



PUC Minas
Virtual
educação sem distância

e - **B**iosafety



UNITED NATIONS
INDUSTRIAL DEVELOPMENT ORGANIZATION

The UNIDO *e*-Biosafety Training Programme



The programme provides a unique combination of distance learning with on-campus training. While the core curriculum is the same for all network nodes, each node gives special emphasis on regional priorities and approaches to regulation.

The programme provides comprehensive information on:

- current developments and future trends in biotechnology
- national and international norms and regulations in biotechnology

and develops advanced skills in:

- biosafety assessment, risk management and risk communication
- managing biosafety regulatory systems
- setting up and managing information resources relevant to biosafety
- formulating and/or assessing applications for environmental releases of biotechnology-derived products

The programme targets professionals:

- engaged in regulation at the government, industry and research level
- involved in the implementation of the Cartagena Protocol and other international regulatory norms and conventions
- involved in research



e-Biosafety

A South-South Biosafety Training Network

Biotechnology is transforming industry. It is an integral part of the knowledge-based economy and the main driver for the creation of new types of enterprises and the revitalisation of old industries.

Numerous new products are emerging from the use of modern biotechnology, such as:

- Life-saving medicines and vaccines
- Improved crops and new biofortified foods
- Biofuels and high-added value chemicals
- New products to replace fossil fuel derivatives as inputs for industry.

Biotechnology applications are also creating new opportunities in the process industries (e.g. food, paper and pulp, textiles and leather, mining) as well as in environmental clean up (bio- and phytoremediation). For the developing world, biotechnology promises better health, food security as well as wealth creation through increased industrial productivity. However, capturing the benefits of biotechnology ultimately depends not only on technological capacities but also on institutions that ensure that public and environmental health are not compromised by its application.

The ability of developing countries to institute adequate safety systems and enforce regulation in biotechnology are vital elements in their efforts to exploit current and emerging biotechnology opportunities. It is widely recognised that the lack of expertise in regulation is a major bottleneck for these countries to reap the benefits of biotechnology at the research, industry and government level. The need to strengthen professional expertise in biosafety has thus become a priority of national and international efforts.

The UNIDO e-Biosafety training network is intended to meet this need. It addresses the demand of biosafety regulatory systems in developing countries for intensive training in biosafety. International experts with decades long experience in modern biotechnology have developed the curriculum in modular format drawing from best practices in distance education and instructional design.

The strategic objective in establishing the network is to encourage South-South cooperation and generate hubs of expertise at the regional level.

The UNIDO e-Biosafety Training network is unique in several respects:

- *It fosters South-South cooperation by pooling of resources of the network nodes;*
- *It offers long-term (18 months) in-depth training in biotechnology, risk assessment and management;*
- *It gives priority to training the trainers;*
- *It provides academically accredited postgraduate specialisation at the Diploma or Master degree level;*
- *It combines innovative distance learning multimedia with extensive on-campus tuition;*
- *It is taught by an international faculty of eminent scientists and biosafety professionals;*
- *It is supervised by an International Advisory Board thus ensuring the integrity and high standards of the training material.*

Training Curriculum

The structure of the UNIDO e-Biosafety Training Programme ensures that trainees from different backgrounds such as life sciences, social sciences, law or economics successfully acquire the skills necessary to gain proficiencies in basic biotechnological knowledge, regulatory concepts and risk assessment procedures. The Programme is delivered in modular form covering the entire range of disciplines related to biosafety. For each module, students engage in real time online tutorials and the preparation of specific training assignments. The modular character allows the material to be tailored to specific regional or national needs.

Module 1

Background for non-specialists

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- **Biosafety: a Historical Overview**
A historical overview of biosafety from Asilomar to the present time. Summary of the key issues of the public debate on biosafety.
- **Are biotechnology-derived products needed?**
Science and technology trends and their relevance to the developing world. The effectiveness of modern biotechnology to address intractable problems.
- **Genetics and evolution – an introduction**
Mendelian genetics, selection, adaptation, evolution.
- **Principles and methods of genetic transformation**
A description of the techniques used for transforming prokaryotic and eukaryotic cells and characterising the transformants.

- **Information Resources and Knowledge-based Systems**
Biosafety databases and techniques of data analysis and management.
- **Case Studies**
Case studies using computer-based decision support systems (DTREE) and simulation of expert panels.

Module 2

Application of Biotechnology

2

- **Agri-biotech Applications**
Biotic and abiotic resistance in food crops. Agri-forestry products.
- **Food applications**
Novel biofortified foods.
- **Industrial applications**
Energy crops and biofuel production. Industrial and pharmaceutical crops.
- **Environmental applications**
Bio- and phytoremediation. Bio-control agents.

Module 4

Food and Feed Safety

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- **Overview of Safety Assessment**
Food-related risks: toxic compounds, allergens, antinutritional factors, undesired interactions between food components. Limitations of conventional toxicology studies.
- **Components of Food Safety Assessment**
Toxic compounds in foods (biological role and removal by processing). The allergic response. The distinction between food allergies and other food intolerances (e.g., gluten sensitive enteropathy, celiac disease). Removal of allergens by biotechnology methods.
- **The Concept of Substantial Equivalence**
Molecular, phenotypical and compositional basis of the substantial equivalence approach. Situations of non-equivalence.
- **Procedures for Food Safety Assessment**
Information and data management. Checklists: from molecular characterisation to consumption. Post-commercialisation monitoring.
- **Food Labelling**
Scientific and the public policy issues. Labelling and public perception of the technology. Social and economic issues. Consequences on trade. Traceability and identity preservation of food commodities.

Module 3

Theoretical & Practical Foundations of Biological Risk Assessment

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- **Definitions and Concepts in Risk Assessment**
Techniques for hazard identification, risk evaluation and management. Risk benefit analysis. The concept of familiarity and the precautionary principle.

Module 5 Environmental Safety

5

- **Risks related to host/transgene/environment combinations**
Gene flow, spread, establishment and invasiveness.
- **Ecological considerations**
Weediness. Gene introgression. Impacts on biodiversity. Changes in agricultural practice.
- **Best practice for the design and management of living modified organisms (LMOs)**
Physical and biological containment. Risk mitigation and integrated resistance management.
- **Environmental monitoring of LMOs**
Traceability: analytical methods and implementation procedures.

Module 6 Regulation

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- **National and International Regulatory Systems**
Comparative analysis of regulations (European Union, USA, Canada). Regulatory systems in Africa, Asia, Latin America and the Caribbean.
- **International Conventions and Agreements Relevant to Biotechnology**
In-depth analysis of the Cartagena Protocol, the WTO agreements (SPS, TBT), Codex Alimentarius and their respective implementation requirements.

Module 7 Risk Perception and Risk Communication

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- **Risk Perception**
Factors shaping public perception and acceptance of biotechnology
- **Scientific Uncertainty and the Precautionary Approach Risk Communication**
Coping with scientific uncertainty. The Precautionary Approach and decision making. The role of public institutions. Separating biological from socio-economic risks. Risk communication as an integral part of risk assessment. Mass media communication of risks.

Module 8 Bioethics

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- **Introduction into Ethics**
Ethics and morale. Ethics and risks. Ethical arguments.
- **General Questions in Bioethics**
Broad benefits of biotechnology. Implications of different concepts of nature. Natural/Unnatural? Religious views. Clinical studies. Ethical implications of intellectual property protection.

→ Bioethical Issues related to Agriculture

Usage and commercial implementation of GM crops. Consumer choice and food quality (labeling). Ethical implications of environmental releases. Ethical implications of risk assessment regimes, regulation and control of GM technologies.

→ Bioethical Issues related to Medicine and Healthcare

Ethical implications of stem cell technology. Ethical implications of human cloning. Ethical implications of genomic medicine.

→ Ethical considerations on biotechnology applications for transgenic animals

Consequential ethical issues for gene engineering in animals.

→ Bioethical Issues related to Developing Countries

Access and benefit sharing related to genetic resources and Indigenous knowledge & practices. Access to and sovereign use of technology. Trade-off biosafety regulations - food security?

Module 9 Recombinant Vaccine Biosafety

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→ Development and Use of Recombinant Vaccines

Vaccine Strategies: Development and use of Recombinant Vaccines. Safety issues & potential environmental and social risks.

→ Mitigating Risks: Regulatory Aspects of Vaccine Development

Overview of relevant international regulations. Current Good Manufacturing Practices. Immunogenicity and Pharmacodynamic Studies. Toxicology. Clinical Studies. Post-Marketing Safety Surveillance.

Module 10 Microbial, animal and human biosafety considerations

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→ Risk assessment for working with infectious agents in biological laboratories and production plants

Biosafety considerations for DNA, viral gene transfer vectors, DNA-based vaccines and xeno transplantation. Bacteria, fungi, yeast, animal and human cells, viruses, transgenic plants and animals.

→ Containment infrastructure, contamination, accidents, decontaminations and inactivation

Undesired spread of organisms and genetic material. Containment infrastructure and management practices. Design considerations for large-scale production of biologicals: GMP and containment synergies. Brazilian experience in design and operationalisation of Level 3 laboratories. Emerging challenges to containment.

International Faculty

The UNIDO e-Biosafety Training Programme is taught by an international faculty of eminent scientists and biosafety professionals.

The faculty members are:

George T. Tzotzos (Austria)

- UNIDO Biotechnology Programme, Vienna, Austria.

Bruno Mezzetti (Italy)

- Professor of Fruit Crop Breeding and Biotechnology, Department of Environmental and Crop Science, Marche Polytechnic University, Ancona, Italy.
- Responsible for field trials with GM plants (strawberry, raspberry, table grape and tomato) authorised by the National Competent Authority.

Moisés Burachik (Argentina)

- Professor of Biotechnology, Faculty of Exact and Natural Sciences, University of Buenos Aires, Argentina.
- Executive Secretary, National Advisory Commission on Agricultural Biotechnology (CONABIA), Buenos Aires, Argentina.
- Head Coordinator, Biotechnology Bureau of the Secretary of Agriculture (SAGPyA) at the Ministry for Economics and Production, Buenos Aires, Argentina.

Howard Davies (United Kingdom)

- Director, Scottish Crop Research Institute, Dundee, UK.
- Coordinator, Scottish Government Research Programme on Sustainable and Profitable Agriculture-Plants.
- Member, GMO Panel as well as Molecular Characterisation Group of the European Food Safety Authority (EFSA), Parma, Italy.

Jonathan Gressel (Israel)

- Emeritus Professor of Plant Sciences, Weizmann Institute of Science, Rehovot, Israel.

Elizabeth Hodson (Colombia)

- Emeritus Director, Department of Biology, Pontificia Universidad Javeriana, Bogotá, Colombia.
- Emeritus Coordinator, GEF-Worldbank Biosecurity Project Colombia, Instituto Alexander von Humboldt, Bogotá, Colombia.

Roger Hull (United Kingdom)

- Emeritus Fellow, John Innes Centre, Norwich Research Park, Colney, Norwich, UK.

Harry Kuiper (The Netherlands)

- Chair, GMO Panel as well as Member, Scientific Committee of the European Food Safety Authority (EFSA), Parma, Italy.

Jeremy Sweet (United Kingdom)

- Independent Environmental Consultant, Cambridge, UK.
- Member, GMO Panel of the European Food Safety Authority (EFSA), Parma, Italy.

Gijs Kleter (The Netherlands)

- Member, GMO Panel of the European Food Safety Authority (EFSA), Parma, Italy.
- Food Safety Specialist, Institute of Food Safety (RIKILT), Wageningen University and Research Centre, The Netherlands.

Dulce de Oliveira (Brazil)

- Visiting Professor, Department of Plant Biotechnology and Genetics, Ghent University, and Institute of Plant Biotechnology for Developing Countries (IPBO), Ghent, Belgium



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The Economic and Social Council of the United Nations, through Resolution 1999/61 adopted on 30 July 1999 and renewed through Resolution 2004/68, has given UNIDO, amongst other UN bodies and other international institutions, the mandate to “exchange information on biosafety regulation and capacity-building, including through case studies on (a) partnerships in biotechnology, (b) biosafety, (c) bioethics and (d) approaches to biotechnology and intellectual property rights issues”.

UNIDO is Task Manager for Chapter 16 of Agenda 21 on “Environmentally Sound Management of Biotechnology”.

To date, more than 150 trainees have been trained through the UNIDO e-Biosafety training programme. More than half of the students are currently serving as members of national regulatory authorities and/or have been involved in the GEF-funded programmes »Development of National Biosafety Frameworks« and »Implementation of National Biosafety Frameworks.«

Gintaras Jodinskas

Lithuania, National Project Coordinator (NPC) to manage the UNEP/GEF funded projects (Support for Implementation of the National Biosafety Framework in Lithuania)

»... My current position requires the general perception and understanding of administrative and scientific matters of GMO handling and management. The respective sections of UNIDO e-Biosafety course helped me to acquire relevant knowledge on GM food/feed safety; risk assessment, perception and communication to obtain public acceptance and involvement...«

Julia Benavides Molineros

Colombia, Information Products and Services area of Colombia Biodiversity Information System (BIS). GEF/Worldbank Colombia Biosafety Programme

»Two things to highlight: the high scientific qualifications and vast experience of the faculty, and the rigorous emphasis placed on the need for science-based GMO risk assessment, making extensive use of existing and available information and evidence. The course allowed us to acquire a whole perspective of the current and future situation within a very strong conceptual framework.«

Francisca Acevedo

Mexico, Risk Assessment and Biosafety Coordinator in the National Commission on the Knowledge and Use of Biodiversity

»The most important piece of knowledge that I have gained is that biosafety must be dealt with at several different levels.«



Heidi Primo

Federated States of Micronesia, National Project Coordinator for UNEP/GEF Biosafety Enabling Activities for the Government of the Federated States of Micronesia

»The face-to-face introductory component was unbelievable for connecting with peers and experts in the field which continue to support me electronically on my remote island. The network of connected biosafety professionals that UNIDO is creating is invaluable.«

»My background is mainly sociology and anthropology. Therefore, most of the course modules have been new information for me, especially the basics on genetics and molecular biology.«

Daneshwar Puchooa

Republic of Mauritius, Chairperson of the National Biosafety Committee

»The case studies on GMO risk assessment simulated realistic scenarios and helped me to gain the experience in GMO biosafety I need to implement the Mauritian GMO Act.«

»Visits to institutions dealing with GMOs demonstrated us students how biosafety regulations are implemented. The knowledge acquired will help me in executing my advisory role to the Government for defining infrastructure & equipment requirements for laboratories mandated to carry out tests for GMOs.«

The UNIDO *e* - Biosafety Network Nodes

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