

**MAJOR BASED ELECTIVE II : IPR, BIOSAFETY AND BIOETHICS**

**UNIT -I**

**Biosafety:** Introduction; biosafety issues in biotechnology-historical background; Introduction to Biological Safety Cabinets; Primary Containment for Biohazards; Biosafety Levels; Biosafety Levels of Specific Microorganisms; Recommended Biosafety Levels for Infectious Agents and Infected Animals.

**UNIT -II**

**Biosafety Guidelines:** Biosafety guidelines and regulations (National and International) – operation of biosafety guidelines and regulations of Government of India; Definition of GMOs & LMOs; Roles of Institutional Biosafety Committee, RCGM, GEAC etc. for GMO applications in food and agriculture; Environmental release of GMOs; Risk Analysis; Risk Assessment; Risk management and communication; Overview of National Regulations and relevant International Agreements including Cartagena Protocol.

**UNIT -III**

**Introduction to Intellectual Property:** Types of IP: Patents, Trademarks, Copyright & Related Rights, Industrial Design, Traditional Knowledge, Geographical Indications- importance of IPR – patentable and non patentables – patenting life – legal protection of biotechnological inventions – world intellectual property rights organization (WIPO). Protection of GMOs IP as a factor in R&D; IPs of relevance to Biotechnology – few Case Studies.

**UNIT -IV**

**Patent Filing Procedures:** National & PCT filing procedure; Time frame and cost; Status of the patent applications filed; Precautions while patenting – disclosure/non-disclosure; Financial assistance for patenting - introduction to existing schemes Patent licensing and agreement Patent infringement-meaning, scope, litigation, case studies.

**Agreements and Treaties:** History of GATT & TRIPS Agreement; Madrid Agreement; Hague Agreement; WIPO Treaties; Budapest Treaty; PCT; Indian Patent Act 1970 & recent amendments.

**UNIT -V**

**Bioethics:** Introduction to ethics/bioethics – framework for ethical decision making; biotechnology and ethics –benefits and risks of genetic engineering – ethical aspects of genetic testing – ethical aspects relating to use of genetic information – genetic engineering and biowarfare; Ethical implications of cloning: Reproductive cloning , therapeutic cloning ; Ethical, legal and socioeconomic aspects of gene therapy, germ line, somatic, embryonic and adult stem cell research-GM crops and GMO's – biotechnology and biopiracy – Ethical implications of human genome project

**REFERENCES:**

1. Ethics in engineering, Martin. M.W. and Schinzinger.R. III Edition, Tata McGraw-Hill, New Delhi. 2003.
2. BAREACT, Indian Patent Act 1970 Acts & Rules, Universal Law Publishing Co. Pvt. Ltd., 2007
3. Kankanala, K . C. 2007. Genetic Patent Law & Strategy, 1st Edition. Manupatra Information Solution Pvt. Ltd., Noida, India.
4. Jose B. Cibelli, Robert P. Lanza, Keith H. S . Campbell, Michael D. West. 2002. Principles of Cloning, Academic Press, San Diego, Gurdon.
5. Hoosetti, B.B. 2002. Glimpses of Biodiversity. Daya, New delhi.
6. Senthil Kumar Sadhasivam and Mohammed, Jaabir. 2008. IPR, Biosafety and Biotechnology Management. Jasen Publications, Tiruchirapalli, India.
7. <http://www.cbd.int/biosafety/background.shtml>
8. <http://web.princeton.edu/sites/ehs/biosafety/biosafetypage/section3.html>