GUJARAT TECHNOLOGICAL UNIVERSITY
Integrated Master of Science (Biotechnology)
Semester: 6
Subject Name: Bioethics & Biosafety
Subject Code: 1360404

Teaching and Examination Scheme:

Teaching Scheme			Credits	Examination Marks				Total Marks
				Theory Marks		Practical Marks		
L	T	P	C	ESE (E)	PA (M)	PA (I)	ESE (V)	
4	0	0	4	70	30	0	0	100

Prerequisite:

Students should have knowledge of genetic engineering techniques. The students should be aware of tools and techniques utilized in biotechnology.

Rationale:

This course is designed to make students understand the biosafety and risk assessment of products derived from biotechnology and regulation of such products and to become familiar with ethical issues in biological research

Course Content:

Unit No.	Content	No. of Hours	Weightage (%)
1	**Biosafety** Introduction; historical background; introduction to biological safety cabinets; primary containment for biohazards; biosafety levels; GRAS organisms, biosafety levels of specific microorganisms; recommended biosafety levels for infectious agents and infected animals; definition of GMOs & LMOs; principles of safety assessment of transgenic plants – sequential steps in risk assessment; concepts of familiarity and substantial equivalence; risk – environmental risk assessment and food and feed safety assessment; problem formulation – protection goals, compilation of relevant information, risk characterization and development of analysis plan; risk assessment of transgenic crops *vs* cisgenic plants or products derived from RNAi, genome editing tools.	15	25
2	**National and international regulations for Biosafety** International regulations – Cartagena protocol, OECD consensus documents and Codex Alimentarius; Indian regulations – EPA act and rules, guidance documents, regulatory framework – RCGM, GEAC, IBSC and other regulatory bodies; Draft bill of Biotechnology Regulatory authority of India - containments – biosafety levels and category of rDNA experiments; field trails – biosafety research trials – standard operating procedures - guidelines of state governments; GM labeling – Food Safety and Standards Authority of India (FSSAI).	15	25
3	**Bioethics** Introduction, ethical conflicts in biological sciences - interference with nature, bioethics in health care - patient confidentiality, informed consent, euthanasia, artificial	15	25

	reproductive technologies, prenatal diagnosis, genetic screening, gene therapy, transplantation		
4	**Bioethics in research** Cloning and stem cell research, Human and animal experimentation, animal rights/welfare	5	8
5	**Bioethics in Agricultural biotechnology** Genetically engineered food, environmental risk, labeling and public opinion; Sharing benefits and protecting future generations - Protection of environment and biodiversity – biopiracy	10	17
	Total Hours:	60	

Textbook:

1. Kuhse, H.Bioethics: an Anthology, Blackwell, Latest Edition
2. Craig, W., Tepfer, M., Degrassi, G., & Ripandelli, D. An Overview of General Features of Risk Assessments of Genetically Modified Crops Euphytica Latest Edition

Reference Books:

Course Outcomes:

No.	Course Outcomes	RBT Level*
1	Distinguish knowledge of biosafety and risk assessment of products derived from recombinant DNA research and environment release of genetically modified organisms, national and international regulation	UN,RM,AN,AP,EV
2	Analyze ethical aspects related to biological, biomedical, health care and biotechnology research	UN,RM,AN,AP,EV
3	Transparency, honesty and ethical reasoning in handling animal cells as well as toxic, corrosive or mutagenic	UN,RM,AN,AP,EV

*RM: Remember, UN: Understand, AP: Apply, AN: Analyze, EL: Evaluate, CR: Create

List of Laboratory/Learning Resources Required

1. https://nptel.ac.in/courses/109106092
2. https://onlinecourses.swayam2.ac.in/aic20_ge07/preview