

<b>BGeneral Information</b>	<b>BACELOR DEGREE IN BIOTECHNOLOGIES</b>
Title of the subject	Principles of International and European Union Law for Biotechnologies
Degree Course (class)	Industrial and agro-food biotechnologies (L – 2) Medical and pharmaceutical biotechnologies (L – 2)
ECTS credits	4
Compulsory attendance	NO, BUT IT IS HIGHLY RECOMMENDED
Language	ITALIAN
Academic year	2020/2021

<b>Subject Teacher</b>		
Name and Surname	Annita Larissa Sciacovelli	
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Place and time of reception	monday 9.30/12 in Corso Italia 23, III floor, room n. 4, Bari (annitasciacovelli@gmail.com) <b>Actually, due to COVID 19, she receives on web platform TEAMS</b>	
<b>ECTS credits details</b>	Discipline sector (SSD)	Area
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<b>Study plan schedule</b>	Year of study plan		Semester	
	first		first	
<b>Time management</b>	Lessons	Laboratory	Exercises	Total
CFU	4			4
Total hours	100			100
In-class study hours	32			32
Out-of-class study hours	68			68

<b>Syllabus</b>	
Prerequisites / Requirements	
<b>Expected learning outcomes (according to Dublin descriptors)</b>	
Knowledge and understanding	Besides developing scientific skills, the student will acquire an appropriate knowledge of the international and European legal disciplines applicable to biotechnologies. After a preliminary and indispensable study of the principal notions and institutes of constitutional law and of the main international and European

	<p>institutions operating in the scientific sector, the student will learn the international and European regulatory disciplines that regulate the main issues of interest of biotechnologies.</p> <p>During the lessons, he/she will receive the methodological and technical legal tools necessary to understand international and European sources concerning biotechnologies.</p> <p>Thus the student will be able to acquire the basic technical and juridical skills to be applied in some of the work areas for which the two courses prepares.</p>
Applying knowledge	<p>The student, in parallel with the progression of his or her scientific skills, will acquire the ability to understand the scope of the relevant international conventions, European Union acts and domestic laws that apply to the biotechnology sector, as well as the relevant European and international practice. The legal knowledge learned will allow to frame the problems inherent to the sector in question allowing him to work in public bodies, private companies and international organizations.</p>
Making informed judgments and choices	<p>The knowledge and interpretation of the sources of international and European Union law that bind our State in the field of biotechnology specifically on the international and European protection of drug patents, food safety and consumer protection, will allow the student to deepen legal issues, but also to develop critical skills in relation to technical issues-</p>
Communicating knowledge	<p>The student will learn the meaning of the technical-legal expressions of common use, but also specific notions of the subject in question (i.e. "convention on biodiversity", "EU regulation", "intellectual property" and "food security") and he will learn how to use the necessary legal lexicon appropriate in the professional situations in which he will operate</p>
Capacities to continue learning	<p>Once the methodological tools for the study of the subject in question have been acquired and the correct vocabulary learned, the student will be able to use the skills acquired to address the legal problems of different nature that he will encounter in the professional reality for which, currently, specific preparation is also required legal aspects.</p>
<b>Study Program</b>	
Content	<p>Characteristics of the international community and its legal system. The peculiar phenomenon of European integration. Notions of the Italian juridical system. International legal sources.</p> <p>Origin and development of European integration. European citizenship. The institutions of the European Union. The sources of the European Union law. The protection of human rights in the European Union. The free movement of persons and goods.</p> <p>Characteristics of the international community and its legal system. The peculiar phenomenon of European integration. The protection of human health and the environment in</p>

	<p>international and European law. The Convention on biodiversity and the Cartagena Protocol on bio-security. The principle of prevention and precaution. The duty to protect. The risk assessment as a limit to the free movement of goods.</p> <p>The World Trade Organization. The Agreement on Sanitary and Phytosanitary Measures. TRIPS and the problem of patents on essential and generic medicines in developing countries. The solution of international trade disputes regarding biotechnological products.</p> <p>International and European regulations on the use of Genetically Modified Organisms (GMOs) in medicines, food and feed. The marketing of GMOs and the authorization procedures.</p> <p>Traceability and labeling. The role of the European Commission, the European Medicines Authority (EMA) and the European Food Safety Authority (EFSA) and other industry agencies. The responsibility of stakeholders.</p> <p>The international and European discipline of the patent protection of biotechnological inventions. The open source system and cross licensing practices. The protection of the human genetic heritage.</p>
Bibliography and textbooks	<p>1) <b>U. Villani</b>, <i>Istituzioni di diritto dell'Unione europea</i>, 2018, Bari, Cacucci ed., chap. I, chap. II, chap. IV, chap. V (till pg. 205) and chap. VII (till pg. 320).</p> <p>2) <b>P. Acconci</b>, <i>Tutela della salute e diritto internazionale</i>, 2011, Milano, CEDAM, only chap. V (only section I [only par. 4], and sections II and III), chap. VI (section II) and chap. IX.</p>
Notes to textbooks	<p>For a more profitable understanding of the course, it is strongly recommended to follow it, during which the study material will be provided directly by the professor (ppt slides, regulatory texts, articles from scientific journals, practical case studies)</p>
Teaching methods	<p>The course is organized in lectures using Power Point; the legal analysis of the various topics will always be carried out with the help of the reference regulatory texts (international conventions, Treaty of the European Union, EU regulations and directives, italian laws) and bearing in mind the common principles developed by the EU Court of Justice and the European Court of Human Rights in order to <b>encourage the active participation of students</b>. For this sake, educational workshops will be organized useful for studying particular issues concerning international and European regulation on biotechnology and related activities</p>
Assessment methods (oral, written, ongoing assessment)	<p>written test with closed multiple choice</p>
Evaluation criteria (describe criteria for each of the above expected outcomes)	<p>-Knowledge and understanding</p> <p>The student will combine the scientific skills, which characterize his course of study, with a legal knowledge of the discipline of biotechnology in the more general framework of international law and the European Union.</p>

	<p>- Applied knowledge and understanding Supported by basic technical-legal knowledge and by a more specific one in the sector in question, the student will be able to both read and interpret a normative document, and to understand the logical-argumentative path developed in judgments and present it orally and/or in written form.</p> <p>- Autonomy of judgment. The acquired ability to understand regulatory and jurisprudential texts will also be corroborated and verified through questions posed in the classroom during lectures and educational workshops</p> <p>- Communication skills The scientific skills of the chosen study path will be enriched thanks to the technical-legal skills acquired by the student in the sector and his ability to deal with discussing current issues arising from the use biotechnological products, their patent protection and their marketing in other EU and non EU countries using appropriate lexicon and notions.</p>
Further information	