17BTU304A I.P.R., ENTREPRENEURSHIP, BIOETHICS & BIOSAFETY 3H - 3C
Total hours/week: L:3 T:0 P:0 Marks: Internal: 40 External: 60 Total: 100

Scope: This course deals with the study of intellectual property rights, entrepreneurship, bioethics and biosafety.

Objective: This paper will enable the students to learn in detail about Indian patent law, regulation of excise, national and international ethical issues, bio safety and health hazards and good laboratory practices and good manufacturing practices.

UNIT-I

Introduction to Indian Patent Law: World Trade Organization and its related intellectual property provisions. Intellectual/Industrial property and its legal protection in research, design and development. Patenting in Biotechnology, economic, ethical and depository considerations.

UNIT-II

Entrepreneurship: Selection of a product, line, design and development processes, economics on material and energy requirement, stock the product and release the same for making etc. The basic regulations of excise: Demand for a given product, feasibility of its production under given constraints of raw material, energy input, financial situations export potential etc.

UNIT-III

Bioethics: Necessity of Bioethics, different paradigms of Bioethics – National & International. Ethical issues against the molecular technologies.

UNIT-IV

Biosafety: Introduction to biosafety and health hazards concerning biotechnology. Introduction to the concept of containment level.

UNIT-V

Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP), NABL, FSSAI.

References

1. David H. Holt, (1992). *Entrepreneurship: New Venture Creation*.
2. Jack M. Kaplan, (2015). *Patterns of Entrepreneurship*.
3. Gupta, C.B., Khanka, S.S. (2002). *Entrepreneurship and Small Business Management*. Sultan Chand & Sons.
4. Sateesh, M.K., (2010). *Bioethics and Biosafety*, I. K. International Pvt Ltd.
5. Sree Krishna, V, (2007) *Bioethics and Biosafety in Biotechnology*. New age International publishers.

LECTURE PLAN

S.NO	Topics to be covered	Support Materials
	UNIT 1	**10 hr**
1.	Introduction to Indian Patent law	T2: 1 -4
2.	Indian patent law act	T2:9
3.	IPR introduction	T1:1 - 3
4.	World Trade Organization and its related intellectual property rights	T2: 21
5.	Intellectual/ industrial property and its legal protection in research design and development	T1: 18
6.	Patenting in Biotechnology-Introduction	T1: 23
7.	Patenting in Biotechnology	T2: 67
8.	Patenting –economic and ethical depository considerations	T1: 30
9.	Generating patents- steps	T1: 49
10.	Unit test	
	Unit II	**10 hr**
11.	Entrepreneurship introduction	T1: 70
12.	Entrepreneurship- selection of product, line and design development process	T1: 72
13.	Entrepreneurship-economics on material and energy requirement	T1: 74 -79
14.	Entrepreneurship- stock the product and release the same for marketing	T1: 80
15.	Basic regulations of excise	T1: 91
16.	Excise: demand for a given product	T1: 79
17.	Excise: feasibility of its production under given constrains of raw material	T1: 92
18.	Excise – energy input	T1: 93
19.	Excise: Financial regulations and export potential	T1: 94
20.	Unit test	
	Unit III	**6 hr**
21.	Introduction to Bioethics	T3: 1-4
22.	Bioethics: rules and regulations	T3: 3 -6
23.	Necessity of Bioethics	T3: 1-5
24.	Different paradigms of Bioethics- national and international	T3: 17
25.	Ethical issues against molecular technologies	T1: 39
26.	Unit test	
	Unit IV	5 hr
27.	Biosafety: Introduction	R1: 3
28.	Biosafety -WHO guidelines	R1: 3 - 9
29.	Health hazards concerning Biotechnology	T3: 43
30.	Introduction to the concepts of the contaminant level	T1: 32

31.	Unit test	
Unit V		5 hr
32.	Good laboratory practices	R1: 117
33.	Good manufacturing practices NABL, FSSAI	R1: 118
34.	Unit test	
35.	ESS question paper revision	
36.	ESS question paper revision	
	Total	**36 hr**

References

1. David H. Holt, (1992). Entrepreneurship: New Venture Creation. (T1)
2. Jack M. Kaplan, (2015). Patterns of Entrepreneurship. (T2)
3. Sateesh, M.K., (2010). Bioethics and Biosafety, I. K. International Pvt Ltd. (T3)
4. Sree Krishna, V, (2007) Bioethics and Biosafety in Biotechnology. New age International publishers. (R1)

Unit: 1 Introduction to Indian Patent Law: World Trade Organization and its related intellectual property provisions. Intellectual/Industrial property and its legal protection in research, design and development. Patenting in Biotechnology, economic, ethical and depository considerations.

The WTO

- The World Trade Organization (WTO) is the only global international organization dealing with the rules of trade between nations. At its heart are the WTO agreements, negotiated and signed by the bulk of the world's trading nations and ratified in their parliaments. The goal is to ensure that trade flows as smoothly, predictably and freely as possible.
- The WTO has many roles: it operates a global system of trade rules, it acts as a forum for negotiating trade agreements, it settles trade disputes between its members and it supports the needs of developing countries.
- All major decisions are made by the WTO's member governments: either by ministers (who usually meet at least every two years) or by their ambassadors or delegates (who meet regularly in Geneva).
- All major decisions are made by the WTO's member governments: either by ministers (who usually meet at least every two years) or by their ambassadors or delegates (who meet regularly in Geneva). The primary purpose of the WTO is to open trade for the benefit of all.
- The WTO's top decision-making body is the Ministerial Conference. Below this is the General Council and various other councils and committees.

WTO INTELLECTUAL PROPERTY: PROTECTION, PROVISION AND ENFORCEMENT

1. The WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), negotiated during the 1986-94 Uruguay Round, introduced intellectual property rules into the multilateral trading system for the first time.

Origins: into the rules-based trading system

- The idea of trade, and what makes trade valuable for societies, has evolved beyond simply shipping goods across borders. Innovation, creativity and branding represent a large amount of the value that changes hands in international trade today. How to enhance this value and how to

facilitate the flow of knowledge-rich goods and services across borders have become integral considerations in development and trade policy.

- The TRIPS Agreement plays a critical role in facilitating trade in knowledge and creativity, in resolving trade disputes over intellectual property, and in assuring WTO members the latitude to achieve their domestic objectives.
- The Agreement is legal recognition of the significance of links between intellectual property and trade."Intellectual property" refers to creations of the mind. These creations can take many different forms, such as artistic expressions, signs, symbols and names used in commerce, designs and inventions. Governments grant creators the right to prevent others from using their inventions, designs or other creations — and to use that right to negotiate payment in return for others using them. These are “intellectual property rights”.
- They take a number of forms. For example, books, paintings and films come under copyright; eligible inventions can be patented; brand names and product logos can be registered as trademarks; and so on. Governments grant creators these rights as an incentive to produce and spread ideas that will benefit society as a whole.
- The extent of protection and enforcement of these rights varied widely around the world; and as intellectual property became more important in trade, these differences became a source of tension in international economic relations. New internationally-agreed trade rules for intellectual property rights were seen as a way to introduce more order and predictability, and to settle disputes more systematically.
- The Uruguay Round achieved that. The WTO’s TRIPS Agreement is an attempt to narrow the gaps in the way these rights are protected and enforced around the world, and to bring them under common international rules. It establishes minimum standards of protection and enforcement that each government has to give to the intellectual property held by nationals of fellow WTO members.
- Under the TRIPS Agreement, WTO members have considerable scope to tailor their approaches to IP protection and enforcement in order to suit their needs and achieve public policy goals. The Agreement provides ample room for members to strike a balance between the long term benefits of incentivising innovation and the possible short term costs of limiting access to creations of the

mind. Members can reduce short term costs through various mechanisms allowed under TRIPS provisions, such as exclusions or exceptions to intellectual property rights. And, when there are trade disputes over the application of the TRIPS Agreement, the WTO's dispute settlement system is available.

The TRIPS Agreement covers five broad areas:

1. How general provisions and basic principles of the multilateral trading system apply to international intellectual property
2. What the minimum standards of protection are for intellectual property rights that members should provide
3. Which procedures members should provide for the enforcement of those rights in their own territories
4. Show to settle disputes on intellectual property between members of the WTO
5. Special transitional arrangements for the implementation of TRIPS provisions.

Basic principles: national treatment, MFN, and balanced protection

- As in the General Agreement on Tariffs and Trade (GATT) and the General Agreement on Trade in Services (GATS), the starting point of the TRIPS Agreement is basic principles. And as in the two other agreements, non-discrimination features prominently: national treatment (treating foreign nationals no less favourably than one's own nationals), and most-favoured-nation (MFN) treatment (not discriminating among nationals of trading partners). National treatment is also a key principle in other intellectual property agreements outside the WTO.
- The TRIPS Agreement has an additional important general objective: intellectual property protection should contribute to technical innovation and the transfer of technology. Both producers and users should benefit, and economic and social welfare should be enhanced, the TRIPS Agreement says.

How to protect intellectual property: common ground-rules

- The second part of the TRIPS Agreement looks at different kinds of intellectual property rights and how to protect them. The purpose is to ensure that minimum standards of protection exist in all WTO members. Here the starting point is the obligations of the main international agreements of the World Intellectual Property Organization (WIPO) that already existed before the WTO was created:
- Te Paris Convention for the Protection of Industrial Property (patents, industrial designs, etc)
- The Berne Convention for the Protection of Literary and Artistic Works (copyright).
- Some areas are not covered by these agreements. In some cases, the standards of protection prescribed were thought inadequate. So the TRIPS Agreement adds significantly to existing international standards.

Copyright

- Copyright usually refers to the rights of authors in their literary and artistic works. In a wider sense, copyright also includes 'related rights': the rights of performers, producers of phonograms and broadcasting organizations.
- During the Uruguay Round negotiations, members considered that the standards for copyright protection in the Berne Convention for the Protection of Literary and Artistic Works were largely satisfactory. The TRIPS Agreement provisions on copyright and related rights clarify or add obligations on a number of points:
- The TRIPS Agreement ensures that computer programs will be protected as literary works under the Berne Convention and outlines how databases must be protected under copyright;
- It also expands international copyright rules to cover rental rights. Authors of computer programs and producers of sound recordings must have the right to prohibit the commercial rental of their works to the public. A similar exclusive right applies to films where commercial rental has led to widespread copying, affecting copyright-owners' potential earnings from their films; and
- It says performers must also have the right to prevent unauthorized recording, reproduction and broadcast of live performances (bootlegging) for no less than 50 years. Producers of sound recordings must have the right to prevent the unauthorized reproduction of recordings for a period of 50 years.

Trademarks

- A trademark is a sign or a combination of signs used to distinguish the goods or services of one enterprise from another.
- The TRIPS Agreement defines what types of signs must be eligible for protection as trademarks, and what the minimum rights conferred on their owners must be. It says that service marks must be protected in the same way as trademarks used for goods. Marks that have become well-known in a particular country enjoy additional protection.

Geographical indications

- A name or indication associated with a place is sometimes used to identify a product. This "geographical indication" does not only say where the product comes from. More importantly, it identifies the product's special characteristics, which are the result of the product's origins.
- Well-known examples include "Champagne", "Scotch Whiskey", "Tequila", "Darjeeling" and "Roquefort" cheese.
- Using the indication when the product was made elsewhere or when it does not have the usual characteristics can mislead consumers, and can lead to unfair competition. The TRIPS Agreement says members have to provide ways to prevent such misuse of geographical indications.
- For wines and spirits, the TRIPS Agreement provides higher levels of protection, i.e. even where there is no danger of the public being misled.
- Some exceptions are allowed, for example if the term in question is already protected as a trademark or if it has become a generic term.
- The TRIPS Agreement provides for further negotiations in the WTO to establish a multilateral system of notification and registration of geographical indications for wines, which was subsequently extended to include spirits. The question of whether to negotiate extending this higher level of protection beyond wines and spirits is also being discussed in the WTO.

Industrial designs

- Industrial design is generally understood to refer to the ornamental or aesthetic aspect of an article rather than its technical features.
- Under the TRIPS Agreement, original or new industrial designs must be protected for at least 10 years. Owners of protected designs must be able to prevent the manufacture, sale or importation of articles bearing or embodying a design which is a copy or substantially a copy of the protected design for commercial purposes.

Patents

- The TRIPS Agreement says patent protection must be available for eligible inventions in all fields of technology that are new, involve an inventive step and can be industrially applied. Eligible inventions includee both products and processe.
- They must be protected for at least 20 years. However, governments can refuse to issue a patent for an invention if its sale needs to be prohibited for reasons of public order or morality. They can also exclude diagnostic, therapeutic and surgical methods, plants and animals (other than micro-organisms), and biological processes for their production (other than microbiological processes) from patent protection.
- Plant varieties, however, must be protectable by patents or by a special system (such as the breeder's rights provided in the conventions of UPOV — the International Union for the Protection of New Varieties of Plants) or by both.
- The TRIPS Agreement describes the minimum rights that a patent owner must enjoy, and defines the conditions under which exceptions to these rights are permitted. The Agreement permits governments to issue "compulsory licences", which allow a competitor to produce the product or use the process under licence without the owner's consent. But this can only be done under specific conditions set out in the TRIPS Agreement aimed at safeguarding the interests of the patent-holder.
- If a patent is issued for a process invention, then the rights must extend to the product directly obtained from the process. Under certain conditions alleged infringers may be ordered by a court to prove that they have not used the patented process.

Anti-competitive practices in licensing

- One way for a right holder to commercially exploit his or her intellectual property rights includes issuing a license to someone else to use the rights. Recognizing the possibility that right holders might include conditions that are anti-competitive, the TRIPS
- Agreement says that under certain conditions, governments have the right to take action to prevent anti-competitive licensing practices. It also says governments must be prepared to consult each other on controlling anti-competitive licensing practices.
- More generally, the TRIPS Agreement recognizes that right holders could use their rights to restrict competition or impede technology transfer. The Agreement gives governments the right to take action against anti-competitive practices. In certain situations, the TRIPS Agreement also waives some conditions required for the compulsory license of a patent in cases where the government grants the compulsory license in order to remedy a practice determined to be anti-competitive

Enforcement

- In order for the protection of intellectual property rights to be meaningful, WTO members must give right holders the tools to ensure that their intellectual property rights are respected. Enforcement procedures to do so are covered in part III of the TRIPS Agreement.
- The Agreement says governments have to ensure that intellectual property rights can be enforced to prevent or deter violations. The procedures must be fair and equitable, and not unnecessarily complicated or costly. They must not entail unreasonable time-limits or unwarranted delays. People involved must be able to ask a court to review an administrative decision or to appeal a lower court's ruling.
- The TRIPS Agreement is the only international agreement that describes intellectual property rights enforcement in detail, including rules for obtaining evidence, provisional measures, injunctions, damages and other penalties. It says courts must have the right, under certain conditions, to order the disposal or destruction of goods infringing intellectual property rights.
- Wilful trademark counterfeiting or copyright piracy on a commercial scale must be subject to criminal offences. Governments also have to make sure that intellectual property rights owners

can receive the assistance of customs authorities to prevent imports of counterfeit and pirated goods.

Technology transfer

- Developing country members in particular see technology transfer as part of the bargain in which they have agreed to protect intellectual property rights. The TRIPS Agreement aims for the transfer of technology (see above) and requires developed country members to provide incentives for their companies to promote the transfer of technology to least-developed countries in order to enable them to create a sound and viable technological base. More on technology transfer.

Transitional arrangements: One year, 5 years or more

- While the WTO agreements entered into force on 1 January 1995, the TRIPS Agreement allowed WTO members certain transition periods before they were obliged to apply all of its provisions. Developed country members were given one year to ensure that their laws and practices conform to the TRIPS Agreement.
- Developing country members and (under certain conditions) transition economies were given five years, until 2000. Least-developed countries initially had 11 years, until 2006 — now extended to 1 July 2021 in general.
- In November 2015, the TRIPS Council agreed to further extend exemptions on pharmaceutical patent and undisclosed information protection for least-developed countries until 1 January 2033 or until such date when they cease to be a least-developed country member, whichever date is earlier. They are also exempted from the otherwise applicable obligations to accept the filing of patent applications and to grant exclusive marketing rights during the transition period.

Institutional arrangements

- The main forum for work on the TRIPS Agreement is the Council for TRIPS, which was created by the WTO Agreement. The TRIPS Council is responsible for administering the TRIPS Agreement. In particular, it monitors the operation of the Agreement. In its regular sessions, the TRIPS Council mostly serves as a forum for discussion between WTO members on key issues. The TRIPS Council also meets in "special sessions". These are for negotiations on a multilateral system for notifying and registering geographical indications for wines and spirits.

Cooperation with other intergovernmental organizations

- The preamble to the TRIPS Agreement calls for a mutually supportive relationship between the WTO and WIPO as well as other relevant international organizations. Cooperation between the WTO and WIPO covers notifications of laws, technical assistance and implementing the TRIPS obligations that stem from Article 6*ter* of the Paris Convention for the Protection of Industrial Property.
- The WTO also coordinates with a wide range of other international organizations, in particular as regards the organization of symposia, training activities and other events on intellectual property and trade and how these relate to other policy dimensions, such as public health and climate change.

WHAT IS INTELLECTUAL PROPERTY RIGHTS?

- Intellectual property refers to creations of the mind: inventions, literary, artistic works, symbols, names and images used in commerce. Intellectual property is divided into two categories: Industrial Property includes patents for inventions, trademarks, industrial designs and geographical indications.
- Copyright covers literary works (such as novels, poems and plays), films, music, artistic works (e.g., drawings, paintings, photographs and sculptures) and architectural design. Rights related to copyright include those of performing artists in their performances, producers of phonograms in their recordings, and broadcasters in their radio and television programs.
- Intellectual property rights are like any other property right. They allow creators, or owners, of patents, trademarks or copyrighted works to benefit from their own work or investment in a creation. These rights are outlined in Article 27 of the Universal Declaration of Human Rights, which provides for the right to benefit from the protection of moral and material interests resulting from authorship of scientific, literary or artistic productions.

Why Intellectual Property Rights?

- Intellectual property protection is critical to fostering innovation. Without protection of ideas, businesses and individuals would not reap the full benefits of their inventions and would focus less on research and development. Similarly, artists would not be fully compensated for their creations and cultural vitality would suffer as a result.

- The intellectual property rights were essentially recognized and accepted all over the world due to some very important reasons. Some of the reasons for accepting these rights are:-
    1. Intellectual Property Drives Economic Growth and Competitiveness
    2. Strong and Enforced Intellectual Property Rights Protect Consumers
    3. Strong IP rights help consumers make an educated choice about the safety, reliability, and effectiveness of their purchases.
    4. Intellectual Property Helps Generate Breakthrough Solutions to Global Challenges
    5. Intellectual Property Rights Encourage Innovation and Reward Entrepreneurs
- Bringing all of these important and diverse points together is the fact that protecting IP is an impartial issue that is shared by a broad coalition of interests. These rights are embraced by all sectors of industry small, medium and large companies alike and by labor organizations, consumer groups, and other trade associations.

For Whom Is This Meant?

- This policy covers all staff, faculty members, students and also persons engaged in sponsored schemes and projects, from Government and Private funding agencies and any other initiatives of the Institute as well as visiting scientists/professors/personnel who participate in the research work being carried out at the Institute Definitions:

1. Intellectual property (IP)

- It refers to creations of the intellect for which a monopoly is assigned to designated owners by law. Intellectual property rights (IPRs) are the rights granted to the creators of IP, and include trademarks, copyright, patents, industrial design rights, and in some jurisdictions trade secrets.
- Artistic works including music and literature, as well as discoveries, inventions, words, phrases, symbols, and designs can all be protected as intellectual property.

2. Copyright

- Copyright is a legal right created by the law of a country that grants the creator of an original work exclusive rights for its use and distribution. This is usually only for a limited time. A copyright is a legal device that gives the creator of a literary, artistic, musical, or other creative work the sole right to publish and sell that work.

- Copyright owners have the right to control the reproduction of their work, including the right to receive payment for that reproduction. An author may grant or sell those rights to others, including publishers or recording companies. Violation of a copyright is called infringement.

3.Database

- It is a collection of information that is organized so that it can be easily accessed, managed and updated. Data is organized into rows, columns and tables, and it is indexed to make it easier to find relevant information.
- Data gets updated, expanded and deleted as new information is added. Databases process workloads to create and update themselves, querying the data they contain and running applications against it.
- Database right is considered to be a property right, comparable to but distinct from copyright, that exists to recognise the investment that is made in compiling a database, even when this does not involve the "creative" aspect that is reflected by copyright.

4. Patent

- Patent is an exclusive right or rights granted by a government to an inventor for a limited time period in exchange for the public disclosure of an invention. Examples of classes of patents include business method patents, software patents, biological patents and chemical patents.
- In general, the granting of a patent is dependent on passing tests of patentability, patentable subject matter, novelty (i.e. new), inventive step or nonobviousness and industrial applicability (or utility).

5.Design rights

- There are two types of design rights: the registered design right (Registered Design Act 1949) and the unregistered design right. A registered design protects the visual appearance of a product or item and gives you exclusive rights for that appearance to the extent that, if necessary, there is a legal right to stop an unauthorized party from producing or using your design.
- Design right protects the shape of a three-dimensional design. It subsists if the design is recorded on paper, or if an article has been made according to that design. It does not subsist in designs made before the commencement of part of the 1988 Act relevant to design right. It has rules on qualification for protection by both citizenship of the designer and place of the designing.

Qualifying countries include the United Kingdom, the rest of the European Economic Area and British overseas territories. The registered design right provides up to 25 years protection.

- The unregistered design right is similar to copyright in that it attaches automatically when a new design is created. However, its length is much more limited, since it only lasts for 10 years after it was first sold or 15 years after it was created whichever is earliest. It was introduced into British law by the Copyright

6. Trade Marks

- It Distinctive design, graphics, logo, symbols, words, or any combination thereof that uniquely identifies a firm and/or its goods or services, guarantees the item's genuineness, and gives it owner the legal rights to prevent the trademark's unauthorized use.
- A trademark must be:
    1. Distinctive instead of descriptive, (2) affixed to the item sold, and (3) registered with the appropriate authority to obtain legal ownership and protection rights.
    2. Trademark rights are granted usually for 7 to 20 years and, unlike in case of patents, are renewable indefinitely. These rights are protected worldwide by international intellectual property treaties and may be assigned by their owner to other parties.

7. **Assignment**

- An assignment is a transfer of ownership of a trademark application or trademark registration from one entity to another. For Patents: An assignment involves the sale and transfer of ownership of a patent by the assignor to the assignee.
- For Copyright: An assignment is a transfer of the copyright owner's economic rights. In contrast to the economic rights under copyright, moral rights cannot be sold or assigned to another person (moral rights are the right to be identified as the author of the work or to object to derogatory treatment or to a distortion or mutilation of the work, to protect the personality and reputation of authors).
- Ownership: In-House Research: All rights in respect of investigations carried out at the University shall vest in and be the absolute property of the University except in respect of the activities carried out jointly with other institutions or agencies or under a sponsorship by an agency, in which case the ownership will be decided and agreed upon mutually.

- Sponsored Research: Intellectual Property Rights (IPR) of inventions arising out of research projects undertaken on behalf of the sponsoring agencies shall be taken jointly in the name of the University and sponsoring agencies, when the sponsoring agencies bear the cost of filing and maintaining of the IPR equally .

8. License and Licensing

- A license is an official permission or permit to do, use, or own something (as well as the document of that permission or permit). In particular, a license may be issued by authorities, to allow an activity that would otherwise be forbidden.
- It may require paying a fee or proving a capability. The requirement may also serve to keep the authorities informed on a type of activity, and to give them the opportunity to set conditions and limitations. A licensor may grant a license under intellectual property laws to authorize a use (such as copying software or using a (patented) invention)) to a licensee, sparing the licensee from a claim of infringement brought by the licensor.
- A license under intellectual property commonly has several components beyond the grant itself, including a term, territory, renewal provisions, and other limitations deemed vital to the licensor. Term: many licenses are valid for a particular length of time.
- This protects the licensor should the value of the license increase, or market conditions change. It also preserves enforceability by ensuring that no license extends beyond the term of the agreement.
- Territory: a license may stipulate what territory the rights pertain to. For example, a license with a territory limited to "North America" (Mexico/United States/Canada) would not permit a licensee any protection from actions for use in Japan.

PATENTING BIOTECHNOLOGY

- Biotechnology has given us the power to manipulate genes, proteins and organisms. It has the potential to revolutionize the way that diseases are diagnosed and treated, our food is produced, our energy is generated and how we deal with our waste. The patentability of biotechnological inventions is judged in the same way as other inventions: the invention must be novel, non-obvious and capable of an industrial use.

What is a patent application?

- A patent application is essentially a 20-50 page book which describes an invention in a combination of legal and scientific language. After the patent application has been submitted, examined and, if necessary, amended, the patent may be granted (based on the text of the patent application).
- The patent will include 'claims' which define the scope of the invention. After the patent has been granted, the Applicant will be given rights to stop others from making, using and selling the invention - as defined in the patent claims - in the countries where patents have been granted.

What can be patented?

- The patent system allows patent protection to be obtained for products, processes and methods of use. In the context of bioscience inventions, patents are often granted for products such as polypeptides, nucleic acids, cell lines, vectors, gene delivery systems, micro-organisms, genetically modified plants and animals, antibodies, vaccines and pharmaceuticals; and methods such as diagnostic assays, therapeutic methods, screening methods, purification protocols, sequencing protocols and cell culture techniques.

Proteins and nucleic acids

- The patentability of proteins and DNA/RNA is assessed by the Patent Offices in the same way as any other chemical entities. If they are claimed in isolated or purified form, then that form will be novel over the forms that are present in the organism from which they are obtained.
- And if it can be shown that it was not obvious to produce those proteins or DNA/RNA, then the inventive step hurdle may be overcome. Patents may also be granted for artificial DNA constructs such as cDNA, and genetically engineered proteins

Antibodies

- There are several ways to claim antibodies in patent applications: these range from purely functional definitions based on the antibody's binding affinity, by reference to CDR sequences, through to defining the complete heavy and light chain amino acid sequences of the antibodies.
- Increasingly, the Patent Offices are requiring more structural (i.e. sequence) information in the patent claims as it becomes more recognised that small changes to the antibody's sequence can have profound effects on its properties.

Micro-organisms

- Novel and non-obvious micro-organisms are patentable. Here, it must be remembered that the 'novelty' criterion for patentability does not mean "is it new?" in terms of "did it previously exist?"; it means "has it previously been made available to the public?" Hence newly-discovered bacteria are patentable. Genetically-modified bacteria are also patentable.

Transgenic plants and animals

- The Patent Office's treat transgenic plants and transgenic animals as complex chemical compositions. For example, if the insertion of a foreign gene into a known organism produces a novel and non-obvious transgenic organism, then that organism is novel and potentially patentable. Transgenic plants and animals are generally claimed by reference to a parent plant or animal, and the new gene which has been inserted into it.

Methods of diagnosis and therapy

- New methods of diagnosis and methods of therapy are also patentable. In method of diagnosis patents, the patent claims refer to one or more of the steps which form part of the diagnosis. Therapeutic methods are also patentable, although the format of the patent claims varies from country to country. Generally, new uses of known drugs are patentable, as are new formulations, new dosage regimes and new methods of administration.

Exclusions and restrictions

- Whilst the above comments apply to biotechnological inventions in general, there are numerous differences between countries as to what is patentable and the way in which inventions are claimed.
- For example, as a result of a decision from the US Supreme Court, products of nature (including genomic DNA and naturally-occurring proteins) are no longer patentable in the US. This decision only applies, however, to US patents. It is therefore important to seek specialist advice on any particular matter.

List of Possible Questions

1. Explain WTO
2. Give the basic principles of TRIPS agreement
3. How to protect intellectual property
4. What is meant by Trademark
5. Write about the technology transfer based on TRIPS agreement
6. What is Intellectual Property Rights
7. Explain Copyright
8. What is a patent application
9. What can be patented?
10. Explain process of granting patent

Unit: 2 Entrepreneurship: Selection of a product, line, design and development processes, economics on material and energy requirement, stock the product and release the same for making etc. The basic regulations of excise: Demand for a given product, feasibility of its production under given constraints of raw material, energy input, financial situations export potential etc.

WHAT IS ENTREPRENEURSHIP?

- Entrepreneurship is to a large degree a mind-set, always striving to do new things in an innovative and better way.
- The meaning of entrepreneurship is derived from the French seventeenth-century term for someone who "undertakes" and more specifically someone who undertakes a specific project or activity.
- In the nineteenth century, the French economist Jean Baptiste Say refined the meaning of entrepreneurship to individuals who create value by shifting resources from lower- to higher-valued activities. The higher value activities can be activities that bring value to both individuals and society.
- It is the twentieth-century thought on entrepreneurship from Joseph Schumpeter, an Austrian born and then Harvard University–based economist and sociologist, which has most influenced contemporary thinking about entrepreneurship.
- In Schumpeter's view, entrepreneurs are innovators who drive the "creative destruction" process, reforming or revolutionizing the pattern of production. In many respects, sustainable businesses are significantly changing, if not revolutionizing, the patterns of production and service delivery, transforming business practices in ways that benefit the environment and society.
- Another helpful view of entrepreneurship is provided by the twenty-first-century management scholar Peter Drucker.
- Drucker suggests that entrepreneurs always search for change, respond to it, and exploit it as an opportunity. Entrepreneurs take risks in starting new activities and take on significant personal responsibility.

- Many sustainability entrepreneurs perceive opportunities emanating from increased public concern about the environment and climate disruption and are responding to this opportunity with profit-making ventures that address these concerns.

Putting these perspectives together, entrepreneurship can be viewed as

1. recognizing change,
2. pursuing opportunity,
3. taking on risk and responsibility,
4. innovating,
5. making better (higher value) use of resources,
6. creating new value that is meaningful to customers,
7. doing it all over again and again.
8. entrepreneurship is an attitude and drive to pursue opportunity and create something new and of value.

Entrepreneurial Opportunities

- Many different conditions in society can create entrepreneurial opportunities for new goods and services. Opportunity conditions arise from a variety of sources. At a broad societal level, they are present as the result of forces—such as changes in knowledge and understanding, the development of a new technology, shifting demographics, political change, or changing attitudes and norms—that give rise to new preferences and concerns. These forces constantly open up new opportunities for entrepreneurs.
- Related to sustainability concerns, certain demographic shifts and pollution challenges create opportunities. For example, with 50 percent of the world's population, for the first time in history, now living in urban areas, city air quality improvement present opportunities for entrepreneurs.
- The entrepreneur must first recognize the opportunity and then innovate by proposing a business solution that provides an attractive alternative to customers. A solution is just the first step in the process, the entrepreneur must also investigate the economic value of and business proposition emanating from that opportunity.
- They must research the market to understand how their potential product or service provides value to a customer and whether the amount a customer is willing to pay, which reflects the

value of the product or service to the customer, exceeds the costs to provide that value, product, or service to the customer. In this way, the entrepreneur is contributing to economic growth and society by providing customers with goods and services whose costs to provide are less than their value to consumers.

- An entrepreneur can come up with a new approach that meets a customer's need or want, but if not enough customers are willing or able to pay a price above the cost of that product or service, it will not be financially viable.
- Therefore the opportunity becomes a true business opportunity when it is of sufficient scale and value—that is, revenues will cover costs and promise to offer net revenue above operating costs after the initial startup investment expenditures are repaid.

Entrepreneurial Resources

- Successful entrepreneurial efforts require the mobilization of a wide array of resources quickly and efficiently. All entrepreneurial ventures have to have resources such as capital, talent and know-how (e.g., accounting and finance, operations, management, legal, and regulatory), equipment, and facilities.
- Breaking down a venture's required resources offers a picture of the components required and when they are needed. Resource needs change over the growth stages of a venture; at each stage, the entrepreneur should be clear about the priority resources that enable moving to the next stage of venture development.
- While management teams must be recruited relatively quickly, typically there are one or two individuals who initially drive the entrepreneurial process through hard work and determination to succeed. As the business grows, the business team becomes the key factor. The entrepreneur's skills, education, and capabilities must be augmented and complemented by the competencies of other team members.
- It is essential to have adequate financial resources when starting any new entrepreneurial activity; this is no different for sustainable business activity. Funding can come from a variety of sources including personal savings, credit lines of entrepreneurs, family members, friends, and other sources.
- Depending on the type of business, venture capital or other investors may be an option. Typically, a company might acquire investors if there are expectations for high growth in the

industry. Clean technology is an industry sector that can potentially attract investors for this reason.

- All the previously stated resources in the entrepreneurial process are important, but the single most important factor is the individual entrepreneur—that is, their ability to identify a market opportunity and develop a creative response to that opportunity with market potential, to get a product or service out, to sell to customers, to organize an organizational team, and to garner the confidence of potential investors. Entrepreneurs must have passion, drive, excitement, and unique capabilities to do what they do.
- Entrepreneurship is not constrained to starting a private for-profit company. While the definition of entrepreneurship is commonly assumed to be individuals creating new for-profit enterprises and pursuing private benefit, entrepreneurship and entrepreneurial innovation can occur in a variety of settings including small or large companies, nonprofits, and government agencies. And entrepreneurship can be focused on a local, national, or global marketplace.
- The Simply Green case in this textbook is focused on a sustainability entrepreneur serving a local market. Chapter 13 "Case: Strategic Mission–Driven Sustainable Business: Stonyfield Yogurt" tells the story of Gary Hirshberg, the highly successful Stonyfield Yogurt entrepreneur competing in a global market with a sustainability mission. Entrepreneurship focused on bringing value to society is often referred to as social entrepreneurship, while entrepreneurship focused on individual and private enhancement of value is simply called entrepreneurship.

Why Do Entrepreneurs Do It?

- The only factor found to be associated consistently with becoming an entrepreneur is that one or both of your parents were entrepreneurs. This suggests that if the entrepreneurial path is familiar to you, then you are more likely to follow that path yourself.
- Beyond having the common trait of having parents who were entrepreneurs, there are many personal reasons why individuals decide to become entrepreneurs. Becoming an entrepreneur can be motivated by personal interests and values, the prospects of financial rewards, or lifestyle preferences. It is also sometimes driven by “necessity” when there is a paucity of other employment or income-earning opportunities.
- The motivations for being an entrepreneur include the ability to pursue a passion or interest that is exciting and one feels deeply about. It can include the opportunity to create something new,

enhance one's personal reputation, and make an impact or a difference in customers' and employees' lives and in society in general. All of these are motivations for many sustainability entrepreneurs.

- The motivation for becoming an entrepreneur can also be driven by a desire to be independent, to be your own boss, to make your own decisions, and to make your own schedule. This moves into the so-called lifestyle motivations for being an entrepreneur—to have a more flexible work schedule that allows time for other activities including more time for family and recreational and creative pursuits.

Intrapreneurship

- While entrepreneurship is normally thought of as starting a new business, it applies to applying innovation to existing organizations. Often, this type of entrepreneurial activity is distinguished as intrapreneurship (meaning entrepreneurship from within).
- Intrapreneurship applies the entrepreneurial mindset characterized by innovation, risk taking, and flexibility to an established firm. The objective is to enhance the ability of an established firm to react to market opportunities in a timely and effective manner much like start-up ventures do.
- Large established companies like General Electric (GE) often encourage intrapreneurship to foster innovation and accelerate new product development, to take advantage of a new opportunity, or to assess feasibility of a new process or design.

Entrepreneurial Risk and the Importance of Resilience and Persistence

- Being a successful entrepreneur is not easy and there is no guarantee of success. It requires broad competence across a range of functional areas—including finance, accounting, strategy, marketing, management and operations, and strong interpersonal skills.
- There are also significant risks and significant likelihood of failure. Part of being an entrepreneur is assessing and managing risk.
- Also part of being an entrepreneur is being resilient and persistent. As an entrepreneur, there will always be challenges and difficult times and being able to endure through the tough times and being persistent in working to achieve success is critical for entrepreneurs.
- Remember that even Steve Jobs got removed from his position at Apple before he came back to transform the company with the introduction of innovative new products including the iPod, iPhone, and iPad.

- More business start-ups fail before four years than make it to their fifth year according to the US Small Business Administration. The risks and failures can come from internal factors—such as limited access to funding, poor planning and decision making, or the idea just simply being a bad idea for a business.
- Failure can also be a result of external factors beyond the entrepreneur's influence, such as weak economic conditions and changing public policies, that can have profound market implications. Also with entrepreneurship—and with ownership, independence, and decision-making authority—comes significant responsibility and the potential for high personal stress and possible burnout.
- While this chapter highlights several entrepreneurial success stories, it is important to understand that not all ideas for businesses are good business opportunities. Potential customers have to perceive that the product has value to them (above its cost and better than the products or services provided by competitors) and have the means and desire to purchase it.
- Furthermore, the pricing options have to cover expenses, and funds have to be available to finance the start-up of the business before revenue from sales cover expenses.
- These various dimensions must be explored rigorously before a business is launched. While business plans can serve multiple purposes, the first and most important reason for writing a business plan is to test whether an idea is truly an economically promising market opportunity.

Key points

1. Entrepreneurship is the introduction of a new product or service through the creation of a new company or the innovation of an existing organization.
2. Entrepreneurs search for change, respond to the change, and seize on the change as an opportunity.
3. Entrepreneurship requires hard work, dedication, passion, resilience, and persistence.
4. Entrepreneurship is to a large degree a mind-set, always striving to do new things in an innovative and better way.
5. Entrepreneurs require access to capital, equipment, land, talent, and business know-how.
6. Intrapreneurship refers specifically to entrepreneurial activity that originates from within an existing company.

7. The key elements of entrepreneurial success include recognizing change, identifying market opportunities inherent in that change, and delivering value to customers by addressing customer needs or problems associated with the change.

SELECTION OF A PRODUCT

In selecting product for your business venture, the following factors must be taken into consideration:

1. **Supply-gap**: The size of the unsatisfied market demand which constitute a source of business opportunity will dictate, to a great extent the need to select a particular product. The product with the highest chances of success as reflected in its demand will be selected. In essence, there must be existing obvious demand for the selected product.
2. **Fund**: The size of the funds that can be mobilized is another important factor. Adequate fund is needed to develop, produce, promote, sell and distribute the product selected.
3. **Availability of and Access to Raw Materials:** Different products require different raw materials. The source quality and quantity of the raw materials needed are factors to be seriously considered, Are the raw materials available in sufficient quantities? Where are the sources of raw materials located? Are they accessible? Could they be sources locally or imported? Satisfactory answers should be provided to these and many other relevant questions.
4. **Technical Implications:** The production process for the product needs to be considered. There is need to know the technical implications of the selected product on the existing production line, available technology and even the labour force. The choice of a particular product may require either acquisition of the machineries or refurbishing of the old ones. The product itself must be technically satisfactory and acceptable to the user.
5. **Profitability/Marketability:** Most often, the product that has the highest profit potential is often selected. However, a product may be selected on the basis of its ability to utilize idle capacity or complement the sale of the existing products. The product must be marketable.
6. **Availability of Qualified Personnel:** Qualified personnel to handle the production and marketing of the product must he available. The cost of producing the product must be kept to the minimum by reducing wastages. This is achievable through competent hands.
7. **Government Policies:** This is quite often an uncontrollable factor. The focuses of government policies can significantly influence the selection of product. For instance, a package of incentives

from government for a product with **100% local input** contents can change the direction of the business's R & D and hence the product selected.

8. **Government objectives:** The contributions of the product to the realization of the company's short and long range objectives must be considered before selection. For instance, the company goal maybe the achievement of sale growth, sales stability or enhancement of the company's social value.

MARKETING OF A PRODUCT FROM AN ENTREPRENEURSHIP

One must consider the following factors for achieving successful marketing

1. **Study your competition.**
   - ❖ Many business marketing classes teach participants how to perform a SWOT (strengths, weaknesses, opportunities and threats) analysis. You have to start by taking a serious look at your competitors.
   - ❖ Make a list of the businesses that offer products or services similar to the one you plan to launch. Even if you think your new product or service is entirely unique and without existing competition, it's important to put yourself in your prospective customers' shoes and imagine what they might buy in lieu of what you plan to offer. Once you decide whom your competitors will be, review their marketing materials, including their ads, brochures and websites.
   - ❖ Evaluate how your new product or service will stand up against what's already being offered, in what ways you'll excel, and which companies or their offerings pose the greatest threats to your success.
2. **Target the ideal customer.**
   - ❖ To successfully launch your new product or service with minimum financial outlay, it's essential to focus exclusively on the prospects you believe are most likely to purchase from you. These may be customers who are currently buying something similar and will appreciate the additional features your new product or service provides.
   - ❖ Your best prospects have a perceived need for what you offer, can afford to buy it and have demonstrated a willingness to do so--probably by purchasing from your competition. Bear in mind, it's always easier to fill a need than to create one.

3. **Create a unique value proposition.**
   - ❖ At this stage, you should have a clear understanding of what you must offer in order to stand apart from your competition and who will want to take advantage of your offer. But do you know why customers will want to buy from you vs. the vast field of competitors out there? What benefits and features will you provide that your prospective customers will value most? The bottom line is that your product or service "bundle" should be unique and meet the needs and desires of your best prospects.
4. **Define your marketing strategy and tactics.**
   - ❖ Next, choose your sales and marketing channels. Will you market online, via catalog or through dealers, for example? Generally, multichannel marketers achieve the greatest success because customers who can shop when and however they like tend to spend more and shop more often.
   - ❖ Suppose your strategy is to market a low-cost workout device to people who can't afford gym memberships or high-priced home equipment. You might choose traditional direct marketing plus online sales as your primary channels, and employ tactics including direct-response TV spots and online ads and e-mail solicitations that link to your website.
5. **Test your concept and marketing approach.**
   - ❖ With all the money it takes to bring a new product or service to market, it's foolhardy to rush headlong into the launch phase prior to testing. What should you test? It's best to examine your product or service bundle plus your marketing message and you're your marketing materials.
   - ❖ Depending on what you plan to market and your budget, you can use formal focus groups (or simply host roundtable discussions with members of the target audience), employ online research or mall intercept studies, or distribute your product to a select group of users for testing. Only after testing is complete, should you proceed to the final creation of your marketing tools and materials.
6. **Roll out your campaign.**
   - ❖ Public relations often plays a vital role in the launch of a product or service. You can use media relations tactics to place articles and win interviews, get coverage by allowing key

press to review your product, hold a launch event, or use grass roots marketing to build buzz. But no matter what publicity route you choose, first make sure your product or service is completely ready and available for purchase in order to maximize returns from the coverage you receive. And your other marketing efforts should follow closely on the heels of your press roll out.

- Monitor the results from all media, and in the first weeks and months, be prepared to adjust your campaign to take advantage of what's working best.

7. **Know your product's lifecycle.**
   - The campaign you use during the introduction and education phase of your product or service launch will need to be updated as your product or service matures. If you're monitoring your marketing results carefully, you'll begin to see diminishing returns that will indicate when it's time to revise the product or service itself, alter your media message, or even phase out this particular offering and lay the groundwork for the launch of your next great idea.

EXCISE DUTY

- An excise tax can be defined as a kind of indirect taxation that is applicable for goods that are produced and sold within the territorial limits of a country. It is basically different from custom duties, which are levied on goods that have been produced outside a country. Excise tax is also known as excise duty. The initial purpose of this tax was to help the government generate the maximum possible revenue but in time it has become an important part of fiscal policies and has been playing a critical role in economic growth.

Types of Excise Taxes in India

There are seven types of excise taxes that are presently in operation in India.

Basic Excise Duty

The basic excise taxes are levied as per the First Schedule of the Central Excise Tariff Act, 1985.

National Calamity Contingent Duty

It is also referred to as NCCD and is applied as per the Section 136 of the Finance Act, 2001. It is taken as an additional tax on certain specified goods.

Special Excise Duty

The special excise taxes are taken as per the Second Schedule of the Central Excise Tariff Act, 1985.

Excise Duties and Cess Leviable under Miscellaneous Act

These duties are additional in nature.

Additional Duties of Excise (Textiles and Textile Articles)

- This tax is imposed as per the Section 3 of the Additional Duties of Excise (Textiles and Textiles Articles) Act, 1978. This tax has been determined at 15% of the basic excise duty that is being paid on previously mentioned textile articles.

Education Cess

- The education cess is applied as per existing law for excise taxes such as the Central Excise Act 1944. These are basically additional in nature.

Additional Duties of Excise (Goods of Special Importance)

- This tax is charged as per the First Schedule of the Additional Duties of Excise (Goods of Special Importance) Act, 1957. The decisions regarding the special excise taxes are taken on a yearly basis by the Finance Act. Since the tax deals exclusively with manufacturing of products, sale of the same is not regarded as a mandatory requirement.
- In case of excise taxes, the duty is paid in case of removal of goods. The following transactions and activities are deemed as removal:
    1. Sale
    2. Transfer to a different unit
    3. Transfer to depots
    4. Free distribution
    5. Captive consumption

Excise Tax Rules in India

- The Central Excise Act 1944 mentions the rules for levying and collecting the central excise duties and gives the Union Government the authority necessary to make rules for implementing the same. The rules are classified under the following heads:
    1. The Central Excise Rules, 2002 (Section 143 of the Finance Act, 2002)
    2. Consumer Welfare Fund Rules, 1992
    3. The Central Excise (Settlement of Cases) Rules, 2001 The Central Excise (Advance
    4. Rulings) rules, 2002
    5. The Central Excise (Removal of Goods at Concessional Rate of Duty for Manufacture of Excisable Goods) Rules, 2001
    6. Central Excise (Compounding of Offences) Rules, 2005
    7. Central Excise Valuation (Determination of Price of Excisable Goods) Rules, 2000

Central Board of Excise and Customs

- The Central Board of Excise and Customs (CBEC) are responsible for administering the laws that govern these laws. The CBEC itself is a part of the Union Ministry of Finance's Department of Revenue.

  Following are its main responsibilities:
    1. Making policies for collecting and levying central and customs excise duties
    2. Managing matters of Customs, Narcotics and Central Excise according to the previously set limits
    3. Preventing the smuggling of goods
    4. Its subsidiary organizations have been enumerated as below:
    5. Custom Houses
    6. Central Revenues Control Laboratory
    7. Central Excise Commission rates

Excise Taxes in India

Possible Taxpayers

At a basic level, the producer or manufacturer of goods are responsible for paying the excise duty. Following are the major entities who are supposed to pay these taxes:

1. Ones who have personally manufactured the goods being subjected to taxation
2. Ones who outsource the production of their goods
3. Ones who employ workers and professionals to manufacture or produce their goods.

The central excise duties operate on the basis of two major processes:

Self removal procedure: As per this system, the assessees themselves determine whether they need to pay the taxes and then clear the goods. This process does not involve actual supervision or previous permission the excise officers.

Physical control: In this process, the assessment is done before clearance. Here the officers themselves supervise the products and determine the duty that needs to be levied on the same. The goods have to be moved once the duties are paid. Goods, on which duty has been paid, cannot be kept in the factory without special permission. This facility is only provided to cigarettes.

Classification of Goods

Classification of goods is an important precondition for applying the excise taxes and this categorization has been done in the Central Excise Tariff Act, 1985. This act provides a list of the items that can be subjected to central excise taxes.

The act has 96 chapters that have been divided into 20 sections. The sections deal with a broad array of goods. Some examples may be provided as below:

1. Section I – animal and dairy products
2. Chapter XI – textiles and textile products
3. Section VI – chemical products and related industries

The Central Excise Tariff Act had been modified in 2004 – now 8 digit codes are used for classifying goods as opposed to 6 digit codes that were previously in use.

Goods Valuation

The excise duties are basically ad valorem taxes and the valuation of goods is done as mentioned in the Central Excise Act 1944:

Tariff value: The tariff value is decided by notifications issued by the Central Government and the taxes are decided on the basis of these values.

Transaction value: This is the most commonly used way of determining the assessable worth of a particular good. The important ingredients of this value may be mentioned as below:

1. The good should have been transferred by the assessee for the purpose of delivery at a particular place or time of removal. The word "place of removal" basically means a warehouse or a factory.
2. Price is the only factor considered for selling a good.
3. The buyer and the assessee must not be related.

It needs to be noted that for a goods transfer to be deemed as transaction all the factors should be fulfilled.

Exemption from paying the excise duty

It is important to note in this regard that excise taxes have to be paid on a regular basis unless the person in question is exempted from the same. These taxes need not be paid in case the tax payer is exporting them.

Exceptions are also provided on the basis of the following criteria:

1. Raw materials used
2. Kinds of manufacturing or production processes used
3. Financial worth of clearances or turnover in a fiscal

Punitive Measures

The rates of fine for evading excise taxes normally range from 25 to 50 percent of the tax amount that has not been paid and these rates are determined by various sections of the Central Excise Act.

What is the consequence of evading payment of excise duty?

Under the different sections of the central excise act, the fines for evading tax can range from twenty-five to fifty per cent of the amount of duty evaded. When you look at the amount of excise you may

have to pay, this is a rather large amount and along with the financial repercussions, you also have to encounter a tarnished image.

Export potential is the value and importance of a product in the international market.

List of Possible Questions

1. What is Entrepreneurship?
2. Write about the Entrepreneurial Opportunities
3. Give a brief note on Entrepreneurial Resources
4. What is meant by Intrapreneurship
5. How will you market a product from an entrepreneurship
6. What is meant by excise duty
7. What are the types of Excise duty

Unit: 3 Bioethics: Necessity of Bioethics, different paradigms of Bioethics – National & International. Ethical issues against the molecular technologies

Bioethics

- The term bioethics is typically used to study the controversial ethical issues emerging from new situations and possibilities brought about by advances in biology and medicine. It is also moral discernment as it relates to medical policy, practice, and research.
- Biotechnology is playing an important role for the improvement of human life. However due to extensive and absurd use of natural resources deterioration to social and natural environment has also been occurred.
- The ethical evaluation of biotechnological interventions rests first upon a good understanding of the science behind these interventions, and second upon balancing the risks and benefits such interventions pose.
- In addition, the power of new molecular techniques to manipulate life, insert the genes of one species into the genes of another species, and otherwise redirect living organisms both in captivity and in the wild to specific human purposes, raises questions about the proper role of humans in their environment and in the alteration of living organisms.
- Bioethics is not local affairs that can be solved by a local society, inspite they are global issues who's effects will be universal. An ethical system that is exclusive or discriminatory in any other way is so factor ,morally damaged.
- In general, there is nothing wrong with technology, as such. In itself, it is ethically neutral, neither right nor wrong. It is an important non-moral value, connected with human skills and achievements.
- But, the uses to which any technology is put, is a moral issue. For example, developing, let's say, an infectious contraceptive is a technological affair, it is a local and localizable affair, even a personal/individual affair, but the 'exploding population' amongst which such a putative contraceptive is released or unleashed, is an ethical matter

- Current approaches in bioethics largely overlook the multicultural social environment within which most contemporary ethical issues unfold. In multicultural settings, patients and their families bring many different cultural models of morality, health, illness, healing, and kinship to clinical encounters.
- Religious convictions and cultural norms play significant roles in the framing of moral issues. At present, mainstream bioethics fails to attend to the particular moral worlds of patients and their family members

Different paradigm of Bioethics

Socio-economic issues

- Biotechnology is more than just a scientific issue. Scientific community assuring us that biotechnology is harmless, and promises marvelous advantages to humankind, even that it may be the key to our survival in an ever-changing world.
- On the other hand there exist a diverse array of arguments about the right of man to interfere in nature or God's process and the dangers to the environment, the food chain and ultimately our own health. Such issues are largely related to cultural backgrounds and levels of public perception and awareness.
- It is therefore necessary that decisions on the use of new technologies should respect socio-economic realities. Public understanding of biotechnology as a science and technology is important because the products of biotechnology and consequent benefits and risks are ultimately going to affect everyone.
- Biotechnology holds great promise as a tool to preserve and enhance environmental quality. Years of plant breeding show that genetics is the most cost-effective, environmentally safe way to address problems that reduce yields.
- But without public understanding, acceptance, and support, the role that biotechnology could play in solving environmental and food production problems could be stymied. Biotechnology is offered as a solution to human problems, and often, to problems caused by humans. Yet biotechnology may create as many problems as it solves.

- Some environmentalists and other critics have pointed out that perhaps we would be better off learning to live in harmony with nature, rather than attempting to make nature conform to our specific needs.
- Biotechnology promises to play an increasingly powerful role in the further taming and manipulation of our natural and unnatural worlds. In part due to the technological imperative, our destruction of the environment is a result of the very impetus which drives the biotechnological interventions to ameliorate it.
- Biologists and biotechnologists must take a broader view of their practice than the instant goals they seek to address. Potential benefits of biotechnology to mankind have led to multi-billion dollar per year investments involving new companies and many existing enterprises.

Cultural issues

- Before its practical reality biotechnology was the science of imaginations. Biotechnology is quietly different in reality from the literary and science novel fantasies of popular culture. The ethics of biotechnology entails both a reflection on the immediate consequences of its use, and on the underlying social and cultural conditions of which it is a part.
- The eugenics movement that occupied serious and well-respected scientists and politicians in Europe and America earlier in this century testifies to the ways in which the application of science can go morally wrong.
- It is, therefore, not surprising that as the biological sciences and biotechnology have enjoyed remarkable success during the past 30 years, public awareness and discomfort, particularly with genetic engineering, have increased.
- All technology modifies our relationship to our environment, to our work, and to ourselves, but biotechnology strikes much closer to home, enabling us to modify life itself. These considerations raise the question of the scientists' responsibility in the application of the knowledge and techniques they have produced.
- Historically, biotechnology has grown out of the simple search for biological knowledge. As biologists sought to penetrate to the molecular core of living processes, they invented tools to assist them in that process.

- As in the case of PCR---a method for making many copies of specific DNA sequences for analysis and many other biotechnologies, biologists have put to use the very processes of life itself in their study of life, borrowing the molecular machinery of life to analyze living processes.
- But as with all scientific endeavors, the tools by which science investigates the world often yield tools by which we may transform the world. While science is often pursued for its own sake and the simple pleasure of understanding the world, the combination of the tools of knowledge with practical ends cannot be ignored when considering the moral value of the enterprise.
- Investigation of the structure of the atom led inexorably to the application of this knowledge in the building of atomic weapons. It is a legitimate and by no means resolved moral question to ask what the moral responsibility of the scientific community is in guiding the use of the fruits of its intellectual labors.

Environmental issues

- Biotechnology has been proven better for the improvement of our environmental health. Biological pesticides are being used more efficiently which has also reduced the chemical pesticides. Genetically engineered plants have also reduced the need of fertilizers thus minimized the pesticide pollution to rivers and costal water resources.
- One of the first modifications through genetic engineering in microorganisms was done in bacteria that have the ability to digest oil spilled in the oceans. Bioremediation and, in general, the improvement of the environment have been the primary aims of a great deal of biotechnological research.
- In the marine context, much of the scientific work being done is aimed at ameliorating the effects on food species and marine ecosystems of overdevelopment, pollution, and loss of breeding habitats.
- While biotechnological methods promise a variety of important social and environmental benefits, public response, especially to the release of genetically modified species into the environment, has been mixed.
- Though not always based on a sound understanding of the science and technologies involved, the public is wary of genetically altered foods and concerned about the inability to control biological

agents once they are released into the environment. The benefits of a particular biotechnological intervention in the environment typically accrue directly to the sponsor, often a commercial interest.

- However, the harms that may result from such interventions typically do not remain confined to those interests or the individuals responsible for introducing them, but instead may propagate throughout the environment and affect the general public.
- A gene that protects a food crop from certain pests benefits the farmer and the seed company directly, but should that gene cross into a noxious species, it may well create problems for the general public.

Legal issues

- Legal issues are being arises in the use of biotechnological techniques. Particularly modern techniques such as stem cell technology, gene therapy, and human genome project have generated many issues in the society and there is need to resolve them for the satisfaction of the person who is receiving treatment or getting benefit from these techniques.
- But due to lack of motivation, in developing countries like Pakistan governments have not yet established the necessary legislation, institutions or infrastructures to protect vulnerable persons and to address bioethical issues.
- As a result, people are not interested in bioethics issues since measures are not taken to create awareness on the field in the country. More over it has been assumed by the people that bioethics is a field of Western discipline or field of study that deals with issues on High-Tech and addresses directly issues arising from or related to the use of High-Tech, health related issues and practice in the West and modern medicine which does not needed by developing countries.
- In western countries laws have been formulated that regulates the biotechnological products. In U.S.A the Plant pest act is used to regulate the genetically engineered plants under the supervision of U.S. Department of Agriculture (USDA).
- The Environmental Protection Agency (EPA) regulates the release of genetically engineered microbes into the environment under Section 5 of the Toxic Substances Control Act, Microbial Products of Biotechnology.

- Under this act, the EPA must operate under the risk-benefit approach and is required to meet a substantial burden of proof before it can even request data on a particular organism or before it can regulate or prohibit the production and release of microorganisms.
- This patchwork of Federal regulatory authorities covering biotechnology is confusing and inefficient. The public interest would be better served by a single office or agency responsible for evaluating the variety of biotechnological interventions and their impact on the environment.
- A possible impediment to biotechnology development in the United States is the current litigious climate. The concepts of a risk-free society and cradleto grave security have created "glitches" in the legal system that allows a single individual to halt important scientific projects. For example, Rifkin (1983) has successfully used the courts to stop genetic engineering projects by invoking the need for environmental impact statements.
- Recently, a highly promising vaccine against swine pseudo-rabies was recalled because it involved a deletion of genetic material from the virus. It is interesting that less precise genetic alterations and deletions made with the old technology are acceptable for vaccine development, even though they are not well understood. It is clear that lawyers, judges, and the public will react out of fear and ignorance if they do not understand the processes involved.

Religious issues

- Scientists and technologists are able to play real games with God/Nature, manipulating the building blocks of living things at will. It is a dangerous game, its purported anticipated benefits notwithstanding, in which they are being encouraged, aided and abated, supported and funded by powerful industries and corporations, for motives of profit.
- The newly developed molecular techniques of gene identification, genetic engineering, and artificial reproductive procedures represent a quantum leap in our ability to manipulate life itself, a domain long held by culture and religion to be the province of a divine agency.
- Religious scholars have criticized the use of biological techniques to expose the privacy and dignity of human being. Some religions have taken the issue of stem cell technology very serious. As according to them research on embryonic stem cell is like to kill the human. Similarly the criticism of religious scholars on human genome project was very severe. It is often

argued by religious people that biotechnological interventions are not natural, or that they go against some divine or natural order of things.

- But human beings are also natural---natural products of evolution. Our technological development is no less natural than the mud wasp's construction of a nest. Thus, it might be concluded that genetic engineering is a natural phenomenon, akin to the "genetic engineering" that takes place in nature every time a gene crosses over on chromosomes, a gene mutates, or a bacterial plasmid migrates from one species to another. T
- here is an important difference between "natural evolutionary processes" and "natural genetic engineering." Natural evolutionary processes do not make a choice, they do not deliberate with the intention of achieving an end. What distinguishes natural evolutionary processes is that they are not goal directed, whereas human actions are always goal directed.
- To argue that genetic engineering is simply an extension of natural evolutionary processes does not morally justify the practice. With this line of reasoning, any biotechnological intervention could be justified as simply a natural process.
- But clearly not every intervention is good. It can only be determined to be good based upon a moral deliberation that takes into account its risks and benefits and the appropriateness of intervening in the first place.

Ethical issues against Molecular Technology

- An essential element in the ethical evaluation of biotechnology is the analysis of the possible harms and their likelihood of occurring, weighing these risks against the probable benefits. Since biotechnology encompasses a wide variety of biological methods and techniques in a wide variety of circumstances, the analysis of the risks and benefits will be highly contextual, depending upon the peculiarities of each specific application.
- For instance, the use of genetically engineered bacteria to produce insulin in a commercial laboratory is quite different from the release of genetically engineered bacteria into the natural environment.

- Conditions can be controlled in the laboratory and, with appropriate safety measures, the modified bacteria can be prevented from escaping. But the release of a genetically engineered species into the environment poses additional risks depending on the viability of the organism, the nature of its genetic modification, and the purpose for which it is introduced.
- This discussion will be confined to the principles that may apply to the ethical evaluation of biotechnology in general, recognizing that the ethical evaluation of each particular intervention will depend upon its specific circumstances.
- Adequate assessment of the risks of releasing a genetically modified species into the environment entails a thorough knowledge of the ecology of the environment and how the modified species will interact with other species.
- Proposals for the introduction of genetically modified species into the environment have been criticized on the grounds that there is insufficient ecological knowledge and that, in general, the science of predictive ecology is underfunded and poorly understood.
- Even in individual species, it is difficult to predict the health effects of inserting foreign DNA into an organism or otherwise modifying the expression of genes it already contains. A number of deleterious pleiotropic effects have been shown to occur in genetically modified species.
- In fact, the only way to determine these effects is through experiments upon individual organisms, a fact not lost upon animal welfare advocates. The ultimate safety of transgenic organisms can only be evaluated through careful study of their release into the environment, with the consequent risk that we will discover a cascade of harmful effects on the environment only after it is too late to stop the spread of the organism.
- The ecology of environments is highly complex and relational. Individual species can play a variety of roles within an environment and the effects of a change in a species can be highly unpredictable.
- The problem is not simply inadequate knowledge but rather the complexity of ecological systems. Complex systems, in general, may be highly nonlinear, meaning that there may be little or no correlation between incremental changes in a system and how it behaves.

- In mathematical models of complex systems, the effects of changes in a system are, in principle, unpredictable. The only way to discover these effects is to observe how the system behaves upon the introduction of a specific change.
- Since adequate risk assessment depends upon prediction and quantification of risk, the effects of the introduction of new or modified species into an ecosystem may not be adequately quantifiable or manageable, making each such introduction truly experimental.
- The lessons learned from the endangered species program are valuable in this context. Biologists have learned that in order to save a species, it is necessary to save its habitat. We might postulate a biotechnology corollary to this principle: Altering a species may alter its habitat, even if you do not know exactly how.
- The complexity of ecological systems makes it very difficult to identify specific causes of environmental change, and since one may not be able to anticipate specific changes, it is possible that scientific observation will fail to detect them.
- Without the development of a much richer general science of ecology, and specific ecological studies of the environments into which biotechnology is introduced, adequate risk assessment may be impossible.
- It follows, then, that in the absence of adequate ecological study before biotechnological interventions take place, and in the absence of a commitment to long-term study after they have been introduced, the ethical evaluation of risks and benefits is incomplete. Proceeding on the basis of inadequate study may be unethical.
- One especially troubling risk of the introduction of genetically engineered species into the environment is the possibility that the modified genes will cross to other species. This problem is most characteristic of plants and microbes, especially bacteria.
- It is also possible that genetically modified viruses may target unexpected species, spreading either deleterious or beneficial genes in unexpected ways. A related risk is the short generation time and potentially rapid evolution of microbes.

- If a genetically altered microbe persists in the environment, it is possible that it may evolve in unforeseen ways, producing unforeseen effects. Controlling the spread of genetically engineered species in the environment is also difficult, especially in the marine context where individual organisms can be quickly spread to vast areas by ocean currents.
- In addition to the unpredictability associated with introducing new or modified species into the environment, harmful effects may be irremediable. Once a genetic modification has hopped to another species, there is little that biologists can do to effectively contain the spread of the gene.
- Once disrupted in this fashion, the ecological balance may be irrevocably altered, to the detriment of the ecosystem and its associated benefits to humans. One promising method for protecting marine environments against the adverse consequences of introducing genetically modified species of fish has been to limit the reproductive capabilities of the fish. In this way, adverse ecological impacts may be reversed by discontinuing the release of the modified species.

How to manage risks

There are two ways in which risks can be managed.

They are reflected in the differing approaches to biotechnology taken by Americans and Europeans.

a- Risk-Benefit Approach

- This approach is based on the probability that what is more than harm. it is a process that is intended to support the decision maker by providing an in-depth analysis of the problem, thereby enabling the decision maker to take a more informed decision.
- We can then make our decision about using the item in accordance with the results. This is a risk-benefit approach, and it comes naturally for Americans.
- In United States commercial interests are favored over environmental concerns until it can be confirmed that a particular prasctice is unsafe for humans. A notable exception to the risk-benefit approach is the Food and Drug Administration's (FDA) process for granting approval for medical drugs and devices.

b- Precautionary Approach

- This approach is more commonly favored by Europeans, which dictates that no product is acceptable until it has been proven safe scientifically. This approach prevents the patients from unseen problems as the product or practice has already been demonstrated before it is admitted to that person.
- One of the basic problems with assessing the risks of biotechnological interventions is that it may be very difficult to establish the exact cause of a particular harmful effect in the environment.
- Several solutions have been offered for this problem, including the use of unique genetic markers to label genetic modifications of organisms. Should the release of such organisms into the environment cause problems, the modified genes can be traced back to the specific project responsible for their release.
- The Institute of Virology at Cambridge University has demonstrated that such genetic markers can indeed be used to track modified genes. The use of these markers for genetically engineered organisms would promote accountability and provide an added incentive to ensure the safety of genetically modified organisms prior to release.
- An additional inducement to minimize risks can be created by amending the legal liability incurred by the release of genetically modified organisms.
- For instance, the European Parliament's Committee on the Environment, Public Health and Consumer Protection recommended that the release of genetically modified organisms into the natural environment should be conducted under strict' liability, "whereby any individual or organization claiming for damages caused by another party does not have to prove that the other party acted negligently in order to claim damages, but merely to show that the damage was caused by the actions, activities or products of the other party.
- Commercial interests involved in the release of genetically engineered organisms into the natural environment would, thereby, have a strong financial incentive to minimize the risks of their intervention.

- The Committee also recommended that the release of genetically engineered species be conducted only if appropriate insurance coverage has been provided by the sponsor prior to the release.
- Ethical deliberation requires impartiality, that is, disinterestedness on the part of those who judge. Thus, scientific grants are awarded through blind peer review so as not to be biased by personal relationships.
- But the use of biotechnology may affect us all. One of the problems with the peer review mechanism is that the practice of science itself predisposes practitioners to particular values.
- If the question is strictly scientific, then peer review can provide impartial assessment, but if the question concerns the place of scientific values in public policy or ethical deliberation, then scientific peer review is inherently biased.
- Because of the uncertainties of the risks of many biotechnological applications and the impacts of these risks to both human and ecological interests, the ethical evaluation of biotechnological applications requires a very different kind of process than our present regulatory system provides.
- Our system relies heavily upon scientific expertise and a general predisposition to minimize regulation and promote trade. Questions regarding the application of biotechnology in the environment require far greater public participation and, in general, greater impartiality.

Ethical and Biosafety Issues for the use of Modern Biotechnology

- The bioethics committee of UNESCO established in 1993 has evolved guidelines for ethical issues associated with the use of modern biotechnology. Biosafety guidelines for genetically improved organisms (GIOs) need to be strictly followed to prevent harm to human health or the environment.
- A three-tier mechanism of Institutional Biosafety Committees has been instituted in India: the Review Committee on Genetic Manipulation, the Genetic Engineering Approval Committee, and the state level coordination committee.
- It is important to give a clear explanation of the new biotechnologies to the public to allay their fears. New models of cooperation and partnership have to be established to ensure close linkages among research scientists, extension workers, industry, the farming community, and consumers.

Gene transformation is done worldwide with four broad objectives:

(a) To develop products with new characteristics

(b) to develop pest and disease resistance

(c) to improve nutritional value

(d) to modify fruit ripening to obtain longer shelf life.

- Thus the aims and objectives are laudable and the tools are available.
- The new technology does, however, call for a cautious approach following appropriate biosafety guidelines. About 25,000 field trials of genetically modified crops have been conducted worldwide. The anticipated benefits are better planting material, savings on inputs, and genes of different varieties can be introduced in the gene pool of crop species for their improvement.
- The potential risks include weediness, transgene flow to non-target plants, and the possibility of new viruses developing with wider host range and their effects on unprotected species. For crops such as com and cotton with single gene introductions, there is very little problem expected. When multiple genes are involved scientists have to be more cautious.
- The time has arrived for a serious look at ethical and biosafety aspects of biotechnology.
- Researchers, policymakers, NGOs, progressive farmers, industrialists, government representatives, and all concerned players need to come together and share a platform to address the following issues:

1. Environmental safety
2. Food and nutrition security
3. Social and economic benefits
4. Ethical and moral issues
5. Regulatory issues.

- There are about 50 approved MS, postdoctoral, and MD training programmes in biotechnology in progress or just about to start, in different institutions and universities covering most Indian States. Short-term training programmes, technician training courses, fellowships for students to go abroad, training courses in Indian institutions, popular lecture series, awards, and incentives form an integral part of the human resource development activities in India.
- A special feature of the programme has been that since 1996 many students after completion of their training course join industries or work in biotechnology-based programmes in institutions and laboratories. National Bioscience Career Development Awards have been instituted. Special awards for women scientists and scholarships to the best students in biology help promote biotechnology in India and give recognition and reward to the scientists.
- Biotechnology-based activities to benefit the poor and weaker sections and programmes for women have been launched. A unique feature is the establishment of a Biotechnology Golden Jubilee Park for Women which will encourage a number of women entrepreneurs to take up biotechnology enterprises that benefit women in particular. This will also encourage women biotechnologists to develop relevant technologies.
- States are taking a keen interest in developing biotechnology-based activities. The States of Uttar Pradesh, Arunachal Pradesh, Madhya Pradesh, Kerala, West Bengal, Jammu and Kashmir, Haryana, Mizoram, Punjab, Gujarat, Meghalaya, Sikkim and Bihar have already started large- scale demonstration activities and training programmes.
- The Indian Government has made substantial investments in biotechnology research. Bringing Indian biotechnology products to market will require the involvement of large and small entrepreneurs and business houses. This will require substantial investments

from Indian and overseas investors. The worldwide trend is that large companies are becoming major players in development of biotechnology products, and also in supporting product-related biotechnology research.

- In the years ahead, biotechnology R&D should produce a large number of new genetically improved plant varieties in India, including cotton, rice, brassicas, pigeonpea, mung bean, and wheat. Tissue culture regeneration protocols for important species such as mango, saffron, citrus, and neem will lead to major commercial activities. Micro-propagation technology will provide high-quality planting materials to farmers.
- Environment-friendly bio-control agents and biofertiliser packages will hopefully be made available to farmers in such a way that they can produce these in their own fields. The country should be in a position to fully utilise, on a sustainable basis, medicinal and aromatic plants.
- The development through molecular biology of new diagnostic kits and vaccines for major diseases would make the health care system more efficient and cheaper. Genetic counselling clinics, molecular probes, and fingerprinting techniques should all be used to solve the genetic disorders in the population.
- The establishment of ex situ gene banks to conserve valuable germplasm and diversity, and a large number of repositories, referral centers for animals, plants, and microorganisms should be possible. Detailed genetic readouts of individuals could be available.
- Information technology and biotechnology together should become a major economic force. It is expected that plants as bioreactors would be able to produce large numbers of proteins of therapeutic value, and many other important items. The recent discovery of the gene for recalcitrant species was a landmark event.
- In vitro mass propagation can be carried out on any desired species with nonrandom programming. Certainly the 21st century could witness a major increase in new bio-products generated through modem biology. To achieve the goal of self-reliance in this field, India will require a strong educational and scientific base, clear public understanding of the value of new biotechnologies, and involvement of society in many of these biological ventures.

- India has a large research and educational infrastructure comprising 29 agriculture universities, 204 central and state universities, and more than 500 national laboratories and research institutions. It should therefore be possible to develop capabilities and programmes so that these institutions act as regional hubs for the farming community, community, where they can get direct feedback about new technological interventions. It will be equally important to establish strong partnerships and linkages with industry, from the time a research lead has emerged until the packaging of the technology and commercialisation are achieved.
- The future impact of biotechnology on industrial development, but this does not yet apply to the less developed countries that lack this infrastructure and industrial strength. In view of the current power of biotechnology and its even brighter future, there is no question that the less developed countries must now position and strengthen their status in biotechnology.

List of Possible Questions

1. What is biosafety
2. Explain various paradigm related with biotechnology
3. Write the ethical issue concerning about transgenic technology
4. Comment on the ethical issues against Molecular Technology

Unit: 4 Biosafety: Introduction to biosafety and health hazards concerning biotechnology. Introduction to the concept of containment level.

What is biosafety?

- Biosafety is about the intrinsic hazards of living organisms and how to handle them safely. Genetic material as such ('naked' DNA) can be dangerous as well.
- Before starting to work with pathogens or genetically modified organisms (GMOs) in a laboratory one should stop and think about the possible hazards of these organisms and take proportionate measures to minimize any risks for human health and the environment

What are the hazards?

- Biological material and living organisms are neither intrinsically dangerous, nor intrinsically safe. Any danger will depend on the characteristics of the material or the organisms.

Characteristics that represent a danger are the following:

Pathogenicity

- The pathogenicity of an organism indicates whether an organism - for instance a bacterium, a virus, fungus or a parasite - is able to cause a disease in a plant, animal or human.
- Factors like infectious dose, virulence and the production of toxins by the pathogen play a role in the extent to which the organism is able to cause disease.
- Toxicity means poisoning. Most substances are not poisonous when they are used under normal circumstances.
- The toxicity of a substance is mostly given as an LD50 for vertebrates in weight units per kilogram body weigth.
- The LD_{50} (LD stands for: lethal dose) is the amount at which exposure to the substance leads to the death of the animals exposed.
- When the toxicity of living organisms (especially bacteria) is considered, toxicity often coincides with pathogenicity.

Allergenicity

- Allergenicity is a non-toxic, immune system mediated, undesired reaction of the body to a substance or agent. Immune globuline E (IgE) and mast cells (immune system cells that, among other things, produce heparin) often play a role in the allergic reaction.

- An allergic reaction may lead to sneezing, skin irritation, asthma attacks, chronic lung disorders, and sometimes even to a lifethreatening shock

Disturbance of ecological balances

- The aspect of disturbance of ecological balances is especially relevant for activities involving GMOs.
- Disturbance of an ecological balance may happen when a GMO pos- sessing a certain characteristic is accidentally spread to the environment, or when gene- tic material originating from that organism spreads to other organisms in the environment.
- The potential hazards of recombinant-DNA technology and the risk assessment of activities involving this technology

Other harmful effects

- Sometimes there are other unwanted effects that urge one to be even more cautious when handling biological material. It is not possible to give an exhaustive list of these effects.
- What matters is that one stops to think about the characteristics of biological material, before starting to work with it.
- One important class of genes that should be looked at carefully are genes that produce proteins with immune modulating properties, although not all immune modulations are harmful.
- For certainty about the possible level of harm the effects of the immune modulation should be thought through care- fully and quite often consultation with experts will be necessary.
- One example is the handling of a vaccinia virus in which a gene responsible for immune suppression is cloned.
- Immune suppression may lead to the body not being able to fight an infection by the virus. In some exceptional cases, infections with vaccinia viruses may lead to fatal encephalitis.

CLASSIFICATION AND RISK ASSESSMENT

Pathogenic organisms

- Organisms are divided into four categories of risk.
- Organisms that are not able to cause disease belong to risk group 1.
- Pathogenic organisms belong to the risk groups 2, 3 or 4, depending on their degree of pathogenicity and the availability of effective treatment.

- To distinguish between the classification of natural non-modified pathogens and GMOs, the pathogen classification uses the term risk groups or sometimes also biological risk class, while for the GMO classification the term risk class is used.

Below an overview is given of the definitions of the different risk groups.

Group 1	Very unlikely to cause disease in humans, animals or plants.	
Group 2	Human pathogens	Microorganisms that can cause disease in humans and pose a hazard to persons that are directly exposed to it. Their spread to the community is unlikely. Prophylaxis or effective treatment is mostly available.
	Animal pathogens	Microorganisms that can cause disease in animals and that possess in different extend one of the following properties: limited geographical importance, transmission to other limited or non-existent species, absence of vectors or carriers. Limited economic and/or medical impact. Prophylaxis and/or effective treatment is mostly available.
	Phytopathogens	Microorganisms that can cause disease in plants, but for which there is no higher risk of an epidemic when they are accidentally disseminated into the environment. Prophylaxis or effective treatment is available. Non-indigenous or exotic phytopathogens that are not able to survive in Belgium because of the absence of target plants or because of unfavorable weather conditions, belong to this risk group.
Group 3	Human pathogens	Microorganisms that can cause serious disease in humans and pose a hazard to persons that are directly exposed to it. There is a risk of spread to the community. Prophylaxis or effective treatment is mostly available.
	Animal pathogens	Microorganisms that can cause serious disease or epizotic in animals. Spread to other species is more than possible. Some of these pathogenic agents require specific sanitary measures. Prophylaxis or effective treatment is mostly available.
	Phytopathogens	(micro-)organisms that can cause a disease in plants with important economic or environmental consequences and for which treatments are non-existent, difficult to apply or costly. Accidental spread may lead to local epidemics. Exotic strains of fytopathogens usually occu- ring in the Belgian environment and not in the list of the quarantine organisms also belong to this risk group.

- In addition to classifying a pathogen, it is very important to mention its host, since infectious diseases are an interaction between a pathogen and a host.
- Some pathogens have a broad host range, whereas others may only be able to infect one or a few hosts.
- Moreover, the risk group of a particular pathogen that can infect both humans and animals may differ from one host to another.
- For instance, the biological risk class of Herpes virus B is 3 for humans, while it is 2 for animals.

Genetically modified organisms (GMOs)

Recombinant-DNA technology has become so important that one can no longer imagine modern biological and biomedical laboratories without the technique.

Escherichia coli K12 is the number one laboratory organism, which is used by almost every researcher as a means of cloning or expressing genes or sequences.

The following GMOs are excluded from the regulations on the condition that they do not involve the use of recombinant-nucleic acid molecules or GMOs other than those produced by one or more of the techniques listed below:

1. Mutagenesis.
2. Cell fusion (including protoplast fusion) of prokaryotic species that exchange genetic material by known physiological processes.
3. Cell fusion (including protoplast fusion) of cells of any eukaryotic species, including production of hybridomas and plant cell fusions.
4. Self-cloning consisting in the removal of nucleic acid sequences from a cell of an organism which may or may not be followed by reinsertion of all or part of that nucleic acid (or a synthetic equivalent) with or without prior enzymatic or mechanical steps, into cells of the same species or into cells of phylogenetically closely related species which can exchange genetic material by natural physiological processes where the resulting micro organism is unlikely to cause disease to humans, animals or plants.
5. Self-cloning may include the use of recombinant vectors with an extended history of safe use in the particular microorganisms.

Recombinant-DNA GMO's

- Today a whole range of organisms can already be genetically modified, a.o bacteria, yeasts, fungi, insects (fruit fly), parasites, nematodes, plants, frogs, mammals (mice, rats, rabbits, goats, sheep, pigs, cattle).
- Genetic modification in general involves the following components:
- A host organism (the organism which is to be modified); note that the meaning of the term 'host' in this context differs from that in the context of pathogenic organisms

See clarification of terms.

1. A donor sequence or insert, isolated from a certain organism (the donor organism). However, synthetically produced DNA sequences are also being used more and more often. These sequences can be identical to sequences present in living organisms, but they can also be completely new.
2. And in many, but not all cases a (genetic) vector.
3. In the case of transformation of bacteria, plasmids are mostly used as a vector. In other cases viruses or viral vectors may be used. Examples where no genetic vector is used are the micro-injection of DNA in the pronucleus of a fertilised egg, or the modification of plants by means of particle bombardment. Depending on the system used the vector will remain present in the final GMO or not.

Risk assessment

- GMOs, like non-GMOs, are neither intrinsically hazardous, nor intrinsically safe. That is why risk assessment is performed on a case-by-case basis.

The risk assessment procedure consists of of three subsequent steps:

- Firstly, the characteristics of the host, vector and donor sequences that are potentially hazardous like pathogenicity, toxicity, the possibility of uncontrolled spreading of the organism or its genetic material, are identified.This leads to a preliminary identification of the risk level.
- Secondly, the circumstances under which the organisms can be handled safely are determined, taking into account the following aspects:
- The characteristics of the environment that could be exposed to the GMOs
- The type and scale of the activity

- Any non-standard activities or actions

Finally, a risk class is determined, based on the results of the first two steps.

As for pathogens, four risk classes have been determined for GMOs:

Risk class 1	GMO activities holding no or a negligible risk	Activities for which level 1 containment is appropriate to protect human health as well as the environment
Risk class 2	GMO activities holding a low risk	Activities for which level 2 containment is appropriate to protect human health as well as the environment
Risk class 3	GMO activities holding a moderate risk	Activities for which level 3 containment is appropriate to protect human health as well as the environment
Risk class 4	GMO activities holding a high risk	Activities for which level 4 containment is appropriate to protect human health as well as the environment

Risk classes as defined by the European directive 98/81/EC concerning the contained use of genetically modified micro-organisms.

Class	Pathogens	GMOs	Basic containment level
Risk class 1	Non-pathogens	No or negligible risk	Level 1 for GMOs, SMP for non-modified micro-organisms or cells*
Risk class 2	Mild pathogens	Low risk	Level 2
Risk class 3	Moderate pathogens	Moderate risk	Level 3
Risk class 4	Strong pathogens	High risk	Level 4

THE SPREAD OF ORGANISMS IN THE LABORATORY

Natural routes of infection

Pathogens all have their own route of infection, by which they spread from one host- organism to another.

The table below lists a number of important routes of infection:

Route of infection	Example
Skin contact	Fungi
Through air or aerosols	Flu
Through pricking (insects or needles)	Malaria; Yellow fever
Blood-blood contact	HIV-virus; Hepatitis B
Through wounds	*Staphylococci*
Through faecal material	Typhoid bacteria Poliovirus

- All these routes of infection may, depending on the type of work that is being performed, occur in the laboratory.
- As regards organisms that are able to spread through the air, very small droplets play a role, but infection may also be the result of direct contact, for instance with hands, hand kerchieves, or clothes.

Routes of contamination

- Laboratory personnel may be exposed to organisms in different ways. Any open source of organisms (for instance an open petri dish) may lead to the spread of organisms.
- However, under normal circumstances, a container holding living pathogens of GMOs will only be opened in (semi) sterile surroundings, so as to prevent contamination of the container's content itself: for instance close to a Bunsen burner or in a safety cabinet.
- In practice, the cause of most laboratory infections is unknown. When the cause of the infection is known, it often concerns prick accidents, spilling, broken glassware, mouth pipetting, or biting or scratching by a laboratory animal.

Aerosols

- One of the routes of infection that deserves special attention is infection through aerosols. Aerosols are very small droplets of fluid that can spread through the air.
- They are formed during activities such as opening bottles containing fluids and having a wet cap, vor- texing, blending, emptying a pipette by blowing, or heating a wet inoculation needle in a flame. The formation of aerosols should be avoided as much as possible.
- When working with organisms that hold a certain risk (starting from risk class 2), one should perform aerosol producing activities in a safety cabinet.
- Undesired spread of organisms or genetic material
- It may have become clear that the spread of hazardous organisms represents a danger both to yourself and to your colleagues.
- When it is possible for organisms to spread to a colleague, they may spread to the environment as well.
- This dissemination of organisms or genetic material to the environment is often undesired, since it may involve the spread of pathogens or toxins, or lead to the disruption of ecological balances. This is undoubtedly true with regard to organisms belonging to risk classes 2, 3 and 4.
- However, even the spread of organisms (and their genetic material) belonging to risk class 1, and thus presenting only a minor risk, should be limited.

Bacteria, yeasts and fungi

- Bacteria are often capable of transferring genetic material.
- This is especially the case when vectors are used that are self-transmissible.
- In practice, to avoid genetic material from being easily transferred, vectors are usually used that are difficult to mobilise, or not mobilisable at all.

Animal and human cells

- Animal and human cells cannot spread to the environment just like that. In addition, non-contaminated cells are unable to spread genetic material to the environment by accident.
- Animal and human cells cannot survive in non-sterile surroundings.
- Cells that are specially designed to survive in non-sterile surroundings, such as fish or frog eggs, are an exception to this rule.

- As regards non-contaminated cells, the measures that are taken to prevent the cell culture from being contaminated are sufficient to prevent the cells from being spread to the environment. Genetic material of animal or human origin can only be spread to the environment when the cells involved are infected by biological agents, such as viruses, that are able to mobilize their genetic material. From a biosafety point of view, the question whether or not cells are infected by biological agents is very important.
- Any viruses present may represent a danger to the researcher or to the environment, and any safety measures should take account of this.

Viruses

- A distinction can be made between wild type viruses and viral vectors (constructions derived from viruses). The use of viruses or viral vectors always implies the use of host cells. Without host cells no virus can be replicated.

In practice, there are three types of activity:

1. the growing of cells to produce viral particles,
2. the handling of viral particle-containing supernatants (for quality controls, etc.), and the transduction of a cell line, test animal or plant.

- Especially supernatants may contain very high levels of viral particles. These supernatants should be handled carefully.
- Once the cell, animal or plant has been infected, the danger depends on the virus' or viral particle's ability to replicate.
- In some cases a replication-defective virus is used, which means that the virus can infect the cells, but is no longer able to replicate.
- The ability to spread or replicate may differ from one virus to another. Some viral particles are able to spread through the air or to survive for very long periods of time.
- Other viruses, such as HIV, are extremely vulnerable outside their host. Plant viruses sometimes need 'vectors' to be able to spread.
- These vectors are often insects that suck up the virus and spread it to other plants.

Transgenic plants

- Transgenic plants are grown in-vitro, in growth chambers or greenhouses, and the plants are not able to disseminate just like that. Nevertheless, the undesired spread of transgenic plants deserves special attention.
- If no proper containment measures are taken, pollen may be disseminated to the environment through the air or aided by insects.
- Whether or not this presents a genuine risk, depends on how the plant reproduces: by self-pollination or by cross-pollination.
- The spread of pollen by strict self-pollinators has no effect what- soever, but when a cross-pollinator is involved, it should be carefully checked whether any of its wild relatives, which it might successfully hybridize with, is growing in the vicinity.
- In addition to pollen, seeds originating from transgenic plants may sometimes easily be disseminated in the environment.
- Especially when they are very small or sticky, these seeds are very likely to be accidentally taken along by a researcher leaving the growth chamber or greenhouse.
- It is not only pollen or seeds that may be responsible for the undesired spread of transgenic plants. Some plant parts may grow and turn into whole new plants themselves.
- These reproductive parts of plants should not be discarded without destroying them properly. For example, the branch of a willow can grow roots and leaves very easily, and the stem base of a cabbage can also grow roots.
- This is why laboratory staff handling transgenic plants or plant material should pay special attention to the possible spread of plant parts that are still able to reproduce.
- If there is a genuine possibility that a transgenic plant will be able to establish itself in the environment, or that it will hybridize with wild relatives, reproductive plant parts should be destroyed before they are discarded as waste.

Transgenic animals

- The unwanted spread of transgenic animals should be prevented. Depending on the ani- mal, this can be very easy or rather difficult.
- Small rodents, like mice, should be kept in appropriate cages and the animal houses should be designed in such a way that it is impossible for the animals to escape.
- When a genetically modified micro-organism or a wild-type pathogen is administered to the animal, it should be determined on a case-by- case basis how to prevent the micro-organism from spreading. It may be necessary to keep the animals in individually ventilated cages, and to inactivate all materials that have been in contact with the animals (for instance the bedding material).
- When cells or other biological material are used in animals, it should be taken into account that viruses may be present in this material.
- Some cell lines are contaminated by viruses. If such viruses are present, the containment measures should be adapted if there is a risk that the virus might spread.

Introduction to the concept of contaminant level

- Containment levels provide the description of the minimum containment required for handling organisms safely in a laboratory setting.
- The containment system includes the engineering, operational, technical and physical requirements for manipulating a particular pathogen.
- The classification of pathogens into Risk Groups does not provide instructions on how to actually handle the organism in the laboratory.
- The concept of the Containment Level has been devised to provide the worker with a description of the minimum engineering, operational, technical and physical requirements for handling a pathogen safely within the laboratory setting.

Four containment levels exist and are described as follows:

Containment Level 1 (CL1)

1. This applies to a basic laboratory handling organisms requiring CL1. It requires no special design elements beyond those required in a functional laboratory.
2. Work can be carried out on open bench tops, with containment being achieved though good laboratory practice

Containment Level 2 (CL2)

1. This applies to a laboratory handling organisms requiring CL2. Primarily, the routes of exposure of pathogens requiring CL2 is via ingestion, inoculation or mucosal membranes.
2. Although not generally transmitted via airborne routes, care must be taken with CL2 pathogens to avoid the formation of bioaerosols, which after contact with the workers hands (can become an ingestion risk) or splashes.
3. Primary containment is through Biological Safety Cabinets (BSCs) and aerosol-proof centrifugation, as well as the wearing of appropriate Personal Protective Equipment (PPE).
4. Contamination of the environment is kept to a minimum by employing specified hand washing sinks and the use of autoclaves and other decontamination methods. All wet bench areas in the KRCBS are certified and registered as CL-2.

Containment Level 3 (CL3)

1. This applies to a laboratory handling organisms requiring CL3. Pathogens can cause serious or life threatening disease at low doses and may be transmitted via the airborne route.
2. Primary and secondary are required to prevent transmission of the pathogen into the laboratory and environment e.g. work on infectious material is conducted inside a CL3-complient BSC with the worker wearing appropriate respiratory protection.
3. Containment Level 4 (CL4)
4. Maximum containment available and is used by facilities handling pathogens requiring containment level 4.
5. Pathogens have a high risk of being transmitted via aerosols, have a very low dose of infection and often produce lethal diseases, with little or no effective treatment.
6. CL4 emphasizes maximal containment, within an isolated unit, with researchers working in positive containment suits, in a CL4-compliant BSC.
7. Air, as well as waste, leaving the facility is decontaminated.

List of Possible Questions

1. Explain the biosafety regulation
2. What are biohazards?
3. Give a detailed note on classification of different risk groups
4. Write about the risk assessment of GMO in the environment
5. Write the natural route of infections in the laboratory
6. Give a brief note on the concept of contaminant level

Unit: 5 Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP), NABL, FSSAI.

GOOD LABORATORY PRACTICES (GLP)

- **GLP** is an FDA regulation.
- "*GLP embodies a set of principles that provides a framework within which laboratory studies are planned performed, monitored, reported and archived".*
- GLP is sometimes confused with the standards of laboratory safety like wearing safety goggles
- GLP is a formal regulation that was created by the FDA (United States food and drug administration) in 1978.
- Although GLP originated in the United States, it had a worldwide impact. Non-US companies that wanted to do business with the United States or register their pharmacies in the United States had to comply with the United States GLP regulations. They eventually started making GLP regulations in their home countries.
- In 1981 an organization named OECD (organization for economic co-operation and development) produced GLP principles that are international standard aware of cases of poor laboratory practice all over the United States.

FDA decided to do an in-depth investigation on 40 toxicology labs.

1. They discovered a lot fraudulent activities and a lot of poor lab practices.
2. Examples of some of these poor lab practices found were
3. Equipment not been calibrated to standard form , therefore giving wrong measurements.
4. Incorrect/inaccurate accounts of the actual lab study
5. Inadequate test systems

OBJECTIVES OF GLP

1. GLP makes sure that the data submitted are a true reflection of the results that are obtained during the study.
2. GLP also makes sure that data is traceable.
3. Promotes international acceptance of tests.

MISSION OF GLP

1. Test systems
2. Archiving of records and materials.
3. Apparatus, material and reagent facilities.
4. Quality assurance programs.
5. Performance of the study.
6. Reporting of study results.
7. Standard operating procedures (SOP)
8. Personnel and test facility organization

Standard Operating Procedures (SOP)

1. Written procedures for a laboratories program.
2. They define how to carry out protocol-specified activities.
3. Most often written in a chronological listing of action steps.
4. They are written to explain how the procedures are suppose to work
5. Routine inspection, cleaning, maintenance, testing and calibration.
6. Actions to be taken in response to equipment failure.
7. Analytical methods
8. Definition of raw data
9. Keeping records, reporting, storage, mixing, and retrieval of data

Statistical Procedures for Data Evaluation

1. Statistical procedures are not simply chosen from a text book
2. Practitioners in a particular field may adopt certain standards which are deemed acceptable within that field.
3. Regulatory agencies often describe acceptable statistical procedures.

Instrumentation Validation

1. This is a process necessary for any analytical laboratory.
2. Data produced by "faulty" instruments may give the appearance of valid data.
3. The frequency for calibration, re-validation and testing depends on the instrument and extent of its use in the laboratory.
4. Whenever an instrument's performance is outside the "control limits" reports must be discontinued
5. Equipment records should include:
6. Name of the equipment and manufacturer
7. Model or type for identification
8. Serial number
9. Date equipment was received in the laboratory
10. Copy of manufacturers operating instruction (s)

Reagent/ Materials Certification

1. This policy is to assure that reagents used are specified in the standard operating procedure.
2. Purchasing and testing should be handled by a quality assurance program.
3. Requirements:
4. Reagents and solutions shall be labeled
5. Deteriorated or outdated reagents and solutions shall not be used
6. Include Date opened
7. Stored under ambient temperature
8. Expiration date

Analyst Certification

1. Some acceptable proof of satisfactory training and/or competence with specific laboratory procedures must be established for each analyst.
2. Qualification can come from education, experience or additional trainings, but it should be documented
3. Sufficient people

Laboratory Certification

1. Normally done by an external agency
2. Evaluation is concerned with issues such as
3. Adequate space
4. Ventilation
5. Storage
6. Hygiene

Specimen/Sample Tracking

1. Vary among laboratories
2. Must maintain the unmistakable connection between a set of analytical data and the specimen and/or samples from which they were obtained.
3. Original source of specimen/sample (s) must be recorded and unmistakably connected with the set of analytical data.

Documentation and Maintenance of Records

1. Maintenance of all records provide documentation which may be required in the event of legal challenges due to repercussions of decisions based on the original analytical results.
2. General guidelines followed in regulated laboratories is to maintain records for at least five years
3. Length of time over which laboratory records should be maintained will vary with the situation

GOOD MANUFACTURING PRACTICES (GMP)

- GMP is that part of quality management which ensures that products are consistently produced and controlled according to the quality standards appropriate to their intended use and as required by the marketing authorization, clinical trial authorization or product specification. GMP is concerned with both production and QC.
- GMP is aimed primarily at managing and minimizing the risks inherent in pharmaceutical manufacture to ensure the quality, safety and efficacy of products.

Under GMP:

- all manufacturing processes are clearly defined, systematically reviewed for associated risks in the light of scientific knowledge and experience, and shown to be capable of consistently manufacturing pharmaceutical products of the required quality that comply with their specifications;
- qualification and validation are performed;
- all necessary resources are provided, including:
    1. sufficient and appropriately qualified and trained personnel,
    2. adequate premises and space,
    3. suitable equipment and services,
    4. appropriate materials, containers and labels,
    5. approved procedures and instructions,
    6. suitable storage and transport,
    7. adequate personnel, laboratories and equipment for in-process controls;
    8. instructions and procedures are written in clear and unambiguous language, specifically applicable to the facilities provided;
- procedures are carried out correctly and personnel are trained to do so;
- records are made (manually and/or by recording instruments)
- during manufacture to show that all the steps required by the defined procedures and instructions have in fact been taken and that the
- quantity and quality of the product are as expected. Any significant deviations are fully recorded and investigated with the objective of determining the root cause and appropriate corrective and preventive action is implemented;
- records covering manufacture and distribution, which enable the complete history of a batch to be traced, are retained in a comprehensible and accessible form;
- the proper storage and distribution of the products minimizes any risk to their quality and takes account of good distribution practices (GDP);
- a system is available to recall any batch of product from sale or supply;
- complaints about marketed products are examined, the causes of quality defects investigated and appropriate measures taken in respect of the defective products to prevent recurrence.

Sanitation and hygiene

- A high level of sanitation and hygiene should be practiced in every aspect of the manufacture of medicines. The scope of sanitation and hygiene covers personnel, premises, equipment and apparatus, production materials and containers, products for cleaning and disinfection, and anything that could become a source of contamination to the product.
- Potential sources of contamination should be eliminated through an integrated comprehensive programme of sanitation and hygiene.

Qualification and validation

- In accordance with GMP, each pharmaceutical company should identify what qualification and validation work is required to prove that the critical aspects of their particular operation are controlled.
- The key elements of a qualification and validation programme of a company should be clearly defined and documented in a validation master plan.
- Qualification and validation should establish and provide documentary evidence that:
    1. the premises, supporting utilities, equipment and processes have been designed in accordance with the requirements for GMP (design qualification or DQ);
    2. the premises, supporting utilities and equipment have been built and installed in compliance with their design specifications (installation qualification or IQ);
    3. the premises, supporting utilities and equipment operate in accordance with their design specifications (operational qualification or OQ);
- a specific process will consistently produce a product meeting its predetermined specifications and quality attributes (process validation or PV, also called performance qualification or PQ).
- Any aspect of operation, including significant changes to the premises, facilities, equipment or processes, which may affect the quality of the product, directly or indirectly, should be qualified and validated.
- Qualification and validation should not be considered as one-off exercises.
- An ongoing programme should follow their first implementation and should be based on an annual review.
- The commitment to maintain continued validation status should be stated in the relevant company documentation, such as the quality manual or validation master plan. The responsibility for performing validation should be clearly defined.
- Validation studies are an essential part of GMP and should be conducted in accordance with predefined and approved protocols.
- A written report summarizing the results recorded and the conclusions reached should be prepared and stored.
- Processes and procedures should be established on the basis of the results of the validation performed.

- Particular attention should be paid to the validation of analytical test methods, automated systems and cleaning procedures.

Complaints

- All complaints and other information concerning potentially defective products should be carefully reviewed according to written procedures and the corrective action should be taken.
- A person responsible for handling the complaints and deciding the measures to be taken should be designated, together with sufficient supporting staff to assist him or her. If this person is different from the authorized person, the latter should be made aware of any complaint, investigation or recall.
- There should be written procedures describing the action to be taken, including the need to consider a recall, in the case of a complaint concerning a possible product defect.
- Special attention should be given to establishing that the product that gave rise to a complaint was defective.
- Any complaint concerning a product defect should be recorded with all the original details and thoroughly investigated. The person responsible for QC should normally be involved in the review of such investigations.
- If a product defect is discovered or suspected in a batch, consideration should be given to whether other batches should be checked in order to determine whether they are also affected. In particular, other batches that may contain reprocessed product from the defective batch should be investigated.
- Where necessary, appropriate follow-up action, possibly including product recall, should be taken after investigation and evaluation of the complaint.
- All decisions made and measures taken as a result of a complaint should be recorded and referenced to the corresponding batch records.
- Complaints records should be regularly reviewed for any indication of specific or recurring problems that require attention and might justify the recall of marketed products.
- The competent authorities should be informed if a manufacturer is considering action following possibly faulty manufacture, product deterioration, a suspect product or any other serious quality problems with a product.

Product recalls

- There should be a system to recall from the market, promptly and effectively, products known or suspected to be defective.
- The authorized person should be responsible for the execution and coordination of recalls. He or she should have sufficient staff to handle all aspects of the recalls with the appropriate degree of urgency.
- There should be established written procedures, which are regularly reviewed and updated, for the organization of any recall activity. Recall operations should be capable of being initiated promptly down to the required level in the distribution chain.

- An instruction should be included in the written procedures to store recalled products in a secure segregated area while their fate is decided.
- All competent authorities of all countries to which a given product has been distributed should be promptly informed of any intention to recall the product because it is, or is suspected of being, defective.
- The distribution records should be readily available to the authorized person, and they should contain sufficient information on wholesalers and directly supplied customers (including, for exported products, those who have received samples for clinical tests and medical samples) to permit an effective recall.
- The progress of the recall process should be monitored and recorded. Records should include the disposition of the product. A final report should be issued, including a reconciliation between the delivered and recovered quantities of the products.
- The effectiveness of the arrangements for recalls should be tested and evaluated from time to time.

Contract production, analysis and other activities

- Principle. Contract production, analysis and any other activity covered by GMP must be correctly defined, agreed and controlled in order to avoid misunderstandings that could result in a product, or work or analysis, of unsatisfactory quality.
- All arrangements for contract production and analysis, including technology transfer and any proposed changes in technical or other arrangements, should be in accordance with the marketing authorization for the product concerned.
- The contract should permit the contract giver to audit the facilities and activities of the contract acceptor or mutually agreed subcontractors.
- In the case of contract analysis, the final approval for release must be given by the authorized person in accordance with GMP and the marketing authorization as specified in the contract.

The contract giver

- The PQS of the contract giver should include the control and review of any outsourced activities. The contract giver is responsible for assessing the legality, suitability and competence of the contract acceptor to successfully carry out the work or tests required, for approval for contract activities, and for ensuring by means of the contract that the principles of GMP incorporating QRM principles are followed.
- The contract giver should provide the contract acceptor with all the information necessary to carry out the contracted operations correctly in accordance with the marketing authorization and any other legal requirements. The contract giver should ensure that the contract acceptor is fully aware of any hazards associated with the product, work or tests that might pose a risk to premises, equipment, personnel, other materials or other products.
- The contract giver should review and assess the records and results related to the outsourced activities. The contract giver should ensure that all products and materials delivered by the

contract acceptor have been processed in accordance with GMP and the marketing authorization; comply with their specifications and that the product has been released by the authorized person in accordance with GMP and the marketing authorization.

- The contract giver should monitor and review the performance of the contract acceptor including the implementation of any needed improvements and their effectiveness.
- The contract giver is responsible for ensuring that the contract acceptor understands that his or her activities may be subject to inspection by competent authorities.

The contract acceptor

- The contract acceptor must have adequate premises, equipment, knowledge, experience and competent personnel to satisfactorily carry out the work ordered by the contract giver.
- Contract manufacture may be undertaken only by a manufacturer who holds a valid manufacturing authorization.
- The contract acceptor should not pass to a third party any of the work entrusted to him or her under the contract without the contract giver's prior evaluation and approval of the arrangements.
- Arrangements made between the contract acceptor and any third party should ensure that information and knowledge, including that from assessments of the suitability of the third party, are made available in the same way as between the original contract giver and contract acceptor.
- The contract acceptor should refrain from any activity (including unauthorized changes outside the terms of the contract) that may adversely affect the quality of the product manufactured and/or analysed for the contract giver.

The contract

- There must be a written contract between the contract giver and the contract acceptor which clearly establishes the responsibilities of each party, covering the outsourced activities, the products or operations to which they are related, communication processes relating to the outsourced activities and any technical arrangements made in connection with it.
- The contract must clearly state the way in which the authorized person, in releasing each batch of product for sale or issuing the certificate of analysis, exercises his or her full responsibility and ensures that each batch has been manufactured in, and checked for, compliance with the requirements of the marketing authorization.
- Technical aspects of the contract should be drawn up by competent persons with suitable knowledge of pharmaceutical technology, analysis and GMP.
- All arrangements for production and analysis must be in accordance with the marketing authorization and agreed by both parties.
- The contract should clearly describe who is responsible for contracted activities, e.g. knowledge management, technology transfer, supply chain, subcontracting, testing and releasing materials and undertaking production and QC, including in-process controls, and who has responsibility for sampling and analysis. In the case of contract analysis, the contract should state whether or not the contract acceptor should take samples at the premises of the manufacturer.

- Manufacturing, analytical and distribution records, and reference samples, should be kept by, or be available to, the contract giver. Any records relevant to assessing the quality of a product in the event of complaints or a suspected defect, or to investigating in the case of a suspected falsified product or laboratory fraud, must be accessible and specified in the procedures of the contract giver.
- The contract should describe the handling of starting materials, intermediate, bulk and finished products, if they are rejected. It should also describe the procedure to be followed if the contract analysis shows that the tested product must be rejected

The National Accreditation Board for Testing and Calibration Laboratories (NABL)

- Accreditation is the formal recognition, authorization and registration of a laboratory that has demonstrated its capability, competence and credibility to carry out the tasks it is claiming to be able to do.
- It provides feedback to laboratories as to whether they are performing their work in accordance with international criteria for technical competence.
- The concept of laboratory accreditation was developed to provide third-party certification that a laboratory is competent to perform the specific test or type of tests.
- Laboratory accreditation is a means to improve customer confidence in the test reports issued by the laboratory so that the clinicians and through them the patients shall accept the reports with confidence.
- The National Accreditation Board for Testing and Calibration Laboratories (NABL) is an autonomous body under the aegis of the Dept. of Science & Technology, Govt. of India, and is registered under the Societies Act.
- NABL, which was initially established with the objective to provide accreditation to testing & calibration laboratories, later on extended its services to the clinical laboratories in our country.
- Govt. of India has authorized NABL as the sole accreditation body for testing and calibration laboratories.
- The objective of NABL is to provide third party assessment of quality and technical competence. Four years ago NABL established links with international bodies - Asia Pacific Laboratory Accreditation Cooperation and International Laboratory Accreditation Cooperation.
- This has imparted international recognition to NABL accredited laboratories. The international standard currently followed by NABL is ISO 15189, specific for medical laboratories.
- Getting Ready for Accreditation It is very important for a laboratory to make a definite plan for obtaining accreditation and nominate a responsible person as QUALITY MANAGER (who should be familiar with the laboratory's existing quality system) to co-ordinate all activities related to seeking accreditation.

The laboratory should carry out the following important tasks towards getting ready for accreditation:

- Contact NABL Secretariat with a request for procuring relevant NABL documents (NABL Contact address and the list of NABL documents given in Annexure-3 and 1, respectively).

- Get fully acquainted with all relevant documents and understand the assessment Procedure and methodology of making an application.
- Train a person on Quality Management System and Internal Audit (4-day residential training courses conducted by NABL. Contact NABL Secretariat for details).
- Prepare QUALITY MANUAL as per ISO 15189 standards.
- Prepare Standard Operating Procedure for each investigation carried out in the laboratory.
- Ensure effective environmental conditions (temperature, humidity, storage placement, etc.).
- Ensure calibration of instruments / equipment.
- Only NABL ACCREDITED CALIBRATION LABORATORIES are authorized to provide calibration. NABL website gives the names of NABL accredited calibration laboratories in the various fields of Accreditation.
- Impart training on the key elements of documentation, such as document format, authorization of document, issue and withdrawal procedures, document review and change, etc. Each document should have ID No., name of controlling authority, period of retention, etc.
- Ascertain the status of the existing quality system and technical competence with regard to NABL standards and address the question "Is the system documented and effective OR does it need modification?".
- Remember Quality Manual is a policy document, which has to be supplemented by a set of other next level documents. Therefore ensure that these documents are well prepared.
- Ensure proper implementation of all aspects that have been documented in the Quality Manual and other documents.
- Incorporate Internal Quality Control (IQC) practice while patients' samples are analysed.
- Document IQC data as well as uncertainty of measurements. Maintain Levy Jennings charts.
- Participate in External Quality Assessment Schemes (EQAS).
- If this is not available for certain analytes, participate in inter-laboratory comparison through exchange of samples with NABL accredited laboratories.
- Document corrective actions on IQC / EQA outliers.
- Conduct Internal Audit and Management Review.
- Apply to NABL along with appropriate fee.

Accreditation Process

- An applicant laboratory is expected to submit to NABL 5 copies of the application and 5 copies of Quality Manual.
- The Quality Manual will be forwarded by NABL to a Lead Assessor to judge the adequacy of the Quality Manual as to whether it is in compliance with ISO 15189 standards.
- Thereafter the Lead Assessor will conduct a Pre- Assessment of the laboratory for one day. Based on the Pre-Assessment report the laboratory may have to take certain corrective actions, so as to be fully prepared for the final assessment.

- It is essential for the applicant as well as accredited laboratories to satisfactorily participate in Proficiency testing/ Interlaboratory comparisons/External quality assessment programme as Asia Pacific Laboratory Accreditation Cooperation (APLAC) Mutual Recognition Arrangement calls for mandatory participation in such programmes.
- Finally when the laboratory is ready, the Lead Assessor and a team of technical assessors will conduct the final assessment. The number of technical assessors will depend on the number of disciplines applied for.
- The accreditation process involves a thorough assessment of all the elements of the laboratory that contribute to the production of accurate and reliable test data. These elements include staffing, training, supervision, quality control, equipment, recording and reporting of test results and the environment in which the laboratory operates. The laboratory may have to take certain corrective actions, after the final assessment.
- After satisfactory corrective actions are taken by the laboratory (within a period of 3 months), the Accreditation Committee will examine the report and if satisfied recommend accreditation.
- The time required for the process of accreditation will depend upon the preparedness of the laboratory and its response to the non - conformances raised during the pre-assessment and final assessment. The total duration ranges between 6 and 8 months.

Surveillance and Re-Assessment

- Accreditation to a laboratory shall be valid for a period of three years. NABL shall conduct annual surveillance of the accredited laboratories. The laboratories may enhance or reduce the scope of accreditation during surveillance.
- The laboratories need to apply for renewal of accreditation, at least six months before the expiry of validity of accreditation for which a re-assessment shall be conducted.

Food Safety and Standards Authority of India (FSSAI)

- The Food Safety and Standards Authority of India (FSSAI) has been established under Food Safety and Standards Act, 2006 which consolidates various acts & orders that have hitherto handled food related issues in various Ministries and Departments.
- FSSAI has been created for laying down science based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import to ensure availability of safe and wholesome food for human consumption.

Highlights of the Food Safety and Standard Act, 2006

- Various central Acts like Prevention of Food Adulteration Act, 1954 , Fruit Products Order , 1955, Meat Food Products Order , 1973, Vegetable Oil Products (Control) Order, 1947,Edible Oils Packaging (Regulation)Order 1988, Solvent Extracted Oil, De- Oiled Meal and Edible Flour (Control) Order, 1967, Milk and Milk Products Order, 1992 etc will be repealed after commencement of FSS Act, 2006.
- The Act also aims to establish a single reference point for all matters relating to food safety and standards, by moving from multi- level, multi- departmental control to a single line of command.
- To this effect, the Act establishes an independent statutory Authority – the Food Safety and Standards Authority of India with head office at Delhi. Food Safety and Standards Authority of India (FSSAI) and the State Food Safety Authorities shall enforce various provisions of the Act.

- **Establishment of the Authority**
  - Ministry of Health & Family Welfare, Government of India is the Administrative Ministry for the implementation of FSSAI.
  - The Chairperson and Chief Executive Officer of Food Safety and Standards Authority of India (FSSAI) have already been appointed by Government of India. The Chairperson is in the rank of Secretary to Government of India.

FSSAI has been mandated by the FSS Act, 2006 for performing the following functions:

- Framing of Regulations to lay down the Standards and guidelines in relation to articles of food and specifying appropriate system of enforcing various standards thus notified.
- Laying down mechanisms and guidelines for accreditation of certification bodies engaged in certification of food safety management system for food businesses.
- Laying down procedure and guidelines for accreditation of laboratories and notification of the accredited laboratories.
- To provide scientific advice and technical support to Central Government and State Governments in the matters of framing the policy and rules in areas which have a direct or indirect bearing of food safety and nutrition .
- Collect and collate data regarding food consumption, incidence and prevalence of biological risk, contaminants in food, residues of various, contaminants in foods products, identification of emerging risks and introduction of rapid alert system.
- Creating an information network across the country so that the public, consumers, Panchayats etc receive rapid, reliable and objective information about food safety and issues of concern.
- Provide training programmes for persons who are involved or intend to get involved in food businesses.
- Contribute to the development of international technical standards for food, sanitary and phyto-sanitary standards.
- Promote general awareness about food safety and food standards.

List of Possible Questions

1. Explain Good Laboratory Practices (GLP)
2. Write about the objectives of GLP
3. Write the mission of GLP
4. What is meant by Standard Operating Procedure (SOP)
5. Discuss in detail GMP
6. Explain the significance of NABL
7. Give a detailed account on Food Safety and Security Act 2006.

Unit I	A	B	C	D	Ans
Intellectual Property Rights (IPR) protect the use of information and ideas that are of	Ethical value	Moral value	Social value	Commercial value	Commercial value
The term ‘Intellectual Property Rights’ not covers	Copyrights	Know-how	Trade dress	goods value	goods value
The following can not be exploited by assigning or by licensing the rights to others	Patents	Designs	Trademark	All of the above	Trademark
The following can not be patented	Machine	Process	Composition of matter	milk	milk
Trade mark is not	represented graphically	capable of distinguishing the goods or services of one	includes shapes of goods or combination of colours	applicablefor every item for sale	applicablefor every item for sale
Which of following would not gain copyright protection?	A DVD	An unrecorded speech	Written lyrics of a song	books	An unrecorded speech
What is the duration of copyright protection for a novel?	A novel will not gain copyright protection.	The day the author dies	The end of the calendar year in which the author died.	70 years from the end of the calendar year in which the author died.	70 years from the end of the calendar year in which the author died.
Which one of the following actions is not a breach of copyright?	To import copied CDs	To make a copy of a CD and sell it.	To borrow a CD from a friend and copy it to your laptop for your own private use	To purchase a CD and copy it to your laptop for your own private use.	To purchase a CD and copy it to your laptop for your own private use.

Which of the following is not one of the three essential elements for a patent to be granted for an invention?	Be a product.	Be new to the public.	Involve an inventive step.	Be capable of industrial application.	Be a product.
Which one of the following statements is true?	A patent must be registered in order to gain protection.	Copyright must be registered in order to gain protection.	The owner of a patent cannot sell it but can prevent others using his invention.	The definition of an invention is set out in the Patents Act 1977.	A patent must be registered in order to gain protection.
The law governing registered trade marks can be found in which Act?	The Intellectual Property Act 1994.	Copyright, Designs and Patents Act 1988.	The Registered Trade Marks Act 1994.	The Trade Marks Act 1994.	The Trade Marks Act 1994.
Which one of the following could not be registered as a trade mark?	The mark is an image.	The mark is made up of letters and numbers.	The mark is made up of a symbol with no words or letters.	The mark represents the natural or technical shape of the goods.	The mark represents the natural or technical shape of the goods.
Which one of the following statements is false?	The maximum duration for an unregistered design right is 15 years.	A registered design right may cover 2 dimensional and 3 dimensional objects.	A registered design right only applies to 3 dimensional objects.	The maximum duration for a registered design right is 25 years.	A registered design right only applies to 3 dimensional objects.
Unless a contract provides otherwise, who is the first owner of a design right created on or after 1 October 2014?	The person who commissioned the design.	The manufacturer of the design.	The government.	The designer.	The designer.

The tort of passing off is governed by which statute?	The Passing-off Act 1977.	The Tort Act 1977.	The Unfair Contract Terms Act 1977.	There is no statute that governs the law of passing-off.	There is no statute that governs the law of passing-off.
International organization with objective to encourage creative activity and to promote intellectual property throughout world is	WIPO	UPU	IBRD	UNDP	WIPO
World Intellectual Property Organization was established in	14-Mar-59	14 July, 1967	14-Aug-65	14-Oct-60	14-Jul-67
World Intellectual Property Organization is specialized agency of	United Nations	United Nations Security Council	United nations Economic Council	United Nations Social Council	United Nations
First World Intellectual Property Organization on Changing Face of Innovation was published in	2005	2007	2011	2009	2011
Headquarter of World Intellectual Property Organization is located in	Rome, Italy	Bern, Switzerland	Berlin, Germany	Geneva, Switzerland	Geneva, Switzerland
The present Copyright Act in India came to force in	1957	1987	1894	1953	1957
In which of the article the TRIPS agreement deals with Copyright and related matters ?	Article 9-14	Article 20-24	Article 2-8	Article 14-20	Article 9-14
The WIPO was established in the year	1987	1925	1970	1956	1970
The copyright board shall be deemed to be a	Supreme Court	Civil Court	High Court	Criminal Court	Civil Court
The term of the copyright in anonymous and pseudonymous is	60 years	15 years	25 years	45 years	60 years

The present Copyright Act in India came to force in	1947	1957	1967	1977	1957
Which one of the following is not coming under copyright?	Books	Computer Program	Brand	Cinem a	Brand
The Name Kanchipuram Silks comes under the division	Copyright	Geographic al indication	Trade mark	Patent	Geographic al indication
Expansion of WIPO is	World infringement property Organization	World inter patent Organizatio n	World intel patent Organization	World invesment property Organ ization	World infringement property Organization
Which one of the following is included in Geographical indication of Goods ?	Handicrafts	Foodstuff	Manufactured product	All of the above	All of the above
The Validity of a Patent is	10 years	20 years	30 years	40 years	20 years
World Intellectual Property Organization was established in	14-Mar-59	14-Aug-65	14-Oct-60	14-Jul-67	14-Jul-67
World Intellectual Property Organization is specialized agency of	United Nations	United Nations Security Council	United nations Economic Council	United Nations Social Council	United Nations
WIPO copyright treaty established in the year	1996	1990	1998	1993	1996
Indian patent right established in	1965	1975	1970	1985	1970
Indian patent right is a background of which country ?	USA	England	UAE	Germany	England
The Statutory life of Patent is 20 years from the	date of completion	date of establishmen t	date of filling of the ap plication	date of acceptance	date of filling of the ap plication
The Country which deals with DNA Sequence in plant species for patent is	India	Japan	Spain	USA	USA

Musical, Literary artistic works , photographs , computer software comes under	Patent	Designs	Copyright	layouts	Copyright
Recent Patent act was amended in the year	2013	2009	2005	2007	2005
TRIPS means	Trade required intellectual product	Trade related intellectual property	Trade related inter probes	Trace related intellectual property	Trade related intellectual property
Patent can be revoked in India	Yes	No	Yes in some cases	none of the above	Yes in some cases
Computer program is considered as	Literary work	artistic work	station work	none of the a bove	Literary work
Plan of a building can be protected by	Trade mark	Law	Copy right	Patent	Copy right
Genetically engineered mice have been granted patent by	Belgium and Finland	India and US	German and It aly	Russia and Africa	Belgium and Finland
Patent ,design and trademark was govern by	Ministry of Law	Ministry of Law and social justice	Ministry of Commerce and industri es	Ministry of Labour	Ministry of Commerce and industri es
A USA patent was taken for	Basmati rice	Lerma Roja	CO-668	Sharbati Sonara	Basmati rice
Patents are classified into how many types ?	4	3	8	9	8
The design act of 1911 was replaced by design act	2000	2002	2005	2009	2000
Trademark act passed in the year	1998	1999	1987	1989	1999
WTO head office located in	Geneva	Delhi	London	Moscow	Geneva
Symbol of Maharaja of Air India is	Copyright	Patent	Trademark	All of the a bove	Trademark
Berne Convention held in the year	1887	1889	1886	1890	1886

If you file provisional specification, the complete specification is required to be filed within	8 months	10 months	12 months	18 months	12 months
Plant varities patent comes under the ministry of	Agriculture	law	Justice	Researc h and Development	Agriculture
Utility Model protection is available in which country	USA	China	German	All the a bove	All the a bove
set standards used to regulate own or community activity in relation to biological world is	Biopotency	Biowar	Bioethics	Biopiracy	Bioethics
National application office in India for patent receiving in	Chennai	Gujarat	New Delhi	Mumbai	New Delhi
Commercial use domain names will normally use the following suffix in their website address.	.net	.org	.com	.edu	.com
Utility model protects	Creation	Invention	Design	All the a bove	Invention

UNIT II

'Emerging market' refers to:	Any developing country	A fast-growing developing country	Any growing consumer market	China and India	A fast-growing developing country
In the following list of ways by which governments exert control over businesses, which one is out of place?	Full ownership of a company	Partial stake in a public company	Privatization of a nationalized company	Sovereign wealth fund	Privatization of a nationalized company
Over which of the following does the MNE parent company have most control?	A wholly-owned subsidiary	An affiliate company	A strategic partner	A subsidiary in which it owns 60% of the shares	A wholly-owned subsidiary
"Research is an organized and systematic enquiry" Defined by	a) Marshall	b) P.V. Young	c) Emory	d) Kerlinger	Emory

Research is a “Scientific undertaking” opined by	a) Young	b) Kerlinger	c) Kothari	d) Emory	a) Young
“A systematic step-by-step Procedure following logical process of reasoning” called	a) Experiment	b) Observation	c) Deduction	d) Scientific method	d) Scientific method
Ethical Neutrality is a feature of	a) Deduction	b) Scientific method	c) Observation	d) experience	b) Scientific method
Scientific method is committed to …….	a) Objectivity	b) Ethics	c) Proposition	d) Neutrality	a) Objectivity
“One of the methods of logical reasoning process” is called	a) Induction	b) Deduction	c) Research	d) Experiment	a) Induction
The method by which a sample is chosen	a) Unit	b) design	c) Random	d) Census	b) design
Basing conclusions without any bias and value judgment is ……	a) Objectivity	b) Specificity	c) Values	d) Facts	a) Objectivity
Research is classified on the basis of …….. and methods	a) Purpose	b) Intent	c) Methodology	d) Techniques	b) Intent
Research undertaken for knowledge sake is	a) Pure Research	b) Action Research	c) Pilot study	d) Survey	a) Pure Research
Example for fact finding study is	a) Pure Research	b) Survey	c) Action Research	d) Long term Research	b) Survey
Research conducted to find solution for an immediate problem is …….	a) Fundamental Research	b) Analytical Research	c) Survey	d) Action Research	d) Action Research
Motivation Research is a type of …… research	a) Quantitative	b) Qualitative	c) Pure	d) applied	b) Qualitative
Research related to abstract ideas or concepts is	a) Empirical research	b) Conceptual Research	c) Quantitative research	d) Qualitative research	b) Conceptual Research
A research which follows case study method is called	a) Clinical or diagnostic	b) Causal	c) Analytical	d) Qualitative	a) Clinical or diagnostic

Research conducted in class room atmosphere is called	a) Field study	b) Survey	c) Laboratory Research	d) Empirical Research	c) Laboratory Research
Research through experiment and observation is called	a) Clinical Research	b) Experimental Research	c) Laboratory Research	d) Empirical Research	d) Empirical Research
Population Census is an example of …….. Research	a) Survey	b) Empirical	c) Clinical	d) Diagnostic	a) Survey
…….. is a way to systematically solve the research problem	a) Technique	b) Operations	c) Research methodology	d) Research Process	c) Research methodology
Good Research is always ……	a) Slow	b) Fast	c) Narrow	d) Systematic	d) Systematic
Research method is a part of ……..	a) Problem	b) Experiment	c) Research Techniques	d) Research methodology	d) Research methodology
Identifying causes of a problem and possible solution to a problem is	a) Field Study	b) diagnosistic study	c) Action study	d) Pilot study	b) diagnosistic study
…… is a motivation for research in students	a) Research degree	b) Research Academy	c) Research Labs	d) Research Problems	a) Research degree
Which of the following is an example of primary data?	a) Book	b) Journal	c) News Paper	d) Census Report	c) News Paper
JRF is for	a) Junior Research Functions	b) Junior Research Fellowship	c) Junior Fellowship	d) None of the above	b) Junior Research Fellowship
…….. is the first step of Research process	a) Formulation of a problem	b) Collection of Data	c) Editing and Coding	d) Selection of a problem	d) Selection of a problem
Converting a question into a Researchable problem is called ……	a) Solution	b) Examination	c) Problem formulation	d) Problem Solving	c) Problem formulation
While Selecting a problem, problem which is …….. is no taken	a) Very Common	b) Overdone	c) Easy one	d) rare	b) Overdone

The first step in formulating a problem is	a) Statement of the problem	b) Gathering of Data	c) Measurement	d)Survey	a) Statement of the problem
Second step in problem formulation is	a) Statement of the problem	b) Understanding the nature of the problem	c) Survey	c) Survey the available literature	b) Understanding the nature of the problem
Third step in problem formulation is	a) Statement of the problem	b) Understanding the nature of the problem	c) Survey	c) Survey the available literature	c) Survey the available literature
Fourth step in problem formulation is	a) Develop ideas through discussion	b) Survey	c) Statement of problem	Enactment	a) Develop ideas through discussion
Last step in problem formulation is	a) Survey	b) Discussion	c) Literature survey	d) Re Phrasing the Research problem	d) Re Phrasing the Research problem
In the formulation of the problem we need to give a …….	a) Title	b) Index	c) Bibliography	d) Concepts	a) Title
Concepts are ……. of Research	a)guide	b) tools	c)methods	d) Variables	b) tools
A Hypothesis which develops while planning the research is	a) Null Hypothesis	b) Working Hypothesis	c) Relational Hypothesis	d)Descriptive Hypothesis	b) Working Hypothesis
When a hypothesis is stated negatively it is called	a) Null Hypothesis	b) Working Hypothesis	c) Relational Hypothesis	d)Descriptive Hypothesis	a) Null Hypothesis
The first variable is …….. variable	a) Abstract	b) Dependent	c) Independent	d) Separate	c) Independent
The second variable is called ……	a) Abstract	b) Dependent	c) Independent	d) Separate	b) Dependent
Hypothesis concerned with analytical variable is	a) Null Hypothesis	b) Working Hypothesis	c) Relational Hypothesis	d)Analytical Hypothesis	d)Analytical Hypothesis

…….. from theory leads to Hypothesis	a) Deduction	b) induction	c) Logical deduction	d) Observation	c) Logical deduction
Statistical Hypothesis is derived from	a) Frame	b) Data	c) Sample	d) Facts	b) Data
The first purpose of a survey is to ……..	a) Description	b) Evaluation	c) Propagation	d) Provide Information	d) Provide Information
In a survey the number questions is	a) Unlimited	b) limited	c) Both limited and un limited	d) None of the above	b) limited
A Research Report is a formal statement of …….	a) Research Process	b) Research Problem	c) Data collection	d) Data Editing	a) Research Process
Technical Report is otherwise called	a) Interim Report	b) Popular Report	c) Thesis	d) Summary	c) Thesis
A short summary of Technical Report is called	a) Article	b) Research Abstract	c) Publication	d) Guide	b) Research Abstract
Bibliography means	a) Foot Note	b) Quotations	c) List of Books referred	d) Biography	c) List of Books referred
Data related to human beings are called	a) Territorial data	b) Organizational data	c) Peripheral data	d) Demographic data	d) Demographic data
Data related to geophysical characteristics are called	a) Territorial data	b) Organizational data	c) Peripheral data	d) Demographic data	a) Territorial data
Probability sampling is otherwise called	a) Multiple choice	b) Uni-variate Analysis	c) Random Sampling	d) Bi-variate Analysis	b) Uni-variate Analysis
Office Editing and …….. are two types of Editing in Research	a) Lab editing	b) Field Editing	c) Class Roam Editing	d) Book Editing	b) Field Editing
Summarizing raw data and displaying them on compact statistical tables for analysis is	a) Tabulation	b) Coding	c) Transcription	d) Editing	a) Tabulation
Camera, tape recorder, video tape etc are ……. Devices of observation	a) Casual	b) Mechanical	c) Technical	d) Manual	b) Mechanical

The Friendly relationship between Interviewer and respondent is called	a) Morale	b) Managemen t	c) Rapport	d) Conclusion	c) Rapport
An example of non-personal method of Data collection is	a) Interview	b) Group Interview	c) Schedule	d) Telephone Interview	d) Telephone Interview
Questionnaire is filled by …….	a) Respondent	b) Everybody	c) Enumerator	d) None of the above	a) Respondent
A member of the population is called ……	a) Element	b) Census	c) Sample	d) Group	a) Element
An example of probability sampling is	a) Quota Sampling	b) Snow-ball sampling	c) Purposive sampling	d) Lottery method	d) Lottery method
In which sample population is divided into different strata and sample is taken from different strata	a) Quota Sampling	b) Snow-ball sampling	c) Stratified sampling	d) Lottery method	c) Stratified sampling
Assigning numerals or other symbols to the categories or response is called	a) Editing	b) Coding	c) Transcription	d) calculating	b) Coding

UNIT III

In most colleges, microbiology	Standard	Biosafety	Biosafety Level 3	Biosafety	Standard
Laboratory workers handling	Standard	Biosafety	Biosafety Level 3	Biosafety	Biosafety Level 4
The process by which all living	Antisepsis	Disinfection	Sanitation	Sterilization	Sterilization
A process that kills, inhibits, or	Antisepsis	Disinfection	Sanitation	Sterilization	Disinfection
A process that destroys or inhibits	Antisepsis	Disinfection	Sanitation	Sterilization	Antisepsis
A process that reduces microbes	Antisepsis	Disinfection	Sanitation	Sterilization	Sanitation
The time required for a control	The contact	The D value	The Z value	None of the	The D value
A microbe is considered to be	The cell wall	The cell is	It does not grow	None of the	It does not grow
Which of the following microbial	Sterilization	Disinfection	Sanitation	Antisepsis	Sterilization
Which of the following factors	Contact time	Concentrati	Composition of	All of the	All of the above
Which of the following	Ability to form a	Acidic	Presence of	All of the	All of the above
Moist heat readily destroys	Inhibiting	Denaturing	Lysing cells	Damaging the	Denaturing nucleic
A common form of moist heat	Boiling water	The hot	The autoclave	Ultraviolet	The autoclave
The practice of heating food and	Tyndallization	Autoclaving	Antisepsis	Pasteurizatio	Pasteurization

A practice that physically removes	Filtration	Pasteurizati	Dry heat	Antisepsis	Filtration
N-95 masks exclude	All microbes	95% of	95% of microbes	50% of	95% of microbes
A high-efficiency particulate air	All particles	All particles	99.97% of	None of the	99.97% of
Ultraviolet (UV) radiation is an	It oxidizes	It damages	It damages the cell	All of the	It damages DNA
Sterilization of meats and foods	Ultraviolet	Ionizing	Dry heat	Autoclaving	Ionizing radiation
Phenolics act on microbes by	Dissolving	Denaturing	Oxidizing cellular	Precipitate	Denaturing
The most widely used group of	Phenols	Alcohols	Halogens	Heavy metals	Alcohols
Halogens act on microbes by	Dissolving	Denaturing	Oxidizing cellular	Precipitate	Oxidizing cellular
Quaternary ammonia compounds	Denaturing	Dissolving	Oxidizing cellular	Precipitate	Denaturing
Which of the following is an	Ethylene oxide	Betapropiol	Vaporized	All of the	All of the above
Which agency is responsible for		Environment	Food and Drug	World Health	Environmental
An example of an in-use test to	National	The Z value	The standard	The phenol	The phenol
UNESCO created International	The D value	1973	1993	2003	1993
The ‘Cartagena Protocol on	1970	1990	1980	2000	2000
The exhaust air would be	Class I BSC	Class II	Class III BSC	Class IV BSC	Class III BSC
The inward air would be	Class I BSC	Class II	Class III BSC	Class IV BSC	Class III BSC
Infectious agents must be handled	Class I BSC	Class II	Class III BSC	Class IV BSC	Class III BSC
Non-infectious agents would be	Class I BSC	Class II	Class III BSC	Class IV BSC	Class I BSC
Infectious agents for which	Biosafety Level	Biosafety	Biosafety Level III	Biosafety	Biosafety Level III
Infectious agents for which	Biosafety Level	Biosafety	Biosafety Level III	Biosafety	Biosafety Level IV
The non-infectious agents could	Biosafety Level	Biosafety	Biosafety Level III	Biosafety	Biosafety Level I
The infectious agents that would	Biosafety Level	Biosafety	Biosafety Level III	Biosafety	Biosafety Level II
The exhaust air only filtered in	Class I BSC	Class II	Class III BSC	Class IV BSC	Class I BSC
The exhaust and as well inward air	Class I BSC	Class II	Class III BSC	Class IV BSC	Class II BSC
The lab having anteroom with	Biosafety Level	Biosafety	Biosafety Level III	Biosafety	Biosafety Level IV
PPPS is essential to work in	Biosafety Level	Biosafety	Biosafety Level III	Biosafety	Biosafety Level IV
Which of the following	Bacillus subtilis	Hepatitis A	Mycobacterium	Ebola virus	Bacillus subtilis
Which of the following	Bacillus subtilis	Hepatitis A	Mycobacterium	Ebola virus	Hepatitis A
Which of the following	Bacillus subtilis	Hepatitis A	Mycobacterium	Ebola virus	Mycobacterium
Which of the following	Bacillus subtilis	Hepatitis A	Mycobacterium	Ebola virus	Ebola virus
The ‘Human Immunodeficiency	Risk group 1	Risk group	Risk group 3	Risk group 4	Risk group 2
The ‘Flavivirus’ belongs to	Risk group 1	Risk group	Risk group 3	Risk group 4	Risk group 4
When you are mixing or heating	Gloves	Goggles	Gloves and	Jogging shoes	Gloves and
If you met an accident like injury,	Report to	Run	Hide	Leave lab	Report to teacher
If a chemical get into your mouth	Spit it out	Rinse your	Visit a doctor	All of them	All of them
Typical common apparatus used	Stove	Bunsen	Lantern	Woods	Bunsen burner

What was the contribution of	Physcian who	Discovered	Man who	None of them	Discovered the
Which of the following involves	Biosafety	Biosecurity	Bioethics	BSC	Biosafety
Which of the following is not the	Create safety	Train users	Care and	Report	Care and
Which of the following is not the	Purchase	Participate	Observe safety	Report	Purchase poersnal
Who publishes the Laboratory	Public Health	CFIA	PHAC	Canadian	Public Health
Who published the Containment	Public Agency	CFIA	PHAC	Canadian	CFIA
Commercial use domain names	.net	.org	.com	.edu	.com
Utility model protects	Creation	Invention	Design	All the a bove	Invention
Which of the following statement	Standard error	Standard	Standard error is	Standard	Standard error is
Random sampling is also known	Probability	Non-	Sampling error	Random error	Probability
Non-random sampling is also	Biased sampling	Non-	Sampling error	Random error	Non-probability

UNIT IV

The worldwide increase of development and use of new technology to increase the yield of food crops is termed the	Industrial Revolution	Agricultural Revolution	Green Revolution	Medical Revolution	Green Revolution
The greatest single disadvantage of planting a single crop would be	Monoculture	Soil erosion	Attraction of pests	Depletion of soil nutrients	Depletion of soil nutrients
Plants which are able to synthesize their own food substances are called	Autotrophs	Heterotrophs	Saprophytes	Anaerobes	Autotrophs
A condition when fields remain unplanted for several years in order to regain moisture and nutrients.	Rotation	Terracing	Fallowing	Desertification	Fallowing
The range of animal and plant species and the genetic variability of these species are referred to as	Biosphere	Biodiversity	Survival of the fittest	Biomagnification	Biodiversity
The continent with the most serious food shortages is	Europe	Africa	Australia	South America	Africa
Food quantity is expected to increase due primarily to	Increased yields	Increased cropping intensities	Arable land expanses	Red Cross donations	Increased yields

Which of the following are tools used in risk analysis?	toxicology	Epidemiology	Clinical trials	All of the above	All of the above
An organism containing a gene which doesn't belongs to it and is derived from somewhere else then the organism is said to be	Transformed	Transgenic	Mutant	Modified	Transgenic
E.coli is a	Gram negative bactrium	Gram positive bactrium	Not bacterium	Virus	Gram negative bactrium
If a host other than E.coli is to be used, what property of DNA to be inserted is disadvantageous?	Circular DNA	Linear DNA	Replicating DNA	Non Relicating DNA	Replicating DNA
If plasmids direct their own transfer from one bacterium cell to another, then they are called as:	Self-transmissible	Auto - transmissible	Autonomously replicating	Auto transfer	Self-transmissible
If a plasmid can't be transferred from one cell to another, then it is called as	Non-transmissible	Non-mobilizable	Untransferrable	Immobilized	Non-mobilizable
Choose the incorrect statement for shuttle vectors.	These are vector hybrids constructed from E.coli and other plasmids	They are having a varied use	They can replicate and selected in both the species	They are the plasmids which are having naturally broad host range	They are the plasmids which are having naturally broad host range
Which of the bacteria are used as hosts?	Gram positive only	Gram negative only	Both are preferred equally	Both can be used but gram positive is preferred	Both can be used but gram positive is preferred
Basically, there are how many methods for introduction of DNA into the bacterial cells?	1	2	3	4	3

Competence is determined by the excretion of	Cellular high molecular weight proteins	Cellular low molecular weight proteins	Extracellular low molecular weight proteins	Extracellular high molecular weight proteins	Extracellular low molecular weight proteins
What are protoplasts?	Protoplasts are the cells from which cell membrane has been removed	Protoplasts are the cells from which cell wall has been removed	Protoplasts are the cells from which vacuole has been removed	Protoplasts are the cells from which golgi bodies are removed	Protoplasts are the cells from which cell wall has been removed
The plasmid that is transferred by conjugation is known as	Cargo	Conjugal	Helper	Vector	Cargo
The cargo plasmid relies on other plasmid known as	Cargo	Conjugal	Helper	Vector	Conjugal
The transfer of plasmid from one bacterial cell to another when cargo and conjugal plasmids are used, it is usually is carried out by	Diparental mating	Uniparental mating	Triparental mating	Multiparental mating	Triparental mating
Technique of inserting deoxyribonucleic acid (DNA) into plants is known as	Bio injection	Bio fission	Bio genetic	Bio diffusion	Bio fission
Transformation method of plants and animals in which plants and animals are given shocks is known as	Microinjection	Genome breeding	Electroporation	Genome engineering	Electroporation
Technique of inserting DNA into animal cells is known as	Microinjection	Macro injection	Fusion injection	Genome injection	Microinjection
Element which allows easy visualization of genetic modification products is known as	Green fluorescent protein	Blue fluorescent protein	White fluorescent protein	Red fluorescent protein	Green fluorescent protein

Traditional breeding methods are	Selective	Cell fusion	Mutation breeding	All of the above	All of the above
Which toxic is used to protect plants from insects?	Blue green bacteria	Bacterium Bacillus thuringinsis	Acidobacteria	Proteobacteria	Bacterium Bacillus thuringinsis
Bt Stands for	Genetically Modified Crops	Bacterium bacillus Theogin	Bacterium Bacillus thuringiensis	Bacteria Bacili thuringien	Bacterium Bacillus thuringiensis
Bt reduce use of	Fertizers	pesticides	seeds	Manure	pesticides
What is GM crops?	Genetically Modified Crops	Genetically poor crops	Gene pool	Nomadic crops	Genetically Modified Crops
Asia uses what percentage of water for agricultural purpose?	85%	88%	81%	83%	85%
Anti-viral proteins that are produced by virus infected cells are called	Interferon	Thymosin	Beta-endorphin	Urokinese	Interferon
A vector is used to	Transfer gene	Copy a gene	Produce a gene	Remove a gene	Transfer gene
In 1977 an E.coli was created to synthesize	Animal growth hormone	Plant growth hormone	Human growth hormone	Human reproductive hormone	Human growth hormone
Ligase is a	Breaking enzyme	Joining enzyme	Releasing enzyme	Removing enzyme	Joining enzyme
The disease crown gall is caused by which bacteria?	Agrobacterium tumefaciens	Agrobacterium rhizogenes	Both of the above given bacterium cause the disease crown gall	Any bacteria belonging to genera Rhizobium	Agrobacterium tumefaciens
Agrobacterium tumefaciens form _____ plasmids	Root inducing	Tumour inducing	Shoot inducing	Leaf inducing	Tumour inducing
Agrobacterium rhizogenes form _____ plasmids.	Root inducing	Tumour inducing	Shoot inducing	Leaf inducing	Root inducing

The region which is transferred from bacterium to the nucleus of the plant cell is called as	T-DNA	A-DNA	B-DNA	Z-DNA	T-DNA
Transfer of T-DNA depends on a set of genes called as	Vir	Chv	Tum	Chromosome	Chv
What is the function of onc genes in T-DNA?	Tumour suppressing potential	Tumour inducing potential	Tumour suppressing potential	Act as replicative genes	Tumour inducing potential
Which of the plant growth regulators are produced by T-DNA?	Salicyclic acid	Cytokinin	Cytokinin nad Auxin	Jasmonic acid	Cytokinin nad Auxin
If a small intermediate vector system is used along with a selectable marker, then it is called as:	Fusion plasmids	Hybrid plasmids	Co-integrative plasmids	Complex plasmids	Co-integrative plasmids
If transfer of DNA from Agrobacterium to plants is done via incubation of explanted material and the vector containing DNA of interest and then selection is done via selectable marker then this method is called as	Transformation	Co-cultivation	Co-transformation	Floral dipping	Co-cultivation
If gene of interest is inserted into protoplasts but the transformation is not stable, then it is called as _____ expression systems.	Permanent	Temporary	Transient	Unstable	Transient
35S promoter is obtained from	Tobacco mosaic virus	Cauliflower mosaic virus	Agrobacterium	Arabdopsis	Cauliflower mosaic virus
What is the function of glyphosate?	It is a fungicide	It is an herbicide	It is an enzyme used in place of glucose as a carbon source	It is used for adding phosphate groups	It is an herbicide

Baciullus thuringiensis is used for production of toxins which can be used as	Insecticides	Pesticides	Germicides	Fungicides	Insecticides
Which of the following compounds control ripening in tomatoes?	Auxin	Cytokinin	Ethylene	Jasmonic acid	Ethylene
A recombinant DNA molecule is produced by	Joining of two DNA fragments	Joining of three DNA fragments	Joining of many DNA fragments	Joining of two or more DNA fragments originating from different organisms	Joining of two or more DNA fragments originating from different organisms
The gene formed by the joining of DNA segments from two different sources are called as	Recombinant gene	Joined gene	Both A and B	Chimeric gene	Chimeric gene
Which of the following enzyme is used to cut DNA molecule in rDNA technology	Ligase	Phosphatase	Ribonuclease	Restriction enzymes	Restriction enzymes
Restriction enzymes are also called as	Biological scissors	Molecular scalpels	Molecular knives	All of the above	Biological scissors
The most important discovery that lead to the development of rDNA technology was	Double helix model of Watson and Crick	Discovery of restriction enzymes	Discovery of ligaese enzymes c	Discovery of plasmid	Biological scissors
Energy source of the cell	ATP	ADP	NADP	NADH	ATP
Who created the first rDNA molecules	Nathan, Arber and Smith	Watson, Crick and Wilkins	Boyer and Cohen	Palul Berg	Palul Berg
The DNA molecule to which the gene of insert is integrated for cloning is called	Carrier	Transformer	Vector	Transporter	Vector

The DNA segment to be cloned is called	Gene segment	DNA fragment	DNA insert	All of these	DNA insert
Which of the following statements are true regarding rDNA technology	rDNA technology is used to obtain larger number of copies of specific DNA fragments	rDNA technology is used to obtain large quantity of the protein	rDNA technology is used to integrate genes into chromosomes	all of the above	rDNA technology is used to integrate genes into chromosomes
For cloning to occur, plasmid of bacteria must be cut by	Restriction enzymes	Polymerase enzymes	Helicase enzyme	Gyrase enzyme	Restriction enzymes
A technique that measures degree of genetic similarity between pools of DNA sequences is called	Annealing	Denaturing	Hybridization	Folding	Hybridization

UNIT V

Sample is a sub-set of:	Population	Data	Set	Distribution	Population
Any population constant is called as	Statistic	Parameter	Estimate	Estimator	Parameter
List of all the units of the population is called	Random sampling	Bias	Sampling frame	Probability sampling	Sampling frame
Any calculation on the sampling data is called	Parameter	Static	Bias	Error	Static
Any measure of the population is called:	Finite	Parameter	Without replacement	Random	Parameter
If all the units of a population are surveyed, it is called	Random sample	Random sampling	Sampled population	Complete enumeration	Complete enumeration
Probability distribution of a statistics is called	Sampling	Parameter	Data	Sampling distribution	Sampling distribution
The difference between a statistic and the parameter is called	Probability	Sampling error	Random	Non-random	Sampling error

The sum of the frequencies of the frequency distribution of a statistic is equal to	Sample size	Population size	Possible samples	Sum of X values	Possible samples
Standard deviation of sampling distribution of a statistic is	Serious error	Dispersion	Standard error	Difference	Standard error
A distribution formed by all possible values of a statistics is called	Binomial distribution	Hypergeometric distribution	Normal distribution	Sampling distribution	Sampling distribution
In probability sampling, probability of selecting an item from the population is known and is	Equal to zero	Non zero	Equal to one	All of the above	Non zero
A population about which we want to get some information is	Finite population	Infinite population	Sampling population	Target population	Target population
The population consists of the results of repeated trials is named as	Finite population	Infinite population	Hypothetical population	Target population	Hypothetical population
A population consisting of the items which are all present physically is called	Real population	Infinite population	Sampling population	Target population	Real population
Sampling based upon equal probability is called	Probability sampling	Systematic sampling	Simple random sampling	Stratified random sampling	Simple random sampling
In sampling with replacement, an element can be chosen	Less than once	More than once	Only once	All of the above	More than once
In sampling without replacement, an element can be chosen	Less than once	More than once	Only once	All of the above	Only once
In sampling with replacement, the following is always true	n = N	n < N	n > N	All of the above	All of the above
Which of the following statement is true?	Standard error is always one	Standard error is always zero	Standard error is always negative	Standard error is always positive	Standard error is always positive

Random sampling is also known as	Probability sampling	Non-probability sampling	Sampling error	Random error	Probability sampling
Non-random sampling is also called	Biased sampling	Non-probability sampling	Sampling error	Random error	Non-probability sampling
Sampling error can be reducing by	Increasing the population	Increasing the sample size	Decreasing the sample size	Decreasing the population	Increasing the sample size
A complete list of all the sapling units is termed as	Sampling design	Sampling frame	Population frame	Cluster	Sampling frame
A Plan for obtaining a sample from a population is	Population design	Sampling design	Sampling frame	Sampling distribution	Sampling design
If a survey is conducted by a sampling design is called	Sample survey	Population survey	Systematic survey	None	Sample survey
The difference between the expected value of a statistic and the value of the parameter being estimated is	Sampling error	Non-sampling error	Standard error	Bias	Bias
The standard error increases when sample size is	Increase	Decrease	Fixed	All of the above	Decrease
The mean of the sample means is exactly equal to the	Sample mean	Population mean	Weighted mean	Combined mean	Sample mean
A sample which is free from bias is called	Biased	Unbiased	Positively biased	Negatively biased	Unbiased
When a random sample is drawn from each stratum, it is known as	Simple random sampling	Stratified random sampling	Probability sampling	Purposive sampling	Stratified random sampling
When the procedure of selecting the elements from the population is not based on probability is known as	Purposive sampling	Judgment sampling	Subjective sampling	All of the above	All of the above

In random sampling, the probability of selecting an item from the population is	Unknown	Known	Un-decided	One	Known
Sample value is called	Parameter	Core Value	Statistic	Variable	Statistic
Probability sampling is otherwise called	Multiple choice	Uni-variate Analysis	Random Sampling	Bi-variate Analysis	Uni-variate Analysis
Sampling which provides for a known non zero chance of selection is	Probability sampling	Random Sampling	Non probability sampling	Purposive sampling	Probability sampling
…… are used for Random Sample when the population is very large	Calculator	Telescope	Computer	Typewriter	Computer
Drawing a sample from each stratum in the proportion to latter's share in the total population is	Stratified sampling	Proportioned stratified sampling	Probability sampling	Non probability sampling	Proportioned stratified sampling
Selecting sample units in just a "hit and miss" fashion is called	Accidental sampling	Probability sampling	Non probability sampling	Purposive sampling	Accidental sampling
The standard deviation of any sampling distribution is called:	Standard error	Non-sampling error	Type- I error	Type II-error	Standard error
The selection of cricket team for the world cup is called	Random sampling	Systematic sampling	Purposive sampling	Cluster sampling	Purposive sampling
Which toxic is used to protect plants from insects?	Blue green bacteria	Bacterium Bacillus thuringinsis	Acidobacteria	Proteobacteri a	Bacterium Bacillus thuringinsis
Bt Stands for	Genetically Modified Crops	Bacterium bacillus Theogin	Bacterium Bacillus thuringiensis	Bacteria Bacili thuringien	Bacterium Bacillus thuringiensis
Bt reduce use of	Fertizers	pesticides	seeds	Manure	pesticides
What is GM crops?	Genetically Modified Crops	Genetically poor crops	Gene pool	Nomadic crops	Genetically Modified Crops

Asia uses what percentage of water for agricultural purpose?	85%	88%	81%	83%	85%
Anti-viral proteins that are produced by virus infected cells are called	Interferon	Thymosin	Beta-endorphin	Urokinese	Interferon
A vector is used to	Transfer gene	Copy a gene	Produce a gene	Remove a gene	Transfer gene
In 1977 an E.coli was created to synthesize	Animal growth hormone	Plant growth hormone	Human growth hormone	Human reproductive hormone	Human growth hormone
Ligase is a	Breaking enzyme	Joining enzyme	Releasing enzyme	Removing enzyme	Joining enzyme
The disease crown gall is caused by which bacteria?	Agrobacterium tumefaciens	Agrobacterium rhizogenes	Both of the above given bacterium cause the disease crown gall	Any bacteria belonging to genera Rhizobium	Agrobacterium tumefaciens
Agrobacterium tumefaciens form _____ plasmids	Root inducing	Tumour inducing	Shoot inducing	Leaf inducing	Tumour inducing
Agrobacterium rhizogenes form _____ plasmids.	Root inducing	Tumour inducing	Shoot inducing	Leaf inducing	Root inducing
The region which is transferred from bacterium to the nucleus of the plant cell is called as	T-DNA	A-DNA	B-DNA	Z-DNA	T-DNA
Transfer of T-DNA depends on a set of genes called as	Vir	Chv	Tum	Chromosome	Chv
What is the function of onc genes in T-DNA?	Tumour suppressing potential	Tumour inducing potential	Tumour suppressing potential	Act as replicative genes	Tumour inducing potential
Which of the plant growth regulators are produced by T-DNA?	Salicyclic acid	Cytokinin	Cytokinin nad Auxin	Jasmonic acid	Cytokinin nad Auxin

If a small intermediate vector system is used along with a selectable marker, then it is called as:	Fusion plasmids	Hybrid plasmids	Co-integrative plasmids	Complex plasmids	Co-integrative plasmids
If transfer of DNA from Agrobacterium to plants is done via incubation of explanted material and the vector containing DNA of interest and then selection is done via selectable marker then this method is called as	Transformation	Co-cultivation	Co-transformation	Floral dipping	Co-cultivation
If gene of interest is inserted into protoplasts but the transformation is not stable, then it is called as _____ expression systems.	Permanent	Temporary	Transient	Unstable	Transient