**Master in Biosafety and Gene Ecology**

GenØk –Centre for Biosafety

Table of Contents

[Summary 3](#_Toc480967570)

[1. Introduction 3](#_Toc480967571)

[1.1 Biosafety and modern biotechnologies 3](#_Toc480967572)

[1.2 Biosafety course at GenØk-Centre for Biosafety 4](#_Toc480967573)

[1.2.1 Online course, BIO-6301 Web based master module in biosafety 4](#_Toc480967574)

[2. Master programs in Biosafety and Gene Ecology 8](#_Toc480967575)

[2.1 Teaching goals 8](#_Toc480967576)

[2.2 Outline of course modules 8](#_Toc480967577)

# Summary

The urgent need for Master and Ph.D. programs has been strongly emphasized by relevant and authoritative international organizations, scientists and academic institutions, as well as by political and regulatory authorities in a number of developing and developed countries. Norway and other developed countries have a special responsibility for implementation of international biotechnology safety and risk governance agreements through the Cartagena Protocol on Biosafety.

GenØk – Centre for Biosafety in Tromsø is the national competence centre for biosafety. In close cooperation with the University of Tromsø and international partners, GenØk has built an international network of competent scientists that contribute to research and capacity building within the Norad-financed “capacity building program”.

# 1. Introduction

## 1.1 Biosafety and modern biotechnologies

Modern biotechnologies are integral parts of knowledge-based economies. In many sectors modern biotechnologies will be main drivers for the creation of new types of enterprises and for transfusion of “new blood” into established enterprises. By putting modern biotechnology based developments to work, new products are emerging within human and veterinary medicine, agriculture and food/feed production, cleaner energy and chemicals production, as well as for environmental protection and cleanup procedures through bio-remediation approaches.

Modern biotechnologies may hence transform all aspects of human societies and the ecosystems. Whether this provide sustainable solutions depends on our ability to anticipate, hypothesize, prevent, monitor and survey unintended harmful effects and hazards to ecosystem, animal and human health.

The urgent need for academic learning and research programs in risk governance and biosafety have been strongly emphasized by relevant and authoritative international organizations as well as by political and regulatory authorities in a number of developing and developed countries. Norway was a decisive driver of the international negotiations leading to the Convention on Biodiversity and the Cartagena and Nagoya protocols derived from the Convention. Hence, Norway has a special responsibility for implementation of international biotechnology safety and risk governance agreements through competence building, education and research related to risk governance of modern biotechnologies.

An increasing recognition of bias and vested interest in product-oriented research calls for broader engagement of independent academic institutions and professionals to lead risk governance and competence building, education and safety research. GenØk and UiT in collaboration, and their international partners possess cutting-edge, unique competence for delivering the needed education and research.

## 1.2 Biosafety course at GenØk-Centre for Biosafety

GenØk’s capacity building portfolio consists of several components where the biosafety course is one of the most important elements. The international course in biosafety; Holistic Foundations for Assessment and Regulation of Genetic Engineering and Genetically Modified Organisms was for the first time held in 2003 and has been organised annually, except for 2009 and 2011 where specialist courses (different themes) followed by conferences was held in Tromsø.

The main objective of the international biosafety course is to provide policy makers, regulators, scientists, and representatives from NGOs and civil society, especially from developing (ODA) and transitioning countries, with knowledge and training in genetic engineering and GMO issues. The course typically runs from the first of August to the fourteenth; consisting of twelve working days. Lessons and activities are scheduled daily from morning until evening, with a somewhat lighter workload and more free-time available on weekends. The course is supported by NORAD and held at GenØk’s headquarters at the Science Park/University of Tromsø, Norway.

Through lectures from GenØk’s staff and other experts, laboratory exercises and demonstrations, group work on case studies and moderated discussions, the course aims to present a holistic framework for biosafety. The framework is focused on precautionary approaches and an acknowledgement of scientific uncertainties. Particular attention is given to risk assessment and risk management, taking into account environmental, human health, socioeconomic, ethical and political effects and dimensions of GE applications/GMOs. The course also strives to raise the participants’ understanding of international law and regulatory requirements, specifically for biosafety implementation. Another important aspect of the course is that it allows scientists and regulators from different countries and backgrounds to meet and form professional and personal relationships toward the creation of strong international biosafety networks. The ultimate goal of the course is to empower participants with transdisciplinary information on GMOs to critically assess the issue from their country perspective and needs.

Participants are selected on the basis of an application which focuses on their professional experience with biosafety, including their role and relationship with biosafety issues in their home country and internationally. The application is also designed to select participants whose work will benefit the most from participation in the course. Gender, occupation and regional criteria are also considered in the selection of participants in order to achieve representational balance. Sponsorships are given to up to 40 applicants from developing (ODA) countries. This sponsorship covers curricular materials, course-associated travel, visa-fees, accommodation and meals. The course also maintains 15 places for participants from all countries who are able to secure their own funding. In addition, a shorter version of the course has been provided as regional courses in Indonesia 2006, Peru 2007, South-Africa 2009, Brazil 2010, India 2011 and Tanzania 2012.

### 1.2.1 Online course, BIO-6301 Web based master module in biosafety

Based on the increasing interest in the biosafety course, GenØk decided in 2006 to develop an online-course so that more students could get training in biosafety and gene ecology. The course was developed together with UNU-Global Virtual University, using the expertise GVU had established through their different online academic courses and programs. This course was approved by UIT, and 20 students graduated from this course in 2008. Due to financial constraints it was only offered in 2008. See annex 1 for accreditation according to §2-2.

The study program for this online course was based on experiences from the program given annually by GenØk in the Biosafety course (see 1.2). For more details se Box 1.

Box 1, Studyguide BIO-6301

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| --- |
| **1a Course name:** Holistic Foundations for Assessment and Regulation of Genetic Engineering and Genetically Modified Organisms (GMO biosafety)  1b Course code: **BIO-6301**  **1c Date written:** 29 March 2006  **1d Last updated** 13 November 2007 |
| **2 Target group:** Global audience of students. The course is suitable for scientists, governmental officers and members of international organizations working with biosafety of genetic engineering and GMO applications.  Participation is limited to 20 students. Selection of students by the course committee will be done based on scientific qualifications and practical experiences. |
| **3a ECTS credits:** 10  **3b Estimated student workload: 300** hours Part time: 20 weeks **3c Online (Internet) time estimate:** 15-20% |
| **4 Prerequisites** Command of English at academic level. Basic computer skills. Access to the internet.  To qualify for the course, prospective students should have the following qualifications: bachelor’s degree or equivalent (minimum 3 years study at University) in a relevant area and practical experience from University, governmental agencies or international organization (minimum 2 years), |
| **5a Duration:** 20 weeks  **5b Term:** Spring 2008 |
| **6 Type** Online tutor-supported, learner-centred course, comprising individual project work, discussion, self-study and other forms of educational interaction. |
| **7 Language** English |
| **8 Developing institutions** Genøk-Centre for Biosafety / Global Virtual University (GVU) |
| **9 Offering institutions** Institute of Medical Biology, University of Tromsø |
| **10 Course leader** Anne Ingeborg Myhr and Terje Traavik |
| **11 Authors/Teaching group** Terje Traavik, Anne Ingeborg Myhr, Kaare Nielsen, Thomas Bøhn, Jan Husby |
| **12 Academic responsibility**  Terje Traavik |
| 1. **Copyright**   Authors,University of Tromsø, Genøk-Centre for Biosafety |
| **14 Aims** *(What the course shall achieve in general terms)* The course is designed to provide policy makers, regulators, scientists and NGOs/civil society leaders, specifically from developing countries (ODA-countries), with the necessary balanced and critical knowledge and training in crucial GE/GMO issues. |
| **15 Learning resources** *(Types of learning material etc)* Learning Management System (LMS), articles, short online lectures (power point slides), module messages, video clipping, URL-links, online libraries, set book |
| **16 Objectives of the course** (concrete student competence and skills on completion)  *On completion of the GMO Biosafety course the students should have the ability to:*   * Deal effectively with the complexity of issues related to the safety assessment and management of GE/GMO applications * Understand how to take a holistic approach to GE/GMO issues   The students will gain / improve skills in:   * Academic writing * Collaborative work on-line with peers by sharing ideas, analyzing problems and finding solutions   The students should have developed or strengthened attitudes on:   * + Different perspectives in research, risk management and assessment of GE/GMO projects and applications |
| **Content description** *(Content in each learning unit)*  *Note: Each module will contextualise by placing biological, ecological, cultural, social, ethical, legal aspects into a common framework.*  *Module 1*  Introduction to context and issues of the course.   * The Cartagena Protocol. * Foundations of gene ecology * The “ holistic corridor”   *Module 2*  Introduction to genomics and molecular biology.   * The structure of DNA * Function of genes and genomes * The fall of the central dogma; DNA-RNA-protein * Epigenomics * Ethical perspectives on the science underpinning genetic engineering   *Module 3*  Biodiversity as source of genetic resources   * The ecosystem as a donor and recipient of genes * Implications of intellectual property rights * Genomics, commercialization and environmental knowlegde * Biodiversity usage and the rights of indigenous peoples and local communities   *Module 4* Genes, DNA and vectors   * Methods for recombinant DNA technology and genetic engineering * Changes in the genome, transcriptome, proteome and epigenome * Horizontal and vertical gene transfer –where and how * Present and potential future GMO and genetic engineering applications * Risk concerns and knowledge gaps   *Module 5*  Risk assessment issues   * Contained use versus deliberate release of GMOs * Ecological aspects; influence on ecosystem function and impact on biodiversity * Health aspects; toxicology, allergenicity and cocarcinogenesis * How to deal with risk, uncertainty and complexity   *Module 6*  The regulatory framework   * The precautionary principle * Implementing sustainability, ethical and socio-economic concerns * National biosafety policy and law * The Cartagena Protocol on biosafety * The WTO and other international agreements   *Module 7*  Risk management issues   * Monitoring strategies and methods for detecting GMOs * The need, the methods and the mechanisms for public participation * Biosafety forecast service |
| **18 Learning outcomes**  *(Sets of competences, expressing what the student will know, understand or be able to do after completion of a process of learning, and products of this process.)*  Competences and skills according to the objectives for the course. A portfolio of articles, essays, lectures, websites and TMAs. |
| **19. Mode of delivery**  Set book and CD-ROMs to all participants.  E-mail and asynchronous discussions archived in the LMS.  Study calendar with cut-off dates for hand-ins.  Online learning resources |
| **20. Infrastructure needed**  Access to PC, Internet. Preferably broadband. All participants will be given access to a Learning Management System (LMS), and be given access to virtual classrooms and group-rooms. |
| **21. Teaching methods**  Learner focused pedagogical approach, with many-to-many communication, group work, group hand-ins in addition to individual hand-ins. Group and individual studies. Individual studies of learning resources. Support from online tutor. |
| **22. Assessment of participants**  Hand-ins must be approved. Online exam arranged by University of Tromsø. Exam counts 100% of the final mark. |
| **23. Bibliography**  Study guide, “Biosafety First” book published by Genøk-Centre for Biosafety, articles, power point presentations. |
| **24. LMS administration** *(Responsible for the online Learning Management System)*  University of Tromsø |
| **25. Course evaluations:**  Students are asked to do reflective activities. This will give formative feedback to the course.Evaluation questionnaire at course completion. |
| **26. Other remarks** |
| **27. Fees:**  USD 1000 |

# 2. Master programs in Biosafety and Gene Ecology

The aim by developing a master program in Biosafety and Gene Ecology is to achieve a comprehensive training as part of an academic program. Important criteria are efficient use of teaching resources, adherence to the NOKUT criteria and budgeting. We have identified 10 course modules that are necessary for students interested in biosafety.

## 2.1 Teaching goals

On completion of the GMO Biosafety course the students should have the ability to:

* + - Deal effectively with the complexity of issues related to the safety assessment and management of GE/GMO applications
    - Understand how to take a holistic approach to GE/GMO issues

The students will gain / improve skills in:

* + - Academic writing
    - Collaborative work on-line with peers by sharing ideas, analyzing problems and finding solutions
    - Describe, discuss and present risk communication
    - LMS competence

The students should have developed or strengthened attitudes on:

* Different perspectives in research, risk management and assessment of GE/GMO projects and applications
* The necessity of developing critical views on information
* Presenting risk-associated issues in a structured way

## 2.2 Outline of course modules

We have identified 10 modules that are connected and each module is contextualized by placing biological, ecological, cultural, social, ethical, legal aspects into a common framework.This framework is developed to be the backbone for a master in Biosafety and can be given either as a 30 credits course or be broadened into 90 credits (either given as a full course or by breaking it into separate courses).

1. **Setting the stage: background, context and main issues of the master program.**

* What are “modern biotechnologies”?Brief introductions to the principles and applications of i) Recombinant DNA technologies/transgenic technologies/genetic engineering; ii) Synthetic biology; iii) Nano-biotechnology; iv) RNA interference (RNAi) technologies; v) non-invasive genetic modification technologies (e.g. marker-assisted breeding); vi) Converging technologies, combining elements from two or more of the listed technologies
* Foundations of genome and gene ecology in relation to ecosystem, animal and human health issues
* Modern biotechnologies, socioeconomic and sustainable development implications
* General biosafety ethics and philosophy issues
* The need for academic programs and academically trained professionals
* The national and international “biosafety traffic rules” for safe and sustainable modern biotechnologies: (National laws and directives, The Convention on Biological Diversity (“The Rio Convention”) and the protocols derived from the Convention: i) The Cartagena Protocol on Biosafety, and ii) The Nagoya Protocol on Access to Genetic Resources, and other relevant international agreements)

***Aims of this module***

At completion of this module, the student should have knowledge about the history of risk regulation of GE / GMO issues, an overview of what modern biotechnologies implies and includes, an overview of the contents of different legal frameworks, an understanding of gene ecology and holistic approaches to GE/GMO.

***Objectives***

Knowledge: The students should be able to:

Describe the history of risk regulation of GE/GMO issues

Critically discuss the Cartagena Protocol

Conceive the concept gene ecology

Explain what is meant by holistic approaches to GE/GMO issues

1. **The scientific basis for modern biotechnologies**

* The history and the basics of functional genomics
* Function of genes and genomes
* Introduction to some basic features of genetic information: From DNA to peptides
* The complex and interactive pathway from (trans)genes to functional proteins
* Genetic Engineering of Living Cells and Organisms-The Methods and the Products
* Understanding the uncertainties arising from technological interventions in complex biological systems: The case of GMOs
* Genetically Engineered Cells and Organisms: Are they substantially equivalent to their unmodified counterparts?
* The fall of the central dogma: The totally integrated and interactive genome, e.g.:
  + - * One genome – 25 000 “genes” – hundreds of thousands of proteins
      * Epi-genomics and –genetics: the induction, specific actions, interactions
      * DNA methylation, RNA interference and microRNA-mediated regulation of gene expression
    - Environmental (biotic, abiotic, anthropogenic) epigenetic changes
* Ethical perspectives on the science underpinning genetic engineering

***Aim of this module***

The aim of this module is to create a basic understanding of genomics and molecular biology and introduce some key elements on the ethical considerations of the science underpinning genetic engineering.

***Objectives***

Knowlegde; The student should be able to;

* Understand the link between phenotype and genotype, the traits associated with genes, the complications of epigenesis and context issues.
* Discuss some of the ethical aspect of the science underpinning genetic engineering.

The students will gain experience in how to:

* Reflect on the concepts of genomics and molecular biology. Discuss critically the ethical aspect of genetic engineering.

1. **Ecosystems and biodiversity as sources for genetic resources**

* The ecosystem as a donor and recipient of genetically informative macromolecules.
  + - Characterization and isolation of useful, naturally occurring genetic materials
    - Modifications of naturally occurring genetic material (enzymatic trimming, more recipient-friendly codon usage etc.) for biotechnology applications
* The obligations of the Nagoya protocol:
* Implications for intellectual property rights
* Genomics, commercialization and environmental knowledge
* Biodiversity usage and the rights of women, indigenous peoples and local communities
* Development of sustainable and safe socioeconomic applications

***Aims of this module***

The aim of this module is to review how genes of commercial or other value are identified and then enable participants to discuss issues of ownership.

***Objectives***

Knowledge; The student should be able to;

* Describe diversity of knowledge systems and culture.
* Understand the legal aspects of ownership

***Skills***

Using internet based search machines.

Participants will upgrade their skills in; Critically discussing issues of ownership and in communicating the diversity of knowledge systems and culture

1. **Synthetic biology as a basis for biotechnology applications**

* *De novo* synthesis of: Genetically modified organisms and cells, artificial genomes, chromosomes, nucleotides or genetic control elements (promoters, introns etc), Polypeptides, proteins and complex macromolecules (e.g. transcription factors, signal transducers etc.)

***Aims of this module***

On completion of this module the students should have an overview of present and future methods for recombinant DNA technology and genetic engineering and their problems. The students will be introduced to the biosafety forecast service (BAT).

***Objectives***

Knowledge; The student should be able to;

* Describe present and future methods for recombinant DNA technology and genetic engineering.
* Identify potential problems by present methods for recombinant DNA technology and genetic engineering.
* Use the BAT.

1. **Nanotechnology as a basis for biotechnology applications**

* How GE meets nanotechnology, new developments within nanobiotechnology

***Aims of this module***

On completion of this module the students should have an overview of present and future methods for nanobiotechnology including nanomedicine and new developments within vaccinology and their potential problems.

***Objectives***

Knowledge; The student should be able to;

* Describe present developments within nanobiotechnology
* Identify potential problems as well as implications for safety assessment

1. **Novel biotechnologies derived from convergence of existing technologies**

* Introduction into future developments based on convergence of technologies

***Aims of this module***

On completion of this module the students should have an overview of trends within convergence of modern biotechnologies with new emerging technologies as well as an overview of potential ethical, social and legal implications.

***Objectives***

Knowledge; The student should be able to;

* Describe present developments and trends within converging technologies
* Identify ethical, social and legal aspects

1. **Emergent properties in complex biological systems**

* Interactions between constructs, vectors, recipient genomes, organisms and ecosystems
* Knowledge from invasion of exotic species
* Vertical (trans)gene flow: Implications for biodiversity and wild relatives
* Unintended horizontal transfer of recombinant or artificial DNA
* Unintended changes in the genome, interactome, transcriptome, proteome and epigenome ( as well as effect of anthropogenic ecosystem changes)
* How to deal with risk, uncertainty and emergent properties of complex systems

***Aims of this module***

On completion of this module the students should have an overview of what system biology involves and be able to describe what interactions that may occur in complex biological systems.

***Objectives***

Knowledge; The student should be able to;

* Describe approaches in system biology
* Identify potential problems by interactions in complex system
* Dealing with risk concerns as well as different types of uncertainties

1. **Risk assessment**

* Contained use versus deliberate release of GMOs
* Ecological aspects; influence on ecosystem function and impact on biodiversity
* Gene ecology as a basis for risk assessment
* “Ecosystem services” contra “Ecosystem management”
* Health aspects for human domestic animal and wildlife populations: Toxicity, Immune system influence (allergenicity), Anti-nutritional factors, Co carcinogenesis
* Contained use versus deliberate release of GMOs
* Ecological aspects; influence on ecosystem function and impact on biodiversity
* Gene ecology as a basis for risk assessment
* “Ecosystem services” contra “Ecosystem management”
* Health aspects for human domestic animal and wildlife populations:
* How to deal with risk, uncertainty and emergent properties of complex systems

***Aims of this module***

Review potential environmental and health risk aspects by GMOs. Develop a broader understanding of risk issues.

***Objectives***

Knowledge; The student should be able to;

* Explore the nature and effectiveness of containment of GMOs
* Discuss the difference between GMOs used in contained conditions and deliberate release of GMOs
* Identify the main health and environmental risk aspects by GMOs
* Describe the differences between risk, scientific uncertainty and complexity
* Indicate means to reduce risk aspects of GMOs

***Skills***

Use the biosafety forecast service.

1. **Pros and cons of contemporary regulatory frameworks**

* In depth analyses and discussions of:
  + - The precautionary principle
    - Implementing sustainability, ethical and socio-economic concerns
    - National biosafety policy and law
    - The Cartagena Protocol on Biosafety
    - The Nagoya protocol on access to genetic resources and
    - The WTO and other international agreements

***Aims of this module***

In this module the ain is that the students should understand the regulatory framework in regard to obligations and opportunities for biosafety and get an overview of the ethical, sustainable and socio-economic concerns.

***Objectives***

Knowlegde; The student should be able to;

* Identify the scope of the different regulative regimes
* Compare strength and weaknesses of the different regulative regimes
* Discuss implications by implementation of the criteria sustainability, ethical and socio-economic concerns

***Skills:***

Reflection on the legal aspects in relation to biosafety

1. **Risk management issues**

* In depth analyses and discussions of:
* Monitoring strategies and methods for detecting GMOs
* The need, the methods and the mechanisms for public participation
* Biosafety forecast service and BAT

***Aims of this module***

The aim of this module is to create a basic understanding of monitoring strategies and of methods for public participation.

***Objectives***

Knowledge: The student should be able to;

* Elaborate monitoring strategies and methods to detect GMOs that can be used in her/ his country
* Identify needs for public participation and give suggestions for methods for participation

***Skills;***

Risk communication and awareness of methods to use for facilitating public participation and environmental monitoring of GMOs.