**Course Title:** LEGAL ASPECTS OF BIOSAFETY IN BIOTECHNOLOGY

**Course code:** BIOS 6004

**Credits:** 3

**Lecturer:** Mr. Fred Phillips

**Co-ordinator:** Mr. Fred Phillips

**Duration of Course:** 8 weeks

**Contact hours:** 24 hours of lectures, 12 hours of tutorial, and 84 hours of on-line discussions

**Eligibility:** Enrolled in the M.Sc. Biosafety of Biotechnology

**Pre-requisites:** Preliminary

**Course Description:**

This is intended to provide students with current statutes relating to Biosafety and the trade of goods pertaining to the Caribbean region. It covers binding and non-binding frameworks governing international agreements, regulations, guidelines, and national laws on Biosafety worldwide and in the Caribbean. The programme of study includes critical laws and regulations pertaining to the safe use and trade of genetically modified organisms which forms part of the Caribbean development goals in ratification of regional and international agreements such as the Cartagena Protocol.

**Course Rationale**

The legal statues, both regional and international governing the safe use of Biotechnology products forms part of the MSc in Biosafety of Biotechnology Products. In addition, understanding of these fast changing statutes as it pertains to modern biotechnology products seeks to serve practicing and non-practicing professionals in the region through the creation of new knowledge by blending science with society.

**Learning Objectives**

Upon successful completion of this course, students will be able to:

* Discuss National and International agreements on Biotechnology and Biosafety.
* Differentiate between binding and non-binding Biotechnology instruments.
* Analyse relevant statutes in the Cartagena Protocol and the Convention on Biological Diversity.
* Apply the codes of conduct on the import and export of biological agents.
* Evaluate the legal aspects of Biotechnology and Biosafety case studies.
* Produce a Powerpoint presentation on the National Biosafety Frameworks in a Caribbean territory

**Mode of delivery:**

Lectures will be delivered in both the face-to-face mode on-line with Open Campus in a synchronous format. Students will be expected to interact through online discussions in the on-line environments, access on-line learning resources, create course-specific video links, and will constantly be actively engaged with the course material by having access at their convenience.

**Course content and structure:**

**Topics: Biosafety- legal aspects**

1. Overview of existing legal frameworks on Biosafety and biotechnology.
2. International frameworks on Biosafety.
3. Legal relevance to drafting National Frameworks on Biosafety.
4. Review of National Biosafety Frameworks of Caribbean countries.
5. International legal instruments addressing Biosafety and biotechnology.
6. International Treaties with provisions on Biosafety.

**Assessment Methods:**

***Coursework 50%***

The course-work will comprise one term paper, which is worth 15%, a mid-term assessment worth 20%, and three on-line discussions each worth 5% for a total of 15%. The term papers will constitute one (1) full essay; the topics of which will be given by the course lecturer(s) at the *beginning of the course*. These will be related to the course topics taught and should not exceed ten (10) single-spaced type-written pages, excluding references and footnotes. The dates for submission of this paper will be given by the course lecturer(s). The mid-term assessment will be on material covered up to one week before the assessment. On-line discussion will be based on weekly topics and will be given in week 1, week 4, and week 8 in the course.

***Final Exam 50%***

There will be a final exam at the end of the course period worth 50%. In this exam, students will be assessed in essay format on the entire course content. All exams will be of **three hours** duration. Examination outlines will be given to students by the course lecturer(s) at the beginning of the course so as to provide specific details on the exam. structure.

**Lecturer Information:**

**Mr. Fred Phillips**

E-mail: [parhelion1@gmail.com](mailto:parhelion1@gmail.com)

* Office hours: T.B.D.

Communication policy – Student should contact the lecturer through e-mail

**PRESCRIBED TEXTS AND READING MATERIALS**

**Required Reading**

**BOOKS**

1. Legal Aspects of Implementing the Cartagena Protocol on Biosafety. (2013). Eds. Marie-Claire Cordonier Segger, Frederic Perron-Welch, Christine Frison, Cambridge University Press. **ISBN:** 978-1107004382.
2. The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit Sharing. (2003). Kerry ten Kate and Sarah A. Laird. Earthscan Publications Ltd, ISBN: 978-1853839412.

**ARTICLES**

1. **Gerstetter, C., Görlach, B., Neumann, K. & Schaffrin, D.** 2007. The International Treaty on Plant Genetic Resources for Food and Agriculture within the current legal regime complex on plant genetic resources. *The Journal of World Intellectual Property* 10(3/4): 259-283.
2. **Glowka, L.** 2003. Law and modern biotechnology: selected issues of relevance to food and agriculture, 172. Rome, FAO.
3. **Holmes, P.** 2006. Trade and ‘domestic’ policies: the European mix. *Journal of European Politics*13(6): 815-831 (available at: <http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds26_e.htm>)
4. **Mackenzie, R., Burhenne-Guilmin, F., La Viña, A.G.M. & Werksman, J.D.** in cooperation with A. Ascencio, J. Kinderlerer, K. Kummer, and R. Tapper. 2003. An explanatory guide to the Cartagena Protocol on Biosafety. IUCN Environmental Policy and Law Paper No. 46. Gland: IUCN Environmental Law Centre, IUCN.
5. **McLean, M. A., Frederick, R.J., Traynor, P.L., Cohen, J.I. & Komen, J.** 2002. A conceptual framework for implementing biosafety: linking policy, capacity, and regulation. Briefing Paper No. 47. The Netherlands, ISNAR.
6. **Spreij, M.** 2007. The SPS Agreement and Biosafety. FAO Legal Papers Online No. 65. Rome, FAO.
7. **Zarrilli, S.** 2005. International trade in GMOs and GM products: national and multi-lateral legal frameworks. Policy Issues in International Trade and Commodities Study Series No. 29. New York, UNCTAD.
8. **UNEP.** 2007. Glossary of Terms for Negotiators of Multilateral Agreements.

**Recommended Reading**

1. **Klapper, B.S.** 2006. WTO rules against EU modified food ban. *Associated Press* 21 November.
2. **Nap, J-P., Metz, P.L.J., Escaler, M. & Conner, A.J.** 2003. The release of genetically modified crops into the environment: Part I. Overview of current status and regulations. *The Plant Journal* 33: 1-18.
3. FAO Biosafety Resource guide <http://www.fao.org/docrep/014/i1905e/i1905e.pdf>

*Please note these lists are non-exhaustive.*

**Course Evaluation:**

Feedback will be continuous in the online discussion forum, web tools for instant feedback *e.g.* todaysmeet.com, and also at the end of the course an on-line survey tool (esurveypro.com) will be used to get students’ feedback on the entire course.

U.W.I. Semester SCHEDULE by week & topic

Week 1:

Introduction: Overview of existing legal frameworks on biotechnology and biosafety

Week 2:

Selected international frameworks on biosafety (binding agreements)

Week 3:

Non-binding instruments on biosafety

Week 4:

Other agreements & potential overlaps & conflicts between treaties; conclusions cap.2

Week 5:

Legal considerations when drafting national biosafety frameworks’ regulatory triggers

Week 6:

Legal considerations cont’d: pples. of risk assessment, precautionary approach & preventative measures, etc.

Week 7:

Legal considerations cont’d: public pptn. & access to information, monitoring, compliance; liability & redress

Week 8:

Labelling, segregation, issues for countries that have not yet adapted biosafety regulation