INSTITUTO POLITÉCNICO DE BRAGANÇA

Course Unit	Safety and Regulation in Biotechnology			Field of study	Social and entrepreneurial sciences		
Master in	Biotechnological Engineering			School	School of Agriculture		
Academic Year	2023/2024	Year of study	1	Level	2-1	ECTS credits	3.0
Type	Semestral	Semester	1	Code	5010-784-1104-00-23		

Workload (hours)	81	Contact hours	T -	TP -	PL -	TC -	S -	E -	OT -	O -

T - Lectures; TP - Lectures and problem-solving; PL - Problem-solving, project or laboratory; TC - Fieldwork; S - Seminar; E - Placement; OT - Tutorial; O - Other

Name(s) of lecturer(s): Sandrina Alves Heleno

Learning outcomes and competences

At the end of the course unit the learner is expected to be able to:
1. To know National and European legislation that regulates the biotechnological activities;
2. To know the social impact of the biotechnologies;
3. To establish relations between scientific knowledge and the regulations concerning the biological products;
4. To understand the questions regarding the biotechnology application in the agriculture and in the society;
5. To know the regulating and controlling role of the authorities and organisms in the questions of the biossecure;
6. To apply the knowledge to practical questions.

Prerequisites

Before the course unit the learner is expected to be able to:
No prerequisites applied

Course contents

The biotechnological revolution. Risk management. Chemical, physical and biological risk. Genetically Modified Organisms (GMOs). Experimental animals. Governance and regulation in biotechnology.

Course contents (extended version)

1. The biotechnological revolution
   - From chemistry to biotechnology
   - Living Modified Organisms (LMOs): the beginning of the biotechnological revolution
   - The Asilomar Conference, Cartagena Protocol on Biosafety and Convention on Biological Diversity
   - Biological agents: epidemiology, identification and risk assessment
   - Biotechnology applications: from laboratory to industry
   - Positive and negative impacts of biotechnological revolution
   - The need for regulations in biotechnology: coherence in international regulation
2. Risk management
   - Classification of risk.
   - Laboratory and risk; risk analysis
   - Risk map. Symbols.
3. Chemical and physical risk
   - Globally Harmonised System (GHS) of classification
   - Safety Data Sheets (SDS and MSDS)
   - Labelling and storage of chemicals.
   - Waste management
4. Biological risk
   - Biosafety and biosecurity
   - Biological hazards: risk group classification
   - Biosafety levels (BSL): Laboratory facilities, practices and equipment; levels of containment.
   - Biosecurity in Biological Resource Centres
5. Genetically Modified Organisms (GMOs)
   - The international framework
   - Synthetic Biology
   - Major concerns: Potential environmental and human risks
6. Animal testing
   - History, pros and cons, ethical principles
   - Risk assessment and management, levels of biosecurity with animals
   - The 3 R's strategy.

Recommended reading

1. GHS, 2013. Globally Harmonized System of Classification and Labelling of Chemicals (GHS). 5th ed. United Nations. URL: http: //www. unece. org/trans/danger/publi/ghs/ghs_rev05/05files_e. html
2. RODHES C, 2010. International Governance of Biotechnology, Bloomsbury Academic.
3. WHO/OMS, 2005. Laboratory Biosafety Manual.
4. HHS, 2009. Biosafety in Microbiological and Biomedical Laboratories, 5th ed. CDCP U. S. Department of Health and Human Services, HHS Publication No. (CDC) 21-1112, USA.
5. Scientific journals: Frontiers in Bioengineering and Biotechnology; Journal of Law and the Biosciences; Regulation & Governance; Science and Public Policy; Journal of Responsible Science

Teaching and learning methods

Expositive methodology, with audiovisuals followed by discussion of the subjects. Study materials from the e-learning resources; case study. Preparation and discussion of monography about the involved issues. Participation of invited lecturers.

Assessment methods

1. Alternative 1 - (Regular, Student Worker) (Final, Supplementary, Special)
   - Development Topics - 60% (Case study: written assignment and discussion with the class.)
   - Final Written Exam - 40% (Final written exam)

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Assessment methods

2. Second call - (Regular, Student Worker) (Supplementary)
   - Final Written Exam - 100%

Language of instruction

1. English
2. Portuguese

Electronic validation

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