**UNIVERSITY OF GONDAR**

**INSTITUTE OF BIOTECHNOLOGY**

**SYLLABUS FOR THE COURSE BIOSAFETY**

**Course title: Biosafety**

**Course code: Biot. 604**

**ECTS: 5**

**Lecture: 4 hours/week**

**Independent learning: 3 hours/week**

**Collaborative learning: 2 hours/week**

**Length of time to complete module: 16**

**Pre-requisite module: None**

**Co-requisite: Molecular Biology (Biot. 616)**

**Barred combination module: None**

**Course rationale**

The new and emerging tools of biotechnology offer significant opportunities to enhance agricultural productivity, food and nutritional security, health and environmental quality worldwide. Genetically Modifies Organisms (GMOs) in particular have the potential to play a positive role in sustainable agriculture, forestry, aquaculture, bioremediation, and environmental management both in developed and developing counties. However, deliberate or inadvertent release of GMOs into the environment could have negative ecological impacts under some circumstances.

Some countries have already developed and commercialized genetically engineered transgenic crops. Many developing countries have initiated biotechnology research and development programs to benefit from the new tools. Several developing countries are also importing products of biotechnology. However, this has raised biosafety issues related to risk/benefit analysis associated with biodiversity, the environment, and human health. This has been an important factor in the development of the Biosafety Protocol. The Cartagena Protocol on Biosafety is very important, particularly for developing countries. It is an international agreement that specifically focuses on the trans-boundary movement GMOs.

In Ethiopia, the development of biotechnology related research and development has been limited in scope and number partly because of the absence of regulatory framework. Recently, however, the Biosafety Law has been ratified by the Parliament of the Federal Democratic Republic of Ethiopia and there is a felt need to enhance the scientific capacity for conducting risk assessments of Genetically Modified Organisms. Therefore, the knowledge, skills and information gained through this course will help the M.Sc. students to contribute towards the development of environmentally sound and safe use of biotechnology.

**Course Description**

This module will introduce how modern biotechnology through a range of molecular and bioinformatics techniques has revolutionized medical, agricultural, and industrial applications as compared to conventional methods. It will also introduce methods of science-based assessment and management of potential risks related to human health and the environment which includes: hazard identification, risk estimation, risk evaluation and management and Case-by-case and event based risk assessment, best practices for the design and management of GMOs, and environmental monitoring of GMOs. It will provide hands-on experience on risk assessment through the evaluation of specific applications for environmental release of GMOs. Emphasis will be given to food and feed safety such as food related risks, components of food safety assessment and the concept of Substantial Equivalence, procedures to be followed for food safety assessment and scientific and emotional issues behind food labeling. Other issues that will be covered in this module will be Biosafety regulations and their enforcement, the Cartagena Biosafety protocol, Biosafety related Trade issue, IPR related issues in Biotechnology and Methods of GMO detection.

**Learning outcomes**

After completion of this course student should:

* Acquire knowledge on basic current and future applications of biotechnology.
* Be aware of the potential risks and benefits of GMOs as well as concepts such as “Scientific Uncertainty” and “Precautionary Principle”.
* Have a good grasp of principles of risk assessment, risk analysis, risk management and risk communication.
* Be familiar with the existing international legal frameworks and agreements related to Biosafety and GMOs including the African Model Biosafety Law and Biosafety law of Ethiopia.
* Be able to advise Policy makers, regulators and the public at large in the safe and sound use of Biotechnology.

**Modes of teaching and learning**

* Classroom teaching 40% and independent learning 60%
* Modes of Evaluation

Examination – 50%

Seminar paper and/or group assignments– 50%

References

1. **Rissler, J. and Mellon**, M. (1996). The Ecological Risks of Engineered Crops. The MIT press, Cambride, Massachusetts.
2. **Ellstrand, N.C**. (2003). Dangerous Liaisons? When cultivated Plants mate with their wild relatives. The Johns Hopkins University Press, Baltimore and London.
3. **Tzotzos, G.T**. (1995). Genetically Modified Organisms: A Guide to Biosafety. United Nations Industrial Development organization (UNIDO) and CAB International, Wallingford, UK.
4. **Kjellsson, G. and Simonsen, V**. (1994). Methods for Risk Assessment of Transgenic Plants I. Competition, Establishment and Ecosystem Effects. Birkhäuser Verlag, Basel.
5. **Gould F. *et al*.** (2002). Environmental Effects of transgenic Plants: The Scope and Adequacy of Regulation. Committee on Environmental Impacts Associated with Commercialization of Transgenic Plants, Board on Agriculture and Natural Resources, National Research Council, USA.