

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
Type	Semestral	Semester	1
Workload (hours)	81	Contact hours	T - TP - PL - TC - S - E - OT - O -
		Level	2-1
		ECTS credits	3.0
		Code	5010-784-1104-00-23

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)

### 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](http://www.unece.org/trans/danger/publi/ghs/ghs_rev05/05files_e.html)
2. RÓDHES C, 2010. International Governance of Biotechnology, Bloomsbury Academic.
3. WHO/QMS, 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)

**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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