Course title: Biotechnology Law			
Course code MPL 162	**No. of credits:** 2	**L-T-P distribution:** 10-18-0	**Learning hours:** 28
Pre-requisite course code and title (if any): None			
Faculty	**Department:** Department of Policy Studies (Centre for Postgraduate Legal Studies)		
Course coordinator (s) Dr. Shiju M. V.	**Course instructor (s)** Dr. Shiju M. V.		
Contact details mvshiju@teriuniversity.ac.in			
Course type	**Elective**		
Course offered in	**Semester 2**		

Course Description

Modern biotechnology is a rapidly evolving discipline and raises many important legal issues. Like many other technological innovations, modern biotechnology has also raised hopes and concerns. An effective regulatory regime on modern biotechnology has to respond to both these hopes and concerns. This course is an attempt to study the regulatory regime on modern biotechnology in India. A comparative analysis of the European and the US regulatory systems, and the evolving international law on the subject set the background for the study of Indian regulations. In addition, the course also addresses the IPR issues in the sector.

Course objectives

1. To provide an overview of the Indian regulatory regime on biotechnology in a comparative context.
2. To understand the evolving international law on the subject.
3. To analyse the IPR issues involved in the sector

Course content	**L**	**T**	**P**
Module 1: Introduction	**4**	**4**	
Biotechnology – the science – Applications: Agriculture, Pharmaceuticals, Industry Different approaches to regulation: Case study of the US and the EU regulatory systems Multilateral agreements: Convention on Biological Diversity, Cartagena Protocol on Biosafety, WTO Agreements, Codex Alimentarius, Plant Genetic Resources for Food and Agriculture, International Trade and Biotechnology. Bioethics, Human cloning, Human Genome project Relevant UNESCO Declarations			
Module 2: Regulatory system in India	**4**	**10**	
Principles of regulation, Concept of precaution Risk Analysis Framework: Risk Assessment, Risk Management, Risk Communication *Environment (Protection) Act, 1986* *Rules for the manufacture, use, import, export and storage of hazardous microorganisms, genetically engineered organisms or cells, 1989*:			

Institutional Structure, Powers and Functions, Relevant Guidelines and Protocols. *Drugs and Cosmetics Act 1940* – Field Trials and Regulatory Processes Food Standards and Safety Authority of India *Biological Diversity Act 2002* The Biotechnology Regulatory Authority of India Bill, 2013 (BRAI) Judicial outlook			
Module 3: Biotechnology Patenting	**2**	**4**	
Indian Patent Act, 1970, and the 2005 Amendments Patenting of life forms and Genetic information UPOV, PVPFR Privacy and Data protection			
Total	**10**	**18**	

Evaluation criteria

- Class participation : 10
- Term Papers : 25
- Presentations : 25
- Major Test : 40

Learning outcomes

By the end of the course, it is expected that the students will:

1. Be able to appreciate different approaches to biotechnology regulation.
2. Be familiar with the biotechnology regulatory regime in India.
3. Have an understanding of the IPR issues in the sector.

Pedagogical approach

A mixture of lecture and discussion methods will be adopted. The topics under each module will be introduced through an introductory lecture, followed by discussions by students. Students are expected to come prepared and initiate discussions on topics that have been assigned beforehand.

Materials

Suggested Readings

1. Grant E. Isaac & William A. Kerr(2003), "GMOs at the WTO – A Harvest of Trouble" , *Journal of World Trade*, 37(6): 1083
2. Ryan Hill, Sam Johnston, & Cyrie Sendashonga (2004), Risk Assessment and Precaution in the Biosafety Protocol, *RECIEL* 13(3): 263-369.
3. Indur M. Goklany (2000), "Applying the Precautionary Principle to Genetically Modified Crops", *Policy Study Number 157*, CSAB, Washington University, St. Louis.
4. Ruth Mackenzie et al. (2003), *An Explanatory Guide to the Cartagena Protocol on Biosafety,* Cambridge: IUCN Publications Services.
5. Francioni, Francesco and Scovazzi, Tullio (eds.) (2006), *Biotechnology and International Law*, Oxford: Hart Publishing.
6. K.D. Raju (ed.) (2007), *Genetically modified organisms: Emerging law and policy in India*, New Delhi: TERI.
7. Sreenivasalu, N. S. (2016), *Law Relating to Biotechnology*, New Delhi: Oxford University Press.
8. Rebecca Eisenberg (1989), "Patents and the Progress of Science: Exclusive Rights and Experimental Use", *University of Chicago Law Review*, 56: 1017.

Additional information (if any)
Student responsibilities

Course Reviewers

1. Dr. Stellina Jolly, School of Law, South Asian University, New Delhi.
2. Dr. Jacob Joseph, National University Advanced Legal Studies, Kochi.