# Risk Analysis of regulated products

\_ **Module “GMO”**

## Prof. Alessandra Lanubile

***COURSE AIMS AND INTENDED LEARNING OUTCOMES***

The course is carried out in the 2nd term and consists of 3.0 CFU (21 hours) of lectures and 1.0 CFU (12 hours) of practical work. The course aims to: 1) introduce to the main tools for genetic engineering including the new breeding techniques of genome editing; 2) provide an overview of the many and diverse approaches in the development of new traits; 3) illustrate the practical procedures and theoretical framework for risk assessment and the legal background.

Learning outcomes:

After successful completion of this course students are expected to be able to:

- explain the fundamental technologies at the base of the genetic engineering, including the process of molecular cloning, the vectors for cloning, the transformation tools and the identification of recombinants;

- define the genetically modified organisms and explain the basic methods used in their production, including the transgenesis, cisgenesis and genome editing approaches;

- provide examples of possible outcomes for the industrial, agriculture and food production biotechnology sectors;

- list the federal agencies charged with regulating biotechnology and identify the main goals of the regulating biotechnology;

- illustrate the development of guidelines for the recombinant DNA research;

- explain the patenting and intellectual property in agricultural biotechnology.

***COURSE CONTENT***

GMO

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|  | CFU |
| **Genetic** **engineering** |  |
| Recombinant DNA technology. Cloning vector design and construction. Marker genes and promoters. Gene libraries. Sequencing. Stable and transient transformation. Transgenesis, intragenesis, and cisgenesis. RNA interference. Genome editing. | 0.75 |
| **Application of innovative biotechnology** |  |
| Molecular biotechnology of microbial systems: protein therapeutics; vaccines; bioremediation and biomass utilization; plant growth-promoting bacteria; microbial insecticides; large-scale production of proteins from recombinant microorganisms. Molecular biotechnology of eukaryotic systems: methodology of genetic engineering in plants; engineering plants to overcome biotic and abiotic stress; engineering plant quality and proteins; transgenic animals. | 1.25 |
| **Risk assessment and legal background** |  |
| History of genetic engineering and its regulation. Regulating recombinant DNA technology. Deliberate release of genetically modified microorganisms. Regulating food and food ingredients produced by genetically engineered microorganisms, genetically modified crops, and genetically engineered livestock. Patenting and intellectual property in agricultural biotechnology. Societal issues in biotechnology. | 0.75 |
| **Examples of GM risk assessment** |  |
| Case studies on genetically modified organisms (GMOs): potential risk scenarios and associated health indicators. | 0.25 |
| **Tutorials** |  |
| Practical tutorials in the laboratory and educational visits to research centres. | 1.0 |

***READING LIST***

Brown T. A. *Gene Cloning and DNA Analysis: An Introduction*, 7th Ed.

Glick B.R., and Patten C.L. *Molecular biotechnology: principles and applications of recombinant* *DNA*, 5th ed.

Dehlinger C.A. *Molecular biotechnology*,1st ed.

Power point presentations will be made available during the course. Papers from the scientific literature will be provided by the teacher.

***TEACHING METHOD***

The teaching method will embrace the following activities:

1) Indoor classes where main course topics will be covered along with several applied examples of GM risk assessment.

2) Specific topics will be addressed in seminars held by EFSA scientific experts or officers.

3) Laboratory tutorials, during which cloning experiments, PCR reactions and final evaluation of the results will be carried out.

4) Educational visit to a research centre involved in the application of the new breeding technologies (cisgenesis and genome editing).

***ASSESSMENT METHOD AND CRITERIA***

The assessment will take the form of a written test consisting of three open-ended questions and the score assigned will be determined, besides students' knowledge, by mastery of specialised terminology and analytical rigour with respect to the course subjects (maximum score of 10 points for each question). The test lasts 120 minutes. Pass mark is 18/30 out of 30/30.

The final mark of the “GMO” module will be further averaged out (to give a mark out of thirty) with the marks obtained in the “Pesticides” and “Food additives and enzymes” modules to obtain the final mark of the course Risk Analysis of regulated products.

***NOTES AND PREREQUISITES***

The student should possess a basic knowledge of the concepts of biochemistry and microbiology. If required, the student can ask the teacher for supplementary material related to these topics.

In case the current Covid-19 health emergency does not allow frontal teaching, remote teaching will be carried out through synchronous or asynchronous procedures that will be promptly notified to students

Prof. Alessandra Lanubile is available to meet students after class at the Department of Sustainable Crop Production - Agronomy and Plant Biotechnology Area.

# - PESTICIDE

## Prof. Ettore Capri

***COURSE AIMS AND INTENDED LEARNING OUTCOMES***

The overall aim of this course is to provide knowledge for a realistic approach to develop a consistent risk assessment and sustainable risk management of pesticide residues in the food chain. Students will be introduced to risk assessment and sustainable development in the organisation and process solutions form the primary production to the distribution. The course will start from simple concept of chemistry, toxicology, ecotoxicology and human health moving to the ecosystem service approaches and SDGs. Using case studies, the course will also give an overview of the measures available for mitigating risk and achieving sustainable solutions and the strategy used form company to achieve certification complains.

At the end of the course, students will know all the main pesticide contamination sources in the food chain, how assess them, how manage the risk and how take opportunities for achieving sustainability end-points and objectives.

Based on the knowledge acquired, students will be able to: identify the hazard and the risks, define appropriate risk management plan and select appropriate tools to optimize management for the responsible production.

***COURSE CONTENT***

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|  | ECTS |
| The pesticide risk analysis model at international level. Paradigma of the risk analysis. Institutions set up. Policy and management control. Consumer perception and questions. | 1.00 |
| Regulatory system for pesticide. How pesticide are authorised and before hand evaluated. Scientific assessment vs policy assessment. Sustainable uses and the risk managers roles of the end-users. | 1.00 |
| Evidence of the legislative framework: dossier analysis | 0.5 |
| Footprint, primary and secondary standard, certification frameworks | 0.5 |
| **Tutorials** |  |
| Risk mitigation practices | 1.00 |

***READING LIST***

Lecturer's notes.

Aids related to specific topics will be provided during the course.

***TEACHING METHOD***

1. Theoretical frontal and dialogue-based lectures aimed at presenting the key concepts of the subject.

2. Assignment of working groups for the resolution of specific case-studies related to the course topics.

3. Classroom seminars with company testimonials.

***ASSESSMENT METHOD AND CRITERIA***

There will be a final written exam. Students will be indicatively given up to 2 hours to answer both closed and open-ended theoretical questions. The open-ended questions will also assess the student's appropriate use of the specific technical terminology used during the course.

***NOTES AND PREREQUISITES***

The student should possess knowledge of the basic chemistry and agronomy. If required, the student can ask the teacher for supplementary material related to these topics.

In case the current Covid-19 health emergency does not allow frontal teaching, remote teaching will be carried out through synchronous or asynchronous procedures that will be promptly notified to students

***OFFICE HOURS FOR STUDENTS***

Prof. Ettore Capri is available to receive students following specific appointment or through remote meetings. In any case, it is suggested to write an e-mail ([ettore.capri@unicatt.it](mailto:ettore.capri@unicatt.it)) to agree on the day and time of reception.

## **Module: Food Additives and Enzymes**

## Prof. Claudia Cortimiglia

***COURSE AIMS AND INTENDED LEARNING OUTCOMES***

The aim of the course is to provide students with in-depth knowledge on the process behind the authorisation for use of food improvement agents, additives, enzymes. First, the course will address the definition and basics of the legal frameworks at national and supranational levels. Then, the functional role of these agents in food processing, focusing on the most commonly used enzymes and additives in the EU, will be treated. Moreover, the basics of risk assessment of these regulated products will be presented.

At the end of the course, students should possess solid scientific and technical basis on the use of food additives and enzymes in the food processing and on the risk assessment procedures required for the pre-market authorisation of these food improving agents.

***COURSE CONTENT***

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|  | ECTS |
| The food improvement agents, enzymes, additives, and processing aids. Definition and basics of the legal framework (EU, USA and FAO-JECFA). | 0.5 |
| Food enzymes and their function in food processing. Enzyme derived from non-GM and GM microorganisms, from plants and animals. The basics of food enzymes risk assessment. The safety assessment of the production organism, the enzyme characterisation, the TOS concept, and dietary exposure estimation. | 1.5 |
| The categories of food additives (e.g., colourants, preservatives and antioxidants) and their use in food manufacture. The basics of food additives risk assessment. | 1 |
| **Tutorials** |  |
| In the laboratory and practical activities, the students will: (i) test enzymes and additives in pilot scale food production and (ii) simulate the risk assessment of a food improvement agent. | 1.0 |
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***READING LIST***

Reading lists on specific topics, websites of interest in food improvement agents (additives and enzymes) and \*.pdf documents will be indicated during the course and uploaded on Blackboard.

***TEACHING METHOD***

The course is divided into:

* frontal lectures. In order to maximise the effectiveness of the course, other experts in the use of food improvement agents and in the risk assessment will hold specific seminars alongside the lecturer;
* case studies and the simulated application of risk analysis strategies.

***ASSESSMENT METHOD AND CRITERIA***

Report of the practical experiences, discussion of case studies and oral examination. The report of practical activities should be presented at the oral examination. In the case studies, carried out in groups, the ability of the individual student in presenting and critically analyzing the subject addressed will be assessed. The oral exam is aimed at assessing the student's theoretical knowledge and reasoning skills. The final mark is based on the weighted average of the marks obtained for the laboratory activities, the classroom discussion of case studies, and the oral exam questions.

***NOTES AND PREREQUISITES***

Lesson frequency is not mandatory, but highly recommended. Since a report of practical activities is foreseen in the final examination, in case the student cannot attend the practical classes, alternative evaluation systems will have to be agreed on with the teacher.

In case the current Covid-19 health emergency does not allow frontal teaching, remote teaching will be carried out through synchronous or asynchronous procedures that will be promptly notified to students.

Professor Claudia Cortimiglia is available to meet with students after class at DiSTAS -Microbiology or by mail at claudia.cortimiglia@unicatt.it.