work instruction is to ensure all specimens, cultures and other materials used in the microbiological laboratory are made noninfectious before being discarded or leave the factory. The instruction covers how to dispose the wastes from the microbial plates after incubation. Paper towels and tissues used to wipe benches and equipment and to dry hands. Disposable gloves, Glass Pasteur pipettes, slides and covers slip used scalpel blades, scissors, knives, forceps etc.

Instructions:

- ✓ Place the infected material in the sterilizing boxes in the autoclave
- ✓ Ensure the water level in the autoclave is okay.
- ✓ Close the autoclave properly and start heating.
- ✓ Open the air vent until steam starts to come out through the control valve.
- ✓ Close the control valve and let the autoclave attain 1210c then continue heating for 15 minutes.
- ✓ Allow the autoclave to cool down and the pressure to cool down to 00

- ✓ Open the autoclave, remove the material and discard through the normal waste material disposal system.

WATER QUALITY ASSESSMENT:



Water sampling:

Water used for processing fish, washing fish or making ice is supposed to meet drinking water standards if it is to be considered safe. Reason: contaminated water is the main cause for pathogen-loading of fish, posing a serious health hazard to its consumer.

WHO has issued guidelines for drinking water quality a report in three volumes

- Vol. 1 deals with guideline values,
- Vol. 2 deals with each contaminant and
- Vol. 3 gives information on how to handle water supplies in small rural communities.

1. Borewells

Contamination may arise from pollutants entering the water table some distance from the port or from sewage entering the borehole itself in the port area through cracked or corroded casings. In cases where overdrawing is evident (water is brackish), tests should be conducted at least monthly.

2. Municipal mains

Supply could be contaminated at source or through corroded pipelines leading to the fishery harbour. Mixing with sewage lines due to defective piping has been known to occur often. Complete tests should be carried out every half year, and the authorities should be informed when results indicate contamination.

3. Water tanks and reservoirs

Both types of structure are prone to bacterial growth if the residual chlorine levels in them are low or non-existent. Testing may not be necessary if periodic scrubbing is carried out. Bacteriological tests should be done at least half-yearly.

4. Harbour basin water

Typically, harbour basins are tested yearly. However, in areas where monsoons are very active, it may be advisable to test at the peak of the dry season when effluent point discharges tend to remain concentrated in the water body and again during the wet season when agriculture run-off may be considerable. Another critical period for harbours is the peak of the fishing season when the harbour is at its busiest and vessel-generated pollution is likely to be at its peak.

Testing procedures:

Testing procedures and parameters may be grouped into physical, chemical, bacteriological and microscopic categories.

1. ***Physical tests*** indicate properties detectable by the senses.
2. ***Chemical tests*** determine the amounts of mineral and organic substances that affect water quality.
3. ***Bacteriological tests*** show the presence of bacteria, characteristic of faecal pollution.

Physical tests

Colour, turbidity, total solids, dissolved solids, suspended solids, odour and taste are recorded.

- ✓ **Colour** in water may be caused by the presence of minerals such as iron and manganese or by substances of vegetable origin such as algae and weeds. Colour tests indicate the efficacy of the water treatment system.
- ✓ **Turbidity** in water is because of suspended solids and colloidal matter. It may be due to eroded soil caused by dredging or due to the growth of micro-organisms. High turbidity makes filtration expensive. If sewage solids are present, pathogens may be encased in the particles and escape the action of chlorine during disinfection.
- ✓ **Odour and taste** are associated with the presence of living microscopic organisms; or decaying organic matter including weeds, algae; or industrial wastes containing ammonia, phenols, halogens, hydrocarbons. This taste is imparted to fish, rendering them unpalatable. While chlorination dilutes odour and taste caused by some contaminants, it generates a foul odour itself when added to waters polluted with detergents, algae and some other wastes.

Chemical tests

pH, hardness, presence of a selected group of chemical parameters, biocides, highly toxic chemicals, and B.O.D are estimated.

- ✓ **pH** is a measure of hydrogen ion concentration. It is an indicator of relative acidity or alkalinity of water. Values of 9.5 and above indicate high alkalinity while values of 3 and below indicate acidity. Low pH values help in effective chlorination but cause problems with corrosion. Values below 4 generally do not support living organisms in the marine environment. Drinking water should have a pH between 6.5 and 8.5. Harbour basin water can vary between 6 and 9.
- ✓ **B.O.D.**: It denotes the amount of oxygen needed by micro-organisms for stabilization of decomposable organic matter under aerobic conditions. High B.O.D. means that there is less of oxygen to support life and indicates organic pollution.

Bacteriological tests

For technical and economic reasons, analytical procedures for the detection of harmful organisms are impractical for routine water quality surveillance. It must be appreciated that all that bacteriological analysis can prove is that, at the time of examination, contamination or bacteria indicative of faecal pollution, could or could not be demonstrated in a given sample of water using specified culture methods.

In addition, the results of routine bacteriological examination must always be interpreted in the light of a thorough knowledge of the water supplies, including their source, treatment, and distribution.

A more logical approach is the detection of organisms normally present in the faeces of man and other warm-blooded animals as indicators of excremental pollution, as well as of the efficacy of water treatment and disinfection.

The presence of such organisms indicates the presence of faecal material and thus of intestinal pathogens. (*The intestinal tract of man contains countless rod-shaped bacteria known as coliform organisms and each person discharges from 100 to 400 billion coliform organisms per day in addition to other kinds of bacteria*).

Conversely, the absence of faecal commensal organisms indicates that pathogens are probably also absent. Search for such indicators of faecal pollution thus provides a means of quality control. The use of normal intestinal organisms as indicators of faecal pollution rather than the pathogens themselves is a universally accepted principle for monitoring and assessing the microbial safety of water supplies. Ideally, the finding of such indicator bacteria should denote the possible presence of all relevant pathogens.

Indicator organisms should be abundant in excrement but absent, or present only in small numbers, in other sources; they should be easily isolated, identified and enumerated and should be unable to grow in water. They should also survive longer than pathogens in water and be more resistant to disinfectants, such as chlorine. In practice, these criteria cannot all be met by any one organism, although many of them are fulfilled by coliform organisms, especially *Escherichia coli* as the essential indicator of pollution by faecal material of human or animal origin.

PARAMETER	**UNIT**	**LIMIT**
Aluminium	**mg Al/l**	**0.2**
Arsenic	**mg As/l**	**0.05**
Barium	**mg Ba/l**	**0.05**
Berylium	**ug Be/l**	**0.2**
Cadmium	**ug Cd/l**	**5.0**
Calcium	**mg Ca/l**	**200.0**
Chromium	**mg Cr/l**	**0.05**
Copper	**mg Cu/l**	**1.0**
Iron Total	**mg Fe/l**	**0.3**
Lead	**mg Pb/l**	**0.01**
Magnesium	**mg Mg/l**	**150.0**
Manganese	**mg Mn/l**	**0.1**
Mercury	**ug Hg/l**	**1.0**
Selenium	**mg Se/l**	**0.01**
Sodium	**mg Na/l**	**200.0**
Zinc	**mg Zn/l**	**5.0**
Chlorides	**mg Cl/l**	**250.0**
Cyanide	**mg Cn/l**	**0.1**

Fluorides	**mg F/l**	**1.5**
Nitrates	**mg NO3/l**	**10.0**
Nitrites	**mg NO2/l**	**-**
Sulphates	**mg SO4/l**	**400.0**
Suphides	**mg H2S/l**	**0**
Hydrocarbons	**mg/l**	**0.1**
Anionic detergents	**mg/l**	**0**
pH		9.2
Total dissolved solids	mg/l	1500
Total hardness	mg/l	500
Alkalinity	mg/l	500
MICROBIOLOGICAL PARAMETERS		
Total Bacteria	Count/ml	100
Coliform	Count/100ml	0
E. coli	Count/100ml	0
Salmonella	Count/100ml	0

ug = microgram or ppb

mg = milligram or ppm

Water treatment methods

Treatment of raw water to produce water of potable quality can be expensive. It is advisable to determine the quantity of water needing treatment, as **not all water used in a fishery harbour or processing plant needs to be of potable quality**.

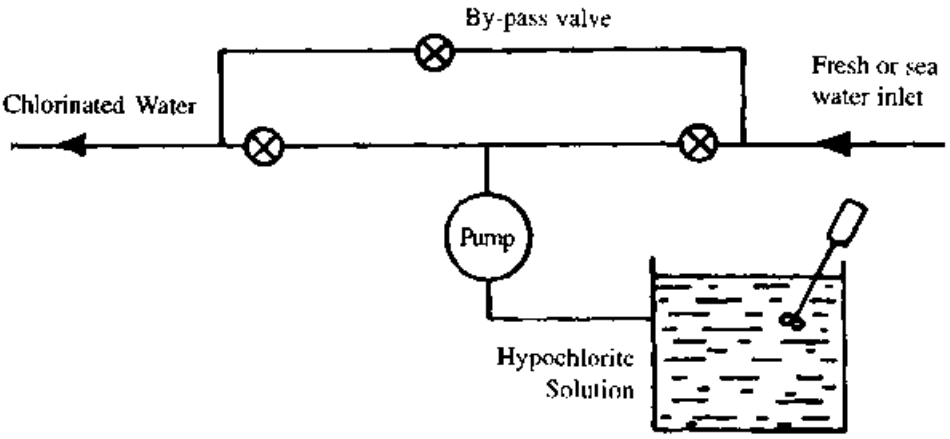
Water used for drinking, cleaning fish and ice-making must be free from pathogenic bacteria and may require secondary treatment or even complete treatment depending on chemical elements that need to be removed. Water for other needs like general cleaning may perhaps need only primary treatment.

1. Primary treatment

There are four methods of primary treatment: chlorination; ozone treatment; ultraviolet treatment; and membrane filtration.

Chlorination: Fresh or sea water can be chlorinated using either chlorine gas or hypochlorites. Chlorinated water minimizes slime development on working surfaces and helps control odour.

CHLORINATION TREATMENT



The main advantages of using chlorine gas are:

- ✓ It is the most efficient method of making free chlorine available to raw water.
- ✓ It lowers the pH of the water slightly.
- ✓ Control is simple; testing simple; and it is not an expensive method.

The main disadvantages are:

- ✓ Chlorine gas is toxic and can combine with other chemicals to form combustible and explosive materials.
- ✓ Automatic control systems are expensive.
- ✓ Chlorine cylinders may not be readily available at small centres.
- ✓ Chlorine expands rapidly on heating and hence the cylinders must have fusible plugs set at 70°C. It also reacts with water, releasing heat. Water should not therefore be sprayed on a leaking cylinder.

Hypochlorites are generally available in two forms - sodium hypochlorite solution normally available at 10% concentration and calcium hypochlorite available as a powder.

The main disadvantages of using hypochlorites are:

- Calcium hypochlorite is not stable and must be stored in air-tight drums.
- Sodium hypochlorite is quite corrosive and cannot be stored in metal containers

- Sodium hypochlorite must be stored in light proof containers.
- It is difficult to control the rate of addition of hypochlorites in proportion to water flow.
- Hypochlorites raise the pH in water.
- They are more expensive than chlorine gas.

It is important to understand the manner in which chlorine or chlorine-releasing substances behave when added to water, depending on other substances present.

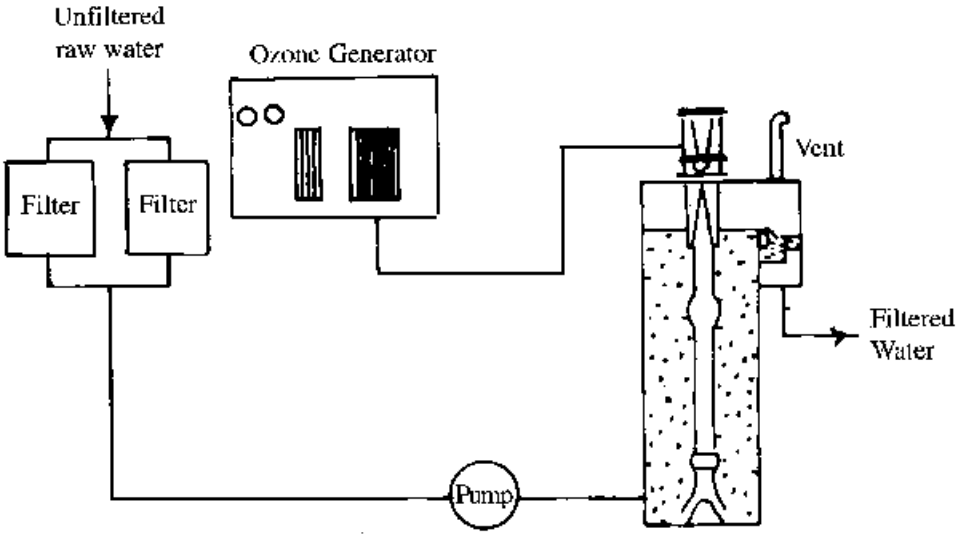
- ✓ When water contains reducing substances like ferrous salts or hydrogen sulphide, these will reduce part of the added chlorine to chloride ions.
- ✓ When water contains ammonia, organic matter, bacteria and other substances capable of reacting with chlorine, the level of free chlorine will be reduced.
- ✓ If the quantity of chlorine added is sufficiently large to ensure that it is not all reduced or combined, a portion of it will remain free in the water. This is termed as *residual free chlorine or free chlorine*.

When chlorine reacts chemically as in the first two cases, it loses its oxidising power and consequently its disinfecting properties. Some ammoniacal chlorides however still retain some disinfecting properties. Chlorine present in this form is termed *residual combined chlorine or combined chlorine.*

From the standpoint of disinfection, the most important form is free chlorine. Routine analysis always aims at determining at least the free chlorine level.

Ozone treatment: Though the principle is relatively simple, this method needs special equipment, supply of pure oxygen and trained operators. Ozone is generated by passing pure oxygen through an ozone generator. It is then bubbled through a gas diffuser at the bottom of an absorption column, in a direction opposite to the flow of raw water. Retention or contact time is critical and the size of the absorption column depends on the water flow.

OZONE TREATMENT



The main advantages of ozone treatment are:

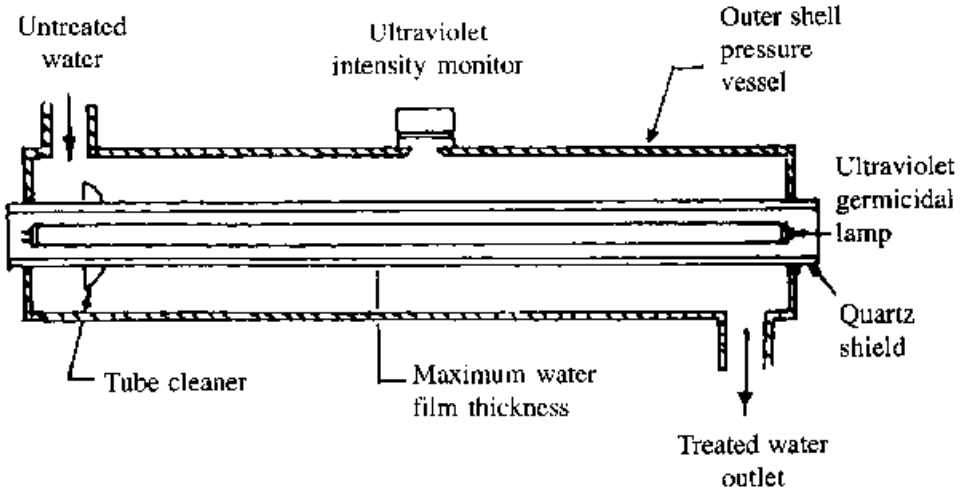
- Ozone is a much more powerful germicide than chlorine especially for faecal bacteria.
- It reduces turbidity of water by breaking down organic constituents.
- The process is easily controlled.

The disadvantages are:

- Pure oxygen may not be readily available locally.
- Ozonized water is corrosive to metal piping.
- Ozone decomposes rapidly into oxygen.
- Water has to be aerated prior to use to remove the ozone.

Ultraviolet irradiation treatment: This method is often used to treat drinking water. Successful commercial installations have been made to purify sea water in large fish processing plants.

ULTRAVIOLET IRRADIATION TREATMENT



The main advantages of U-V treatment are:

- U-V rays in the range of 2500-2600 Angstrom units are lethal to all types of bacteria.
- There is no organoleptic, chemical or physical change to the water quality.
- Overexposure does not have any ill effects.

The main disadvantages are:

- Electricity supply should be reliable.
- Turbidity reduces efficiency.
- Water may require prior treatment like filtration.
- The unit requires regular inspection and maintenance.
- Thickness of the water film should not exceed 7.5 cm.

Membrane filtration: Osmotic membrane treatment methods are generally expensive for commercial scale installations. Combinations of membrane treatment with U-V treatment units are available for domestic use.

2. Secondary treatment

Secondary treatment of water consists of sedimentation and filtration followed by chlorination. Sedimentation can be carried out by holding the raw water in ponds or tanks. The four basic types of filtration are cartridge filtration, rapid sand filtration, multimedia sand filtration, and up-flow filtration.

Cartridge filtration: This system is designed to handle waters of low turbidity and will remove solids in the 5 to 100 micron range.

The main advantages are:

- Low cost and 'in-line' installation.
- Change of cartridge is simple.
- Operation is fool-proof. Once the cartridge is clogged, flow simply stops.

The main disadvantages are:

- Sudden increase in turbidity overloads the system.
- Cartridges may not be readily available and large stocks may be required.

Rapid sand filtration: This system consists of a layer of gravel with layers of sand of decreasing coarseness above the gravel. As solids build up on top, flow decreases until it stops. This is corrected by back-flushing the system to remove the solid build up on top, Figure 12.

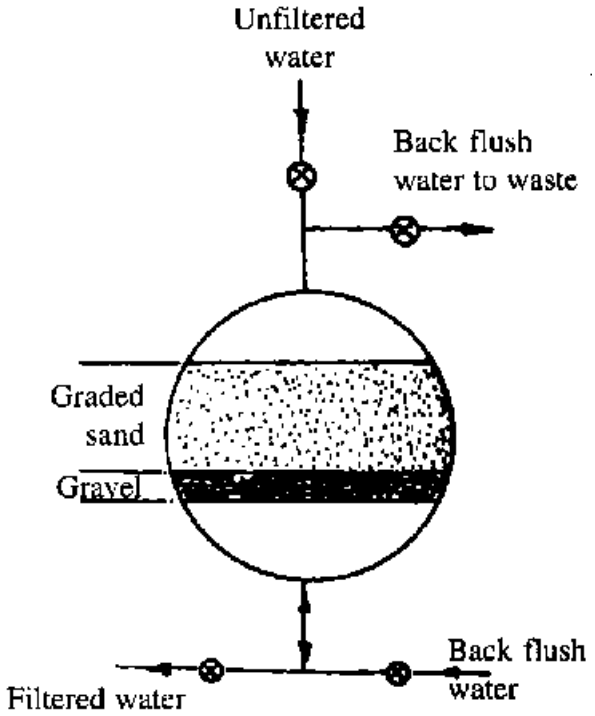
The main advantages are:

- Cost of filtration media is negligible.
- Operation is simple.

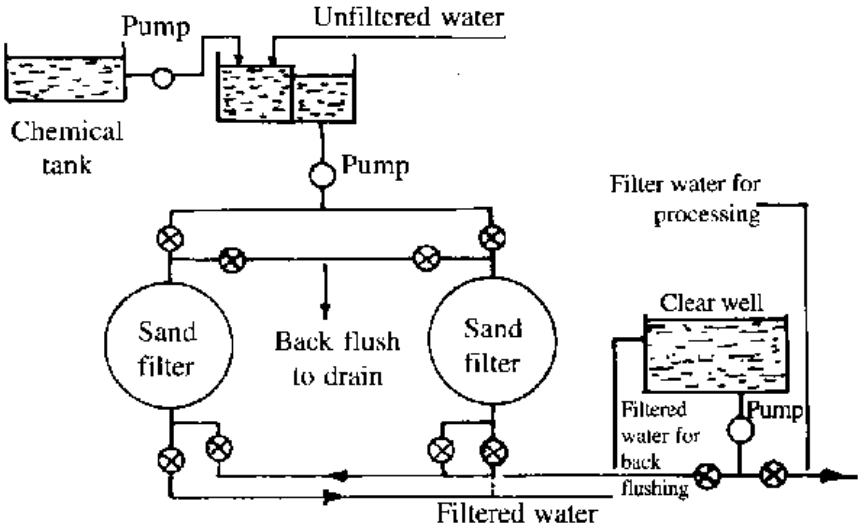
The main disadvantages are:

- A holding tank for filtered water is required to provide clear water back flushing.
- Pumping loads increase as sediments build up.

RAPID SAND FILTRATION

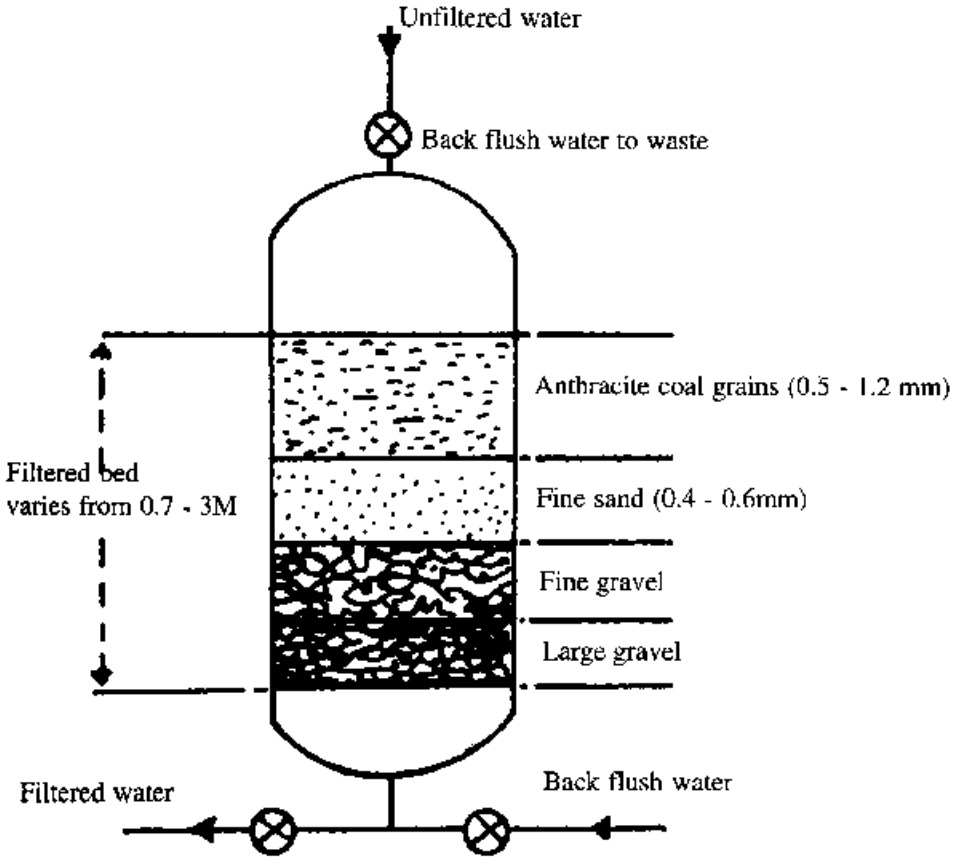


CONVENTIONAL SAND FILTRATION



Multimedia sand filtration: This system is similar to the rapid sand filtration method.

MULTI-MEDIA SAND FILTRATION

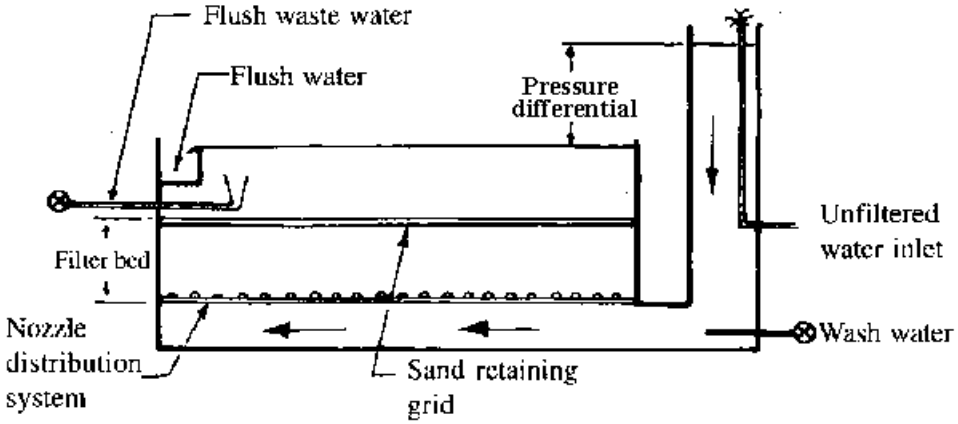


Up-flow filtration: Filtration can be at atmospheric pressure or by using a pressurised system

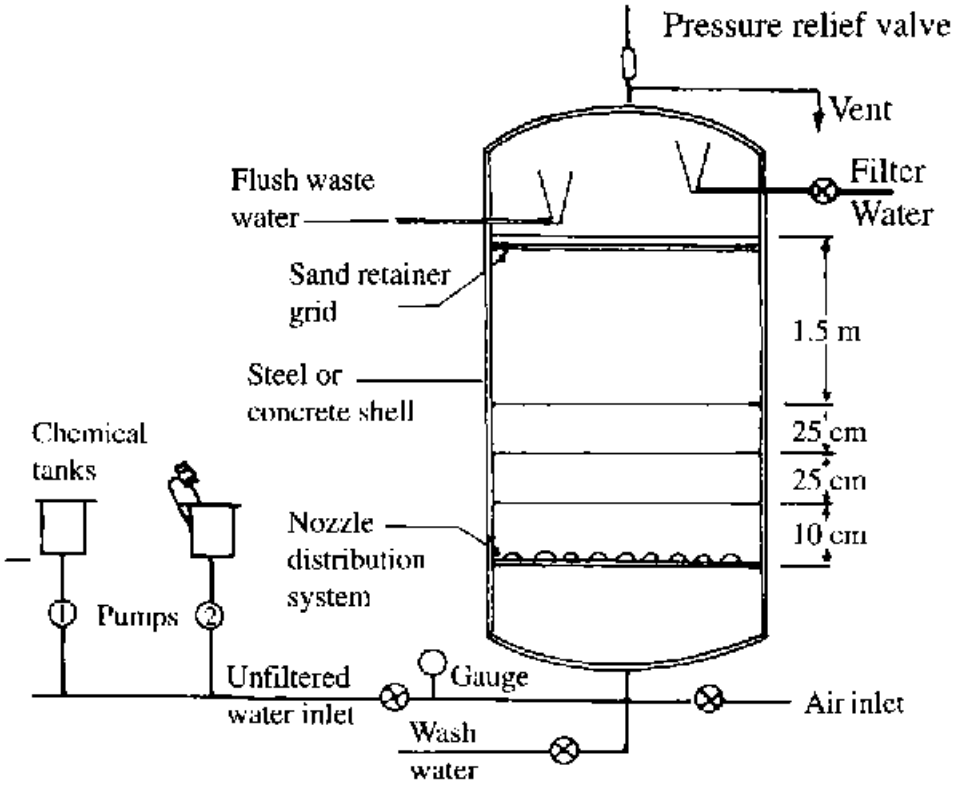
The main advantages are:

- High flow rates are easily attained.
- Water with turbidity up to 1500 ppm can be handled.
- Degree of filtration can be easily adjusted.
- The filter bed can be easily cleaned using the filtered water.

ATMOSPHERIC PRESSURE UP-FLOW FILTER



PRESSURE TYPE UP-FLOW FILTER



The main disadvantage is:

Close supervision is necessary to ensure that the filter bed does not rupture.

3. Complete treatment

Complete treatment consists of flocculation, coagulation, sedimentation and filtration followed by disinfection. Flocculation and coagulation will assist in removing contaminants in the water, causing turbidity, colour odour and taste which cannot be removed by sedimentation alone. This can be achieved by the addition of lime to make the water slightly alkaline, followed by the addition of coagulants like Alum (aluminium sulphate), ferric sulphate or ferric chloride. The resultant precipitate can be removed by sedimentation and filtration.

Chemical treatment may be required to reduce excessive levels of iron, manganese, chalk, and organic matter. Such treatment is usually followed by clarification. Iron may be removed by aeration or chlorination to produce a flocculant which can be removed by filtration. Manganese may be removed by aeration followed by adjustment of pH and up-flow filtration. Most colours can be removed by treatment with ferric sulphate to precipitate the colours.

Unit – V IPR

GATT and IPR, IPR in India, WTO Act, Convention on Biodiversity (CBD), patent cooperation treaty (PCT), forms of patents and patentability, process of patenting, Indian and international agencies involved in IPR and patenting, Global scenario of patents and India's position, patenting of biological material, GLP and GMP.

General Agreement on Tariffs and Trade (**GATT**)

- ❖ The General Agreement on Tariffs and Trade, or GATT for short, was drafted in 1947 as a provisional agreement to regulate international trade
- ❖ However, the International Trade Organization (ITO), which was supposed to take the place of GATT, was never ratified
- ❖ GATT was enforced from January 1, 1948 until December 31, 1994, when it was finally replaced by the World Trade Organization (WTO) on January 1, 1995.

GATT Members:

There were 23 nations that originally signed the GATT in 1947 in Geneva before it went into effect. The **signatories**, or contracting parties, included:

The original 23 GATT members were

The original 23 GATT members were Australia	Belgium	Brazil	Burma (now Myanmar)		Ceylon	Chile	China	Czechoslovakia (now Czech Republic and Slovakia)
France	India	Lebanon	Luxembourg	Netherlands	New Zealand	Norway	Pakistan	Southern Rhodesia (Now Zimbabwe)
South Africa		The United States		Canada	The United Kingdom			Cuba / Syria

The membership increased to 100 countries by 1993.

Purpose

- ✓ The purpose of GATT was to eliminate harmful **trade protectionism**
- ✓ That had sent global trade down 65 percent during the **Great Depression**
- ✓ By removing **tariffs**, GATT boosted **international trade**.

It restored economic health to the world after the devastation of World War II.

Rules of GATT:

- **First rule:** protecting the domestic industry by tariffs only
- **Second rule:** tariffs should be reduced and bound against further increases
- **Third rule:** trade according to the most-favoured-nation clause
- **Fourth rule:** national treatment

Objectives of GATT:

The preamble to the GATT can be linked to its objectives.

1. To raise the standard of living of the people,

2. To ensure full employment and a large and steadily growing volume of real income and effective demand.

3. To tap the use of the resources of the world fully.

4. To expand overall production capacity and international trade.

Principles of GATT:

For the realization of the above mentioned objectives, GATT adopted the following principles.

1. Non Discrimination,
2. Protection through tariffs,
3. A stable basis of trade, and;
4. Consultation

1. Non Discrimination

- ✓ The international trade should be conducted on the basis of nondiscrimination
- ✓ No member country shall discriminate (**Unfavorable)** between the members of GATT in the conduct of international trade
- ✓ On this basis, the principle "**Most favored Nation**" (MFN) was enunciated (**Announced**)
- ✓ This means that "each nation shall be treated as good as the most favored nation"
- ✓ All contracting parties should regard others as most favorable while applying and administering import and export duties and charges
- ✓ As far as quantitative restrictions are concerned, they should be administered without favor.

Exceptions to the principle of non-discrimination: However, certain exceptions to this basic rule are to be allowed. There is no objection to form free trade areas or custom unions. Such integration should facilitate consistent trade between the constituent territories. They should not raise barriers to the trade of other parties. GATT allows its members to follow measures to counter dumping and export subsidies. However, such measures should be applied only to offending countries.

2. Protection through tariffs only

- GATT rules prohibit quantitative restrictions
- Domestic industries should be protected only through customs tariffs
- Restrictions on trade should be limited to the less rigid tariffs

Exceptions: exceptions to this principle are given to the countries which suffer from unfavorable balance of payments position. Developing countries also enjoy this exception. Import restrictions may be applied to agricultural and fishery products if their domestic production is subject to equally restrictive production.

3. A stable basis of trade

GATT seeks to provide a stable and predictable basis for trade. It binds the tariff levels negotiated among the contracting countries. Binding of tariffs prevents the unilateral increase in tariffs, But still there is a provision for renegotiation of bound tariffs. A return to higher tariffs is discouraged by the requirement that any increase is to be compensated for.

4. Consultation

- The member countries should consult one another on trade matters and problems
- The members who feel aggrieved that their rights under GATT are withheld can call for a fair settlement
- Panels of independent experts have been formed under the GATT council
- Panel members are drawn from countries which have no direct interest in the disputes under investigation
- They look into the trade disputes among members. The panel procedure aims at mutually satisfactory settlement among members.

Three Provisions:

GATT had three main provisions.

Reason for GATT Creation

- GATT was established in 1948 to regulate world trade.
- It was created as a means to boost economic recovery after the Second World War by reducing or eliminating trade tariffs, quotas and subsidies.

During the Great Depression, a breakdown of international relations and an increase in trade regulation made poor economic conditions worse and contributed to the outbreak of the Second World War. After the war, the Allies believed that a multilateral framework for world trade would loosen the protectionist policies that defined the 1930s and create an economic interdependency that would encourage partnership and reduce the risk of conflict.

The idea was to establish a code of conduct that would progressively liberalize (remove or loosen restrictions on) international trade. Within this code of conduct, consultation on trade issues among member nations could take place and be resolved, and data on world trade characteristics and trends could be collected and shared.

- Divided into 3 phases:
  - First:
    - From 1947 until the Torquay Round
    - Largely concerned which commodities would be covered by the agreement
    - Freezing existing tariff levels
  - Second:
    - From 1959 to 1979
    - Focused on reducing tariffs
  - Third:
    - Consists only of the Uruguay Round from 1986 to 1994
    - It extended the agreement to new areas such as intellectual property, services, capital, and agriculture
    - Final outcome was creation of WTO

INTELLECTUAL PROPERTY (IPR)

In common sense intellectual property is a product of mind. It is similar to the property (**consisting of movable and immovable thing**) like a house or car where in the property or owner may use his property as his wishes nobody else can use his property without his permission as per Indian law.

Types of Intellectual Property

- Patents
- Copyright
- Trademarks
- Related Rights
- Geographical Indications
- Industrial Designs
- Unfair Competition
- Enforcement of Intellectual Property Rights
- Emerging Issues in Intellectual Property
  1. Biotechnology
  2. Traditional Knowledge

Patents

A patent is a government granted and secured legal right to prevent other forms of making, using or selling the invention covered by the patent. A patent is a personal property which can be licensed or sold by the person/organization like any other property.

Examples:

- Electric lighting- patents held by Edison and Swan
- Plastic- patents held by Baekeland
- Ballpoint pens- patents held by Biro
- Microprocessors- patents held by Intel.
- Telephones-patents held by Bell

Patents for:

- ✓ The drug substance itself:
  - Chemical composition of the API
- ✓ Method of use:
  - Use of the drug to treat a particular condition
- ✓ The formulation:
  - The physical form of a drug and method of administration
- ✓ The process of making it:
  - Manufacturing methods

Copyright

Copyright aims at providing protection to authors (writers, artists, music composers, etc) on their creations. Such creations are usually designated as 'works".

The best example of copyright is the authored and edited books, or audio and video cassettes, which cannot be reproduced without the permission of the person (author, editor or publisher), who holds the copyright. In biotechnology, the copyright may cover DNA sequence data which may be published.

Trademarks

A trademark is a sign that is used to identify certain goods and services as those produced or provided by a specific person or enterprises.

E.g. "DELL" is trademark that identifies goods (computers and computer related objects).

E.g. "CITY BANK" is a trademark that relates to services (banking and financial services).

Related Rights

Related rights provide protection to the following persons or organizations:

- **Performers** (actors, musicians, singers, dancers, or generally people who perform), in their performances

- **Producers of sound recordings** (for example, cassette recordings and compact discs) in their recordings and
- **Broadcasting organizations,** in their radio and television programs.

Sometimes, these rights are also referred to as neighboring rights.

Industrial Designs

An industrial design is the ornamental or aesthetic aspect of an article. The design may consist of three-dimensional features, such as the shape of an article, or two-dimensional features, such as patterns, lines or color.

Industrial designs are applied to a wide variety of products of industry and handicrafts such as technical and medical instruments, watches, jewelry, house ware, electrical appliances, vehicles, architectural structures, textile designs and other luxury items.

To be protected under most national laws, an industrial design must appeal to the eye. This means that an industrial design is primarily of an aesthetic nature, and does not protect any technical features of the article to which it is applied.

Unfair Competition

Unfair competition is generally understood as any act of competition that is contrary to honest practices in industrial or commercial matters.

A dishonest practice is not something that can be defined with precision.

The standard of fairness or honesty may change from country to country, as well as evolve with time. It is, therefore, difficult to attempt to encompass all existing acts of unfair competition in one definition.

Enforcement (a law) of Intellectual Property Rights

A publisher may own copyright in a book, which has been reproduced and sold without his or her consent, at a cut price.

A sound producer, who has invested large amounts of money, in terms of talent and technical skill, in producing records, sees that copies of it are sold on the market, at cheap prices, without his authorization.

Someone else's trade mark may have been used by a company on similar or identical goods of lesser quality, harming thus the reputation of the legitimate owner, and inflicting on him or her serious financial loss, let alone exposing customer's health to danger.

Somebody may be using the geographical denomination of "Roquefort" on cheese manufactured elsewhere than in the region of Roquefort in France, thus deceiving the consumers as well as taking away business from legitimate producers.

In all such cases intellectual property rights (i.e. copyright, related rights, trademarks and geographical indications) have been infringed. It is important that in such cases enforcement mechanisms be called into play to protect not only the legitimate interests of the rights of the owners, but also of the public.

Emerging Issues in Intellectual Property

Intellectual property plays an important role in an increasingly broad range of areas, ranging from the internet to health care, to nearly all aspects of science and technology, literature and the arts.

The following two topics, ***Biotechnology*** and ***Traditional Knowledge***, are now being discussed at length at the international arena.

❖ Biotechnology

Biotechnology is a field of technology of growing importance in which inventions may have a significant effect on our future, particularly in medicine, food, agriculture, energy and protection of the environment.

The science of biotechnology concerns living organisms, such as plants, animals, seeds and microorganisms, as well as biological material, such as enzymes, proteins and plasmids (which are used in "genetic engineering")

❖ Traditional Knowledge□

Traditional knowledge-used here broadly to refer to tradition-based innovations and creations resulting from intellectual activity in the industrial, scientific, literary or artistic fields-had been largely over-looked in the IP community until quite recently.

It is now increasingly recognized that the economic value of traditional knowledge assets could be further enhanced by the use of IP.

IPR in India:

Patent Administration in India

The Head Office is in **Kolkata**

Four branches:

1. Kolkata

2. Mumbai

3. Delhi

4. Chennai

The appropriate office of the patent office shall be the head office of the patent office or the ranch office as the case may be within whose territorial limits …

- Residence of applicant or domicile; or
- His the place of business; or
- The place where the invention actually originated.

If the applicant has no business or domicile in India, the address for service in India is given by such applicant

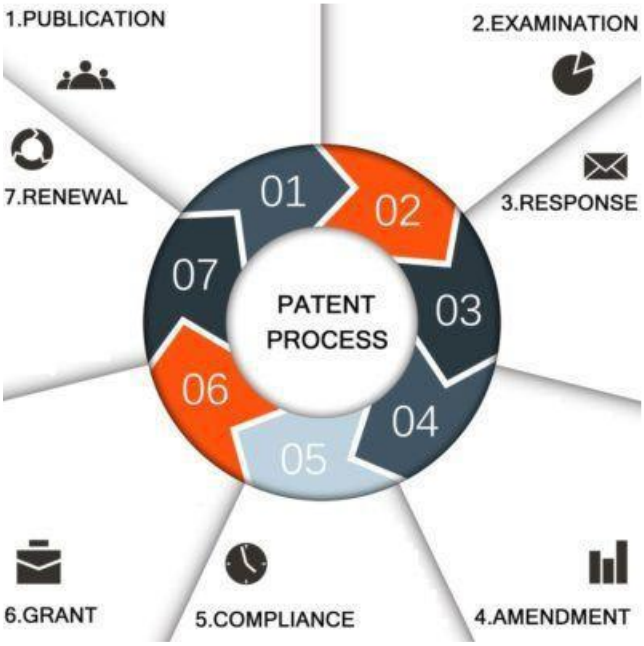
Territorial Jurisdiction Patent Office Branch,

- **Mumbai:** The States of Maharashtra, Gujrat Madhya Pradesh and Goa, Daman & Diu & Dadar & Nagar Haveli
- **Chennai:** The States of Andhra Pradesh, Kerala Tamil Nadu, Mysore and Pondicherry, Laccadive, Minicoy and Aminidivi Islands.
- **New Delhi:** States of Haryana, Himachal Pradesh, Jammu & Kashmir, Punjab, Rajasthan and Uttar Pradesh, Chandigarh and Delhi.
- **Kolkata:** The rest of India.e from the act

Who can file Patent Application in India

Either alone or jointly:

- ✓ By any person claiming to be true and first inventor(s)
- ✓ By any person being the assignee of person claiming to be true and first inventor(s)
- ✓ By the legal representative of any deceased person who can immediately after his death is entitled to make such application



Documents Required / Patent Forms***

✔Application Form (Form 1)

✔Request for Early Publication (Form 9)

✔Proof of Right to Apply

✔Request for Examination (Form 18)

(Paragraph 9 of Form 1)

✔Provisional or complete Specification (Form 2)

✔Power of Attorney, if required (Form 26)

✔Certified Copy of Convention Application, if required

✔Statement of Foreign Filing (Form 3)

✔Abstract of Invention

✔Declaration as to Inventor ship (Form 5)

✔Drawing(s), if any

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 20th 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 2oth may 2003
2005	the patents (amendment) act 2005 effective from Ist January 2005

Provisional Specification

- ✓ It should describe the nature of invention & contain the description of essential features of the invention.
- ✓ No need to include claims & details of the manner in which it to be performed

Advantages of Provisional Specification

- Priority for invention
- No risk of losing priority
- Liberty to develop
- Disclose to interested person to obtain financial support
- Virtually extend the term
- Utilize for exploring commercial feasibility
- Avoid incurring further expenses, if no commercial possibility

Contents of Complete Specification

- Title of the invention

- Field & background of the invention
- Use of the invention
- Prior art in the said field of invention & its drawback(s)
- Comparison between prior art & present invention
- Object (aim) of the present invention
- Summary of the present invention
- Brief description of drawings, if any
- Statement of the invention
- Detailed description of the invention w.r.t. drawings, if any
- Working examples for best method of the invention
- Claims for legal monopoly

Request for early Publication (Form 9)

Applicant may in Form-9 request the controller to publish the application at any time before the expiry of 18 months and such application will be published within 1 month of such request (Sec. 11A).

Publication of Patent Application

[Under Section 11A]

- Every application for patent shall be published in Patent Office Official Journal on expiry of period of 18 months from the date of filing or date of priority, whichever is earlier & shall be open for public inspection (Rule 27)
- Except in the case, where the application –
  (a) in which secrecy direction is imposed U/s. 35
  (b) has been abandoned U/s. 9(1)
  (c) has been withdrawn 3 months prior to 18 months

Importance of Publication

- On and from the date of publication of the application for patent and until the date of grant of a patent in respect of such application, the applicant shall have the like privileges and rights as if a patent for the invention has been granted on the date of publication of the application.
- The applicant shall not be entitled to institute any proceedings for infringement until the patent has been granted

- Right of the patentee in the case of applications filed u/s 5(2) shall accrue from the date of grant of the patent

Examination of Application [Under Section 12 & 13]

Every application after request for examination (U/s. 11B) shall be examined for -

(a) Whether application is in accordance with the requirements of the Act or the rules made there under

(b) Whether there is any lawful ground of objection to the grant of patent

(c) Whether the novelty & inventive step is anticipated by prior claiming in India or publication anywhere in the world

(d) Any other matter which may be prescribed under the Act

Grant or Refuse or Abandonee (Remove) [Under Section 43, 15, & 21]

If, within 12 months from the date FER -

(a) all requirements met, patent will be granted immediately with seal of the Patent Office (Letters Patent) & grant publication U/s. 43(2);

(b) requirement(s) not met, patent application will abandoned U/s. 21(1); or

(c) requirement(s) met or not met even after hearing U/s. 15, patent will be granted or refused, as the case may be.

• Term of patent will be 20 years from the date of filing (sec. 53)

What rights a Patent confers on the patentee

If the patent is for a product:-

- The right to prevent others from
- making
- using
- offering for sale
- selling
- importing the patented product

If the patent is for a process:-

- the right to prevent others from
- using the process

- offering for sale the product using the process
- selling the product using the process
- importing the product using the process

Post-Grant Opposition [Under Section 25(2)]

- Any time after the grant or before expiry of 1 year from the date of publication of grant U/s. 43(2), any interested person may give notice of opposition on any of the grounds (a) to (k) of Section 25(2)
- Opposition board [constituted U/s. 25(3) (b)] after completion of proceeding & maturation of case for hearing will examined the matter & submit its report
- On receipt of report & after hearing the patentee & opponent, the patent will be either maintained or amended or revoked by order U/s. 25(4)

WTO (*World Trade Organization*)

- ✓ The *World Trade Organization* (*WTO*) deals with the global rules of trade between nations
- ✓ Its main function is to ensure that trade flows smoothly, predictably and freely as possible

They deal with: agriculture, textiles and clothing, banking, telecommunications, government purchases, industrial standards and product safety, food sanitation regulations, intellectual property, and much more. The WTO agreements are lengthy and complex because they are legal texts covering a wide range of activities.

Fact files of WTO:

Headquarters:	Geneva, Switzerland
Purpose:	Regulate international trade
Founded:	1 January 1995
Membership:	164 member states
Formation:	1 January 1995; 22 years ago
Official language:	English, French, Spanish
Secretariat staff:	625

Current WTO members: 153 members, Observers (31)

History:

- The WTO was officially created in January of 1995 and essentially replaced the General Agreement on Tariffs and Trade (GATT), which had been in force since 1948, a few years after the Second World War
- Before the WTO was created, an initiative to start something similar known as the International Trade Organization (ITO) took place
- Unfortunately, the ITO treaty was not approved by the U.S. and a few other countries and ultimately never went into effect
- It was the outcome of the lengthy (1986-1994) Uruguay round of GATT negotiations. The WTO was essentially an extension of GATT
- It extended GATT in two major ways.
    - First GATT became only one of the three major trade agreements that went into the WTO (the other two being the General Agreement on Trade in Services (GATS) and the agreements on Trade Related Aspects of Intellectual Property Rights (TRIPS))
    - Second the WTO was put on a much sounder institutional footing than GATT. With GATT the support services that helped maintain the agreement had come into being in an ad hoc manner as the need arose. The WTO by contrast is a fully fledged institution (GATT also was, at least formally, only an agreement between contracting parties and had no independent existence of its own while the WTO is a corporate body recognized under international law).

Objectives:

The important objectives of WTO are:

1. To improve the standard of living of people in the member countries
2. To ensure full employment and broad increase in effective demand
3. To enlarge production and trade of goods
4. To increase the trade of services
5. To ensure optimum utilization of world resources
6. To protect the environment
7. To accept the concept of sustainable development

PRINCIPLES OF WTO

The basic principles of the WTO (according to the WTO):

• Trade without Discrimination

1. Most-favoured-nation (MFN): treating other people equally Under the WTO agreements, countries cannot normally discriminate between their trading partners. Grant someone a special favour (such as a lower customs duty rate for one of their products) and you have to do the same for all other WTO members.
2. National treatment: Treating foreigners and locals equally Imported and locally-produced goods should be treated equally — at least after the foreign goods have entered the market. The same should apply to foreign and domestic services, and to foreign and local trademarks, copyrights and patents.

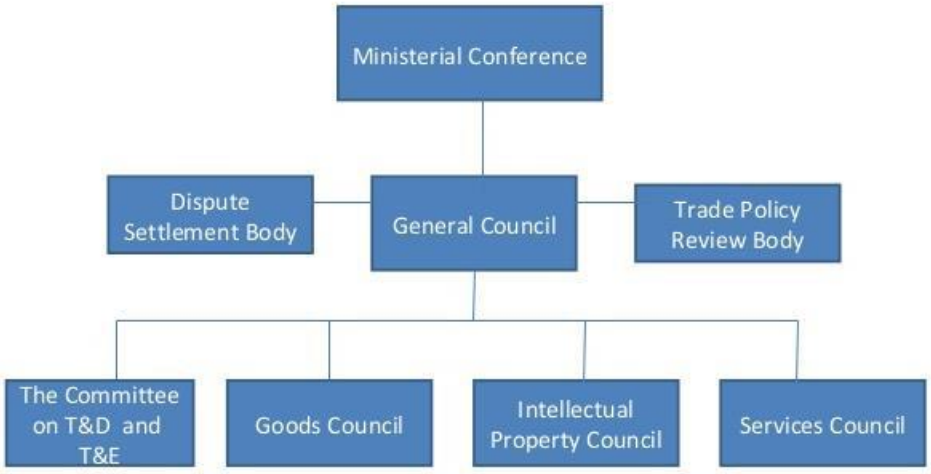
• **Freer trade**: gradually, through negotiation Lowering trade barriers is one of the most obvious means of encouraging trade. The barriers concerned include customs duties (or tariffs) and measures such as import bans or quotas that restrict quantities selectively

• **Predictability:** through binding and transparency Sometimes, promising not to raise a trade barrier can be as important as lowering one, because the promise gives businesses a clearer view of their future opportunities. With stability and predictability, investment is encouraged, jobs are created and consumers can fully enjoy the benefits of competition — choice and lower prices. The multilateral trading system is an attempt by governments to make the business environment stable and predictable.

• **Promoting fair competition:** The WTO is sometimes described as a “free trade” institution, but that is not entirely accurate. The system does allow tariffs and, in limited circumstances, other forms of protection. More accurately, it is a system of rules dedicated to open, fair and undistorted competition.

• **Encouraging development and economic reform:** The WTO system contributes to development. On the other hand, developing countries need flexibility in the time they take to implement the system’s agreements. And the agreements themselves inherit the earlier provisions of GATT that allow for special assistance and trade concessions for developing countries.

STRUCTURES OF WTO



Functions:

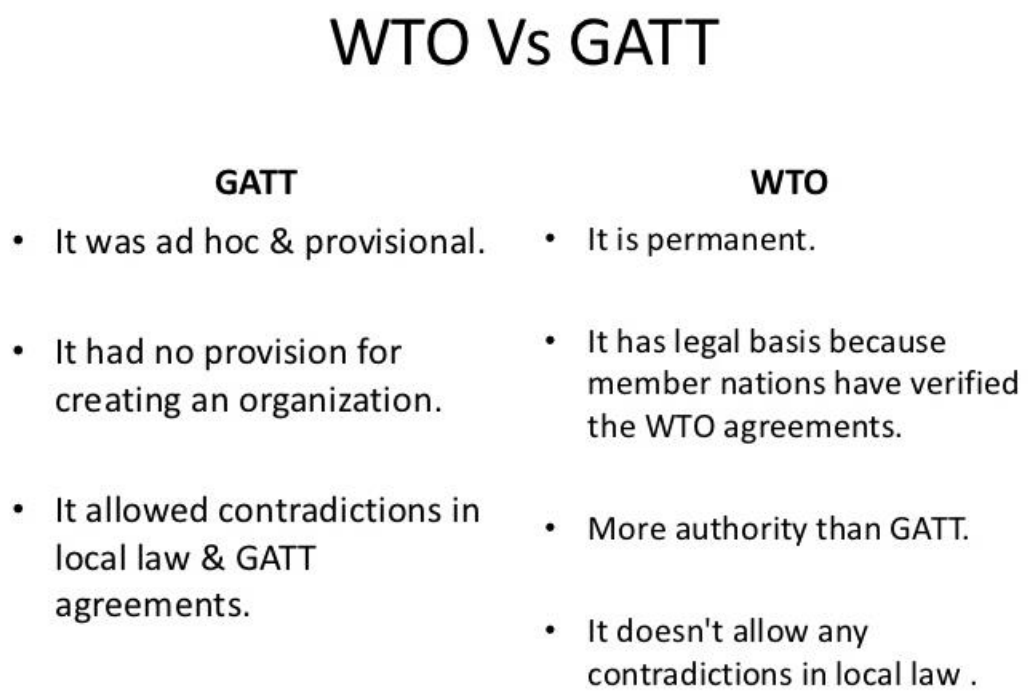
- Administering WTO trade agreements
- Forum for trade negotiations
- Handling trade disputes
- Monitoring national trade policies
- Technical assistance and training for developing countries
- Cooperation with other international organizations

WTO – Why?

- ✓ To arrange the implementation, administration and operations of multilateral (involving three or more participants) and Plurilateral trade agreements (power which shared between different countries)
- ✓ To arrange the forum for deliberations for the member nations in regard to their multilateral trade relations in issues deal with under the agreements
- ✓ To provide a framework for implementing of the results arising out of the deliberations (long and care full agreements/consideration) which taken place at ministerial conference level
- ✓ To manage the created understanding on rules and procedure governing the settlement of disputes
- ✓ To manage effectively and efficiency the trade policy review mechanism (TRIM)
- ✓ To create more together relationship with all nations in respect of global economic policy-making, it would cooperate with the IMF and the World Bank & its affiliated Organizations.

WTO Ministerial Conference:

Conference	Year	Place
I	9-13 Dec., 1996	Singapore
II	18-20 May 1998	Geneva (Switzerland)
III	30 Nov.-3 Dec., 1999	Seattle (USA)
IV	9-14 Nov., 2001	Doha (Qatar)
V	10-14 Sep., 2003	Cancun (Mexico)
VI	13-18 Dec.. 2005	Hong Kong
VII	30 Nov-2Dec., 2009	Geneva (Switzerland



Convention on Biodiversity

Introduction

The Convention on Biological Diversity (CBD) entered into force on 29 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

Biodiversity

Biological diversity (Biodiversity) is the degree of variation of life forms within a given ecosystem, biome, or an entire planet.

It is measured by two parameters:

1. Alpha diversity which represents the no. of species in a specified area

2. Beta diversity which represents the turnover of species across space.

A unified view of the traditional three levels at which biological variety has been identified are:

1. Species Diversity
   - Species diversity which refers to the numbers and kinds of living organisms
2. Genetic Diversity
   - Genetic diversity which refers to the genetic variation within a population of species
3. Ecosystem Diversity
   - Ecosystem diversity which is the variety of habitats, biological communities and ecological processes that occur in the biosphere

History of the Convention:

- The Earth's biological resources are vital to humanity's economic and social development
- As a result, there is a growing recognition that biological diversity is a global asset of tremendous value to present and future generations
- At the same time, the threat to species and ecosystems has never been so great as it is today
- Species extinction caused by human activities continues at an alarming rate.

In response, the United Nations Environment Programme (UNEP) convened the Ad Hoc Working Group of Experts on Biological Diversity in November 1988 to explore the need for an. international convention on biological diversity. Soon after, in May 1989, it established the Ad Hoc Working Group of Technical and Legal Experts to prepare an international legal instrument for the conservation and sustainable use of biological diversity. The experts were to take into account "the need to share costs and benefits between developed and developing countries" as well as "ways and means to support innovation by local people".

Biodiversity – the web of life:

Biological diversity – or biodiversity – is the term given to the variety of life on Earth and the natural patterns it forms. The biodiversity we see today is the fruit of billions of years of evolution, shaped by natural processes and, increasingly, by the influence of humans. It forms the web of life of which we are an integral part and upon which we so fully depend.

This diversity is often understood in terms of the wide variety of plants, animals and microorganisms. So far, about 1.75 million species have been identified, mostly small creatures such as insects. Scientists reckon that there are actually about 13 million species, though estimates range from 3 to 100 million.

Biodiversity also includes genetic differences within each species – for example, between varieties of crops and breeds of livestock. Chromosomes, genes, and DNA – the building blocks of life – determine the uniqueness of each individual and each species.

Our personal health, and the health of our economy and human society, depends on the continuous supply of various ecological services that would be extremely costly or impossible to replace. These natural services are so varied as to be almost infinite.

For example, it would be impractical to replace, to any large extent, services such as pest control performed by various creatures feeding on one another, or pollination performed by insects and birds going about their everyday business

"Goods and Services" provided by ecosystems include:

- ✓ Provision of food, fuel and fibre
- ✓ Provision of shelter and building materials
- ✓ Purification of air and water
- ✓ Detoxification and decomposition of wastes
- ✓ Stabilization and moderation of the Earth's climate
- ✓ Moderation of floods, droughts, temperature extremes and the forces of wind
- ✓ Generation and renewal of soil fertility, including nutrient cycling
- ✓ Pollination of plants, including many crops
- ✓ Control of pests and diseases
- ✓ Maintenance of genetic resources as key inputs to crop varieties and livestock breeds, medicines, and other products
- ✓ Cultural and aesthetic benefits

- ✓ Ability to adapt to change

Patent Cooperation Treaty (PCT):

The **Patent Cooperation Treaty** (**PCT**) is an international patent law treaty, concluded in 1970. It provides a unified procedure for filing patent applications to protect inventions in each of its contracting states. A patent application filed under the PCT is called an **international application**, or **PCT application**.

Languages: English; French
Signatories: **36**
Parties: **152**
Effective: 24 January 1978
Location: Washington, United States
Condition: ratification by 8 States, 4 of which have significant patenting activity
Signed: 19 June 1970

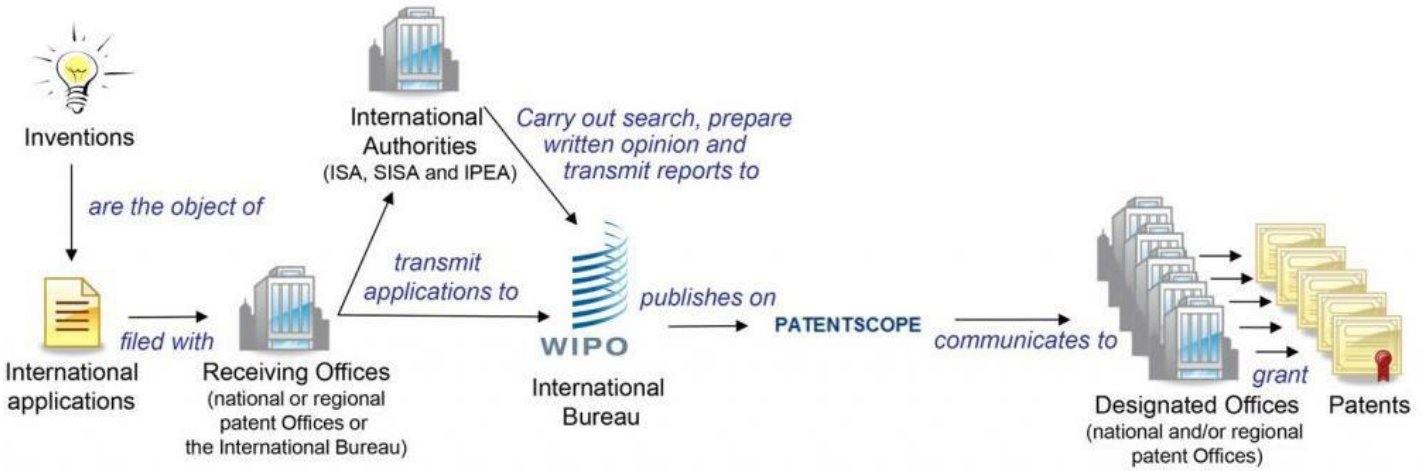
Steps involved in PCT:

- ✓ Filing of international application in a Receiving Office (RO)
- ✓ International Search by an International Searching Authority (ISA)
- ✓ International Preliminary Examination by an International Preliminary Examining Authority (IPEA)

Process of filling a PCT-application:

- ❖ ***Filing:*** you file an international application with a national or regional patent Office or WIPO (if permitted by your State's national security provisions), complying with the formality requirements, in one language (preferably English), and you pay **one set of fees**.
- ❖ ***International Search:*** an "International Searching Authority" (ISA) identifies the published patent documents and technical literature ("prior art"). So it's a check whether your invention is patentable or not.
- ❖ ***International Publication:*** after the expiration of 18 months from the earliest filing date, the content of your international application is disclosed to the world.
- ❖ ***Supplementary International Search (optional):*** a second authority identifies published documents which may not have been found by the first ISA.

- ***International Preliminary Examination (optional):*** another way to get clarification whether your invention is patentable. A third ISAs carries out an additional patentability analysis, usually on an amended version of the application.
- ***National Phase:*** after the end of the PCT procedure, usually at 30 months from the earliest filing date of your initial application, from which you claim priority, you start to pursue the grant of your patents directly before the national (or regional) patent Offices of the countries in which you want to obtain them.



Advantages of PCT:

- Use of the PCT saves effort—time, work, money—for any person or firm seeking protection for an invention in a number of countries
- Use of the PCT also helps the applicant to make decisions about the prosecution of the application before the various national Patent Offices in the PCT National Phase of processing
- The saving arises primarily from the fact that, under the PCT, the applicant files one application—the PCT international application—in one place, in one language and pays one initial set of fees, and that this PCT international application has the effect of a national or regional application, which, without the PCT, he would have to file separately for each country or region

- The help to the applicant in the PCT National Phase prosecution of the application follows from the "advice" he obtains from the PCT international search report, a report which is established for each PCT international application, according to high, internationally regulated standards, by one of the Patent Offices that are highly experienced in examining patent applications and that have been specially appointed to carry out international searches.

Patent:

Patents protect inventions and new discoveries that are new and non-obvious.

Types of patents:

1. Utility patents
2. Design patents
3. Plant patents

1. Utility Patents:

- A utility patent is the most common type of patent that people seek
- This type of patent covers processes, compositions of matter, machines, and manufactures that are new and useful
- A utility patent can also be obtained for new and useful improvements to existing processes, compositions of matter, machines, and manufactures
- Processes refer to any acts or methods of doing something, usually involving industrial or technical processes. Compositions of matter are basically chemical compositions, which can include a mixture of ingredients or new chemical compounds. Machines include things that are generally defined as a machine, such as a computer, while manufactures are defined as goods that are manufactured or made.

2. **Design Patents**

- In terms of obtaining a design patent, a design is defined as the "surface ornamentation" of an object, which can include the shape or configuration of an object
- In order to obtain this type of patent protection, the design must be inseparable from the object
- While the object and its design must be inseparable, a design patent with only protect the object's appearance
- In order to protect the functional or structural features of an object, a person must also file for a utility patent.

3. Plant Patents

- A plant patent can be obtained to protect new and distinctive plants
- A few requirements to obtain this type of patent are that the plant is not a tuber propagated plant (i.e. an Irish potato), the plant is not found in an uncultivated state, and the plant can be asexually reproduced.
- Asexual reproduction means that instead of being reproduced with seed, the plant is reproduced by grafting or cutting the plant
- Plant patents require asexual reproduction because it's proof that the patent applicant can reproduce the plant.

Forms of Patent:

(Refer Previous Notes* - Document Required / Patent Forms)**

Patentability

Inventions which are new, involve an inventive step and are susceptible of industrial application are **patentable** even if they concern a product consisting of or containing biological material *. Biological material which is isolated from its natural environment or produced by means of a technical process may also be the subject of an invention.

The following are **not patentable**:

- ✓ plant and animal varieties;
- ✓ Essentially biological processes for the production of plants or animals, such as crossing or selection. This exclusion from patentability does not, however, affect the patentability of inventions which concern a microbiological process
- ✓ The human body and the simple discovery of one of its elements, including the sequence or partial sequence of a gene.

However, an element isolated from the human body or produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention.

The following inventions include those that are unpatentable where their exploitation would be **contrary to public policy or morality**

- processes for cloning human beings;
- processes for modifying the germ-line genetic identity of human beings;
- uses of human embryos for industrial or commercial purposes;

- Processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

Patenting process:

An invention is patentable only if it is:

- New and previously undisclosed
- Distinguished by an inventive step not obvious to someone expert in that technology
- Capable of industrial application - that is, it is physically possible to make the invention

Some issues to consider before deciding to patent:

- Do you really need a patent? Would some combination of other forms of IPR protect your idea adequately? And be honest with yourself - are you perhaps motivated more by vanity (the prospect of a patent in your name) than by commercial necessity?
- Have you studied the total cost of patenting (which should include annual renewal fees in every country in which you have protection)? Is your invention likely to earn enough income to justify the cost? Normally, you should not apply for a patent until you have thoroughly researched the commercial and financial potential of your idea.
- Is the time right to apply for a patent? Application starts a sequence of events which cannot be delayed. Do you apply for a patent early on, or wait until the invention is market-ready and more capable of quickly recouping its IPR costs? Later may be better than sooner, but circumstances will vary so you should always seek the advice of a patent attorney.
- Does your invention have a short product life cycle? The patenting process typically takes 3-4 years. If your invention is aimed at a highly competitive market in which products are rapidly replaced or improved, your patent may be worth little by the time it is granted.
- Who will pay to enforce your patent? National IP offices do not enforce patents or monitor them for infringement. These are the responsibilities of the patent owner or a licensee. Until funds are potentially available to enforce your patent - from royalties or sales income - it may offer limited practical protection.
- How strongly might your patent resist legal challenge? You will definitely need a patent attorney's advice on the strength of your claims. This is important because the validity of patent claims is often

challenged, usually by competitors who want to copy a successful product. If they succeed, you may be left with a valueless patent and an order to pay the victor's legal costs.

Applying for a patent

Applying for a patent is a legal process governed by strict timescales and usually immovable deadlines. It is not something to rush into! To maximize your chances of a worthwhile patent you should:

- Study the application procedure in detail.
- Aim to apply not in haste, but **strategically** - at a time and for a reason that most benefits your exploitation plans.
- Use a patent attorney! **Do not** do it all yourself - the risk of making mistakes is too great.

Here is only a very brief guide to the application process for a European Patent according to the European Patent Convention (EPC).

Applying for a patent at a national IP office is roughly similar to stages 1-6 below, but an application must be made in the local language.

Making an international application through the Patent Co-operation Treaty (PCT) involves a single procedure for stages 1-4, but 30 months after filing the application goes through stages 5 and 6 in every national or regional IP office where you wish to take up protection.

Choosing your route for a patent application (EPC, PCT, national and regional, or combinations thereof will depend on:

- Your invention.
- Your business plan.
- Your available funds.
- Your intended market.
- The likeliest sources of infringing products.

A patent attorney will be able to advise you on the route that is best **for you and your invention**.

Stage 1: Beginning the process:-

Your patent attorney must provide documentation consisting of:

- A request for a patent.
- Details of the applicant (you).

- A description of the invention.
- Claims.
- Drawings (if any).
- An abstract.

A fee must also be paid. In order to avoid delay, it is vital that all documentation conforms in every detail to official requirements. Your patent attorney will ensure that it does. At the EPO, applications are accepted in English, French or German.

For your patent attorney to prepare all the information about your invention, he or she will obviously need to work closely with you. **Do not assume that you know best because it is your invention**. You must trust the skill and judgment of your patent attorney, as patenting involves a complex mix of law and technology. The claims in particular need to be drafted with skill, as they are the most important aspect of a patent.

Stage 2: Filing date and initial examination:-

If your documentation appears correct, your application is given a **filing date** - also known as your **priority date**. After filing there is a **formalities examination** to ensure that your documentation is correct and complete.

At any time in the next 12 months you can file for patent protection in other countries and have those later filings treated as if they had been filed on your priority date. In practice, this gives you a year to decide how many countries you wish to include in your patent protection.

Stage 3: Search:-

A **search report** is sent to you, listing and including copies of all prior art documents found by an experienced examiner and regarded as relevant to your invention. The search is based mainly on your claims for novelty, but your description and any drawings will also be taken into account. The report will often include an initial opinion on the patentability of your invention.

Stage 4: Publication:-

Your application is **published** 18 months after the filing date. Your invention will appear in databases accessible to other people around the world. It will act as **prior art** against any future patent applications from other inventors or companies for similar inventions.

You then have six further months to make two decisions:

- Do you want to continue with your application? You indicate ‘yes' by requesting a more thorough (‘substantive') examination.
- Which countries do you want to include (‘designate') in your patent protection? Designation fees must be paid.

After your patent is granted, you may claim damages for infringements originating as far back as the publication date of your application. However, to enjoy this right in some countries it may be necessary to file a translation of your claims with their national IP office and for them to publish the translated claims.

Stage 5: Substantive examination:-

If you request **substantive examination**, the EPO has to decide whether your invention **and** your application meet the requirements of the European Patent Convention. For maximum objectivity there are usually three EPO examiners, one of whom maintains contact with your patent attorney. This stage will often involve dialogue between the examiners and your patent attorney, which may result in the re-drafting of key parts of your application. Your patent attorney will defend your application, and this is one more reason why it is essential to have professional representation.

Stage 6: Decision to grant a patent:-

If the examiners decide to grant a patent, and all fees have been paid and any claims translations filed, the decision is reported in the European Patent Bulletin. The **decision to grant** takes effect on the date of publication.

Stage 7: Validation:-

What you have now got is a ‘bundle' of individual national patents. After the EPO decision to grant is published, your patent has to be **validated** in each designated state within a specific time limit. If this is not done, your patent may not be enforceable in that state. In some states, validation may include having to file (and pay for) a translation of the whole patent, or just a translation of the granted claims.

Stage 8: Opposition:-

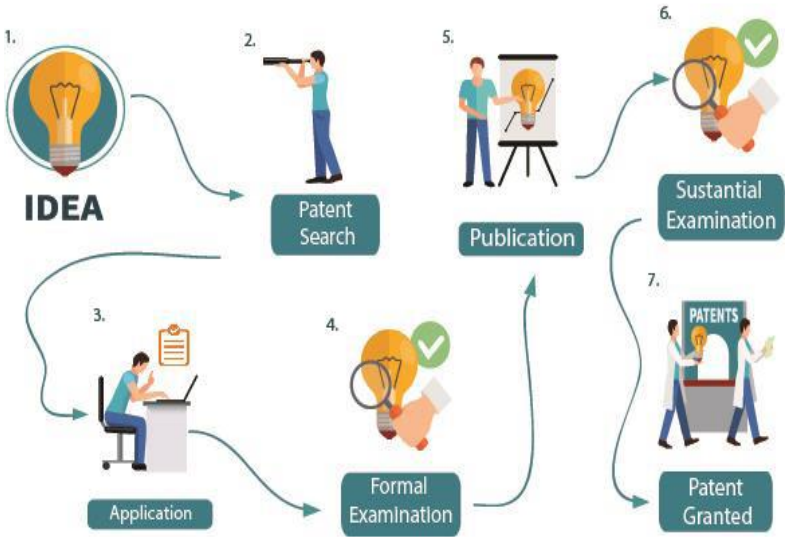
A granted patent may be **opposed** by third parties - usually the applicant's competitors - if they believe it should not have been granted. After the grant is reported in the European Patent Bulletin they have nine months in which to file notice of opposition. The most common charge is that the invention is not novel or lacks an inventive step. The case will be examined by an EPO team, again of three examiners.

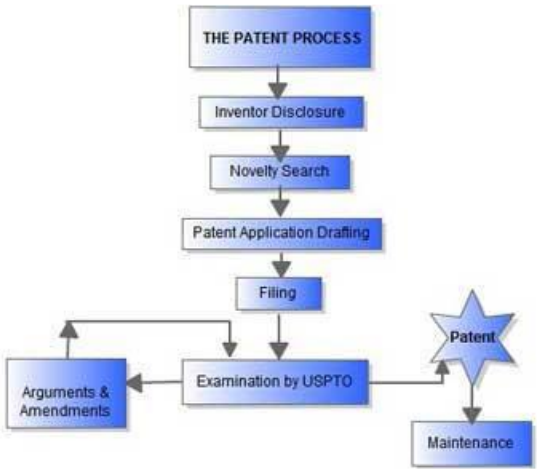
Opposition is the last chance to attack a European patent **as a single entity in a single forum**. Later, the patent can only be challenged in national courts and a ruling in one country has no effect on the patents for the same invention in other countries. This gives competitors a strong incentive to challenge an

invention during the opposition period, as challenging patents in separate national courts can be much more expensive.

Stage 9: Appeal:-

All EPO decisions are open to appeal. Responsibility for decisions on appeals is taken by independent boards of appeal.





Step by step guide for how to get patent in India

Step 1: Write down the invention (idea or concept) with as much details as possible

Collect all the information about your invention such as:

- Area of invention
- Description of the invention what it does
- How does it work
- Advantages of the invention

Ideally, if you have worked on the invention during research and development phase you should have something call lab record duly signed with date by you and respective authority.

Step 2: include drawings, diagrams or sketches explaining working of invention

The drawings and diagrams should be designed so as to explain the working of the invention in better way with visual illustrations. They play an important role in patent application.

Step 3: check whether the invention is patentable subject matter

All inventions may not be patentable, as per Indian patent act there are certain inventions that are not patentable explained in detail in(inventions not patentable)

Step 4a: Patentability search

The next step would be finding out whether your invention meets all patentability criteria as per Indian patent act? That is,

- Novelty
- Non-obviousness
- Industrial application
- Enabling

The detailed explanation for patentability criteria is given here (what are patentability criteria's). The patentability opinion is provided by the patent professionals up on conducting extensive search and forming patentability report.

Step 4b: Decide whether to go ahead with patent

The patentability report and opinion helps you decide whether to go ahead with the patent or not, chances are what you thought as novel might already been patented or know to public in some form of information. Hence this reports saves lots of time, efforts and cost of the inventor by helping him decide whether to go ahead with the patent filing process or not.

Step 5: Draft (write) patent application

In case you are at very early stage in the research and development for your invention, then you can go for **provisional application**. It gives following benefits:

- Secures filing date
- 12 months of time to file complete specification
- Low cost

After filing provisional application, you secure the filing date which is very crucial in patent world. You get 12 months of time to come up with the complete specification, up on expiry of 12 months your patent application will be abandoned.

When you complete the required documents and your research work is at level where you can have prototype and experimental results to prove your inventive step you can file complete specification with patent application.

Filing the provisional specification is the optional step, if you are at the stage where you have complete information about your invention then you can directly go for complete specification.

Step 6: Publication of the application

Up on filing the complete specification along with application for patent, the application is published after 18 months of first filing.

An early publication request can be made along with prescribed fees if you do not wish to wait till the expiry of 18 months from the date of filing for publishing your patent application.

Generally the patent application is published within a month form request form early publication.

Step 7: Request for examination

The patent application is examined only after receiving request for examination that is RFE. Up on receiving this request the controller gives your patent application to a patent examiner who examinees the patent application with different patentability criteria like:

- ✓ Patentable subject matter
- ✓ Novelty
- ✓ Non-obviousness
- ✓ Inventive step
- ✓ Industrial application
- ✓ Enabling

The examiner creates a first examination report of the patent application upon reviewing it for above terms. This is called patent prosecution. Everything happening to patent application before grant of patent is generally called as patent prosecution.

The first examination report submitted to controller by examiner generally contains prior arts (existing documents before the date of filing) which are similar to the claimed invention, and same is reported to patent applicant.

Step 8: respond to objections

Majority of patent applicants will receive some type of objections based on examination report. The best thing to do it analyse the examination report with patent professional (patent agent) and creating a response to the objections raised in the examination report.

This is a chance for an inventor to communicate his novelty over prior arts found in the examination report. The inventor and patent agent create and send a response to the examination that tries to prove to controller that his invention is indeed patentable and satisfies all patentability criteria's.

Step 9: clearing all objections

This communication between controller and patent applicant is to ensure that all objections raised in the patent application are resolved. (if not the patent will not be granted) and the inventor has his fair chance to prove his point and establish novelty and inventive step over existing prior arts.

Up on finding the patent application in order of grant, it is grant to the patent applicant as early as possible.

Step 10: Grant of patent

The application would be placed in order for grant once it is found to be meeting all patentability requirements. The grant of patent is notified in the patent journal which is published time to time.

Indian Patent Office:

- The **Indian Patent Office** is administered by the Office of the Controller General of Patents, Designs & Trade Marks (CGPDTM).
- This is a subordinate office of the Government of India and administers the Indian law of Patents, Designs and Trade Marks.

Patent administration

The CGPDTM reports to the Department of Industrial Policy and Promotion (DIPP) under the Ministry of Commerce and Industry and has five main administrative sections:

- Patent Office
- Designs Registry
- Trademarks Registry
- Geographical indications Registry
- Rajiv Gandhi National Institute of Intellectual Property Management (NIIPM)
- Patent Information System

The patent office is headquartered at Kolkata with branches in Chennai, New Delhi and Mumbai, but the office of the CGPDTM is in Mumbai.

The Indian Patent Office has 526 Patent Examiners, 97 Assistant Controllers, 42 Deputy Controllers, 1 Joint Controller, and 1 Senior Joint Controller, all of whom operate from four branches. Although the designations of the Controllers differ, all of them (with the exception of the Controller General) have equal authority in administering the Patents Act.

International Patent Office:

- The **World Intellectual Property Organization** (**WIPO**) is one of the 17 specialized agencies of the United Nations (UN)
- WIPO was created in 1967 "to encourage creative activity, to promote the protection of intellectual property throughout the world"
- WIPO currently has 191 member states, administers 26 international treaties, and is headquartered in Geneva, Switzerland
- The current Director-General of WIPO is Francis Gurry, who took office on 1 October 2008.

1. Food and Agriculture Organization (FAO)
2 International Civil Aviation Organization (ICAO)
3 International Fund for Agricultural Development (IFAD)
4 International Labour Organization (ILO)
5 International Maritime Organization (IMO)
6 International Monetary Fund (IMF)
7 International Telecommunication Union (ITU)
8 United Nations Educational, Scientific and Cultural Organization (UNESCO)
9 United Nations Anti-Terrorism Coalition (UNATCO)
10 United Nations Industrial Development Organizations (UNIDO)
11 Universal Postal Union (UPU)
12 World Bank Group (WBG)
    12.1 International Bank for Reconstruction and Development (IBRD)
    12.2 International Finance Corporation (IFC)

12.3 International Development Association (IDA)

13 World Health Organizations (WHO)

14 World Intellectual Property Organizations (WIPO)

15 Worlds Meteorological Organization (WMO)

16 World Tourism Organizations (UNWTO)

17 Former specialized agencies

Present Indian Scenario

PATENTS IN THE INDIAN SCENARIO:

The laws pertaining to Patent in India is governed by the Patents Act, 1970 which has been amended twice by The Patents (Amendment) Act, 1999 and The Patents (Amendment) Act, 2002. The new Patent Act, 2002 has although been notified on June 25th 2002, however, currently only limited sections of it have been made applicable vide Gazette Notification from the Government of India, dated May 20, 2003. Although, it is being implemented in phased manner, however, it is a matter of time before the new Act shall be applicable in its entirety.

In the current scenario, the old Acts i.e. The Patent Act, 1970 and The Patent Rules, 2003 are applicable except for the sections made applicable through the Gazette Notification, as stated above.

WHAT IS PATENTABLE:

Patents are granted in respect of any invention in goods. An invention means any new and useful art, process, method or manner of manufacture, machine, apparatus or other article, or substance produced by manufacture, and includes any new and useful improvement in any of them.

No patent is granted in respect of claims for the substances themselves; however, claims for the methods or processes of manufacture are patentable. However, in compliance with its commitment under the TRIPS agreement, India has been given time to introduce product patent by the year 2005.

WHO CAN APPLY:

Both the Indian nationals and foreigners can make an application for patent in India. But, in case of foreigners applying for patent in India, it is necessary that the country of such applicant should also be providing such reciprocal rights to the Indian nationals.

Application for patents can be made by any person claiming to be the true and first inventor of the invention or by his assignee or legal representative. An application for patent can be made by any of these persons either alone or jointly with any other person. Two or more companies as assignees may also make an application jointly.

STEPS INVOLVED IN GRANT OF PATENT:

- Filing of an application for grant of a patent accompanied by either a provisional specification or a complete specification before any public disclosure of the invention.
- In case provisional specification accompanies the original application, then filing of the complete specification within 12 months from the date of filing of the provisional specification. The said period may be extended by a further period of 3 months by paying appropriate fee for extension.
- Overcoming objections, if any laid by the examiner after the technical examination of the application by the patent office.
- Acceptance of the application and advertisement of such acceptance in the official gazette.
- Overcoming opposition, if any, to the grant of a patent.
- Grant and sealing of the patent.
- Maintenance of patent by payment of renewal fee.
- Enforcement/revocation.

PATENT COOPERATION TREATY:

Patent Cooperation Treaty is the sister treaty of the Paris Convention, which is administered by the World Intellectual Property (WIPO). The PCT facilitates filing of patent applications under a single umbrella and provides for simplified procedure for the search and examination of such applications.

Under the Paris convention an inventor gets a grace period of 12-months to file a patent application in other member countries after filing in the home country. This period of grace is extended to 30-months under the PCT, whereby an inventor can file an "international patent application" in each of the PCT member countries within this prescribed period. In India a grace period of 31 months is granted for such "international patent application".

FILING PROCEDURE UNDER THE PCT:

1) International Phase

2) National Phase

1. International Phase

India being one of the contracting state in the "PCT", any Indian applicant may file an international application in the standard format [Form "PCT" /RO/101] through any of the Indian Patent Offices as the Receiving Office i.e. The Patent Office, Kolkata, and its branch Offices at New Delhi, Mumbai, Chennai (RO/IN) along with the copy of Specification and Statutory Fees. Language of filing may be either in English or Hindi.

At the time of filing the said application the applicant is also required to mention the number of countries wherein eventually registration of patent is desired to be sought and also has to specify the name of the International Search Authority and the International Preliminary Examination Authority.

The following are the documents that must accompany a PCT Application filed through an Indian Patent office as the receiving office:

1. PCT Request (Form PCT/RO/101).
2. The complete specification in triplicate.
3. Power of Attorney
4. Certified priority Document.

On the receipt of the application, the patent office shall prepare a certified copy of the priority documents and transmit the same to the International Bureau and the International Search Authority with intimation to the applicant. Thereafter the international search is conducted and the copy of the search report is also forwarded to the applicant.

2. National Phase

Once the formalities under step one are duly complied and the applicant receives the International Search Report or once the Final International Preliminary Examination Report is complete and issued, the application enters the National Phase.

Filing of National Phase Application in India requires the request for the grant of patent to be made to the competent Receiving Office i.e. The Patent Office, Kolkata, and its branch Offices at New Delhi, Mumbai, Chennai in the prescribed form i.e. Form 1A. Language of filing may be either in English or Hindi.

Further the following information/ documents are also required to be submitted along with the necessary fees with the Patent office:

1. Request (PCT/RO/101)

2. Drawings (where applicable)

3. P.A./G.P.A. (where applicable)

4. The Specification including drawing figures as published in the "PCT" Gazette;

5. Verified English translation of international application, if not in English;

6. International Search Report;

7. International Preliminary Examination Report (if India is elected for using the IPE results);

8. Certified Copies of the Priority Documents;

9. Particulars of amendments made to the specification/claims during the "PCT" International Phase;

10. Verified English translation of amendments filed during the international phase.

11. Such other information and documents that the patent office may require to be submitted.

NOTE: Refer previous topics:

Good laboratory practice or **GLP:**

Good laboratory practice or **GLP** is a set of principles intended to assure the quality and integrity of non-clinical laboratory studies that are intended to support research or marketing permits for products regulated by government agencies.

In the experimental (non-clinical) research arena, the phrase **good laboratory practice** or **GLP** specifically refers to a quality system of management controls for research laboratories and organizations to ensure the uniformity, consistency, reliability, reproducibility, quality, and integrity of chemical (including pharmaceuticals) non-clinical safety tests; from physiochemical properties through acute to chronic toxicity tests.

GLP was first introduced in New Zealand and Denmark in 1972, and later in the US in 1978 in response to the Industrial BioTest Labs scandal. It was followed a few years later by the Organization for Economic Co-operation and Development(OECD) Principles of GLP in 1992; the OECD has since helped promulgate GLP to many countries.

GLP is a quality system concerned with the organizational process and conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported

GLP principles include

1. Organization and Personnel

- ✓ Management-Responsibilities
- ✓ Sponsor-Responsibilities

- ✓ Study Director-Responsibilities
- ✓ Principal Investigator-Responsibilities
- ✓ Study Personnel-Responsibilities

2. Quality assurance program

- ✓ Quality Assurance Personnel

3. Facilities

- ✓ Test System Facilities
- ✓ Facilities for Test and Reference Items

4. Equipment, reagents and Materials
5. Test systems

- ✓ Physical/Chemical
- ✓ Biological

6. Test & Reference items
7. Standard operating procedures
8. Performance of Study

- ✓ Study Plan
- ✓ Conduct of Study

9. Reporting of results
10. Archival - Storage of Records and Reports

Good Manufacturing Practice (GMP)

Good Manufacturing Practice (**GMP**) is a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product.

Current Good Manufacturing Practice:

CGMP refers to the **Current Good Manufacturing Practice** regulations enforced by the US Food and Drug Administration (FDA). CGMPs provide for systems that assure proper design, monitoring, and control of **manufacturing** processes and facilities.

All guidelines follow a few basic principles:

- Manufacturing facilities must maintain a clean and hygienic manufacturing area.
- Controlled environmental conditions in order to prevent cross contamination of food or drug product from adulterants that may render the product unsafe for human consumption.
- Manufacturing processes are clearly defined and controlled. All critical processes are validated to ensure consistency and compliance with specifications.
- Manufacturing processes are controlled, and any changes to the process are evaluated. Changes that affect the quality of the drug are validated as necessary.
- Instructions and procedures are written in clear and unambiguous language (good documentation practices).
- Operators are trained to carry out and document procedures.
- Cross contamination with unlabelled major allergens is prevented.
- Records are made, manually or by instruments, during manufacture that demonstrate that all the steps required by the defined procedures and instructions were in fact taken and that the quantity and quality of the food or drug was as expected. Deviations are investigated and documented.
- Records of manufacture (including distribution) that enable the complete history of a batch to be traced are retainesd in a comprehensible and accessible form.
- The distribution of the food or drugs minimizes any risk to their quality.
- A system is available for recalling any batch from sale or supply.
- Complaints about marketed products are examined, the causes of quality defects are investigated, and appropriate measures are taken with respect to the defective products and to prevent recurrence.

Other good-practice systems, along the same lines as GMP, exist:

- Good agricultural practice (GAP), for farming and ranching
- Good laboratory practice (GLP), for laboratories conducting non-clinical studies (toxicology and pharmacology studies in animals)
- Good clinical practice (GCP), for hospitals and clinicians conducting clinical studies on new drugs in humans
- Good regulatory practice (GRP), for the management of regulatory commitments, procedures and documentation
- Good distribution practice (GDP) deals with the guidelines for the proper distribution of medicinal products for human use

- Good transportation practice (GTP) deals with the guidelines for the proper domestic and international transportation of medicinal products for human use
- Good pharmacovigilance practice (GVP) deals with the safety of produced drugs.

Collectively, these and other good-practice requirements are referred to as "GxP" requirements, all of which follow similar philosophies. (Other examples include good agriculture practices, good guidance practices, and good tissue practices.) In the U.S., medical device manufacturers must follow what are called "quality system regulations" which are deliberately harmonized with ISO requirements, not CGMPs.

Topic	GLP	GMP
Study Director	Single point of contact for the study, with overall responsibility and control of the study and its components. Appointed by Testing Facility Management.	No Study Director assigned or appointed. No single point of contact is required.
Quality Assurance Unit vs. Quality Control Unit	Quality Assurance Unit inspects critical phases of each study and periodically inspects the facility to inform Testing Facility Management of the integrity of the studies and compliance or non-compliance with the GLPs. Is entirely separate from the personnel engaged in the study. Is oversight function only, not quality system or control.	Quality Control Unit has responsibility and authority to approve or reject all rocedures and aspects of testing/manufacturing. Is overall quality system.
Testing Facility Management	Is responsible for designating a Study Director with appropriate education / training for each study. Ensures there is a Quality Assurance Unit separate from the personnel engaged in the study. Ensures facility, personnel, equipment, etc. is available and complies with the GLPs.	Supervisors should have proper training. Responsibilities should be in written procedures and followed. Is oversight function.
Type of Testing Conducted	Open-ended determination of product performance, often for submission to the EPA or FDA for pre-market approval.	Determination of whether or not the product/sample has met manufacturing specifications.
Facility	Design and construction must be suitable to the	Design construction must be

	type of testing conducted, with separation of areas for minimizing mix- ups/contamination. Lighting, plumbing, sewage, washing facility regulations are not mentioned under GLPs.	suitable to the type of testing conducted, with separation of areas for minimizing mix-ups/contamination. Lighting, plumbing, sewage, and washing facility requirements are specified under GMPs.
Equipment	Equipment must be appropriate, maintained, and the state of equipment documented to provide study reconstruct ability. Data-generating equipment is calibrated.	Equipment must be qualified for use in manufacturing processes. Data generating equipment for product testing purposes is calibrated. The accuracy, sensitivity, specificity, and reproducibility of test Methods shall be established and documented.
Standard Operating Procedure (SOP) / Written Procedure	Drafted by any qualified personnel, approved by Testing Facility Management.	Drafted by any qualified personnel, approved by Quality Control Unit.
Standard Operating Procedure (SOP) / Written Procedure	Each study requires a specific study protocol indicating study objectives and methods for conduct and is approved by both the Study Sponsor and Study Director prior to initiation. Protocol overrides SOPs.	Study-specific protocols are not required. Standard written procedures are followed.
Master Schedule	An index of all studies is maintained by the Quality Assurance Unit.	Master Schedule is not addressed.
Records and Reports	Signature or initials of personnel conducting all procedures, preparations, calibrations, etc. are	Signature of both the personnel conducting procedures and

	required along with dates completed and must be on all records. Records are maintained in secure archives for at least 5 years following date of registration if used to support a marketing permit or 2 years following study completion/termination. Archivist is responsible for archives and ensures security of documentation.	personnel verifying steps of procedures must be on all records (dual control of procedures/records). Records are maintained (not specified in archives) for at least 1 year following product expiration date.
CAPA System	Not required.	Required.

BHARATHIDASAN UNIVERSITY, TRICHIRAPPALLI

DEPARTMENT OF MICROBIOLOGY

APRIL - 2016

CLASS : I – M.Sc., MICROBIOLOGY **TIME : 3 Hrs.**

SUBJECT: QC & IPR **MARK: 75**

SUBJECT CODE: P 16MBE2B **DATE:**

SECTION – A

I. ANSWER ALL QUESTIONS: **10X2=20**

1. Descriptive ethics.
2. ELSI.
3. Toxicity.
4. Allergenicity.
5. Drug.
6. Physical Containment.
7. Quality Control.
8. Trademark.
9. TRIP.
10. PCT.

SECTION – B

II. ANSWER ALL QUESTIONS: **5X5=25**

11. a) Discuss Tom Beauchamp and James Childress's principle of bioethics.

Or

b) What are the common bioethical issues?

12. a) Give a brief note on personal safety precautions.

Or

b) What are the classification microorganisms based on hazard?

13. a) Illustrate the structure and function of biosafety cabinets.

Or

b) What are the good laboratory practices?

14. a) How will you check acidity of milk?

Or

b) Brief discuss about physical test to check quality water.

15. a) What are the steps involved in patenting?

Or

b) Convention on biodiversity – Discuss.

SECTION - C

III. ANSWER ANY THREE QUESTIONS: 3X10=30

16. Explain in detail about routes and source of laboratory associated diseases.
17. How will you check the quality of water using microbiological analysis?
18. Give an elaborate note on principles and application of biosafety assessment in vaccine production industries.
19. Why should we need quality control system of dairy product?
20. What are the good manufacturing practices followed in industries? Explain with suitable example.

BHARATHIDASAN UNIVERSITY, TRICHIRAPPALLI

DEPARTMENT OF MICROBIOLOGY

NOVEMBER - 2016

CLASS : I – M.Sc., MICROBIOLOGY TIME : 3 Hrs.

SUBJECT: QC & IPR **MARK: 75**

SUBJECT CODE: P 16MBE2B **DATE:**

SECTION – A

I. ANSWER ALL QUESTIONS: 10X2=20

1. Morality
2. Radioactive isotopes
3. Biosafety
4. Quality Assesment
5. Antibiotic
6. Coliform
7. Methylene blue dye reduction test
8. Trade secret
9. Good Laboratory Practice
10. GATT.

SECTION – B

II. ANSWER ALL QUESTIONS: 5X5=25

11. a) List out the principles of bioethics.

Or

b) Write down the steps involved in disposal of laboratory wastes.

12. a) What are the safety precautions to be followed in the laboratory?

Or

b) Illustrate the risks associated with biological laboratory.

13. a) What are the biosafety assessments to be followed in drug production industries?

Or

b) How do we synthesis protein molecules safety?

14. a) What are the quality control methods to be done at milk production units?

Or

b) Write down the applications of HACCP.

15. a) Give a brief note on good manufacturing practice.

Or

b) Comment on convention on biodiversity.

SECTION - C

III. ANSWER ANY THREE QUESTIONS: 3X10=30

16. Write an elaborate note on laboratory associated diseases.
17. What are the quality control methods adopted during vaccine production?
18. Give a detail account on various quality control methods to be followed in the production of drinking water.
19. Elaborate a note on quality management system in food processing industries.
20. What are the steps involved in patenting of biological products.

BHARATHIDASAN UNIVERSITY, TRICHIRAPPALLI

DEPARTMENT OF MICROBIOLOGY

APRIL - 2018

CLASS : I – M.Sc., MICROBIOLOGY **TIME : 3 Hrs.**

SUBJECT: QC & IPR **MARK: 75**

SUBJECT CODE: P 16MBE2B **DATE:**

SECTION – A

I. ANSWER ALL QUESTIONS: 10X2=20

1. Justice
2. Morality
3. Biosafety issues of GMOs
4. Nosocomial infection
5. Biosafety assessment of drugs
6. Biomolecules
7. Fecal contamination of water
8. Pasteurization
9. WTO
10. GATT.

SECTION – B

II. ANSWER ALL QUESTIONS: 5X5=25

11. a) Write an account on autonomy of bioethics.

Or

b) Write in brief about privacy of ethics.

12. a) Write short notes on lab associated infections.

Or

b) Describe the WHO biosafety guidelines for laboratory.

13. a) Discuss the biosafety in biotechnology products.

Or

b) Briefly explain about the biosafety cabinets.

14. a) Describe about HACCP analysis in milk industry.

Or

b) Add short note on MPN technique.

15. a) Write note on patenting of microbes.

Or

b) Describe in detail about the process of patenting in India.

SECTION - C

III. ANSWER ANY THREE QUESTIONS: 3X10=30

16. Explain in detail about the principles of human rights.
17. Discuss about various risk groups of microorganism.
18. Write an essay on BSA of pharma products.
19. Write an elaborate note on quality control and WHO standards of food industry.
20. Explain in detail about patent co operation treaty.

BHARATHIDASAN UNIVERSITY, TRICHIRAPPALLI

DEPARTMENT OF MICROBIOLOGY

APRIL - 2019

CLASS : I – M.Sc., MICROBIOLOGY **TIME : 3 Hrs.**

SUBJECT: QC & IPR **MARK: 75**

SUBJECT CODE: P 16MBE2B **DATE:**

SECTION – A

I. ANSWER ALL QUESTIONS: **10X2=20**

1. Morality
2. Ethics
3. Lab associated infections
4. Biohazards
5. Biosecurity
6. Vaccines
7. EPA
8. WHO
9. GATT
10. CBD

SECTION – B

II. ANSWER ALL QUESTIONS: **5X5=25**

11. a) Write short notes on human rights

Or

b) Write short notes on National Bioethics Committee.

12. a) Write about the perceptions of risk of BSA.

Or

b) Explain briefly about the benefits of biosafety.

13. a) Write short notes on biosafety assessment.

Or

b) Write a brief account on BSA of biotechnology.

14. a) Brief note on quality control in dairy products.

Or

b) Write a brief account on quality control in food process technology.

15. a) What do you mean infringement of patents? Explain.

Or

b) Comment on GLP and GMP.

SECTION - C

III. ANSWER ANY THREE QUESTIONS: 3X10=30

16. Give an account on bioethics.
17. Explain in detail about the biosafety guidelines.
18. Write about biosafety assessment of biomolecules in detail.
19. Explain the quality control of portable water.
20. Write in detail about patent cooperation treaty.

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