

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
Туре	Semestral	Semester	1	Code	5010-784-1104-00-23	
Workload (hours)	81	Contact hours	T - TP T - Lectures; TP - Lectures a	- PL - T	C - S - 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:

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

- 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 Biotechnology applications:

- 2. Risk management
 - Classification of risk.

- Classification of risk.
 Laboratory and risk; risk analysis
 Risk map. Symbols.
 Chemical and physical risk
 Globally Harmonised System (GHS) of classification
 Safety Data Sheets (SDS and MSDS)
 Labelling and storage of chemicals.
 Waste management
 Biological risk
- Waste management
 Waste management
 Biosafety and biosecurity
 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
 Cynetical results

 - 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

- 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
 RODHES C, 2010. International Governance of Biotechnology, Bloomsbury Academic.
 WHO/OMS, 2005. Laboratory Biosafety Manual.
 HHS, 2009. Biosafety in Microbiological and Biomedical Laboratories, 5th ed. CDCP U. S. Department of Health and Human Services, HHS Publication No. (CDC)

- Find, 2009. Biostery in Microbiological and Distribution and

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

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			
Sandrina Alves Heleno	Maria da Conceição Constantino Fernandes	Rui Miguel Vaz de Abreu	Paula Cristina Azevedo Rodrigues
18-01-2024	18-01-2024	23-01-2024	23-01-2024