

Course title: Plant Biotechnology Management and Regulatory Issues				
Course code: BBP 141		No. of credits: 4	L-T-P: 42-14-0	Learning hours: 56
Pre-requisite course code and title (if any): None				
Department: Department of Biotechnology				
Course coordinator: Dr.Udit Soni			Course instructor: Dr Vidhi Madaan Chadda	
Contact details:				
Course type: Core			Course offered in: Semester 3	
Course description: Any technological innovation raises two types of responses. For many it raises hopes about finding solutions to some of the ills plaguing the modern world. But for others it raises concerns about the adverse impacts that this technology may have on environment, human health, society etc. Modern biotechnology is a classic example of this. It has raised hopes as well as concerns. The role of regulation comes here. It has to balance these conflicting perceptions. A student of biotechnology should be aware of these regulations so that she knows the limits within which one can operate. Management especially that of Intellectual property rights is another area which has great significance for a biotechnologist. This course is aimed at providing an introduction to these topics. The course is structured in two parts, viz, Plant technology regulation and plant technology management.				
Course objectives: The course is designed to give the students an introduction to law and how legal systems work in India along with an elaborate exposure to the regulatory framework dealing with plant biotechnology and the working of various statutory authorities. The course also focuses on plant biotechnology management through Intellectual Property rights and other relevant regulations				
Course contents				
S.No	Topic	L	T	P
Part A: Plant Biotechnology Regulation				
1	Introduction to Legal System	4		
	Constitution, Statutes, Rules, Regulations, Judicial System, Judicial Review, Administrative set up.	2	0	0
	International Law, Sources, Treaties	2		
2	Principles of Regulation	8	2	
	Competing Models of Risk Assessment Models of risk consideration: Scientific rationality trajectory and Social rationality trajectory.	2		0
	Risk Analysis Framework Risk Assessment, Risk Management and Risk Communication.	1		
	The Concept of Precaution in Regulation Precautionary principle and precautionary approach	1		
	Country Comparisons about Approaches to Biotechnology Regulation The U.S. and E.U. approaches on Biotechnology research, Intentional introduction into environment, GM Food, labelling etc.	4	2	
3	Multilateral Agreements	8	2	
	Convention on Biological Diversity, Cartagena Protocol on Biosafety, WTO Agreements, Codex Alimentarius, Plant Genetic Resources for Food and Agriculture.	8	2	0
4	Regulatory Systems in India	8	4	
	Environment Protection Act, 1986 Rules for the manufacture, use, import, export and storage of hazardous micro-organisms, genetically engineered organisms or cells. Institutional Structure, Powers and Functions Relevant Guidelines and Protocols.	4	2	0
	Other relevant laws Plant Quarantine order Biological Diversity Act	4	2	

	Protection of Plant Varieties and Farmer's Rights Act Drugs and Cosmetics Act, Policy and the rules Seed Policy DGFT Notification Recent Initiatives Draft National Biotechnology Regulatory Bill 2008			
Part B: Plant Biotechnology Management				
5	IPRs	14	6	
	Introduction A Brief history of IP protection Rationale for IPR Types of IPRs Patents, Copyright, Trademarks, Trade Secrets, Plant Variety protection, Geographical Indications, Farmer's Rights, Traditional Knowledge	2 2	2	
	Patents and Agricultural Biotechnology Patentability criteria Relevant Case law Indian Patent Act, 1970 TRIPS Amendments to Indian Patents Act (2005)	6	2	
	IP applications and Procedures Patent drafting, Patent and prior art searches etc.	2	2	
	Management of IPR Assets Licensing and contracts Negotiations Valuation of patents IPR Enforcement	2	2	
	Total	42	14	0
Evaluation criteria:				
1. Tutorials/assignments 20%				
2. 2 Minor tests 30% (15% each)				
3. 1 Major test (end semester) 50%				
Learning outcomes:				
1. Awareness about the legal systems and the various institutions in a system.				
2. Familiarity with the regulation of Biotechnology and the related aspects.				
3. Understanding the theoretical basis of Intellectual property protection and the importance of the same.				
4. Understanding the criteria for a patent, related procedure in making an application for the same and the ways in which it can be managed.				
Materials:				
Essential Readings				
1. K.D. Raju (ed.) (2007), Genetically modified organisms: Emerging law and policy in India, TERI , New Delhi				
2. P.Narayan(2001), Patent Law, 3rd edn., Eastern Law House, Calcutta				
Suggested readings				
3. Kamala Sankaran and Ujjwal Kumar Singh (eds.) (2008), Towards legal literacy: An introduction to Law in India, Oxford, New Delhi				
4. W.R.Cornish(1999)., Intellectual Property, 4th edn., Sweet & Maxwell, London,				
5. Jayashree Watal(2001)., Intellectual Property Rights in the WTO and Developing Countries, Oxford, New Delhi,				
6. F.H.Erbisch and K.M. Maredia(Eds.) (2004)., Intellectual Property Rights in Agricultural Biotechnology, 2nd edn., CABI Publishing, Oxon				
7. Charles Mc Mannis (ed.) (2007), Biodiversity and the Law, Earthscan, London.				

8. Report of the Task Force on Application of Agricultural Biotechnology, Ministry of Agriculture, Government of India, (2004).
9. National Biotechnology Development Strategy (Draft), Department of Biotechnology, Ministry of Science and Technology, Government of India.
10. Shyam Divan and Armin Rosencranz(2005), Environmental Law and Policy in India, 2nd edn., Oxford, New Delhi, Ch. 4.

Additional information (if any):

Student responsibilities:

1. Class attendance.
2. Study of course materials as specified by the instructor.

Course reviewers: